Federal Court of Appeal | Cour d'appel fédérale

Date: 20230816

Docket: A-92-22

Citation: 2023 FCA 177

CORAM: **DE MONTIGNY J.A.**
LASKIN J.A.
MACTAVISH J.A.

BETWEEN:

LE-VEL BRANDS, LLC

Appellant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

Heard at Ottawa, Ontario, on June 1, 2023.

Judgment delivered at Ottawa, Ontario, on August 16, 2023.

REASONS FOR JUDGMENT BY: DE MONTIGNY J.A.

CONCURRED IN BY: LASKIN J.A.
MACTAVISH J.A.

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REASONS FOR JUDGMENT

DE MONTIGNY J.A.

I. Overview

[1] Le-Vel Brands, LLC (the appellant) sells and markets in Canada the Thrive Premium Lifestyle Derma Fusion Technology Patch (the Patch), a product that is claimed to improve the appearance of a wearer's skin. While the Patch was initially sold as a cosmetic, Health Canada advised the appellant shortly after its launch that it took issue with the Patch's classification as a

cosmetic, and that it should instead be classified as a natural health product (NHP). Over the course of more than five years, the appellant and Health Canada exchanged correspondence where the appellant made submissions and provided evidence as to why the Patch should be classified as a cosmetic, and Health Canada responded with various concerns. Health Canada eventually issued a final decision according to which the Patch was classified as an NHP, and issued a compliance letter to the appellant requiring it to cease sales of the product in Canada.

[2] On judicial review, the Federal Court found that the appellant had failed to demonstrate that Health Canada's decision was unreasonable or that it was denied procedural fairness: see *Le-Vel Brands, LLC v. Canada (Attorney General),* 2022 FC 459 (Reasons).

[3] The appellant now seeks this Court's intervention on appeal, claiming that the Application Judge effectively re-drafted Health Canada's reasons and failed to consider the shortcomings of the initial decision, both in form and in substance. The appellant also raises for the first time a jurisdictional argument, alleging that Health Canada could not rely on the appellant's U.S. website to come to its determination.

[4] After having carefully reviewed the record and considered the oral and written submissions of the parties, I am of the view that the Federal Court properly determined that Health Canada's decision to classify the Patch as an NHP, as opposed to a cosmetic, was reasonable. When read in the overall context of the entire correspondence between the parties, the impugned decision is intelligible and coherent, and is well within the applicable legal and factual constraints.

II. Factual background

[5] The appellant is a self-described “premium lifestyle” company that sells a number of products in Canada, some of which are registered as NHPs, while others are sold as cosmetics. Although based in the United States, the appellant’s products are sold in Canada by its Canadian subsidiary, Le-Vel Brands Canada Inc.

[6] When the Patch was introduced in Canada in 2015, the appellant notified Health Canada of its sale as a purported “cosmetic”. At the relevant time, the marketing materials for the Patch included a Canadian product brochure and a Canadian website (le-vel.ca), whose representations concerning the product were similar. They both stated that the Patch “replenishes the skin’s moisture barrier” and “helps improve skin elasticity”, and that using the Patch results in “skin appear[ing] firm/toned” and “skin appear[ing] visibly younger”. The Patch’s label included these same four benefits, and also included application instructions at this time.

[7] On August 25, 2015, Health Canada sent the appellant an acknowledgement letter of its cosmetic notification and assigned a cosmetic product number. It nevertheless stated that the assignment of a cosmetic product number was not the result of a product evaluation or of an approval procedure, and did not constitute Health Canada’s agreement that the product was a cosmetic pursuant to the regulatory requirements: Reasons at para. 11. Pursuant to section 2 of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (the Act), a cosmetic is defined as including “any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth […]”. Unlike NHPs, cosmetics do not

require a licence for sale, nor are they subjected to the same manufacturing, labelling, packaging, distribution, or inspection requirements as NHPs.

[8] On the other hand, NHPs are a subset of "drugs" within the meaning of the Act, and were defined at subsection 1(1) of the *Natural Health Products Regulations*, S.O.R./2003-196 (NHP Regulations) at the time of Health Canada's decision in the following manner:

natural health product means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in	***produit de santé naturel*** Substance mentionnée à l'annexe 1, combinaison de substances dont tous les ingrédients médicinaux sont des substances mentionnées à l'annexe 1, remède homéopathique ou remède traditionnel, qui est fabriqué, vendu ou présenté comme pouvant servir :
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;	**a)** au diagnostic, au traitement, à l'atténuation ou à la prévention d'une maladie, d'un désordre, d'un état physique anormal, ou de leurs symptômes chez l'être humain;
(b) restoring or correcting organic functions in humans; or	**b)** à la restauration ou à la correction des fonctions organiques chez l'être humain;
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.	**c)** à la modification des fonctions organiques chez l'être humain telle que la modification de ces fonctions de manière à maintenir ou promouvoir la santé.
However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. (*produit de santé naturel*)	La présente définition exclut les substances mentionnées à l'annexe 2, toute combinaison de substances qui contient une substance mentionnée à l'annexe 2 et tout remède homéopathique ou remède traditionnel qui est une substance mentionnée à l'annexe 2 ou qui

contient l'une de ces substances.
(*natural health product*)

[9] There is no dispute between the parties that the Patch's medicinal ingredients are identified in Schedule 1 of the NHP Regulations, such that it meets the substance requirement. It is the functional aspect of the definition that is at issue in the present dispute. More particularly, what divides the parties is whether the Patch can be said to be "modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health".

[10] On February 5, 2016, the Consumer Product Safety Directorate (CPSD) of Health Canada informed the appellant that the Patch could not be classified as a cosmetic because the notification form or product label referred to "fat reduction (including control, reduce and prevent cellulite, weight management)".

[11] The appellant requested clarification and provided a draft product label, which it said demonstrated that the Patch would not be marketed in Canada as a fat-reduction product. The CPSD responded that the draft label did not alter its view, pointing to the appellant's website, which described the Patch as being part of a "wearable product nutrition line", and to the draft label, which described the Patch as containing ingredients that increased bioavailability and topical permeation in a manner that the CPSD determined to go beyond the scope of a cosmetic. The appellant replied in February 2016 with further explanations as to why the Patch should be classified as a cosmetic, but nothing further happened until October 2018 regarding the classification of the Patch.

