Federal Court of Appeal | Cour d'appel fédérale

Date: 20150717

Docket: A-146-14

Citation: 2015 FCA 166

CORAM: **NADON J.A.**
DAWSON J.A.
BOIVIN J.A.

BETWEEN:

ELI LILLY CANADA INC.

Appellant

and

ATTORNEY GENERAL OF CANADA and MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on April 22, 2015.

Judgment delivered at Ottawa, Ontario, on July 17, 2015.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: BOIVIN J.A.

CONCURRING REASONS BY: DAWSON J.A.

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REASONS FOR JUDGMENT

NADON J.A.

[1] This is an appeal from a judgment of Madam Justice Bédard (the Judge) of the Federal Court dated February 17, 2014 (2014 FC 152; the Federal Court Decision) wherein she dismissed Eli Lilly Canada Inc.'s (the Appellant's) application for judicial review of a decision made by the Minister of Health (the Minister) on May 30, 2011 in which the Minister refused to list the Appellant's Canadian patent No. 2,379,329 (the '329 Patent or the Patent) on the patent register (the Register) maintained under the *Patented Medicines (Notice of Compliance)*

Regulations S.O.R./93-133, as am. by S.O.R./98-166, S.O.R./99-379, S.O.R./2006-242 (the Regulations) against the Appellant's drug product Trifexis identified as New Drug Submission No. 141 509 (NDS 141 509).

[2] The main issue in this appeal is whether the Minister was wrong in refusing to list the '329 Patent against the Appellant's approved Trifexis drug product on the Register. In my view, the Minister was wrong to refuse to list the '329 Patent on the Register and consequently the Judge below ought to have intervened.

I. Factual Background

[3] The relevant facts are not complicated and can be summarized as follows.

[4] Trifexis is the Appellant's drug product. On September 16, 2010, the Appellant filed a new drug submission, NDS 141 509, with the Minister for this drug product which is intended for veterinary use, specifically the prevention of heartworm disease, the prevention and treatment of flea infestations and the treatment and control of adult hookworm, adult roundworm and adult whipworm infections in dogs and puppies.

[5] On November 1, 2011, the Minister issued a Notice of Compliance (NOC) in respect of NDS 141 509. More particularly, the Minister approved NDS 141 509 for a precise formulation containing two medicinal ingredients, namely spinosad and milbemycin oxime.

[6] The '329 Patent entitled "Oral Treatment of Companion Animals with Ectoparasiticidal Spinosyns" was filed with the Patent Office on August 2, 2000 and issued on October 20, 2009. Its invention pertains to oral formulations of agricultural insecticides known as spinosyns that are to be administered to companion animals, such as household dogs and cats for control of parasite infections such as fleas and other parasites that can cause heartworm disease.

[7] The '329 Patent, which contains seven claims, indicates that the formulation of the invention may include, in combination with the spinosyn compound, other compounds with antiparasite activity, such as "milbemycins". None of the claims expressly refer to milbemycin oxime. They do, however, expressly refer to spinosad.

[8] The relevant part of the disclosure, for the purpose of this appeal, is found at page 8 of the '329 Patent and provides as follows:

> 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, avermectins, milbemycins, insect growth regulators (including chitin synthesis inhibitors, juvenile hormone analogs, and juvenile hormones), nitromethylenes, pyridines and pyrazoles.
>
> ….
>
> 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.
>
> [Emphasis added]

[9] As to the claims, claims 1 and 5 are relevant and they read as follows:

> 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 100 mg 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 100 mg of spinosad per kg of body weight.

[10] On September 16, 2010, the Appellant filed patent lists with the Office of Patented Medicines and Liaison (OPML) at Health Canada to list the ‘329 Patent in respect of NDS 141 509.

[11] By letter dated November 8, 2010, the Minister advised the Appellant that the ‘329 Patent was not eligible for listing in respect of NDS 141 509 on the grounds that it did not contain a claim for the two compounds found in its drug product. More particularly, the Minister indicated that the ‘329 Patent did not claim the medicinal ingredients spinosad and milbemycin oxime, that it did not claim the formulation containing the two medicinal ingredients and that it did not claim the use of the two medicinal ingredients, as required by subsection 4(2) of the Regulations. In other words, the Minister made it clear to the Appellant that the ‘329 Patent did not contain a claim for the formulation containing both spinosad and milbemycin oxime, but rather that it contained claims for a formulation containing spinosad alone. The Minister’s letter concluded by advising the Appellant that it could provide written representations in response within the next 30 days.

[12] The Appellant responded to the Minister's letter on March 31, 2011. On May 30, 2011, the Minister advised the Appellant that, after consideration of its written representations, the OPML maintained its view that the '329 Patent was not eligible for listing on the Register in respect of NDS 141 509 (the Minister's Decision).

