Federal Court  Cour fédérale

Date: 2022041

Docket: T-1802-21

Citation: 2022 FC 459

Ottawa, Ontario, April 1, 2022

PRESENT: The Honourable Madam Justice Aylen

BETWEEN:

LE-VEL BRANDS, LLC

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

JUDGMENT AND REASONS

[1] The Applicant advertises and sells in Canada the "Thrive DFT Patch" [Patch] as part of a series of "premium lifestyle" products. In June of 2015, the Applicant alerted Health Canada of its intention to sell the Patch as a cosmetic and was subsequently issued a cosmetic number by Health Canada. Shortly after the launch of the Patch, Health Canada advised the Applicant that it took issue with the Patch's classification as a cosmetic and noted that the Patch may satisfy the definition of a natural health product [NHP], for which a license was required.

[2] Between February of 2016 and November of 2021, the Applicant provided Health Canada with detailed submissions and evidence as to why the Patch should be classified as a cosmetic, rather than an NHP. Health Canada responded to these submissions and raised various concerns regarding the representations made by the Applicant regarding the Patch, which led Health Canada to conclude that the Patch was an NHP. The Applicant stated on a number of occasions that the representations viewed by Health Canada as problematic to a cosmetic classification had been made in error, would otherwise cease being made and/or were not in fact problematic to a cosmetic classification.

[3] Following receipt of a final set of submissions from the Applicant dated November 8, 2021, on November 26, 2021, the Minister of Health, through the Health Product Compliance/Regulatory Operations and Enforcement Branch of Health Canada, issued a final decision that the Patch should be classified as an NHP rather than a cosmetic and issued a compliance letter to the Applicant, requiring the Applicant to cease sales of the product in Canada and provide further information regarding the product. It is this final decision that is at issue on this application for judicial review.

[4] The Applicant asserts that the decision of Health Canada was both unreasonable and procedurally unfair. The Applicant asserts that the following items are central to the determination of this application:

A. The conclusions in the final decision are not sufficiently justified and supported, and therefore the “how” and “why” underlying the conclusions reached cannot be properly understood, such that the final decision must be quashed.

B. Health Canada breached its duty of procedural fairness in "locking-in" a prior decision and refusing to reconsider the issue, despite full knowledge that the underlying support for the previous decision no longer existed.

C. In light of the undisputed facts on the record, the inevitable conclusion on product classification is that the Patch is a cosmetic product, or at the very least not an NHP, such that a declaration should be issued to that effect.

D. If the issue must be remitted to Health Canada, the Court should provide reasonable limits to the legislative interpretation of the cosmetic and NHP definitions, so that the accepted facts can be properly applied by Health Canada in the reconsideration.

[5] For the reasons that follow, I find that the Applicant has failed to demonstrate that Health Canada's decision was unreasonable or that the Applicant was denied procedural fairness. Accordingly, the application for judicial review shall be dismissed.

I. Background

[6] The Applicant is a self-described "premium lifestyle" company that sells a number of products in Canada, some of which are registered as NHPs, while others (like the Patch) are sold as cosmetics. The Patch is sold in Canada exclusively through the Applicant's Canadian website (le-vel.ca) and is marketed through the Canadian website's product page, the brochure for the Patch and the Patch's label.

[7] The brochure for the Patch that was used at the date of the final decision depicts the product as follows:

[8] Below the photo are the following descriptive bullet points:

- Cosmetic Derma Fusion Technology
- Replenishes the skin's moisture barrier
- Helps improve skin elasticity
- Skin appears firm/toned
- Skin appears visibly younger

[9] The brochure also contains the following text:

> THRIVE Premium Lifestyle DFT is a technology driven breakthrough in cosmetics. Le-Vel's DFT (Derma Fusion Technology) delivery system is a category creator – the first of its kind – and now, with fusion 2.0 technology, DFT has reached even greater heights. DFT was designed to infuse the derma (skin) with our unique, premium grade THRIVE Lifestyle Formula. Simply put – DFT helps you achieve premium results for a premium lifestyle.
>
> When taken as part of the THRIVE 8-Week Experience – in conjunction with the THRIVE Premium Lifestyle Capsules and the THRIVE Premium Lifestyle Shake Mix – DFT promotes clean and

> healthy skin and an overall healthy lifestyle. Individuals following this plan will experience ultra premium results and incredible benefits.

[10] The website's product page for the Patch (as of the date of the final decision) includes four of the five descriptive bullet points noted above and the same text as the brochure.

[11] The Applicant notified Health Canada of its first sale of the Patch in 2015. On August 25, 2015, Health Canada sent the Applicant an acknowledgement letter of its cosmetic notification and assigned a cosmetic product number. The acknowledgement letter stated that the assignment of a cosmetic product number (a) was not a product evaluation or approval procedure; (b) did not constitute Health Canada's agreement that the product was a cosmetic pursuant to the regulatory requirements; and (c) did not take away responsibility from the company for ensuring that the cosmetic product meets the requirements of the *Food and Drugs Act*, RSC 1985, c F-27 [*FDA*], *Cosmetic Regulations*, CDC, c 869 or other associated legislation.

[12] On February 5, 2016, Health Canada informed the Applicant that the Patch was not classified as a cosmetic in Canada. The letter to the Applicant stated that based on the information provided in its cosmetic notification, the product was making representations that were outside the scope of a cosmetic as defined under section 2 of the *FDA*, as the cosmetic notification form or label made reference to one or more of the words "fat reduction (including control, reduce and prevent cellulite, weight management)".

[13] The Applicant sought clarification from Health Canada on the classification notice and a response was provided by Health Canada on February 9, 2016.

[14] In 2018, Health Canada received a complaint alleging the Patch was an unlicensed NHP being sold in Canada. On October 15, 2018, Health Canada sent the Applicant a compliance request letter with respect to the Patch and another one of the Applicant's products. The Applicant provided Health Canada with a response to the compliance letter. On April 18, 2019, Health Canada confirmed that Consumer Product Safety had classified the Patch as a non-cosmetic, that the Natural and Non-prescription Health Products Directorate classified the Patch as an NHP and that the Applicant was in violation of section 4(1) of the *Natural Health Products Regulations,* SOR/2003-196 [*NHPR*] insofar as they were selling an unlicensed NHP.

[15] The Applicant provided additional submissions in response by letter dated April 26, 2019. The Applicant submitted that the *FDA* defines a cosmetic as "any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes" and that the Patch was 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. Further, the Applicant claimed that the Patch otherwise complied with the *Cosmetic Regulations* and was not indicated for any therapeutic purpose. The Applicant claimed its product could not reasonably be considered to fall within the scope of the definition of an NHP, nor was it marketed as an NHP. The Applicant also asked for confirmation as to whether the classification was a "final decision".