[12] The appellant received a letter from the Regulatory Operations and Enforcement Branch of Health Canada, dated October 15, 2018, stating that Health Canada had been notified that the Patch was being sold as an unlicensed NHP. The letter referred to the sale and advertisement of the Patch on the appellant's U.S. website, and requested that the appellant stop the sale and advertisement of the Patch since it was not a licensed product. The appellant responded three days later, noting that it has a separate Canadian website where Canadian products, which may have the same names and similar formulas and/or packaging as U.S. products but are not identical, are advertised and sold to Canadian consumers. The appellant reiterated that the Patch is intended to "replenish the skin's moisture barrier, improve skin elasticity and promote an appearance that is firm/toned/visibly younger", which are all benefits that do not require licensing as an NHP.

[13] The appellant provided a more detailed response to Health Canada on November 1, 2018. It confirmed that Canadian consumers can buy the U.S. products directly from the U.S. website, but that it does not actively market those products in Canada. Le-Vel Brands Canada Inc. has its own separate website, and employs its independent contractors in Canada to promote and sell its Canadian products. It also enclosed a number of documents and prior correspondence with Health Canada, including correspondence in respect of the Patch's cosmetic classification, a draft label, and information on the cosmetic nature of the ingredients within the Patch.

[14] Health Canada reviewed the appellant's response and material, and its view that the Patch was a cosmetic. Then, on April 18, 2019, Health Canada sent an email to the appellant, confirming that the Patch is not a cosmetic but an NHP without providing any explanation for

this statement. It concluded that the appellant was in violation of subsection 4(1) of the NHP Regulations for selling an NHP without a product license, and demanded that the appellant immediately stop the sale and advertisement of the Patch.

[15] The appellant responded to Health Canada's email on April 26, 2019, explaining why the Patch could not reasonably be considered to fall within the scope of the definition of an NHP. The appellant stated that the Patch was not manufactured, sold, or represented for one of the purposes identified in the NHP Regulations, and more particularly, as "modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health". The appellant further submitted that the Patch is specifically sold and represented "to replenish the skin's moisture barrier, improve skin elasticity and promote an appearance that is firm/toned/visibly younger", all of which are cosmetic purposes within the meaning of the Act's definition of a "cosmetic". The appellant also requested further information as to the basis of Health Canada's decision, and clarification as to whether that decision was final.

[16] Health Canada replied to the appellant in a letter dated May 21, 2019. In its letter, Health Canada advised that it had determined that the claims described by the appellant suggested that they are achieved by modifying organic function, and thus, the Patch falls within the definition of an NHP. Specifically, the letter referenced statements that the Patch used a "DFT [Derma Fusion Technology] delivery system" designed to "infuse the derma (skin)" and "to provide greater bioavailability and absorption". Health Canada found these statements on the product label, the Canadian website, and a linked product brochure. The letter also referenced the Health Canada "Guidance Document: *Classification of Products at the Cosmetic-Drug Interface*"

(Guidance Document), which provides in section 3.3 that "[i]n order to be a cosmetic, the product must exhibit a lack of percutaneous absorption and should not have to be absorbed systemically to achieve the effect". The letter also explained that the product ingredients fall within Schedule 1 of the NHP Regulations. The letter ended with the caveat that it did not constitute a final decision, and that Health Canada would consider further submissions from the appellant.

[17] Following further discussions, Health Canada wrote to the appellant again on July 5, 2019. This letter clarified that the reference in Health Canada's previous correspondence to the website and brochure statements concerning the DFT delivery system was not meant to imply that the statements were therapeutic claims. Rather, Health Canada was concerned that these statements suggested that the Patch required systemic absorption to achieve its purported benefits, such as "appear firm/toned" and "appear visibly younger". Thus, the representations of a systemic mechanism of action met the function aspect of the NHP definition.

[18] The letter also noted that a cosmetic should only achieve its desired effect locally. Consequently, Health Canada took issue with the fact that the claims "appear firm/toned" and "appear visibly younger" were not qualified by the term "skin". It also noted how the photos and a video on the Canadian website showed individuals wearing the Patch on their arm or shoulder; these are unlikely locations for customers seeking younger looking skin or improved elasticity. These representations, together with a lack of clear directions as to where to apply the Patch and absence of any indication to the consumer that the Patch exerts a benefit only where locally applied, suggested therapeutic effects.

[19] The letter ended with a warning that the above-quoted statements ("DFT delivery system was designed to infuse the derma (skin)" and "to provide greater bioavailability and absorption") would not change the Patch's NHP classification. Classification is not based on individual claims, but on the "net impression" created by representations as to the product's use.

[20] The appellant provided further lengthy submissions to Health Canada on July 19, 2019 (Appeal Book (AB), pp. 445-450). It advised that the above-quoted statements were present by error and had been removed. It also noted that Health Canada claimed to consider the totality of information without providing any specific examples of the information relied upon to classify the Patch as an NHP. It made reference to a study (the "Platt Study"), previously submitted to Health Canada, which analyzed the cosmetic aspects of a similar product and supported the cosmetic nature of the Patch. The appellant claimed that the key ingredients in the Patch already exist in Canadian cosmetics (of which it provided examples), and are in Health Canada's NHP Ingredient Database. It further advised that the website had been amended to implement the changes requested by Health Canada (the addition of the word "skin" to the appearance claims).

[21] The appellant's letter also made a number of submissions on the proper interpretation of the NHP definition, including the fact that it does not manufacture, sell, or represent the Patch as a product that modifies an organic function. Even if the Patch did modify an organic function, the appellant submitted such effect, in isolation, would not result in classification as an NHP. With respect to the location of the Patch, the appellant submitted that many cosmetics sold in Canada are for use on more difficult areas of the skin, and that neither the definition of a cosmetic nor that of an NHP considers the location of the body where there is a topical skin

application. Finally, the appellant disagreed with Health Canada that a cosmetic patch should only achieve the desired effect locally, but in any event, asserted that the intended use of the Patch was local.