[13] In the Minister's opinion, although milbemycins are mentioned in the '329 Patent as compounds which can be combined with spinosad, the Patent does not meet the requirements of paragraph 4(2)(*b*) of the Regulations which require that the patent make a claim to the formulation containing the medicinal ingredients found in the NOC-approved drug. The Minister's view is expressed as follows (Minister's Decision, p. 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 ingredients(s), as required by section 2 and paragraph 4(2)(*b*) of the *PM(NOC) Regulations*. Specifically, the passage at page 8 of the disclosure of the '329 patent, to which you refer in your representations, states the following:
>
> > The formulation 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, avermectins, milbemycins, insect growth regulators (including chitin synthesis inhibitors, juvenile hormone analogs, and juvenile hormones), nitromethylenes, pyridines and pyrazoles.
>
> 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. This characterization is consistent with that of your expert, Dr. Manon Paradis who acknowledges at paragraph 24 of her affidavit that:

> 24. Macrocyclic lactones are broad spectrum potent antiparasitic agents derived from soil organisms and include **two closely related chemical groups:** avermectins (e.g., ivermectin, abamectin, eprinomectin, doramectin and selamectin) **and milbemycins (e.g., milbemycin oxime and moxidectin)**. […]
>
> Therefore, even if the OPML accepts your position that the *PM(NOC) Regulations* do not require that all of the medicinal ingredients 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.
>
> [Emphases in original]

[14] As a result of the Minister's Decision, the Appellant brought an application for judicial review under section 18.1 of the *Federal Courts Act*, R.S.C. 1985 c. F-7. On February 17, 2014, the Judge dismissed the Appellant's application with costs.

[15] Before turning to the Federal Court Decision, a few words concerning the administrative framework pursuant to which drug products such as Trifexis are approved for marketing in Canada will be useful in the present case.

II. Administrative Framework

[16] To advertise or sell a new drug in Canada, manufacturers require the issuance of a NOC from the Minister. In order to obtain a NOC, they must file a drug submission for their product which satisfies the Minister that it is safe and effective.

[17] New drug submissions, which are usually filed by innovator companies pursuant to section C.08.002 of the *Food and Drug Regulations,* C.R.C., c. 870 (the FDR), typically contain considerable clinical trial data and detailed studies which form the basis upon which their product will be approved for sale in Canada.

[18] No NOC can be issued by the Minister if prohibited by the Regulations. Prohibition to issue NOCs begins with the filing of a patent list by innovators in which they describe the patents which they seek to list on the Register against their drug products. The Minister, pursuant to subsection 3(2) of the Regulations, is bound to maintain the Register. Hence, through her officials in the OPML, the Minister may add patents to the Register which meet the prescribed requirements and may refuse to add, or may delete, those patents that do not meet the prescribed requirements.

[19] In order to qualify under the Regulations, a patent must meet the requirements of subsection 4(2):

4. (2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains	**4.** (2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :
(*a*) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;	*a*) une revendication de l'ingrédient médicinal, l'ingrédient ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;
(*b*) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of	*b*) une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à

compliance in respect of the submission;	l'égard de la 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.

[20] Of particular relevance to this appeal is paragraph 4(2)(*b*) of the Regulations, i.e. "claim for the formulation." This phrase is defined in section 2 of the Regulations:

"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)

[21] At issue in this appeal is whether the '329 Patent claims a formulation that contains the two medicinal ingredients found in Trifexis for which the Minister has issued a NOC.

III. Federal Court Decision

[22] I now turn to the Federal Court Decision. After setting out the factual background, the Minister's decision and the regulatory framework, the Judge turned to the issues and the standard of review.

[23] She first indicated that the Minister was bound to apply the three-step test enunciated by Hughes J. in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FC 700, 67 C.P.R. (4th) 51 (*Abbott FC*) to determine the eligibility of a patent for listing on the Register (the *Abbott* test). The *Abbott* test has been accepted by this Court in a number of decisions: *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 354, [2009] 3 F.C.R. 547 at paragraphs 29 – 33 (*Abbott FCA*); *G.D. Searle & Co. v. Canada (Minister of Health)*, 2009 FCA 35, 386 N.R. 262 at paragraphs 33 - 35 (*Searle); Purdue Pharma v. Canada (Attorney General)*, 2011 FCA 132, 417 N.R. 223 at paragraphs 111 - 113 (*Purdue*); and *Gilead Sciences Canada Inc. v. Canada (Minister of Health)*, 2012 FCA 254, 435 N.R. 188 at paragraphs 11 – 12 (*Gilead FCA*).

[24] In the context of this case, the Judge formulated the *Abbott* test as follows (Federal Court Decision, para. 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?

[25] The Judge then turned to the applicable standards of review. In her view, based on this Court's decisions in *Abbott FCA*, *Searle*, *Purdue* and *Gilead FCA*, the first step had to be determined on a standard of correctness. The second prong was in turn reviewable on a reasonableness standard. Lastly, the third step involved two questions reviewable on different

standards, correctness with regard to the Minister's interpretation of paragraph 4(2)(*b*) of the Regulations and reasonableness with respect to the Minister's application of paragraph 4(2)(*b*) to the facts before her.