[16] Health Canada responded to the Applicant's April 26, 2019 letter on May 15, 2019 to state that the decision was not considered a final decision but that a formal response to their letter would be forthcoming. Health Canada's May 21, 2019 response stated:

> The classification decision completed jointly by the Consumer Product Safety Directorate's (CPSD) Cosmetics Program and the Natural and Non-prescription Health Products Directorate (NNHPD) was based on information presented in images of the product label as well as the following website: https://le-vel.ca/Products/THRIVE/DFT (including the linked product PDF: https://cdn.le-vel.com/en-CA/Documents/THRV003.pdf).
>
> First, the information on the product website https://le-vel.ca/Products/THRIVE/DFT (including the linked product PDF: https://cdn.le-vel.com/en-CA/Documents/THRV003.pdf) suggests that the patch dosage form delivers ingredients to be absorbed systemically. Specifically, the information indicates the "DFT delivery system was designed to infuse the derma (skin)" and "to provide greater bioavailability and absorption". This suggests that the claims described are achieved by modifying organic function, and "natural health product" is defined, in part, as a product that "modify[ies] organic functions". As per the Guidance Document: *Classification of Products at the Cosmetic-Drug Interface*, Section 3.3: "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."
>
> Second, the product ingredients fall within Schedule 1 of the Natural Health Products Regulations (NHPR). Section 4 of the NHPR prohibits the sale of NHPs unless a product licence has been issued in respect of the product. Further information on the requirements of the Food and Drugs Act and its associated regulations can be found in the attached Appendix as well as on the Health Canada website.

[17] The Applicant submitted further information on May 26, 2019.

[18] On July 5, 2019, Health Canada sent another letter to the Applicant clarifying the information that led to the classification of the Patch as an NHP. In particular, the letter stated:

Health Canada would like to clarify the content of our previous correspondence, specifically the information that resulted in the classification of the Thrive DFT patch as a natural health product (NHP). The reference to the two statements “DTF delivery system was designed to infuse the derma (skin)” and “to provide greater bioavailability and absorption” was not intended to imply that these are therapeutic claims. Instead, Health Canada would like to highlight that these statements suggest that the patch dosage form delivers ingredients to be absorbed systemically and thus the claims made for Thrive DFT patch such as “Appear firm/toned” and “Appear visibly younger” are achieved through a systemic mechanism of action. As such, the product would do so by modifying organic function, thereby meeting the function aspect of the definition of a NHP as set out in section 1(1) of the Natural Health Products Regulations.

A cosmetic patch should only achieve the desired effect locally at the location where the patch is applied. The claims “Appear firm/toned” and “Appear visibly younger” are not qualified with the term “skin” (i.e. “Skin appears firm/toned” and “Skin appears visibly younger”). Additionally, the photos and video included on the website https://le-vel.ca/Products/THRIVE/DFT (including the linked product PDF: https://cdn.le-vel.com/en-CA/Documents/THRV003.pdf) show individuals wearing the Thrive DFT patch on their arm or shoulder, unlikely locations to achieve younger looking skin or an improvement in skin elasticity. These representations in addition to a lack of clear directions on application site location or clarification to the consumer that the products only exert benefit where locally applied, suggest systemic therapeutic effects and support the classification of Thrive DFT patch as an NHP.

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, suggest systemic absorption and action of the ingredients used in this product.

[19] In a letter dated July 19, 2019, the Applicant provided lengthy additional submissions in response to Health Canada' clarifications. This letter included the Platt Study (which researched and analyzed the cosmetic benefits of a similarly formulated and designed product), monographs of the Patch's active ingredients, examples of cosmetics with similar ingredients and an updated draft label which changed the claims "appear firm/toned" and "appear visibly younger" to "skin appears firm/toned" and "skin appears visibly younger". The letter also summarized evidence and legal arguments with respect to cosmetic and NHP definitions that had been provided to Health Canada to date. Specifically, the letter stated:

> Your letter indicates that the removal of the statements "DFT delivery system was designed to infuse the derma (skin)" and "to provide greater bioavailability and absorption" does not itself address the classification issue. …Le-Vel is of the view that these statements should not form any part of Health Canada's decision regarding the classification of the Product, since Le-Vel does not make such representations about the Product.
>
> More specifically, these statements were present by error and did not at all form part of the initial enforcement correspondence from Health Canada nor our client's Product positioning. If the above statements continue to inform Health Canada's position, then please advise so that we can properly address both the statements, and the overall appropriateness of Health Canada's continued reference to these statements…
>
> Your letter goes on to indicate that Health Canada considered the totality of information, but provides no specific examples of what information Le-Vel provided that contributes to the classification of the Product as an NHP. Therefore, notwithstanding your letter, our client continues to be in a position whereby Health Canada seems to be leaning towards a particular decision without providing clear reasons….
>
> […]
>
> *3. Location of the patch*

> Your letter states that the locations of the patch on the arm or shoulder are "unlikely locations to achieve younger looking skin or an improvement in skin elasticity." Please note that our client promotes the Product to help provide cosmetic benefits to more difficult areas, such as the arm or shoulder (amongst others). Important considerations in this regard are as follows:
>
> i. Many cosmetics on the Canadian market are for use on the shoulders, arms, and other areas of the skin. For example, there is an entire market of body creams available to Canadian consumers.
>
> ii. Neither the definition of a cosmetic nor an NHP consider the location of the body where there is a topical skin application. In fact, Health Canada classifies intimate lubricant for personal use as a cosmetic.
>
> iii. As per the Platt Study, the Product "[...] helps diffuse the dermal benefits to a significant surface beyond the patch application area".
>
> iv. Our client sells other products specifically targeting athletic and active individuals. As such, its existing client base typically has a more significant desire to achieve the cosmetic benefits to often-exposed areas of the skin, such as one's arms and shoulders.
>
> We trust the above information better explains why these locations not only make sense for a cosmetic product, but how they are key to achieving the cosmetic effect in very specific areas.
>
> *4. Lack of directions*
>
> Your letter also states that the lack of clear directions regarding the application site suggests systemic therapeutic effects. We are somewhat confused by this statement as such a statement is inconsistent with the *Cosmetic Regulations* and NHPR. The *Cosmetic Regulations* only require directions of use for products that present an avoidable hazard. The NHPR, on the other hand, requires an NHP to include directions for use on its label (i.e. recommended dose, route of administration, duration of use). A lack of directions supports a cosmetic classification, as opposed to classification as an NHP where there is an intent to provide one of the enumerated functional elements of the NHP definition above.

[20] Notwithstanding the Applicant's assertion that the Patch is promoted to provide cosmetic benefits to "more difficult areas", the Court has not been pointed to any evidence in the certified

tribunal record of any such promotional materials. Moreover, the Applicant removed any direction as to where to place the Patch in the product label in use at the time of the final decision.