[22] More than two years went by before Health Canada responded to the appellant by way of letter dated August 5, 2021, but sent on November 3, 2021. In that letter, Health Canada indicated that it considered the totality of information currently available, including:

a) the Canadian website, which linked to a brochure that described the Patch as being associated with weight management, appetite management, nutritional support, mental acuity, and improved energy and circulation, which are considered therapeutic effects;
b) the Canadian website also linked to a video in which the Patch is described as being part of a "premium naturopathic and synergistic formula" and as delivering "vitamins, minerals, plant extracts, digestive enzymes, probiotics, antioxidants, protein fiber, amino acids" via a multi-layer process that involved systemic absorption;
c) the video also showed the dosage from the Patch spreading throughout the body, apparently being absorbed systemically;
d) a web search in Canada for "Thrive DFT" or "Thrive patch" brought up the appellant's U.S. website and other affiliated websites that promote therapeutic uses of the Patch, which Health Canada noted could mislead Canadian consumers as to the product's recommended use, particularly as the U.S. and Canadian labels were almost identical; and
e) the ingredients of the Patch are Schedule 1 substances.

[23] In a follow-up letter dated November 3, 2021, but sent together with the August 5, 2021 letter, Health Canada concluded that the Patch was classified as an NHP product on the basis that it is represented for use in a manner set out in the NHP Regulations, and requested the appellant to stop selling the Patch in Canada.

[24] The appellant provided a detailed response to Health Canada on November 8, 2021. The appellant explained that its Canadian website had inadvertently included links to content beyond the website that was "clearly inconsistent with the intended and longstanding promotion of the [Patch] as a cosmetic". However, the appellant explained that it had taken corrective action as of November 4, 2021, and that it was committed to implementing further unspecified process controls to reduce the risk of this recurring in the future. The appellant, having taken these corrective actions, submitted that "the only information available to classify the [Patch] is cosmetic in nature". This was consistent with its reading of the August 5, 2021 letter, which in the appellant's view, erroneously reclassified the Patch as an NHP on the basis of product representations rather than its actual composition.

[25] On November 26, 2021, Health Canada issued the final decision that became the subject matter of the underlying judicial review (Final Decision). In its opening paragraph, the email stated: "Based on the information available at this time, Health Canada stands firm on the classification of Thrive DFT Patch as a Natural Health Product". The Final Decision also included a compliance letter which was attached to the email dated the same day. In this letter, Health Canada demanded that the appellant cease all sales of the Patch. In its most salient part, the letter provided the following rationale for the decision:

> As indicated in the classification recommendation NNHPD provided previously, NNHPD considers the "THRIVE DFT patch" to be a Natural Health Product (NHP).
>
> The patch includes substances set out in Schedule 1 of the Natural Health Products Regulations (NHPR) and is represented as providing a whole body effect on the skin and not limited to the local application, thereby via systemic absorption and modifying organic function. Therefore, the product meets the definition of an NHP as defined in the NHPR. Furthermore, as per Section 3.3 of the Guidance Document: Classification of Products at the Cosmetic-Drug Interface, in order to be a cosmetic, the product must exhibit a lack of percutaneous absorption and should not have to be absorbed systemically to achieve the effect.
>
> While the ingredients may be found in cosmetics and there may be no explicit therapeutic claims made on the Canadian label or website, the product is represented for therapeutic and systemic use and therefore is considered an NHP.
>
> Given the product "Thrive DFT Patch" is confirmed to be an NHP, **effective immediately, you are required to stop sale, importation and cease all licensable activities of the above-mentioned health product as well as any other unauthorized health products and remove any associated advertisement including websites and/or promotional materials**.
>
> (Emphasis in the original)

[26] The Final Decision also requested that the appellant provide certain information by December 3, 2021, including confirmation that it had ceased sales of the Patch, and reminded the appellant that failure to comply with any legislation could result in more stringent compliance and enforcement actions.

III. The impugned decision

[27] The appellant sought judicial review of the Final Decision to have the Federal Court quash the decision and remit it back to Health Canada for reconsideration. It claimed that the Final Decision was not sufficiently justified and supported, and that the decision was therefore

unreasonable because it was impossible to understand how and why the conclusions were reached. It also argued that Health Canada breached its duty of procedural fairness because it relied on the appellant's representations that were inadvertent and were no longer applicable at the time of the Final Decision, and that Health Canada was trying to "lock in" conclusions reached in its August 5, 2021 letter.

[28] Before dealing with these substantive submissions, the Federal Court (per Justice Aylen) found, as a preliminary matter, that several portions of the appellant's affidavit evidence were irrelevant, argumentative, or had not been before Health Canada at the time of the decision, and should therefore be afforded no weight. That portion of the decision has not been challenged before us.

[29] On the merits, the Application Judge made the following key findings:

- Although the Final Decision is comprised of the email and attached compliance letter dated November 26, 2021, the Final Decision also incorporated by reference reasons provided by Health Canada in earlier correspondence. As such, in determining whether Health Canada's reasons are justified, intelligible, and transparent, the Application Judge found that she could consider the detailed exchange of the appellant's earlier submissions and Health Canada's preliminary determinations (Reasons at paras. 56, 59);
- Within these exchanges, Health Canada identified its concerns at various points in time with the representations being made by the appellant. Some of those concerns were addressed and remedied, whereas others were not. For example, the appellant

did not fully address Health Canada's concerns with respect to the fact that Canadian consumers were not insulated from the promotional materials employed in the United States, where the Patch was being represented as being about nutrition (Reasons at paras. 56-57);