[26] Both sides agreed that there was no issue with respect to the second prong of the *Abbott* test. Therefore, the Judge set out the three issues raised by the Appellant's application as follows:

I. Was the Minister correct in construing the '329 Patent?

II. Was the Minister correct in interpreting the requirements of paragraph 4(2)(*b*) of the Regulations?

III. Was the Minister's refusal to list the '329 Patent on the Register reasonable?

[27] The Judge then reviewed the parties' submissions and evidence. She carefully set out the Appellant's expert evidence, namely the affidavits of Dr. Manon Paradis, a veterinarian and professor at the Department of Clinical Sciences, Faculty of Veterinarian Medicine at the University of Montreal and of Mr. Michel Sofia, a patent agent with Bereskin and Parr LLP, with over 23 years of experience in intellectual property.

[28] She then proceeded to determine the questions before her. Firstly, she dealt with the question of whether the Minister had correctly construed the '329 Patent. She observed that the

Minister had found that the '329 Patent did not contain a formulation containing both spinosad and milbemycin oxime.

[29] She then reviewed the principles of patent construction from the Supreme Court of Canada's decisions in *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 (*Free World*) and *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 (*Whirlpool*), namely that patents are to be construed through the eyes of persons skilled in the art willing to understand the invention and that claims construction must be undertaken in a purposive manner.

[30] The Judge then referred to this Court's decision in *Purdue* for the principle that construction of a patent for the purpose of determining its eligibility under the Regulations is to follow the principles set out in *Free World* and *Whirlpool*.

[31] The Judge then posed the key question, as she saw it (Federal Court Decision, para. 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.

[32] In answer to this question, she held that the claims of the '329 Patent included not only spinosad as the active ingredient, but other active ingredients such as milbemycin oxime. In arriving at this conclusion, the Judge relied mainly on the evidence of both Dr. Paradis and Mr. Sofia (Federal Court Decision, para. 69).

[33] The Judge therefore found that the Minister had erred in her construction of the patent. However, she added that this finding was not conclusive of the '329 Patent's eligibility to be listed on the Register "since the matching exercise under paragraph 4(2)(b) of the regulations has yet to be done" (Federal Court Decision, para. 71).

[34] The Judge then turned to the third prong of the *Abbott* test, i.e. whether the Minister had correctly interpreted the requirements of paragraph 4(2)(*b*) of the Regulations and applied them to the relevant facts.

[35] She began by agreeing with the Minister that, to be eligible for listing under paragraph 4(2)(*b*) of the Regulations, the formulation claimed by the '329 Patent had to include the two medical ingredients found in Trifexis. In the Judge's opinion, this view was in accordance with the principles set out in *Abbott FCA*, *Searle*, *Purdue* and *Gilead*. In her opinion, these cases established that subsection 4(2) of the Regulations, as amended in 2006, had introduced a "product specificity requirement" and that a "perfect match" between the compounds claimed in the patent and those found in the NOC-approved drug was required. In support of that view, the Judge again referred to *Purdue*, *Searle* and *Gilead FCA* quoting those passages from these decisions which she believed supported her perspective (Federal Court Decision, paras. 72-78).

[36] This led her to find that the Minister had correctly interpreted paragraph 4(2)(*b*) of the Regulations (Federal Court Decision, para. 78). Thus she examined whether the Minister's decision to exclude the '329 Patent was reasonable.

[37] She began her inquiry by observing that the Minister had excluded the '329 Patent because of her view that its claims did not match the authorized formulation in Trifexis in that the '329 Patent's claims did not include a formulation containing spinosad and milbemycin oxime (Federal Court Decision, para. 79).

[38] The Judge then reiterated that her construction of the '329 Patent was broader than that of the Minister and 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" (Federal Court Decision, para. 80).

[39] She then made the following, in my view somewhat equivocal, statement (Federal Court Decision, para. 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.

I say that this statement is equivocal because it appears to contradict the clear finding made by the Judge at paragraph 69 of the Federal Court Decision that the '329 Patent claimed a formulation containing both spinosad and milbemycin oxime. I shall return to this point later in these reasons.

[40] In the Judge's view, this case offered a similar situation to that at issue in *Gilead FCA*. She quoted paragraph 46 of the Federal Court's decision in that case (*Gilead Sciences Canada*

Inc. v. Canada (Minister of Health), 2012 FC 2, 403 F.T.R. 86 (*Gilead FC*)) and then opined as follows (Federal Court Decision, paras. 83-86):

> 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.
>
> 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.
>
> 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.
>
> 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.

[41] Thus, the Judge was satisfied that she was bound to follow our decision in *Gilead FCA*. In her view, reference in the '329 Patent to milbemycins was not sufficiently specific so as to allow her to find that its claims matched the formulation found in Trifexis.

[42] As a result, she concluded that the Minister's decision to refuse to list the '329 Patent on the Register was reasonable notwithstanding the fact that the Minister had erred in construing the claims of the '329 Patent.

IV. Issues

[43] In my view, there are two issues to be determined by us in this appeal. First, whether the Judge erred with respect to her construction of the '329 Patent's claims and her consequent overturning of the Minister's determination on that issue and second, whether the Judge erred in respect of the third prong of the *Abbott* test for patent listing eligibility, i.e. whether the formulation claimed in the '329 Patent is the formulation found in the Appellant's drug submission for Trifexis.

V. Analysis

[44] There is no dispute between the parties with regard to the applicable standards of review. However, a few words in regard thereto will be useful.