[21] Health Canada prepared a responding letter dated August 5, 2021. However, due to an administrative oversight, the letter was not transmitted to the Applicant until November 3, 2021, together with a compliance letter dated November 3, 2021. The letters confirmed Health Canada's determination that the Patch was an NHP and requested that the Applicant immediately stop selling the Patch in Canada by November 18, 2021. In the August 5, 2021 letter, Health Canada provided the following reasons for the classification of the Patch as an NHP:

> When classifying a product, Health Canada considers whether the product meets the definition of a therapeutic product, natural health product or cosmetic, as outlined in the Food and Drugs Act (see Appendix A). Product representation includes labelling and any advertisements made about the product such as, but not limited to, websites, radio advertisements, infomercials, magazine advertisements, pamphlets, packaging, mass print, television, etc. While classifications are not solely based on websites, they are considered in the overall representation of the product.
>
> When reviewing the classification of the THRIVE DFT patch, Health Canada considered the totality of information currently available including the Canadian label, Canadian website (www.le-vel.ca) as well as additional Canadian websites promoting the product. The Platt Study was also considered and may support a local (vs. systemic) effect. However, while the label provided does not include therapeutic claims, based on the www.le-vel.ca website, the product is represented for therapeutic use. The Canadian website links to the PRODUCT PDF which describes the product as being for Weight Management, Supports Appetite Management, Nutritional Support, Mental Accuity and Supports Energy & Circulation, which are considered therapeutic effects.
>
> The Canadian website also links to a video providing the impression that the patch is part of a "premium naturopathic and synergistic formula" (0:15) and that the patch delivers "vitamins, minerals, plant extracts, digestive enzymes, probiotics, antioxidants, protein,

> fiber, amino acids" (0:18-0:26). From the visuals, the patch dosage form appears to be absorbed systemically and spread throughout the body. The three layers of the patch are described (0:43) as "Layer 2" being the "active ingredient/formula" and "Layer 3" is the absorption/permeation layer". The patch is represented as providing NHP substances via systemic absorption, to modify organic function, thereby meeting the definition of an NHP as defined in the NHPR. The video ends by directing the viewer to their American website Le-Vel.com. On the American website, the Thrive DFT patch is associated with Weight Management, Mental Acuity, Supports Appetite Management, Supports Energy & Circulation.
>
> Furthermore, the Canadian label is almost identical to the American one and a web search in Canada for "Thrive DFT" or "Thrive patch" brings up the American website and other direct product affiliated websites, promoting therapeutic uses of the product. 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.
>
> The recommendation to classify this product as a health product is based on its representation for use. While the ingredients may be found in cosmetics, the product is considered a health product because the product is represented for therapeutic and systemic use (as identified in some of the examples above). As the ingredients are substances set out in Schedule 1 of the Natural Health Products Regulations (NHPR), the recommendation is to classify the product as a natural health product (vs. a prescription or non-prescription drug)…

[22] In considering the reasons given by Health Canada in its August 5, 2021 letter, it is important to note that product PDF referenced in the letter is not the same as the current brochure for the Patch. Rather, at that time, the brochure for the Patch included the same photograph but with a heading beside the photo that stated "technology meets premium nutrition" and the following entirely different bullet points:

- Weight Management
- Supports Appetite Management
- 2.0 Delivery Technology
- Nutritional Support

[23] The brochure also included the following text:

> THRIVE Premium Lifestyle DFT is a technology driven breakthrough in Health, Wellness, Weight Management, and Nutritional Support. Le-Vel's DFT (Derma Fusion Technology) delivery system is a category-creator – the first of its kind – and now, with fusion 2.0 technology, DFT has reached even greater heights. Our DFT delivery system was designed to infuse the derma (skin) with our unique, premium grade THRIVE Lifestyle Formula, different than the Capsule & Shake formula, and to result in a delivery rate benefitting the individual over an extended period of time. Simply put – DFT helps you achieve premium results for a premium lifestyle. With fusion 2.0 designed to provide greater bioavailability, absorption, and nutritional support your results with DFT 2.0 should only get better.
>
> When taken as part of the THRIVE 8-Week Experience – in conjunction with the THRIVE Premium Lifestyle Capsules and the THRIVE Premium Lifestyle Shake Mix – DFT promotes clean and healthy weight management and an overall healthy lifestyle. Individuals following this plan will experience ultra premium results, with benefits such as improved health, wellness, and fitness, as well as, weight management and nutritional support.

[24] The video referenced in the August 5, 2021 letter includes a graphic depiction of a body wearing the Patch on its shoulder/upper arm with various coloured lines spreading from the location of the Patch throughout the body's arms, torso and legs, arguably through the circulatory system.

[25] Neither the August 5, 2021 letter nor the November 3, 2021 letter invited or committed to reviewing additional submissions. Nevertheless, the Applicant provided additional information for Health Canada's consideration in a letter dated November 8, 2021, which stated:

> …Upon our review of the August Letter, it appears that NNHPD's most recent reclassification decision was based upon product

> representations, rather than the composition of the Product itself: "[t]he recommendation to classify this product as a health product is based upon its representations for use". Our client acknowledges that due to internal oversight, it unintentionally had links to very limited content outside of its Le-vel.ca website. However, as of November 4, 2021, our client corrected the oversight, which was clearly inconsistent with the intended and longstanding promotion of the Product as a cosmetic as is overwhelmingly obvious from its Canadian website and the Product's packaging. Our client is committed to implementing process controls to reduce the risk of this reoccurring. More importantly, the vast majority of and dominant representations with respect to the Product were and continue to be cosmetic in nature. Examples include without limitation:
>
> - replenishes the skin's moisture barrier;
> - helps improve skin elasticity;
> - skin appears firm/toned; and
> - skin appears visibly younger.
>
> […]
>
> With the implementation of the very limited corrective actions noted above, the issues raised by Health Canada in the Letters are now moot. The only information available to classify the Product is cosmetic in nature, and therefore by necessity the Product must remain classified as a cosmetic… NNHPD cannot reclassify the Product solely on the basis of inadvertent, and now removed, statements suggestive of a NHP to the exclusion of clear language and submitted scientific studies showing that the Product is, and is advertised as, a cosmetic…

[26] In this correspondence, the Applicant also asked Health Canada to confirm if the classification decision was a final decision.

[27] On November 10, 2021, Health Canada indicated by email that the question of whether the decision was final was being confirmed and that the stop sale request of November 18, 2021 was no longer applicable.

[28] On November 26, 2021, Health Canada provided the Applicant with its final decision. In a covering email of the same date, Health Canada 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 and regulatory requirements outlined in the Natural Health Products Regulations apply including site licensing and product licensing requirements. In light of this, please see attached the compliance letter issued to your establishment with the response deadline of December 3, 2021.
>
> Please note classification of the Thrive DFT Patch as a Natural Health Product is based on the information presented in product images and websites as no Product Licence Application has been submitted till date…

[29] The accompanying November 26, 2021 letter stated:

> 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.

[30] The letter dated November 26, 2021 also requested the Applicant "stop sale, importation and cease all licensable activities" and "remove any associated advertisements and/or promotional materials".

II. The Regulatory Framework

[31] The *FDA* establishes Health Canada's authority to regulate food, drugs, cosmetics and medical devices sold in Canada. There are many regulations enacted under the *FDA*, including the *NHRP*, which define an NHP.