- Health Canada made it clear that classification decisions are based not only on the submitted product label, but also on how the product and product line are marketed, and the overall representation of the product. Health Canada made it clear that it was not concerned with therapeutic claims, but was of the view that the claimed benefits of the Patch were represented as being achieved through a systemic mechanism of action, by modifying organic action. Such representations included images of the Patch on the model's arm/shoulder, claims that benefits appeared to be achieved by systemic absorption and were not limited to the application area, and representations on the U.S. website that the Patch was associated with weight management, nutrition, energy, and circulation. Therefore, the Application Judge determined that Health Canada has provided intelligible reasons as to why the Patch was represented as providing a whole body effect, as opposed to a local one (Reasons at paras. 62, 66-70);
- Health Canada also reasonably determined that the appellant suggested a systemic therapeutic use for the Patch, based on the lack of clear directions for its area of application, and the absence of any indication that its benefits are limited to the local area of application (Reasons at paras. 71-82);
- Health Canada's determination that the Patch meets the definition of an NHP on the basis that it represented systemic therapeutic use was reasonable. While it may be, as

asserted by the appellant, that systemic absorption alone is not sufficient to meet the "modifying organic functions" requirement of the NHP definition, what matters are the representations made. When viewed in their totality, the appellant's representations suggest more than just local absorption and local effect. Moreover, Health Canada conducted an independent analysis of whether the Patch was an NHP, and did not rely on the Guidance Document entitled "Classification of Products at the Cosmetic-Drug Interface" to render its decision. The issue was not whether the Patch was a cosmetic, but rather, whether the Patch meeting the definition of an NHP was reasonable (Reasons at paras. 83-92);

- Health Canada's request that the appellant stop selling the Patch was not a penalty, but simply a statement of the applicable law (Reasons at paras. 93-97);
- The appellant's assertion that Health Canada had a closed mind and denied it procedural fairness is not borne out by the evidence. On the contrary, the appellant had numerous opportunities to fully respond to the concerns raised by Health Canada. There is no indication that Health Canada's Final Decision was based on the now-removed product brochure and video link referenced in Health Canada's August 5, 2021 letter.

IV. Issues

[30] The appellant does not challenge the Federal Court's ruling on the weight to be afforded to the appellant's affidavit evidence, nor does it pursue its procedural fairness argument. However, the appellant raises for the first time a jurisdictional argument, alleging that Health

Canada could not rely on statements made on Le-Vel's U.S. website to come to its determination.

[31] Since the parties agree that the Application Judge was correct in selecting reasonableness as the standard of review, the questions to be decided on appeal are the following:

A. Was Health Canada's decision reasonable, both in its outcome and in the reasoning process leading to that outcome?

B. Did Health Canada exceed its jurisdiction by considering foreign promotional materials in its Final Decision?

C. Did Health Canada exceed its jurisdiction by ordering the appellant to cease all sales?

V. Analysis

[32] An appeal from the Federal Court on an application for judicial review requires this Court to determine whether the application judge identified the appropriate standard of review for each issue, and whether it was applied correctly: *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at paras. 45-46; *Northern Regional Health Authority v. Horrocks*, 2021 SCC 42 at para. 12 [*Horrocks*]; *Rouleau-Halpin v. Bell Solutions Techniques Inc.*, 2023 FCA 139 at para. 16. This approach accords no deference to the reviewing judge's application of the standard of review: *Horrocks* at para. 10. Instead, this Court effectively "steps into the shoes" of the Court below to focus on the administrator's decision. That being said, where the Federal Court appears to have given a complete answer to an argument advanced on judicial review, an appellant bears a tactical burden to show a flaw in the

Federal Court's reasoning: *Bank of Montreal v. Canada (Attorney General)*, 2021 FCA 189 at para. 4; *Canada RNA Biochemical Inc. v. Canada (Health)*, 2021 FCA 213 at para. 7.

[33] As previously mentioned, there is no debate between the parties on whether the Federal Court appropriately selected the reasonableness standard for reviewing Health Canada's decision. The only issue for this Court, therefore, is to determine whether the Federal Court erred in its application of that standard. When performing that function, the role of this Court is not to ask what decision it would have made in place of the administrative decision-maker, or to seek the correct solution to the problem, but rather whether the decision made by the administrative decision-maker was reasonable. In other words, our analysis must focus on the reasons provided by the decision-maker, as opposed to the reasons that the reviewing court could have come up with: *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653 at paras. 83-84, 116 [*Vavilov*].

[34] I pause to stress that the reasons provided by the administrative decision-maker must be examined with "respectful attention", with a view to understand how the conclusion was arrived at. In so doing, the reviewing court must pay attention to the administrative setting in which the reasons have been given. In particular, judges should pay attention to a decision-maker's demonstrated expertise. Such expertise, after all, is one of the reasons why a legislature may have decided to delegate decision-making authority to a particular administrative decision-maker, and courts must be sensitive to that choice: *Vavilov* at paras. 75 and 93.

[35] Reasonableness review is concerned both with the reasoning process and its outcomes. In other words, a reasonable decision must be based on an internally coherent reasoning, and justified in light of the relevant legal and factual constraints: *Vavilov* at paras. 85 and 99. According to the appellant, the reasons provided by Health Canada fail on both counts.

A. *Was Health Canada's decision reasonable, both in its outcome and in the reasoning process leading to that outcome?*

[36] The appellant argues that Health Canada failed to identify how it reached its conclusion in its decision. The appellant argues, more specifically, that Health Canada failed to identify which specific representations were relied on to conclude that the Patch claimed to have a systemic effect, and that Health Canada provided no explanation for how the representations at issue meet the legislative NHP definition of "modifying organic functions in humans".

[37] The appellant further argues that the Application Judge incorrectly relied on the previous correspondence between the appellant and Health Canada to complete the decision itself. While the appellant agrees that administrative decisions may incorporate elements of the administrative history such that they are read in light of their context, the appellant contends that a court cannot supplement the reasons or draw a conclusion from positions that are inconclusive or absent. In other words, a reviewing court cannot draw a line on a page when the dots are not present: *Komolafe v. Canada (Citizenship and Immigration)*, 2013 FC 431 at para. 11 [*Komolafe*]. According to the appellant, this is precisely what the Application Judge did: she improperly selected discrete items in the record independent of their context or other exchanges.