A. *Standard of Review*

[45] It is trite law that on an appeal from a decision determining an application for judicial review, this Court must determine whether the Judge selected and applied the correct standard of review (*Telfer v. Canada Revenue Agency*, 2009 FCA 23, 386 N.R. 212 at paragraph 19; *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at paragraphs 45 – 47). If the Judge erred in either selecting or applying the correct standard of review, then it is for this Court to examine the Minister's decision in light of the correct standard.

[46] The parties are in agreement that the first prong of the *Abbott* test for patent listing eligibility was to be decided by the Judge on a standard of correctness. On the second prong, I note that our Court has taken different positions on the applicable standard of review (compare *Purdue*, para. 13 which indicates reasonableness with *Gilead FCA*, para. 11 which indicates correctness applies). However, given that there is no dispute between the parties with respect to the second prong, I need not resolve this question in this decision.

[47] The third prong of the *Abbott* test, i.e. whether the formulation claimed in the '329 Patent is the formulation found in Trifexis in respect of which a NOC has been issued by the Minister, is subject to two standards. Firstly, the interpretation of paragraph 4(2)(*b*) of the Regulations must be reviewed on a standard of correctness. Secondly, the determination of whether the formulation claimed in the '329 Patent is the formulation which has been approved by the Minister through the issuance of a NOC stands to be decided on a standard of reasonableness as it requires the application of paragraph 4(2)(*b*) of the Regulations to the specific facts of the case (*Abbott FCA*, paras. 26 – 34).

[48] In my view, the Judge erred in respect of the third prong. More particularly, she misunderstood the requirements of paragraph 4(2)(*b*) of the Regulations which led her to misapply the Regulations to the specific facts before her.

B. *Legislative Test*

[49] Paragraph 4(2)(*b*) of the Regulations provides that a patent is eligible for listing on the Register if it claims a formulation of medicinal ingredients which has been approved by the Minister by reason of the issuance of a NOC.

[50] The purpose of the *Abbott* test is to set out the questions which the Court must resolve in order to determine if the requirements of subsection 4(2) have been met. The Judge clearly understood the relevant test as it appears at paragraph 16 of the Federal Court Decision (quoted at paragraph 24 of these reasons).

C. *First Prong of the Abbott Test*

[51] As noted above, at the first step of the test, the Judge determined what formulation the '329 Patent claimed. In other words, did the formulation claimed in the Patent contain both spinosad and milbemycin oxime? As I have already indicated, the Judge disagreed with the Minister's finding that the formulation claimed in the '329 Patent claimed spinosad only. Her rationale for disagreeing with the Minister is as follows.

[52] First, she correctly instructed herself with regard to the governing principles of claim construction, i.e. that a patent is to be construed through the eyes of the person skilled in the art having a mind willing to understand the invention, that the construction of the patent's claims must be approached in a purposive manner and that the patent had to be construed in light of both the disclosure and of the claims (as per *Free World* and *Whirlpool*).

[53] She clearly understood that she could count on the assistance of the expert witnesses who had given evidence before her in order to arrive at the proper construction of the '329 Patent. However, she noted that it was her responsibility, not that of the experts, to reach a conclusion with regard to what was properly claimed by the Patent (*Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219, 449 N.R. 111. The Judge also understood that claim construction in the context of eligibility assessment under subsection 4(2) of the Regulations is subject to the principles enunciated in *Free World* and *Whirlpool* (*Purdue*, para. 17).

[54] She then turned to the expert evidence before her so as to determine how the person skilled in the art would understand the formulations claimed by the '329 Patent. More particularly, the crucial question was whether a person skilled in the art would understand the formulation to contain both spinosad and milbemycin oxime. In answer to this question, she noted that milbemycin oxime was a member of the family of milbemycins, coming to that view primarily on the basis of Dr. Paradis' opinion. The Judge also noted that Mr. Jubran, the Minister's representative, had conceded that point during his testimony and that the Minister's Decision was also reflective of that view.

[55] The Judge then turned to the real question at issue which she formulated as follows (Federal Court Decision, para. 63):

> 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.

[56] To answer that question the Judge turned to Dr. Paradis' affidavit and more particularly to paragraph 44 thereof where Dr. Paradis opined that although only spinosad was specifically referred to in the '329 Patent, there was also clear reference to milbemycin oxime in the claims because the Patent defined "oral formulation" as including milbemycin oxime and also because the term "comprising", found in the claims, meant that the inventors contemplated that spinosad would be formulated with one or more active ingredients.

[57] The Judge clearly understood that Dr. Paradis' opinion was based on her view that the words milbemycin oxime and milbemycins were, in context, interchangeable when reading the '329 Patent. Dr. Paradis' evidence led the Judge to say that the parties were in agreement that milbemycin oxime was a compound that was included in the class of compounds described as milbemycins and that a person skilled in the art would have had that understanding at the time of the publication of the '329 Patent (Federal Court Decision, para. 68).

[58] As a result, the Judge held that the '329 Patent claimed a formulation which included both spinosad and milbemycin oxime. The Judge therefore found that the Minister had been "too restrictive" in her interpretation of the '329 Patent and had thus erred (Federal Court Decision, para. 71).