[32] The *FDA* defines "cosmetic/cosmétique" as follows:

includes any substance or mixture or substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.	Notamment les substances ou mélanges de substances fabriqués, vendus ou présentés comme pouvant servir à embellir, purifier ou modifier le teint, la peau, les cheveux ou les dents, y compris les désodorisants et les parfums.

[33] A "drug/drogue" is defined in the *FDA* as:

includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its systems, in human beings or animals,	Sont compris parmi les drogues les substances ou mélanges de substances fabriqués, vendus ou présentés comme pouvant servir : 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

(b) restoring, correcting or modifying organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept.

symptômes, chez l'être humain ou les animaux;

b) à la restauration, à la correction ou à la modification des fonctions organiques chez l'être humain ou les animaux;

c) à la désinfection des locaux où des aliments sont gardés.

[34] Under the *FDA*, an NHP is considered to be a subset of "drugs". An NHP is defined in section 1(1) of the *NHPR* as follows:

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

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

(b) restoring or correcting organic functions in humans; or

(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

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) 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) à la restauration ou à la correction des fonctions organiques chez l'être humain;

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.

[35] Pursuant to sections 4 and 5 of the *NHPR*, those seeking to sell an NHP in Canada must submit a product licence application to the Minister and be issued a licence before the product can be sold in Canada.

[36] In this case, there is no dispute between the parties that the Patch includes a substance or combination of substances set out in Schedule 1 of the *NHPR*. Rather, the dispute turns on whether the Patch is "represented for use in …modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health".

III. Preliminary Issues

A. Correction to the Style of Cause

[37] At the commencement of the hearing, I raised with the parties the issue of amendment to the style of cause to remove the Minister of Health as a respondent. As the Minister of Health is the decision-maker at issue, pursuant to Rule 303(1)(a) of the *Federal Courts Rules*, the Minister of Health should not be named as a respondent. The style of cause shall accordingly be amended with immediate effect.

B. Should the disputed portions of the affidavits of Mr. Hoffman and Ms. Richardson be struck?

[38] The Federal Court of Appeal in *Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22, has provided clear guidance on the scope of proper evidence on an application for judicial review:

> …as a general rule, the evidentiary record before this Court on judicial review is restricted to the evidentiary record that was before the [decision-maker]. In other words, evidence that was not before the [decision-maker] and that goes to the merits of the matter before the [decision-maker] is not admissible in an application for judicial review in this Court…
>
> There are a few recognized exceptions to the general rule against this Court receiving evidence in an application for judicial review, and the list of exceptions may not be closed. These exceptions exist only in situations where the receipt of evidence by this Court is not inconsistent with the differing roles of the judicial review court and the administrative decision-maker…In fact, many of these exceptions tend to facilitate or advance the role of the judicial review court without offending the role of the administrative decision-maker. Three such exceptions are as follows:
>
> (a) Sometimes this Court will receive an affidavit that provides general background in circumstances where that information might assist it in understanding the issues relevant to the judicial review…. Care must be taken to ensure that the affidavit does not go further and provide evidence relevant to the merits of the matter decided by the administrative decision-maker, invading the role of the latter as fact-finder and merits-decider…
>
> (b) Sometimes affidavits are necessary to bring to the attention of the judicial review court procedural defects that cannot be found in the evidentiary record of the administrative decision-maker, so that the judicial review court can fulfil its role of reviewing for procedural unfairness…
>
> (c) Sometimes an affidavit is received on judicial review in order to highlight the complete absence of evidence before the administrative decision-maker when it made a particular finding…

[39] The Respondent asserts that the following evidence should be struck or given no weight on the basis that the evidence was not before the decision-maker and does not fall within any of the recognized exceptions:

A. Paragraphs 6 through 38 and exhibits C through P of the affidavit of Ms. Richardson sworn February 10, 2022; and

B. Those portions of the affidavit of Drew Hoffman sworn February 10, 2022 that address geo-blocking.

[40] The impugned portions of the Richardson affidavit contain pictures and information about various products, including ones that describe themselves as patches, located by the affiant following visits to various retail stores in Ottawa. The affiant then conducted a search of the product packaging and Health Canada databases to determine whether any of these products are registered as drugs, NHPs or homeopathic products. The results of those searches are included in the Richardson affidavit.

[41] The Respondent asserts that the impugned portions of the Richardson affidavit are wholly irrelevant to the decision under review, as classification or enforcement of products other than the Patch has no bearing on the reasonableness of the decision or the procedural fairness afforded to the Applicant. Moreover, the Respondent notes that the impugned portions of the Richardson affidavit have no connection to any of the arguments advanced by the Applicant in its memorandum of fact and law.

[42] The Applicant asserts that the impugned portions of the Richard affidavit constitute background information intended to demonstrate that not all patches are classified by Health

Canada as NHPs, which is information that was known to Health Canada at the time that it rendered its decision.

[43] I agree with the Respondent that the impugned portions of the Richardson affidavit are entirely irrelevant to the issues before the Court, and that the evidence is inadmissible as it was not before the decision-maker and does not fall within the "background information" exception. It was entirely open to the Applicant to put this evidence before Health Canada in any of the numerous rounds of submissions and evidence that the Applicant submitted to Health Canada, which it did not do. In any event, I note that the Applicant did not refer to the evidence at all in its written or oral submissions, which demonstrates the lack of relevance of the impugned evidence. Accordingly, I give no weight to the impugned portions of the Richardson affidavit.

[44] With respect to the Hoffman affidavit, the Respondent asserts that while large portions of the affidavit constitute argument, the Respondent is primarily concerned with the fact that the Hoffman affidavit attempts to put before the Court information that was never provided to Health Canada – namely, that at some unknown point in time, the Applicant implement "geo-blocking" of its American website so that internet users in Canada are automatically re-directed away from the content and representations made about the Patch on the American website and sent to the Canadian website. References to this geo-blocking implementation appear at paragraphs 10, 11, 27, 33, and 54 of the Hoffman affidavit. The Respondent asserts that this evidence is inadmissible as it was not before the decision-maker and does not fall within any of the recognized exceptions.

[45] With respect to those portions of the Hoffman affidavit that are argumentative, the Respondent asserts that the case law of this Court is clear that such evidence is to be given little to no weight.