[38] The appellant highlights that the marketing materials changed over time and claims the Application Judge made a clear error when she referred to the 2019 correspondence because the marketing at the time of the Final Decision was different. The appellant also emphasizes that Health Canada's affiant testified that the Final Decision letter incorporated only the correspondence sent on November 3, 2021. Finally, the appellant reviewed the administrative history and argued that there was no specific position taken by Health Canada in its previous correspondence and that there was a 2.5-year gap between the appellant's response to Health Canada's letter of July 5, 2019, and Health Canada's response to that letter in 2021 (which, moreover, made no reference to the 2019 exchange of letters between the parties).

[39] In my view, all these arguments were addressed by the Application Judge and were convincingly put to rest. While I agree that the specific reasons provided by Health Canada in its Final Decision for the classification of the Patch as an NHP could have been more detailed, they have to be read in their entire context. As the Supreme Court stated in *Vavilov*, the history and context of the proceedings may explain an aspect of the decision-maker's reasoning process that is not readily apparent from the reasons themselves or show that what may appear at first sight to be an omission has in fact been dealt with elsewhere: *Vavilov* at para. 94. Of course, this is not an invitation for the reviewing court to provide reasons that were absent to bolster the administrative decision, nor is it a license to come up with findings that might have been made or even to speculate as to why or how the decision was arrived at: *Vavilov* at paras. 95-97; *Williams Lake Indian Band v. Canada (Aboriginal Affairs and Northern Development)*, 2018 SCC 4, [2018] 1 S.C.R. 83 at para. 155; *Komolafe* at para. 11. The Application Judge was well aware of that tension and did not cross the line; she used the context of the proceeding to flesh out the

reasons Health Canada provided in its final letter, but at no point engaged in a redrafting exercise.

[40] It was entirely appropriate, given the wording of the Final Decision, to incorporate by reference the reasons provided by Health Canada in earlier correspondence. In the first paragraph of the Final Decision, Health Canada states:

> Based on the information available at this time, Health Canada stands firm on the classification of [the Patch] as a Natural Health Product and regulatory requirements outlined in the [NHP Regulations] apply including site licensing and product licensing requirements.

[41] Similarly, the opening paragraph of the compliance letter reads:

> As indicated in the classification recommendation NNHPD provided previously, NNHPD considers the [Patch] to be a Natural Health Product (NHP).

[42] As found by the Application Judge, these statements clearly provide the basis to read the Final Decision in light of the previous correspondence between the parties: Reasons at para. 59. As she further noted, the promotional materials used by the appellant in relation to the Patch were somewhat of a moving target as they changed repeatedly over time in response to Health Canada's concerns. While some of these concerns were addressed and remedied by the appellant, in whole or in part, others were not.

[43] Throughout its correspondence with the appellant, Health Canada reiterated on a number of occasions that classification is not only based on individual statements on the product label or website, but also on the overall impression left by the representation of the product and how the product or product line is marketed: see, for example, the email from Tracy McCamis dated

February 9, 2016 (AB, p. 330); letter of July 5, 2019 (AB, pp, 437-438); letter of August 5, 2021 (AB, p. 560).

[44] As noted by the Application Judge, Health Canada made it clear throughout that it did not consider the appellant to be making therapeutic claims. Rather, it was of the view that the Patch was being represented as operating systemically and thereby modifying the body's internal organic function. Health Canada identified such representations in its May 21, 2019 and July 5, 2019 letters, where it referred to the information on the appellant's Canadian website stating that the Patch used a "DFT delivery system" to "infuse the derma" and "provide greater bioavailability and absorption", which in Health Canada's view suggested that the Patch achieved benefits through a "systemic mechanism of action" and therefore, by "modifying organic function". I note that at the hearing, counsel for the appellant mentioned that the statement about providing greater bioavailability was no longer on the website at the time of the Final Decision. Even if that was the case, nothing turns on this; indeed, it would merely confirm the moving target analogy discussed above, and the ongoing nature of this classification exercise.

[45] Another concern raised by Health Canada in relation to the promotional material for the Patch was the images and video on the appellant's website showing a model wearing the Patch on her upper arm or shoulder. In its July 5, 2019 letter, Health Canada considered that these were "unlikely locations to achieve younger looking skin or an improvement in skin elasticity".

[46] Finally, the Application Judge noted that Health Canada repeatedly alerted the appellant that Canadian consumers were not insulated from the American promotional materials that

extolled the therapeutic uses of the product sold under the same name in the United States. This included the fact that a web search in Canada for “Thrive DFT” or “Thrive patch” brought up the U.S. website and other product-affiliated websites that directly promoted the use of the Patch for weight management and other therapeutic purposes. As Health Canada stated in its August 5, 2021 letter, “websites promoting therapeutic uses of this product can be misleading to the average Canadian consumer about the recommended use of the product, particularly in the context of a label that is almost identical”: AB, p. 561; see also email dated February 9, 2016, AB, p. 330 and letter of October 15, 2018, AB, p. 318.

[47] In my view, when read in conjunction with the earlier correspondence, the Final Decision does provide an internally coherent and rational chain of analysis. As previously mentioned, the Final Decision must be read in the context of the previous exchanges between the appellant and the respondent. The representations upon which Health Canada relied to conclude that the Patch was represented as having a systemic therapeutic effect were clearly identified, and the appellant’s argument that it was left in the dark is simply untenable. This is not one of those instances where there are no dots to connect, nor is it one where the reviewing court has to make up its own reasons to justify the administrative decision. Quite the contrary, it is very clear that Health Canada relied on the promotional material (especially the photo), coupled with the broad claim of improved skin and systemic delivery system, to classify the Patch as an NHP. As the Application Judge aptly summarized (at paragraph 80 of her Reasons):

> Health Canada determined that when you look at the image of the model wearing the Patch on her upper arm/shoulder (which it found was an unlikely location to achieve younger looking skin or an improvement in skin elasticity), the lack of clear direction as to where to place the patch, and the absence of any language that the represented product benefits (replenished moisture barrier, improved skin elasticity, skin appearing firm/toned and skin appearing visibly younger) are

> limited to where the Patch is locally applied, taken together, the [Appellant] suggests a systemic therapeutic use for the Patch.

[48] The appellant, however, claims that the Application Judge erred by considering that the exchanges from 2019 were being incorporated into the Final Decision, for three reasons.