[59] Before this Court, the Minister disagrees with the Judge's conclusions on this issue. While the Minister acknowledges that claims construction is a question of law for the Judge to decide and that the Judge could rely on expert evidence for assistance with regard to technical terms and the scientific background to a patent, she argues that the Judge was not required to rely

on the expert evidence to construe the claims of the '329 Patent (citing *Pfizer Canada Inc. v. Canada (Health)*, 2007 FC 446, [2008] 1 F.C.R. 672, para. 35).

[60] In the Minister's view, two factors show that her view of the Patent was correct. First, the fact that none of the '329 Patent's claims specify milbemycin oxime as a second medicinal ingredient present in the formulation of the invention. Second, the insufficiency of the mere mention of milbemycins in the disclosure as one of the many groups of compounds that may be combined with spinosad to constitute a claim for the formulation containing the medicinal ingredients of Trifexis.

[61] The Minister then explains why her construction of the '329 Patent is correct. Specifically, she notes that her construction was conducted prior to and separate from the exercise required by the third prong of the *Abbott* test. She adds that she was under no obligation to call expert evidence to support her construction.

[62] The Minister then argues that the Judge erred in finding that the person skilled in the art would understand that reference to milbemycins would include milbemycin oxime. In support of that proposition, the Minister says that the class of milbemycins is not a medicinal ingredient, but rather a group of compounds, any of which could possibly be combined with spinosad, the medicinal ingredient specified in the Patent's claims.

[63] Thus, according to the Minister, it follows that a person skilled in the art would not conclude that a reference to milbemycins was a reference to milbemycin oxime "if the only clue

to the choice of milbemycin oxime for the formulation was the reference to the entire class of milbemycins" (Minister's Memorandum of Fact and Law, para. 33).

[64] In summary, the Minister says that no guesswork is allowed in pharmaceutical science. Consequently, when the '329 Patent is properly construed, the only possible conclusion is that the only medicinal ingredient claimed in the formulation claimed by the '329 Patent is spinosad. To conclude that the formulation also contains milbemycin oxime necessarily requires a stretch of the imagination for any person skilled in the art.

[65] I cannot agree with the Minister that the Judge either erred in law or made a palpable and overriding error in her construction of the '329 Patent's claims. The Judge's construction of the '329 Patent was based on her reading and understanding of the Patent in the light of the expert evidence adduced before her and more particularly the evidence of Dr. Paradis.

[66] The Minister does not directly challenge the evidence of Dr. Paradis nor criticize the Judge for relying on it with regard to the question of whether the person skilled in the art would conclude that reference to milbemycins was also a reference to milbemycin oxime. While there is no doubt that the Minister did not have to present expert evidence to support her construction of the Patent, she did have to demonstrate that the Judge erred in construing the Patent in the manner that she did. In effect, by not challenging Dr. Paradis' evidence or the Judge's reliance upon it, the Minister has not made any serious attempt to demonstrate that the Judge so-erred.

[67] I therefore conclude that there is no basis for us to interfere with the Judge's analysis of the first step of the *Abbott* test.

D. *Second Prong of the Abbott Test*

[68] As I have already indicated, there is no issue between the parties regarding the second step of the *Abbott* test as both sides agree that NDS 141 509 sought the approval of an oral dosage form of two specified active ingredients, spinosad and milbemycin oxime.

E. *Third Prong of the Abbott Test*

[69] The third prong of the *Abbott* test required the Judge to determine whether the formulation claimed by the Patent was that which was authorized by the Minister when she issued a NOC for Trifexis.

[70] Having concluded that the '329 Patent claimed a formulation of both spinosad and milbemycin oxime, one would have expected the Judge to conclude that the '329 Patent was eligible for listing on the Register. After all, the Patent, as construed by the Judge, claims, in the words of paragraph 4(2)(*b*) of the Regulations, "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". However, as noted above, the Judge did not arrive at this conclusion. Rather, she concluded that the '329 Patent was ineligible for listing on the Register. The question, therefore, is what led her to this conclusion. To answer this question requires a deeper examination of the Judge's consideration of the third prong of the *Abbott* test.

[71] The Judge began her examination of the third prong by stating the view, which no one disputes, that the claimed formulation in the ‘329 Patent must include the two medicinal ingredients found in Trifexis. This view finds support in all of the leading cases on the question and is in accordance with paragraph 4(2)(*b*) of the Regulations.

[72] After a discussion of the 2006 amendments to the Regulations which, in effect, require a match between the formulation claimed by the ‘329 Patent and the NOC-authorized drug product, the Judge said that she was bound by this Court’s interpretation of subsection 4(2) of the Regulations and more particularly by our decision in *Gilead FCA*.

[73] The Judge then reviewed, in turn, *Purdue*, *Gilead FCA* and *Searle* and concluded that the Minister had correctly interpreted paragraph 4(2)(*b*) of the Regulations. In my view, if the Minister’s construction of the ‘329 Patent was correct, then there can be no doubt that her interpretation of paragraph 4(2)(*b*) of the Regulations would have also been correct. The Minister concluded that the formulation claimed by the ‘329 Patent did not contain milbemycin oxime, and therefore correctly concluded that there was no match between the claims of the ‘329 Patent and the NOC-approved drug. The Minister’s conclusion and logic, based upon her construction of the ‘329 Patent, are unimpeachable.