[46] The Applicant asserts that the impugned Hoffman evidence is admissible as it was "indirectly" addressed in the Applicant's correspondence to Health Canada. As noted above, Health Canada raised with the Applicant in its letter dated August 5, 2021 a number of concerns about the content that appeared on the Canadian website (product pdf and a video), as well as a specific concern about Canadians conducting web searches for the Patch being able to access the American website and other direct product affiliated websites that promote therapeutic uses of the Patch. In response to the concerns raised by Health Canada, the Applicant advised in its letter dated November 8, 2021:

> Our client acknowledges that due to internal oversight, it unintentionally had links to very limited content outside of its Level.ca website. However, as of November 4, 2021, our client corrected the oversight, which was clearly inconsistent with the intended and longstanding promotion of the Product as a cosmetic as is overwhelmingly obvious from its Canadian website and the Product's packaging. Our client is committed to implementing process controls to reduce the risk of this reoccurring.
>
> [Emphasis added]

[47] The Applicant asserts that the reference to "implementing process controls" and the corrective actions taken by the Applicant to address Health Canada's concerns included geo-blocking and as such, the impugned Hoffman evidence was known to Health Canada. I reject this assertion. I find that the Applicant's November 8, 2021 letter fails to address Health Canada's concern regarding internet search results obtained by Canadians and the Applicant is now

attempting to remedy this deficiency through the Hoffman affidavit, which is improper. I find that geo-blocking was not "indirectly" addressed in the November 8, 2021 letter and as such, the geo-blocking efforts made by the Applicant were not before the decision-maker. Accordingly, I find that Mr. Hoffman's evidence regarding geo-blocking is inadmissible.

[48] The Applicant asserts that even if the geo-blocking evidence was not before the decision-maker, the evidence is relevant to the exercise to be undertaken by the Court as the classification of a product as an NHP is dependent on the representations being made about the product and the evidence now before the Court is clear that Canadians no longer have access to web search results that would take them to the American website. I reject this assertion. The Court's role on this application for judicial review is to consider the reasonableness of Health Canada's classification of the Patch as an NHP at the time that the decision was made. The Court is not making its own classification determination based on the state of representations currently being made by the Applicant. To the extent that there has been a material change in the representations since November 26, 2021, that is a matter for the Applicant to raise with Health Canada, but it does not transform the exercise currently before the Court or render otherwise inadmissible evidence admissible.

[49] I agree with the Respondent that many paragraphs of the Hoffman affidavit are argumentative, such as where Mr. Hoffman comments on the content of various correspondence. The correspondence speaks for itself and Mr. Hoffman's commentary thereon is of no assistance to the Court.

IV. Remaining Issues and Standard of Review

[50] The following remaining issues arise on this application:

A. Whether the final determination is reasonable; and

B. Whether Health Canada breached its duty of procedural fairness owed to the Applicant.

[51] With respect to the first issue, when a court reviews the merits of an administrative decision, the presumptive standard of review is reasonableness. No exceptions to that presumption have been raised nor apply [see *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at paras 23, 25]. In assessing whether a decision is reasonable, the Court will assess whether the decision is appropriately justified, transparent and intelligible. To meet these requirements, the decision must reflect "an internally coherent and rational chain of analysis" and be "justified in relation to the facts and law that constrain the decision maker". Both the outcome and the reasoning process must be reasonable [see *Vavilov*, *supra* at paras 83, 85 and 99].

[52] With respect to the second issue, the parties agree that no particular standard of review applies, and that the question to be answered is whether, taking into account the particular context and circumstances at issue, the process followed by the administrative decision-maker was fair and offered the affected parties a right to be heard as well as a full and fair opportunity to know and respond to the case against them [see *Tsigehana v Canada (Citizenship and Immigration)*,

2020 FC 426 at paras 14-15; *Canadian Pacific Railway Company v Canada (Attorney General)*, 2018 FCA 69 at para 54; *Vavilov, supra* at para 77].

V. Analysis

A. Health Canada's Final Decision is Reasonable

[53] The Applicant asserts that Health Canada's decision is unreasonable for a number of reasons, which I will address in turn.

[54] First, the Applicant asserts that Health Canada's determination that the Patch is an NHP is unreasonable as Health Canada fails to identify the representations made by the Applicant upon which its decision is based and that a review of the certified tribunal record does not assist in understanding the basis for the decision. As a result, the Applicant asserts that the decision is not sufficiently justified and supported.

[55] A reviewing court must begin its inquiry into the reasonableness of a decision by examining the reasons provided with "respectful attention" and seeking to understand the reasoning process followed by the decision-maker to arrive at the conclusion reached. The reasons should be read holistically and contextually in order to understand the basis on which a decision was made [see *Vavilov, supra* at paras 84, 97].

[56] Before turning to the reasons themselves, it is important to recall the context in which the final decision was made. As I have detailed above, the Applicant and Health Canada engaged in a detailed exchange of submissions and preliminary determinations prior to the release of Health Canada's final decision. During that back and forth, the Applicant's promotional materials for the

Patch in Canada changed significantly, such that Health Canada was required to consider various versions of representations made by the Applicant. Health Canada identified to the Applicant the concerns that it had at various points in time with the representations being made by the Applicant and provided a rationale for those concerns. Some of those concerns were addressed and remedied by the Applicant, whereas others were not addressed or were rejected by the Applicant.

[57] It also became apparent to Health Canada that the Applicant was ultimately pursuing a very different promotional strategy for the Patch in Canada versus the strategy employed in the United States. In Canada, the Patch is represented as targeting the skin (replenishing the skin's moisture barrier, improving skin elasticity, causing skin to appear firm/toned and visibility younger) whereas in the United States, it is represented as being about nutrition (weight management, supporting appetite management and providing nutritional support). Health Canada expressed concerns to the Applicant that Canadian consumers were not insulated from the promotional materials being employed in the United States and provided various examples to the Applicant of the concerning promotional materials. As noted above, the Applicant did not address all of Health Canada's concerns regarding this issue.

[58] Turning to the reasons for decision, the final decision is found in Health Canada's letter dated November 26, 2021 and the accompanying email. The letter and email provide the following reasons for decision:

A. The classification determination was based on the information presented in the product images and websites.

B. The Patch includes substances set out in Schedule 1 of the *NHPR*.

C. The Patch is represented as providing a whole body effect on the skin and not limited to local application, thereby via systemic absorption and modifying organic function.

D. Further, 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.

[59] The final decision letter also incorporated by reference reasons provided by Health Canada in earlier correspondence, by stating "[a]s indicated in the classification recommendation NNHPD previously provided". As such, it is open to the Court to consider the additional reasons for decision provided by Health Canada to the Applicant in its earlier correspondence.

[60] In determining whether Health Canada's reasons are justified, intelligible and transparent, based on the final decision letter and email or when considered more broadly in the context of the earlier correspondence, the Court is not permitted to pick up Health Canada's pen and effectively write supplemental reasons supporting Health Canada's decision. However, the Court is allowed to "connect the dots on the page where the lines, and the direction they are headed, may be readily drawn" [see *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157 at paras 8, 17; *Komolafe v Canada (Minister of Citizenship and Immigration)*, 2013 FC 431 at para 11; *Vavilov*, *supra* at para 97].

[61] I am satisfied that, when considered holistically and contextually, the basis for Health Canada's decision can be readily determined. Health Canada set out clear reasons for decision in its earlier correspondence and the Applicant did not adequately address Health Canada's concerns in its subsequent submissions and evidence. The Applicant's assertion that it is now "wholly uncertain of why or how the decision was reached" is simply untenable.