[49] First, the appellant submits that Health Canada's own affiant, who was part of the team that made the classification decision, confirmed on cross-examination that Health Canada's position of "stands firm" was intended to reference the earlier November 2021 exchange. I fail to see how this statement could have the significance the appellant would like to attribute to it. It is well established that an official cannot supplement the reasons of a decision-maker: *Sellathurai v. Canada (Public Safety and Emergency Preparedness)*, 2008 FCA 255, [2009] 2 F.C.R. 576 at paras. 45-47. By the same token, the affidavit or the cross-examination of an official cannot be used to limit, detract, or in any other way explain Health Canada's decision. More importantly, the Final Decision merely stated that Health Canada stood firm on the "classification" of the Patch, as described in the November 3, 2021 correspondence. Nothing in the Final Decision suggests that Health Canada reiterates the classification of the Patch as an NHP only for the reasons set out in that correspondence.

[50] The appellant further contends that Health Canada failed to rely on a clear, consistent, or specific position throughout the exchanges between the parties. In particular, it claims that the 2.5-year delay between the appellant's response (July 19, 2019) to Health Canada's letter dated July 5, 2019, and Health Canada's next correspondence dated August 5, 2021, coupled with the absence of any reference to the prior positions of Health Canada or to the submissions made by

the appellant, suggest acceptance of the appellant's position and a resolution of the dispute. Such an assertion is clearly without merit and cannot stand. Even if one were to recognize that acceptance can sometimes be inferred from a delay in administrative proceedings (a proposition in support of which the appellant has cited no authority), such an inference would clearly be rebutted here. Health Canada's affiant explained that the COVID-19 pandemic presented unexpected challenges across the Department, and that prioritization had to shift, delaying other activities including the classification of the Patch. This is clearly understandable and does not require an elaborate demonstration. While the pandemic cannot explain the entire delay, it plausibly accounts for some of it. More importantly, the Final Decision expressly relies on Health Canada's earlier correspondence, which also contradicts the notion that the respondent could be taken as having accepted the appellant's prior representations.

[51] Finally, the appellant submitted that the promotional materials for the Patch had changed since 2019, such that there were no lines that could be readily drawn from the correspondence sent by Health Canada prior to the Final Decision. It is true that in its previous communications, Health Canada always stressed that it could revisit the classification of the Patch, and invited the appellant to provide further information to demonstrate that the Patch does not exert systemic absorption to achieve its desired effects and that representations of the product are revised accordingly. It is also beyond dispute that classification decisions must be based on current representations before Health Canada.

[52] As a result of the numerous exchanges of submissions and preliminary determinations prior to the Final Decision, the promotional materials for the Patch in Canada were frequently

altered to respond to Health Canada's concerns. This much was acknowledged by the Application Judge: Reasons at para. 56. For example, the link to the American website was removed from the video found on the le-vel.ca website as of November 4, 2021: AB, p. 573. Similarly, the statements "Appear firm/toned" and "Appear visibly younger" were changed so that they were prefaced with the word "skin" (see above at para. 20 *in fine* of these reasons). The appellant also removed from the draft product label any indication or instruction regarding the intended location of the Patch: AB, pp. 384-385. As noted by the Application Judge, however, the result of that decision was the absence of any guidance as to where to place the Patch; more importantly, nowhere is it stated that the Patch only exerts a benefit where locally applied. At the hearing, counsel for the appellant drew our attention to the Patch's label, under the heading "To Apply", which suggests that the product was to be applied anywhere: "Try to rotate application areas every day or every other day". However, no emphasis seems to have been put on that clarification in the appellant's correspondence with Health Canada. Moreover, "try" to rotate does not really provide a clear direction, and it certainly does not suggest that the effect is purely local.

[53] There is no evidence that Health Canada did not take these modifications into consideration and based its decision on outdated versions of the product's label and website. The covering email to the compliance letter expressly notes that the classification is "[b]ased on the information available at this time": AB, p. 581. In a similar vein, Health Canada's August 5, 2021 letter (in response to the appellant's July 19, 2019 letter) also states that the classification was based on the "totality of information currently available" (AB, p. 560), which would clearly include the revisions outlined in the appellant's July 19, 2019 letter.

[54] Despite the appellant's modifications to its promotional material, it is clear that Health Canada was still concerned with the systemic effect associated with the Patch and the representations made for its therapeutic use. As noted by the Application Judge, the photo showing the Patch on the model's shoulder/upper arm, coupled with the absence of any language suggesting that the Patch only exerts benefits locally, were considered problematic by Health Canada. Health Canada also points to the information on the website which explains how the Patch works, stating that it is designed "to infuse the derma (skin)". Furthermore, Health Canada's preoccupation with the fact that the Canadian label is almost identical to the American one, and that a web search in Canada for "Thrive DFT" or "Thrive patch" brings up the American website and other direct product affiliated websites, still remained even after the video directing the viewer to Le-Vel's U.S. website was removed from the Canadian website. Given the similarity of labels and ingredients, as well as the therapeutic representations of the U.S. product, Health Canada was still concerned at the time of its Final Decision with the risk of confusing Canadian consumers. As it stated in its August 5, 2021 letter: "Websites promoting therapeutic uses of this product can be misleading to the average Canadian consumer about the recommended use of the product, particularly in the context of a label that is almost identical": AB, p. 561.

[55] When read in its full context and holistically, the Final Decision displays the hallmarks of reasonableness. It is understandable and reveals a rational chain of analysis. When the Final Decision is considered in conjunction with the record, it cannot be seriously argued that Health Canada failed to identify the representations upon which it relied to conclude that the Patch is represented to have therapeutic effects, or that it failed to explain how these representations meet

the definition of a natural health product. While the classification process is iterative in nature and allows for an applicant to provide further information and refine its submissions to assuage Health Canada's concerns or objections, the appellant was never left in the dark as to the sticking points of its cosmetic notification for the Patch. Health Canada has always made it clear that the problem was not that therapeutic claims were made, but rather that the product was represented for therapeutic and systemic use and that such use could only be achieved by modifying organic function, thereby meeting the definition of an NHP, as defined in the NHP Regulations. Whether that conclusion is tenable in light of the relevant factual and legal constraints is a separate issue, which I will now address.