[74] However, the real issue in this appeal arises from the fact that the Judge overturned the Minister’s construction of the ‘329 Patent, but nonetheless concluded that the Minister correctly refused to list the ‘329 Patent on the Register.

[75] First of all, there is no difficulty in understanding what paragraph 4(2)(*b*) of the Regulations requires. Indeed, the Judge herself seems to have understood what this paragraph requires when she formulated the *Abbott* test insofar as it applied to the case before her.

[76] The *Abbott* test simply requires the Judge to determine whether the formulation claimed by the patent at issue is the one in respect of which the Minister has issued a NOC. Having understood, at least initially, the meaning of paragraph 4(2)(*b*), the Judge then appears to have resiled from that understanding of the provision when she dealt with the third prong of the test. In my respectful view, this happened because she misunderstood our decisions on the issue and more particularly our decision in *Gilead FCA*.

[77] In *Gilead*, both before the Federal Court and this Court, the issue was whether the appellant's '475 Patent was eligible for listing against its NOC-approved drug product Complera. On the basis of the *Abbott* test, Mosley J. of the Federal Court had to determine if the Minister correctly refused to list the '475 Patent on the Register. In the Minister's view, the '475 Patent did not contain a claim for the three medicinal ingredients found in Complera, namely tenofovir disoproxil fumarate ("tenofovir"), emtricitabine, and rilpivirine. Thus, the Minister concluded there was no match between what the '475 Patent claimed and Complera and refused to list it on the Register (*Gilead FC*, paras. 7-9).

[78] Before Mosley J., there was no dispute between the parties with regard to the second prong of the test, i.e. that Complera contained three medicinal ingredients, tenofovir, emtricitabine and rilpivirine. The parties also agreed that rilpivirine was within a class of agents

known as non-nucleoside reverse transcriptase inhibitors (NNRTIs) and that this class was referenced in the '475 Patent (*Gilead FC*, para. 10).

[79] With regard to the first prong of the *Abbott* test, Mosley J. held that the '475 Patent did not claim rilpivirine. More particularly, he said that (*Gilead FC*, para. 26):

> I construe the relevant claims of the '475 Patent as combinations and formulations of two medicinal ingredients plus a third one of the NNRTI class that could possibly include but is not specifically rilpivirine.
>
> [Emphasis added]

[80] Further, Mosley J. also stated (*Gilead FC*, para. 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.

[81] Having concluded that the '475 Patent did not claim rilpivirine as a medicinal ingredient, Mosley J. proceeded to the third prong of the test and determined that the '475 Patent did not meet the strict product specificity required by paragraph 4(2)(*b*) of the Regulations. He went on to say that the '475 Patent "did not meet the specifics of the NDS" (*Gilead FC*, para. 49). Hence, the Judge concluded that the Minister's decision to refuse to list the '475 Patent on the Register was reasonable.

[82] This Court dismissed the appeal for different reasons than those of Mosley J. in *Gilead FC*. More particularly, our Court was of the view that the claims of the '475 Patent pertained to a new combination of medicinal ingredients and hence that its eligibility for listing had to be determined on the basis of paragraph 4(2)(*a*), rather than 4(2)(*b*), of the Regulations (*Gilead FCA*, para. 3).

[83] After reviewing the relevant facts and the applicable standard of review, Trudel J.A. turned to the construction of the '475 Patent. More particularly, she reproduced paragraph 26 of *Gilead FC* where Mosley J.'s construction of the '475 Patent appears (*Gilead FCA*, para. 19). She then indicated that the parties did not take issue with this construction of the '475 Patent's claims and that, as a result, the only question in dispute concerned the Minister and Mosley J.'s interpretation of paragraphs 4(2)(*a*) and (*b*) of the Regulations and their application to the relevant facts (*Gilead FCA*, para. 20).

[84] After a brief explanation of the regulatory framework, Trudel J.A. turned to the meaning of paragraphs 4(2)(*a*) and (*b*) of the Regulations and concluded that the '475 Patent fell under paragraph 4(2)(*a*) and not 4(2)(*b*). My colleague then dealt with the product specificity requirement of the Regulations (beginning at *Gilead FCA*, para. 33). She first indicated that the parties were agreed that the Regulations made product specificity between the claims of the patent at issue and the NOC-approved drug a requirement for the listing of a patent on the Register. She then reviewed our decision in *Purdue* and adopted Layden-Stevenson J.A.'s comment reproduced below (*Purdue*, para. 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.

[85] This led Trudel J.A. to say that there was no basis to adopt different legislative requirements for the various paragraphs of subsection 4(2). She further added that the product specificity requirement of the Regulations "sets a high threshold of consistency" and that the three medicinal ingredients, "i.e. tenofovir, emtricitabine and rilpivirine must be set out in the patent claims and the NOC for the patent to be eligible on the register" (*Gilead FCA*, paras. 39-40).

[86] My colleague further said that "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" adding that "[i]t 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" (*Gilead FCA*, para. 45). In her view, such an interpretation flew in the face of the ordinary meaning of the words found in the subsection, the purpose and object of the Regulations and the government's position that product specificity was a key consideration in interpreting subsection 4(2).