[62] Health Canada made it clear to the Applicant repeatedly that classification decision are based not only on what is on the product label submitted, but also how the product and product line are marketed, both in terms of words and images used, and is not limited to a consideration of websites. Rather, classification is based on the overall representation of the product [see, for example, the letters dated February 6, 2016, July 5, 2019 and August 5, 2021].

[63] Health Canada made it clear to the Applicant that it had not concluded that the Applicant was making therapeutic claims. Rather, Health Canada was of the view that the Patch was being represented for therapeutic and systemic use. In its May 21, 2019 letter, Health Canada stated:

> First, the information on the product website https://le-vel.ca/Products/THRIVE/DFT (including the linked product PDF: https://cdn.le-vel.com/en-CA/Documents/THRV003.pdf) suggests that the patch dosage form delivers ingredients to be absorbed systemically. Specifically, the information indicates the "DFT delivery system was designed to infuse the derma (skin)" and "to provide greater bioavailability and absorption". This suggests that the claims described are achieved by modifying organic function, and "natural health product" is defined, in part, as a product that "modify[ies] organic functions". As per the Guidance Document: *Classification of Products at the Cosmetic-Drug Interface*, Section 3.3: "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."

[Emphasis added]

[64] In its letter dated July 5, 2019, Health Canada confirmed that it was not suggesting that the Applicant made therapeutic claims regarding the Patch and reiterated Health Canada's position that the Applicant was making representations that the claimed benefits of the Patch were achieved through a systemic mechanism of action, by modifying organic function:

> Health Canada would like to clarify the content of our previous correspondence, specifically the information that resulted in the classification of the Thrive DFT patch as a natural health product (NHP). The reference to the two statements "DTF delivery system was designed to infuse the derma (skin)" and "to provide greater bioavailability and absorption" was not intended to imply that these are therapeutic claims. Instead, Health Canada would like to highlight that these statements suggest that the patch dosage form delivers ingredients to be absorbed systemically and thus the claims made for Thrive DFT patch such as "Appear firm/toned" and "Appear visibly younger" are achieved through a systemic mechanism of action. As such, the product would do so by modifying organic function, thereby meeting the function aspect of the definition of a NHP as set out in section 1(1) of the Natural Health Products Regulations.
>
> [Emphasis added]

[65] The same concern was again reiterated by Health Canada in its August 5, 2021 letter where Health Canada stated that "the product is represented for therapeutic use".

[66] In relation to this issue, Health Canada raised a concern with the Applicant regarding the photo used by the Applicant in its promotional materials showing the placement of the Patch on the upper arm/shoulder area of the model. In its letter dated July 5, 2019, Health Canada stated:

> Additionally, the photos and video included on the website https://le-vel.ca/Products/THRIVE/DFT (including the linked product PDF: https://cdn.le-vel.com/en-CA/Documents/THRV003.pdf) show individuals wearing the Thrive DFT patch on their arm or shoulder, unlikely locations to achieve younger looking skin or an improvement in skin elasticity. These representations in addition to a lack of clear directions on application site location or clarification to the consumer that the products only exert benefit where locally applied, suggest systemic therapeutic effects and support the classification of Thrive DFT patch as an NHP.
>
> [Emphasis added]

[67] In considering this rationale given by Health Canada, it is important to recall that in response to concerns raised by Health Canada over the initial product label submitted by the Applicant, the Applicant removed from the product label any indication/instruction regarding the intended location of the Patch. As such, consumers are not provided with any guidance as to where to place the Patch, nor is any statement made to clarify that the Patch only exerts a benefit where locally applied.

[68] Health Canada also made it clear in its reasons that the representations made by the Applicant on its American website (le-vel.com) were problematic, as they were accessible to Canadians. Specifically, the August 5, 2021 letter from Health Canada advised the Applicant that a video on the Canadian website ended by linking the viewer to the American website and that a web search in Canada for the Patch brings up the American website and other direct product affiliated websites that promote therapeutic uses of the product. Health Canada noted that "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".

[69] While the Applicant advised Health Canada that the video was removed from the Canadian website and that the incorrect product brochure was removed from the Canadian website, the following representations remained in place at the time that the final decision was rendered:

A. The product brochure available on the Canadian website had been corrected to no longer refer to weight management, but rather represented the Patch as targeting the skin (replenishing the skin's moisture barrier, improving skin elasticity, causing skin to appear firm/toned and visibility younger).

B. The photo showing the Patch placement on the model's shoulder/upper arm remained unchanged.

C. The product label did not include a direction on where to place the Patch or any language that suggested that the Patch only exerts benefits locally.

D. No explanation had been provided by the Applicant about geo-blocking the American website, such that Health Canada's concern regarding Canadians' access to the therapeutic weight loss claims for the Patch remained unaddressed. As such, Canadians conducting an internet search continued to be able to access the American and other affiliated websites that promoted the very same Patch for therapeutic uses, such as weight loss.

[70] In light of the above, I am satisfied that Health Canada has provided intelligible and transparent reasons underpinning its finding that the Applicant has "represented" the Patch as "providing a whole body effect on the skin and not limited to the local application".

[71] The question to be addressed next is whether Health Canada's finding that the Applicant's representations are for use of the Patch in "modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health" is reasonable.

[72] The Applicant asserts that Health Canada fails to set out how the representations made by the Applicant meet the legislative definition of an NHP. The Applicant asserts that the statements made by Health Canada in the decision demonstrate that an unreasonable statutory interpretation was undertaken by Health Canada, as the legislative definition for an NHP does not include "systemic absorption" or "whole body effect".

[73] The Regulatory Impact Analysis Statement [RIAS] for the *NHPR* provides that the NHP definition does not include cosmetics. The Applicant asserts that "modifying organic functions" therefore cannot reasonably be interpreted to include "cleaning, improving or altering" the skin in such a manner that unreasonably merges these definitions.

[74] The Applicant further asserts that the need for a narrow interpretation to "modifying organic functions" is emphasized in the RIAS, which states at page 1574:

> At CGI, it was proposed that the third (iii) component read "maintaining or promoting health or otherwise modifying organic

> fuction in humans". However, comments were received that it should be reworded to more clearly indicate that "maintain or promote health" is inextricably tied to "modifying an organic function". This better reflects the understanding that many NHPs, through their effects on organic function, can contribute to good health.

[75] The Applicant asserts that "modifying organic functions" alone does not bring a product within the scope of the NHP definition. There must also be the broader connection to doing so in "a manner that maintains or promotes health".

[76] The Applicant assert that all of its representations about the Patch are directed towards the skin and align directly with non-therapeutic claims that Health Canada recognizes as acceptable for cosmetics. The Applicant assert that "absorption" of an ingredient by the skin does not automatically equate it to "modifying organic function", as many cosmetic lotions, pastes and patches are absorbed by the skin to some degree but do not provide any modification to an organic function. On that basis, the Applicant asserts that absorption alone is insufficient to take a product outside the definition of a cosmetic.

[77] Further, the Applicant asserts that "systemic efficacy" cannot be inferred from absorption. Interpreting it in this manner would, in effect, merge the drug and cosmetic definitions. The Applicant asserts that classification of a topically-applied product as an NHP requires more than mere absorption, it requires the specific element of modifying an organic function to improve health.