[56] The appellant raises three arguments to demonstrate that Health Canada's decision lacks logic, coherence, and rationality. Because the third argument has not been raised before and has therefore not been dealt with by the Federal Court, I will address it separately in the next section of these reasons.

[57] First, the appellant argues that Health Canada never addresses the positions it took in its July 19, 2019 submissions (see above, at paras. 20-21 of these reasons). But the reasons given for a decision do not need to address all the arguments raised by a party, especially when such arguments would make no difference to the ultimate outcome. As noted by the Supreme Court in *Vavilov* (at para. 91), administrative decision-makers are not held to a standard of perfection. Nor are they to be faulted merely for not having dealt with "all possible shades of meaning" of a provision: *Vavilov* at para. 122. Omissions are not stand-alone grounds for unreasonableness; a reviewing court will be justified to intervene only when the omitted aspect of the analysis causes

it to lose confidence in the outcome reached. As this Court stated in *Canada (Citizenship and Immigration) v. Mason*, 2021 FCA 156, [2022] 1 F.C.R. 3 (at para. 41):

> Turning specifically now to legislative interpretation, what is said above about administrative decisions in general applies here too. Among other things, reviewing courts should be aware that the administrator may have made implied findings on issues of legislative interpretation. For example, suppose an administrator finds that almost all of the elements of text, context and purpose support a particular legislative interpretation. Its non-mention of a couple of elements put forward by a party is not necessarily a fundamental gap that is fatal. The reviewing court might be able to conclude that the administrator implicitly found that the preponderance of elements supported its view of the matter—in other words, that although certain matters were not mentioned in the reasons, they were considered and rejected by it or were found to be outweighed by other matters. And even where elements of the analysis are left out and, in the whole scheme of things, the omissions are minor, the decision is "not undermine[d] as a whole" and must stand: *Vavilov* at para. 122.

[58] When reviewing the Final Decision in its context, it is clear that there are no gaps or shortcomings in its reasoning. The Final Decision is infused with the decision-maker's expertise and it is entirely reasonable in light of the statutory scheme.

[59] The second argument raised by the appellant in support of its contention that Health Canada's decision is flawed is that its statutory interpretation is unsupported and unreasonable. As it did before the Federal Court, the appellant makes a number of claims in that respect. Specifically, the appellant argues that Health Canada improperly relied on the Guidance Document to narrow down the legislative definition of an NHP. According to the appellant, the emphasis by Health Canada on systemic absorption and the lack of percutaneous absorption for a product to be classified as a cosmetic are not found in the legislative definition of an NHP nor precluded from the definition of a cosmetic. These requirements come from the Guidance Document, says the appellant, and they impermissibly narrow the legislative definition.

[60] I agree that the Final Decision does refer to the Guidance Document and its requirements for a product to be a cosmetic. But the Guidance Document itself makes it clear that it "is not intended to assist in the determination of whether a drug is further sub-classified as a natural health product": AB, p. 310. Moreover, I agree with the Application Judge that Health Canada reached its decision that the Patch is an NHP independently of the Guidance Document, to which it refers in furtherance of its initial conclusion ("Furthermore" prefaces the reference to the Guidance Document). Finally, it must also be stressed that the sole issue before this Court is whether the determination that the Patch meets the definition of an NHP is reasonable. Whether the Patch could also be classified as a cosmetic is beyond the purview of this judicial review application.

[61] The appellant contends that Health Canada completely disregarded the undisputed evidence of the Patch's cosmetic nature. Again, this argument is not warranted and misses the point. Health Canada did confirm that the ingredients are permissible in cosmetics, and that the explicit language of Le-Vel's marketing material does not treat the Patch as therapeutic in nature. As for the Platt Study, which the appellant says demonstrates that the Patch has local rather than systemic effects, Health Canada also considered it and accepted that it may support a local as opposed to systemic effect (see August 5, 2021 letter, AB, p. 560). That being said, the Application Judge noted that the Platt Study was not a study of the Patch and that the appellant itself had described the Platt Study in a manner that suggested a dermal benefit far beyond the location where the Patch was applied; neither of these conclusions are challenged by the appellant.

[62] In any event, Health Canada's concern was not that therapeutic claims were made, but that the product was "represented" for therapeutic use, as the following paragraph of the July 5, 2019 letter made clear:

> Removing either or both of the statements "DFT delivery system was designed to infuse the derma (skin)" and "to provide greater bioavailability and absorption" from the marketing material would not change the classification of this product as an NHP. Claims and ingredients are not the only factors in determining a product classification; the representations made about the product are also used to create a net impression of what the product is and does. Representations could include a sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisements. The representations of this product in its totality, including the non-exhaustive examples above, suggests systemic absorption and action of the ingredients used in this product.
>
> AB, p. 438. See also August 5, 2021 letter, AB, pp. 560-561

[63] Moreover, as previously noted, it does not matter whether the Patch can be classified as a cosmetic. Contrary to the appellant's submissions, the NHP definition does not exclude cosmetics. The *Regulatory Impact Analysis Statement*, upon which the appellant relies for that proposition, merely says that the NHP definition "does not include cosmetics", which is a far cry from stating that the definitions of a cosmetic and a natural health product are mutually exclusive and that a product cannot fall into both categories: see *Regulatory Impact Analysis Statement*, S.O.R./2003-196, C. Gaz. II, Vol. 137, No. 13 at p. 1578. In the absence of a clear exclusion of a "cosmetic" from the definition of "natural health product", I fail to see how a product cannot be classified both as an NHP and as a cosmetic if it meets the requirements of both: see, by analogy, *Wrigley Canada v. Canada*, [2000] F.C.J. No. 607, 2000 CanLII 15485 at para. 10 (F.C.A.). I also note that section 21.1 of the *Cosmetic Regulations*, C.R.C. c. 869, which regulates the labelling of cosmetics, implicitly acknowledges that the two types of products can overlap since

it expressly excludes from its purview any product whose ingredient labelling is regulated under the NHP Regulations.