[87] Trudel J.A. then noted Mosley J.'s conclusion that the '475 Patent's claims did not meet the requirement for product specificity of the Regulations in that its claims "do not make specific reference to the medicinal ingredient rilpirivine (sic), but only the broad class of compounds" (*Gilead FCA*, para. 49).

[88] In my view, this examination of the facts and holdings in *Gilead FC* and *Gilead FCA* distinguishes these decisions from the present appeal. It is clear from *Gilead FCA* that Trudel J.A. accepted Mosley J.'s construction of the '475 Patent to the effect that it did not claim rilpivirine. In other words, contrary to the matter before us in this appeal, the patent at issue in *Gilead FC* and *Gilead FCA* did not claim the three medicinal ingredients found in the NOC-approved drug product Complera. In the present appeal, the Judge specifically found that the formulation claimed by the '329 Patent was the formulation found in Trifexis, i.e. a formulation which contained both spinosad and milbemycin oxime.

[89] Consequently, when one answers the questions posed by the *Abbott* test in this case, the answers are:

1. What formulation does the Patent claim?

   The Patent claims a formulation containing spinosad and milbemycin oxime.

2. What is the formulation of the NOC issued for the drug in question?

   A formulation containing spinosad and milbemycin oxime.

3. Is the formulation claimed by the Patent that which was authorized by the NOC?

   Yes it is.

[90] The Judge concluded that the formulation claimed by the Patent was not the one which the NOC authorized. As I indicated earlier, the Judge concluded as she did because she misinterpreted our decision in *Gilead FCA*. More particularly, the Judge appears to have understood *Gilead FCA* to require her to find the words milbemycin oxime in the '329 Patent's

claims and that, failing the appearance of those words, the '329 Patent did not claim the formulation which had been approved by the issuance of the NOC and could not be listed.

[91] In expressing her view of the matter, the Judge emphasized the fact that in *Gilead FCA*, this Court endorsed Mosley J.'s reasoning pertaining to the product specificity requirement. In particular, she drew attention to Mosley J.'s conclusion that a patent could not meet the product specificity requirement if it referred to a class of compounds rather than to a specific medicinal ingredient and that the '475 Patent failed this requirement because it claimed the class of NNRTIs rather than rilpivirine specifically (see Federal Court Decision, para. 82).

[92] Again, it is important to point out that Mosley J. actually found in *Gilead FC* that the third medicinal ingredient, rilpivirine, was not claimed by the '475 Patent. Consequently, in my opinion, based upon that premise, Mosley J. was correct to find that there was no match between the '475 Patent's claims and the NOC-approved drug.

[93] I acknowledge that certain statements in *Gilead FCA* arguably led the Judge astray in this regard. For example, Trudel J.A. stated that the medicinal ingredients found in Complera "must be set out in the patent claims and the NOC for the patent to be eligible on the register" and that subsection 4(2) "requires a high degree of specificity between the wording of the claim and the NOC" (*Gilead FCA*, paras. 40 and 45). However, in my respectful opinion, these statements cannot be understood to have changed the requirements of the *Abbott* test. On the contrary, our Court has consistently and repeatedly affirmed the *Abbott* test.

[94] In other words, I do not understand our decision in *Gilead FCA* as an abandonment of the *Abbott* test or the principles of claim construction enunciated by the Supreme Court in *Free World* and *Whirlpool*. Thus, contrary to what the Judge understood from *Gilead FCA*, the question at the third step of the *Abbott* test is not whether the words milbemycin oxime appear in the claims of the '329 Patent, but whether the claims of the '329 Patent claim milbemycin oxime as a medicinal ingredient in the formulation set out in the Patent.

[95] The concept of product specificity must be understood in the context of the 2006 amendments to the Regulations. On this point, it is worth reproducing paragraph 43 of *Gilead FCA* in full where Trudel J.A. elaborated upon the notion of product specificity:

> 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.

[96] Thus, in order to have a patent listed on the Register prior to the 2006 amendments, it was only necessary to demonstrate that the patent claims were "relevant" to the NOC-approved drug. The concept of relevance is a very broad concept and allowed the listing of many patents which, following the 2006 amendments, would no longer be accepted. Thus, the concept of product specificity, brought in by the 2006 amendments, can only be understood by reference to what it sought to replace, i.e. the concept of relevance. Innovators could still list patents against

their drug products but such patents would have to claim, under paragraph 4(2)(*b*) of the Regulations, the very formulation authorized by the Minister in the NOC issued for the drug product.

[97] On my understanding of the Regulations prior to the 2006 amendments, the ‘475 Patent at issue in *Gilead FC* and *Gilead FCA* would have, in all likelihood, been accepted for listing on the Register by the Minister because it would have been demonstrated that the patent at issue was “relevant” to Complera even though the third medicinal ingredient rilpivirine was not claimed by the ‘475 Patent. However, under the amended Regulations, relevancy is no longer sufficient to allow the listing of a patent. In effect, it must now be shown that the patent which the innovator seeks to list on the Register contains, as per paragraph 4(2)(*b*), a formulation of certain medicinal ingredients which the Minister has approved through the issuance of a NOC. In other words, the patent must claim specifically the formulation which the Minister has approved through the issuance of a NOC.