[78] The Applicant asserts that there is no representation being made by the Applicant that the Patch modifies any organic function, nor is there any suggestion by Health Canada that a scientific analysis supports such a conclusion. The Applicant asserts that there remains an unsupported "leap" in Health Canada's conclusion that renders the decision unreasonable.

[79] I reject the Applicant's assertions. The Applicant's arguments ignore what is at the core of Health Canada's determination. Health Canada acknowledged that the Applicant does not make an express therapeutic claim and it is not disputed that the Applicant employs language in its representations that Health Canada deems acceptable for non-therapeutic claims for cosmetics.

[80] However, 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 Applicant suggests a systemic therapeutic use for the Patch. I find that Health Canada's determination in this regard was reasonable.

[81] Moreover, at the time that the decision was made, Canadian consumers had access to the American website for the Patch, which was replete with language and imagery supporting a finding of express therapeutic claims and the modifying of organic functions. While the Applicant does not admit that the representations made on the American website and in American promotional

materials would meet the definition of an NHP, the Applicant has gone to great lengths to remove any and all references to any such representation, which leads me to reasonably conclude that the Applicant acknowledges the problematic nature of such representations in Canada to a cosmetic classification.

[82] Further, I would note that the Applicant has not expressly denied the accuracy of Health Canada's determination that the Patch is represented as improving the skin beyond simply the area where the Patch is applied. While the Applicant provided Health Canada with an explanation for why the model is wearing the Patch on her upper arm/shoulder and why their customers may chose to target that area of skin, the Applicant's explanation did not state that the area of skin intended to be benefitted by the Patch was limited to the local area of application. To the contrary, the Applicant stated "as per the Platt Study, the Product "[…] helps diffuse the dermal benefits to a significant surface beyond the patch application area"".

[83] The question then becomes whether Health Canada's determination that representing a systemic therapeutic use – that is, applying the Patch on your upper arm/shoulder to improve the skin over other parts of your body – meets the definition of an NHP was reasonable.

[84] I agree with the Respondent that Health Canada should be afforded deference in making this determination, as it has relevant specialized knowledge and expertise to make a decision that accords with the purposes and practical realities of the administrative regime. While "systemic absorption" or "whole body effect" are terms not found in the definition of an NHP, Health Canada explained in its letter dated July 5, 2019 that the Applicant's representations suggest that the Patch

is “absorbed systemically” and that its effects are achieved through a “systemic mechanism of action”. It is this systemic mechanism of action that constitutes the modification of an organic function.

[85] I am not satisfied that the Applicant has demonstrated that this conclusion is unreasonable. The Applicant has not pointed to any evidence that was overlooked that would point to the opposite conclusion, such as any representations in the record that would suggest that applying the Patch on your upper arm/shoulder to improve the skin over other parts of your body does not engage the modification of an organic function. While the Applicant relies on the Platt study and points to Health Canada’s comments that the Platt Study “may support a local (vs. systemic) effect”, I note that the Platt study was not a study of the Patch. But more importantly, the focus of the classification is how the Applicant represents the Patch for use. As noted by the Applicant in its July 19, 2019 submissions to Health Canada, even if the Patch modifies organic functions, the key to classification is that the Patch must be represented by the Applicant as modifying organic functions and thus I fail to see how the Platt study is of assistance to the Applicant in attempting to demonstrate that Health Canada’s decision was unreasonable.

[86] While the Applicant asserts that absorption alone is not sufficient to equate it to modifying organic function, the Applicant ignores the fact that the representations, when viewed in their totality, suggest more than just local absorption and local effect.

[87] The Applicant has made much of the fact that modifying organic functions alone is not enough and that the RIAS requires that there be a broader connection to “a manner that maintains

or promotes health". However, the Applicant made no submissions in its memorandum of fact and law to suggest that the Patch is not represented to be used in a manner so as to maintain or promote health. Moreover, I am not satisfied that it was incumbent upon Health Canada to expressly address this component of the NHP definition in its reasons, given that this aspect of the NHP definition was never a live issue between the parties. In that regard, the product brochure clearly represents the Patch to be used to help the wearer "achieve premium results for a premium lifestyle" and as part of a system of products that "promote clean and healthy skin and an overall healthy lifestyle". While the Applicant asserted for the first time in its oral submissions that "lifestyle" cannot be equated with maintaining or promoting health, I am not satisfied that the Applicant has demonstrated that Health Canada's conclusion to the contrary was unreasonable in light of the totality of the representations made by the Applicant.

[88] The Applicant asserts that Health Canada made additional errors in improperly relying upon limitations in an administrative guidance document entitled "Classification of Products at the Cosmetic-Drug Interface" [Guidance Document]. First, the Applicant asserts that whether or not the Patch meets the definition of an NHP is a distinct question from whether or not it is a cosmetic. The Applicant asserts that Health Canada's reference to the Guidance Document suggests it classified the Patch as an NHP because it does not meet the definition of a cosmetic, rather than based on an independent analysis as to whether the Patch meets the legislative definition of an NHP.

[89] I reject this assertion. There is no basis to suggest that Health Canada failed to conduct an independent analysis of whether the Patch met the definition of an NHP. To the contrary, the final

decision letter and Health Canada's earlier correspondence clearly demonstrate that such an analysis was undertaken. Moreover, Health Canada's reference to the Guidance Document in its decision letter was only made after it had already concluded that the Patch was an NHP. A fair reading of Health Canada's reference to the Guidance Document is that Health Canada was of the view that it further supported their determination, not that it was the basis for its determination.

[90] The Applicant further asserts that the Guidance Document appears to add a limitation to the definition of "cosmetic" that is not found within the language of the *FDA*. A cosmetic is defined as "any product represented to cleans, improve, or alter the skin". The Applicant asserts that there is no statutory limitation as to how this cleansing, improving or altering of the skin is achieved, such that the requirement in the Guidance Document that a cosmetic must "exhibit a lack of percutaneous absorption and should not have to be absorbed systemically to achieve the effect" impermissibly narrows the legislative definition.

[91] While the Applicant has, throughout its submissions, attempted to conflate the issue before the Court as also being whether the Patch should properly be characterized as a cosmetic, the issue before the Court is whether the determination that the Patch meets the definition of an NHP is reasonable. As noted above, I do not view Health Canada's final decision that the Patch is an NHP as having been based on the application of the Guidance Document. In that regard, I would note that the Guidance Document expressly provides in section 1.1 that it is not intended to assist in the determination of whether a drug is further sub-classified as an NHP.

[92] Even if that were incorrect, I agree with the Respondent that section 3.3 of the Guidance Document specifies that the product must exhibit a lack of percutaneous absorption and should not have to be absorbed systemically to achieve the effect. This is consistent with the definition of an NHP and the Applicant's own submission to the Court that "classification of a topically-applied product as an NHP requires more than mere absorption, it requires the specific legislative element of modifying an organic function to improve health".