[64] Finally, the appellant submits that Health Canada never identified what organic function is being modified, nor how this modification maintains or promotes health. Once again, this argument does not seem to have been expressly articulated in the Court below and was not raised in the correspondence with Health Canada. In any event, counsel for the respondent urged upon us that a product represented as having a systemic (or whole body) effect must enter the body and modify an organic function (here, more specifically, the skin) if it is to operate beyond the site of its local application. Considering the considerable expertise of Health Canada in these matters, I am prepared to accept the reasonableness of this inference. As to how this modification maintains or promotes health, there was no need for Health Canada to go into such a level of detail, since the definition of an NHP at the time made it clear that the maintenance or promotion of health was only one example of the ways that an NHP might modify organic functions. As noted by the Application Judge, the appellant itself described the Patch in its brochure as helping the wearer “achieve premium results for a premium lifestyle” and as part of a system of products designed to “promote clean and healthy skin and an overall healthy lifestyle”. In light of such claims, it was open to Health Canada to conclude that the Patch was represented as maintaining or promoting health.

[65] For all the foregoing reasons, I am therefore of the view that Health Canada’s decision was reasonable. Its reasons bear the hallmarks of reasonableness, and its outcome is justified in light of the relevant factual and legal constraints.

B. *Did Health Canada exceed its jurisdiction by considering foreign promotional materials in its Final Decision?*

[66] The appellant asserts, for the first time, that Health Canada exceeded its jurisdiction by relying in part on non-Canadian materials when classifying the Patch. According to the appellant, the mere availability of non-Canadian materials is insufficient to allow Health Canada to consider them as part of its classification of the Patch, and Health Canada has no jurisdiction to regulate sales of products in other jurisdictions. Absent any evidence of Le-Vel actively directing Canadians to foreign marketing materials, thereby incorporating them as part of the Canadian product representations (for which there is no need since there is Canadian-specific packaging, a Canadian website, and Canadian marketing brochures), the appellant alleges that Health Canada has no authority to rely upon them.

[67] It is well established that a reviewing court will not exercise its discretion to hear a new issue when it was not raised before the administrative decision-maker. As the Supreme Court noted in *Alberta (Information and Privacy Commissioner) v. Alberta Teachers' Association*, 2011 SCC 61, [2011] 3 S.C.R. 654 at paras. 22 to 26, there are a number of justifications for this rule. One is that a reviewing court should respect the policy choice made by Parliament to entrust the determination of some issues to administrative bodies, and to give them the opportunity to deal with those issues first. Another is that it would deprive the reviewing court of an adequate evidentiary record, and of the administrative body's specialized expertise. This general rule has been even more strictly enforced on appeal from the judgment of a reviewing court: *Shoan v. Canada (Attorney General)*, 2020 FCA 174 at para. 13.

[68] Be that as it may, the argument that Health Canada exceeded its authority has no merit and is belied by the appellant's own conduct. Health Canada did not attempt to regulate sales of products in other jurisdictions, as suggested by the appellant, but merely took into account the appellant's U.S. website and affiliated websites, to the extent they were available to Canadian consumers, in the exercise of jurisdiction conferred on it by the Canadian legislative scheme. Nothing in the Act or the Regulations prohibits Health Canada from considering representations made abroad if they are readily accessible by Canadians.

[69] The appellant itself acknowledged Health Canada's authority to consider the U.S. website material when making classification decisions. First, it acknowledged in its November 8, 2021 letter that the links to the non-Canadian material on its Canadian website were "clearly inconsistent" with a cosmetic classification and advised Health Canada that it had corrected the links. Second, it attempted to argue in the Court below that it now employs "geo-blocking" to restrict Canadian search access to its U.S. website. While the Application Judge rejected this argument on the basis that the appellant failed to notify Health Canada of its efforts related to geo-blocking, the appellant implicitly acknowledged that access to foreign materials is a relevant consideration. It is also inconsistent with the appellant's submission that Health Canada's approach is unworkable, or that it compels companies to modify their foreign promotional materials.

[70] For these reasons, I have not been convinced that Health Canada's reliance on this factor, among others, renders the decision as a whole unreasonable.

C. *Did Health Canada exceed its jurisdiction by ordering the appellant to cease all sales?*

[71] In terms of remedy, the appellant contends that Health Canada exceeded its jurisdiction by issuing a blanket order to cease all sales. Since Health Canada can only preclude sales of the Patch as an NHP, and given that the NHP classification was solely based on its representations, Le-Vel's position is that Health Canada's requirement to cease sales of the Patch must be limited to the sales that were made concomitantly with the identified representations that Health Canada relied upon for its NHP classification.

[72] The Application Judge rejected the appellant's characterization of the Final Decision as imposing a penalty, and concluded that the requirement to stop selling the Patch without an NHP license was quite simply a statement of the applicable law. Contrary to the appellant's assertion, Health Canada's request that the appellant "stop sale, importation and cease all licensable activities of the above-mentioned health product" (AB, p. 591) does not prevent the appellant from revising its representations of the Patch so as to bring it outside the definition of an NHP. If the Patch is no longer represented as "modifying organic functions", it will not be a natural health product, and its sale will not be a licensable activity. That being said, the classification is not lost once the offending representations are withdrawn, as suggested by the appellant. Now that Health Canada has issued its final decision, the product is "locked" as an NHP and can only be re-classified as a cosmetic by Health Canada upon a new application by the appellant.

[73] As for the appellant's suggestion that Health Canada should have precisely identified how the appellant's representations should be reviewed to ensure that the Patch is no longer classified as an NHP, this amounts to turning the NHP Regulations on their head. It is not for

Health Canada to instruct companies how to market their products; its role, consistent with the Regulations and the Act, is to review the representations made and to determine whether or not they support an NHP classification.

[74] For these reasons, I am of the view that Health Canada did not exceed its jurisdiction by ordering the appellant to cease all sales of the Patch.

VI. Conclusion

[75] I would therefore dismiss the appeal, with costs.

"Yves de Montigny"
J.A.

"I agree.
Laskin J.A."

"I agree.
Mactavish J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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