[98] Thus, in the circumstances of this case, it is clear that the third prong of the *Abbott* test has been met. In short, the ‘329 Patent claims a formulation of two medicinal ingredients, spinosad and milbemycin oxime. The Minister has approved of this formulation through the issuance of a NOC for Trifexis.

VI. Conclusion

[99] For these reasons, I would therefore allow the appeal with costs, I would set aside the Federal Court Decision dated February 17, 2014, and rendering the judgement which ought to

have been made, I would allow the Appellant's judicial review application with costs and return the matter to the Minister for reconsideration in the light of these reasons.

"M Nadon"

J.A.

"I agree.
Richard Boivin J.A."

DAWSON J.A. (Concurring Reasons)

[100] I agree with Justice Nadon that this appeal should be allowed with costs. For the reasons given by him, I agree that the Judge construed the 329 patent to claim not only spinosad as the active ingredient but also formulations that contain other active ingredients, including a formulation that contains both spinosad and milbemycin oxime. For the reasons given by Justice Nadon, I also agree that the Judge erred in respect of the third prong of the test articulated in *Abbott Laboratories Ltd. v. Canada (Attorney General)*, 2008 FCA 354, [2009] 3 F.C.R. 547. The single point of divergence I have with my colleague's reasons is that I am unable to distinguish the decision of our Court in *Gilead Sciences Canada Inc. v. Canada (Minister of Health)*, 2012 FCA 254, 435 N.R. 188. As I am unable to distinguish *Gilead*, and as I agree with my colleague's analysis on the merits of this appeal, I respectfully conclude that *Gilead* was wrongly decided. I reach this conclusion on the following basis.

[101] The patent in issue in *Gilead* (475 patent) claimed combinations and formulations of two or more anti-viral agents. The Federal Court construed the relevant claims of the patent as combinations and formulations of two medicinal ingredients (including tenofovir and emtricitabine) plus a third anti-viral agent from the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs). The parties agreed that the drug in issue, Complera, contained three medicinal ingredients: tenofovir, emtricitabine and rilpivirine. They also agreed that rilpivirine was a member of the class of NNRTIs. The issue was whether the 475 patent could be listed because it did not specifically name rilpivirine as a medicinal ingredient.

[102] The Federal Court and this Court concluded that the 475 patent could not be listed because it did not explicitly name rilpivirine as a medicinal ingredient and so there was no match between the subject matter of the patent and the formulation approved in the notice of compliance.

[103] However, given the construction of the 475 patent by the Federal Court, and given the agreement of the parties that Complera contained tenofovir, emtricitabine and rilpivirine, and that rilpivirine was a member of the class of NNRTIs, without doubt the 475 patent claimed the combination and formulation of tenofovir, emtricitabine and rilpivirine; any manufacture or sale of that formulation would infringe the 475 patent. Notwithstanding that the 475 patent claimed this formulation and the notice of compliance approved tablets formulated with tenofovir, emtricitabine and rilpivirine as medicinal ingredients, the 475 patent was found to be ineligible for listing.

[104] This result is not consistent with the result in the present appeal where the 329 patent is found to be eligible for listing because it claims the formulation approved in the notice of compliance issued in respect of Trifexis.

[105] In my view, the result in the present appeal is correct because it accords with the text, context and purpose of paragraphs 4(2)(*a*) and (*b*) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations).

[106] Paragraphs 4(2)(*a*) and (*b*) (set out at paragraph 19 of my colleague's reasons) provide that a patent is eligible for listing if it contains "a claim for the medicinal ingredient" or "a claim for the formulation" (emphasis added) and the medicinal ingredient or formulation has been approved through the issuance of a notice of compliance. A textual reading of the provisions therefore requires inquiry into what the patent in issue claims.

[107] Patent claims are analogized to "fences" and "boundaries" (*Free World Trust v. Electro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at paragraph 14. In this context, the inquiry required by paragraphs 4(2)(*a*) and (*b*) of the Regulations into the claims of the patent supports the interpretation that it is not necessary to require a patent to specifically name every medicinal ingredient approved through the issuance of a notice of compliance. If the patent claims the approved medical ingredient there will be a sufficient nexus between the patent and the subject of the notice of compliance to allow the patent to be listed.

[108] The purpose of the Regulations is to regulate the early working exception under the *Patent Act*, R.S.C. 1985, c. P-4 and to balance patent protection with the early entry of generic drugs. This purpose is not served by denying listing to a patent when the patent claims an innovative and useful medicinal ingredient or formulation and that same medicinal ingredient or formulation has been approved for use through the issuance of a notice of compliance.

"Eleanor R. Dawson"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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(APPEAL FROM A JUDGMENT OF THE HONOURABLE MADAM JUSTICE BÉDARD OF THE FEDERAL COURT DATED FEBRUARY 17, 2014 IN DOCKET NO. T-1071-11.)	
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DATE OF HEARING:	APRIL 22, 2015
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CONCURRED IN BY:	BOIVIN J.A.
CONCURRING REASONS BY:	DAWSON J.A.
DATED:	JULY 17, 2015

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