[93] Finally, the Applicant asserts that Health Canada's issuance of a "stop-sale order" constitutes a penalty that is unreasonable and unjustified. The Applicant asserts that as the definition of an NHP is based upon the representations made regarding the product, the proper classification of the product is not "fixed", but rather is contingent upon the continuing presence of the NHP-qualifying representations. As such, the Applicant asserts that there is a clear alternative to requiring the Applicant to cease all sales of the Patch – namely, the Applicant could be ordered to cease making the representations at issue. The Applicant asserts that Health Canada improperly imposed a total ban on sales of the Patch, without any justification for this "extreme penalty".

[94] The Applicant asserts that even if the Court finds that the classification of the Patch as an NHP was reasonable, the Court should nonetheless find that the "penalty" imposed is unreasonable and the Applicant should be afforded an opportunity to continue to sell the Patch without the representations that Health Canada finds problematic.

[95] I reject this assertion. The Applicant's characterization of the final decision as imposing a penalty is entirely unfounded. The Applicant has not received a penalty. Rather, the Applicant was advised that the Patch is properly classified as an NHP and that an NHP license must be obtained in order to continue to sell the Patch, as prescribed by section 4(1) of the *NHPR*. Health Canada requested that the Applicant stop selling and cease all licensable activities in relation to the Patch. I agree with the Respondent that the requirement to stop selling the Patch without an NHP license was a statement of the applicable law and not the imposition of some form of penalty.

[96] There has certainly been nothing stopping the Applicant from taking steps to secure an NHP licence for the Patch since the Applicant was first alerted to Health Canada's position that the Patch was/could be an NHP over six years ago. Moreover, while the Applicant may prefer to be given the opportunity to modify its promotional materials (yet again) with a view to removing any representations that support an NHP classification, the Applicant has pointed to no statutory or other obligation imposed upon Health Canada to suspend a classification decision or to effectively "negotiate" with the Applicant to arrive at a set of representations that would result in a reclassification of the Patch as a cosmetic. The burden rests with the Applicant to comply with the law and the final decision simply confirms their obligation to do so.

[97] Accordingly, I reject the Applicant's request that it be provided with an opportunity to continue sales of the Patch pending further modifications to its promotional materials.

B. There was No Breach of Procedural Fairness

[98] The Applicant asserts that it was owed a heightened degree of procedural fairness as that the "stop-sale order" is significantly prejudicial to its business, given that the Patch is a central product in Canada and to its business as a whole. The Applicant asserts that Health Canada breached its heightened procedural fairness obligations in that Health Canada relied upon representations made by the Applicant that were inadvertent and no longer being made at the time that the final decision was rendered. Specifically, the Applicant had advised Health Canada that the product brochure and video-link referenced in Health Canada's August 5, 2021 letter were mistakenly and inadvertently included on the Canadian website and had been removed therefrom. As such, the only remaining representations on which to base Health Canada's classification of the Patch as an NHP were removed.

[99] By "standing firm" on its earlier position, the Applicant asserts that Health Canada failed to engage with the Applicant's final submissions and evidence. By refusing to confirm on cross-examination whether it conducted a reconsideration of its classification decision after receipt of the Applicant's November 8, 2021 submissions and by refusing to produce internal documents on the basis of deliberative secrecy, the Applicant asserts that the Court should draw an adverse inference against Health Canada and find that Health Canada chose to "lock-in" its conclusion reached in its August 5, 2021 letter with full knowledge that there had been a material change in circumstances and the support for the August 5, 2021 classification decision no longer existed.

[100] The Applicant asserts that the final decision should be quashed on the basis that Health Canada failed to provide a fair and just procedure in performing the classification of the Patch.

[101] I am not satisfied that the Applicant has established any breach of procedural fairness. The Applicant's assertion that Health Canada based its decision on representations that were inadvertent and that Health Canada knew were no longer being made as of the date of the decision is not borne out by the evidence. To the contrary, I am satisfied that the evidence demonstrates that 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 skim appearing visibly younger) are limited to where the Patch is locally applied, taken together, this suggest a systemic therapeutic use. All of these representations were continuing to be made by the Applicant as of the date that the final decision was rendered. Moreover, the Applicant had not advised Health Canada as of the date of the final decision of any efforts to geo-block Canadians conducting web searches for the Patch, such that access to representations made by the Applicant about the Patch in the US remained a live consideration before Health Canada.

[102] With respect to the Applicant's suggestion that it was denied procedural fairness as Health Canada improperly "locked in" its determination and failed to consider its November 8, 2021 submission, I find this suggestion to be entirely speculative. Simply because Health Canada's final determination was consistent with its earlier determination is not a basis upon which to conclude that Health Canada had a closed mind.

[103] Moreover, the evidence demonstrates no such closed mind on the part of Health Canada. The history of the interactions between Health Canada and the Applicant reveals that Health Canada entertained numerous rounds of submissions and evidence from the Applicant, permitting the Applicant with multiple opportunities to fully respond to the concerns raised by Health Canada. When the Applicant made repeated and significant changes to its representations, Health Canada considered those changes.

[104] I decline to draw any adverse inference against Health Canada as suggested by the Applicant. Contrary to the assertion of the Applicant, the final decision letter and accompanying email clearly state that Health Canada considered the information available to it as of November 26, 2021 and while new information had been provided by the Applicant regarding the removal of the problematic product pdf and video, it remained the case that the original concerns regarding the image and placement of the Patch as detailed above remained in issue, as did Health Canada's concern regarding web search results. As a result, there was a sufficient basis for Health Canada to "stand firm" on its classification of the Patch as an NHP as it had previously communicated to the Applicant. Moreover, I note that nowhere in the final decision letter does Health Canada indicate that its decision was based on the problematic product pdf and video.

VI. Costs

[105] At the hearing of the application, the parties advised that they had agreed that if the Respondent was successful and the application was dismissed, the Respondent should recover their costs of the application fixed in the amount of $10,000.00.

[106] Accordingly, the Respondent shall recover their costs of this application fixed in the amount of $10,000.00. This amount is in addition to the $2,500.00 that is now recoverable by the Respondent in relation to my Order dated January 31, 2022 on the Rule 317 motion.

VII. Conclusion

[107] For the reasons stated above, the application for judicial review shall be dismissed in its entirety and the Respondent shall recover their costs of the application fixed in the amount of $10,000.00.

JUDGMENT in T-1802-21

THIS COURT'S JUDGMENT is that:

1. The style of cause is hereby amended to remove the Minister of Health as a respondent.

2. The application for judicial review is dismissed.

3. The Applicant shall pay to the Respondent costs of this application in the amount of $10,000.00, inclusive of taxes and disbursements.

"Mandy Aylen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1802-21
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APPEARANCES:

Jay Zakaib Alexander Camenzind	FOR THE APPLICANT
Shain Widdifield Monisha Ambwani	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Gowlings WLG (Canada) LLP	FOR THE APPLICANT
Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENT