Federal Court  Cour fédérale

**Date: 20160406**

**Docket: T-1381-07**

**Citation: 2016 FC 381**

**Ottawa, Ontario, April 6, 2016**

**PRESENT: The Honourable Mr. Justice Russell**

**BETWEEN:**

**THE WINNING COMBINATION INC.**

**Applicant**

**and**

**CANADA (MINISTER OF HEALTH) AND THE ATTORNEY GENERAL OF CANADA**

**Respondents**

# JUDGMENT AND REASONS

## I. INTRODUCTION

[1] This is an application under s 18.1 of the *Federal Courts Act*, RSC 1985, c F-7 for judicial review of a series of related decisions of Health Canada, and its subsidiary entities, with respect to The Winning Combination Inc's [TWC] product, RESOLVE. The first decision, dated July 19, 2007 [First Decision], refused TWC's Product Licence Application [PLA] based on safety and efficacy concerns. The second decision, dated August 21, 2007 [Second Decision],

refused TWC's PLA on the grounds that RESOLVE is a drug and not a natural health product [NHP]. TWC also seeks judicial review of all subsequent decisions of Health Canada and its subsidiary entities relating to the RESOLVE PLA that were issued during the reconsideration process between April 7, 2008 and January 30, 2012 [Subsequent Decisions].

## II. BACKGROUND

[2] TWC markets NHPs, including RESOLVE, a smoking cessation aid that employs a confidential active ingredient [Active Ingredient]. RESOLVE was marketed by the Applicant until July 2007.

[3] The Respondent, Health Canada, together with some of its subsidiaries, is responsible for administering, marketing and approving for sale certain products under the *Food and Drugs Act*, RSC 1985, c F-27 [Act] and its regulations, which include the *Natural Health Products Regulations*, SOR/2003-196 [*NHP Regulations*].

[4] The *NHP Regulations* came into force in 2004. That same year, Applied Food and Specialities Inc, the company that sold RESOLVE to TWC, filed a PLA for RESOLVE (at that time called NicCess™ Cesteminol 350™) with the National Health Products Directorate [NHPD], a division of Health Canada under the Health Products and Food Branch [HPFB]. Relying on the authoritative Dictionary of Natural Products [DNP], NHPD initially concluded on December 2, 2004 that RESOLVE met the definition of an NHP as set out in the *NHP Regulations*.

[5] Applied Food and Specialties Inc sold and assigned all of its rights and ownership in RESOLVE to TWC in 2006; written notice of this exchange was provided to NHPD on April 12, 2006. TWC thereby assumed status as the applicant for the RESOLVE PLA.

[6] RESOLVE entered the Canadian market in 2006. Later in December of that year, Pfizer, a competitor of the Applicant's, submitted allegations to Health Canada of non-compliance with marketing and advertising standards as well as health concerns with RESOLVE, which was still in the PLA process. This complaint triggered Health Canada's further assessment of RESOLVE.

[7] Regulatory documents called Health Hazard Evaluations [HHE] were prepared by the Bureau of Clinical Trials and Health Sciences to then be used by the Health Products and Food Branch Inspectorate [HPFBI] for compliance and enforcement activities. HHEs are generally prepared to assess the level of risk from an identified problem and to inform actions to mitigate the potential health hazards created by the product, if any. As of April 1, 2011, these documents were known as Health Risk Assessments.

[8] Dr. Robin Marles, the Director of the Bureau of Clinical Trials and Health Sciences, oversaw the HHE process. As a result of safety concerns identified in the first HHE [HHE #1], the HPFBI requested in a warning letter sent on May 4, 2007 that TWC remove RESOLVE from the market. Based on the evidence of HHE #1, Health Canada concluded that RESOLVE contained a substance allegedly obtained from passionflower and that there was a likelihood of at least temporary adverse health consequences associated with its use.

[9] Five subsequent HHEs were issued between April 23, 2007 and July 17, 2007. TWC submitted information in response to the HHEs, including arguments that passionflower and balsam fir extracts were absent from RESOLVE, which NHPD alleges it considered along with the totality of TWC's evidence. The HPFBI issued a second warning letter to TWC on June 20, 2007.

[10] On June 28, 2007, TWC and officials from Health Canada attended a meeting where Dr. Marles confirmed that RESOLVE did not contain residual passionflower. However, the HPFBI maintained that recall of the product was necessary. On July 27, 2007, Health Canada released a Public Health Advisory in regards to RESOLVE.

[11] As regards the interplay and interaction of the compliance activities of the HPFBI and the PLA-assessment activities of the NHPD, the Respondents submit that it is not the case that they are entirely separate and independent. The Respondents say that the HPFBI's compliance and enforcement activities are necessarily informed by the product classification and HHE activities of the PLA and risk assessment bureaus of the NHPD.

## III. DECISIONS UNDER REVIEW

### A. *The First Decision*

[12] TWC's PLA was rejected by the NHPD by way of the July 19, 2007 Notice of Rejection [NOR] (First Decision). As a result of a designation as a Type II Health Hazard in the HHE of July 17, 2007 [HHE #6], a third warning letter with a stop sale and recall notice was also issued

by the HPFBI on this day. A Type II health risk means that the use of, or exposure to a product may cause temporary moderate adverse health consequences.

[13] The NHPD refused the Applicant's PLA pursuant to ss 7(a) and (d) of the *NHP Regulations* and on the grounds that TWC had submitted insufficient evidence to support the safety and efficacy of RESOLVE when used in accordance with the recommended conditions of use.

[14] Following the issuance of the First Decision, the Applicant filed a Request for Reconsideration on July 26, 2007 pursuant to s 9(2) of the *NHP Regulations* and filed its supporting materials on August 30, 2007.

[15] The Applicant also filed a Notice of Application for the judicial review of the First Decision on July 27, 2007.

B. *The Second Decision*

[16] Health Canada indicated, by way of the August 21, 2007 NOR (Second Decision), that upon further review the primary basis for the rejection of TWC's PLA had been adjusted: RESOLVE was not an NHP, but rather a drug and therefore subject to regulation under the *Food and Drug Regulations*, CRC, c 870 [*Food and Drug Regulations*]. This reclassification of RESOLVE had an important compliance consequence in that it, in effect, prohibited the sale of RESOLVE as an unlicensed drug that had to be removed from the market, notwithstanding its

safety and efficacy or lack thereof. In order to obtain market authorization, TWC would need to file a new drug submission for a notice of compliance.

C. *Subsequent Decisions*

[17] As part of the Request for Reconsideration process and in support of its PLA, the Applicant continued to file material between August 2007 and January 30, 2012. During this period, Health Canada maintained its position that RESOLVE was not an NHP and that efficacy had not been established, but eventually withdrew its objections based upon safety.

(1) First Level Reconsideration

[18] NHPD rendered its first level reconsideration decision on April 7, 2008 and addressed further evidence that had been provided by TWC on the subject of the safety and efficacy of RESOLVE. NHPD ultimately upheld its original decision that there was insufficient evidence to support that the Active Ingredient is an NHP and advised that conclusions regarding RESOLVE's safety and efficacy could only be reached pursuant to a review of an application for market authorization under Part C of the *Food and Drug Regulations*. With regards to data submitted by TWC to support that the Active Ingredient is naturally occurring, NHPD was not satisfied that the results were reliable.

[19] On September 18, 2008, NHPD advised TWC that the refusal of its PLA based on safety and efficacy had been reversed on safety but upheld based on insufficient evidence to

demonstrate that RESOLVE was effective for its intended use. TWC was also offered an opportunity to pursue further reconsideration. It did so on October 1, 2008.

(2) Second Level Reconsideration

[20] In a letter sent on July 22, 2009, the NHPD gave Final Notice on the second Request for Reconsideration for product classification and for efficacy as per s 10(2) of the *NHP Regulations*. The letter upheld NHPD's original decision and referenced a study provided by TWC, deeming it insufficient to establish RESOLVE as an NHP. As a result, the issue of RESOLVE's efficacy as an NHP was determined to be moot. The finality of this letter was confirmed in a subsequent letter on October 19, 2009 in which NHPD indicated that should TWC wish to pursue a product license for RESOLVE, it could do so under the *Food and Drug Regulations*.

[21] On September 20, 2011, NHPD sent another letter to TWC stating that while it had received an August 15, 2011 Request for Reconsideration, it was upholding its decision to refuse to issue a product license and that no further consideration would be given to the PLA.

[22] On January 30, 2012, NHPD sent a letter in response to new information that had been submitted by TWC. The letter indicated that the information had been considered but confirmed that the Active Ingredient was not an NHP and there was insufficient evidence to support RESOLVE's efficacy. NHPD stated that its decision to deny the application was final and that the letter was its ultimate correspondence relating to the reconsideration process.

## IV. ISSUES

[23] TWC has raised a wide range of issues which I will summarize in a general way and deal with in detail later;

1) The statutory interpretation of the *NHP Regulations* regarding efficacy;
2) Whether procedural fairness was afforded to TWC;
3) Did Health Canada fail to comply with relevant legislation, regulations, policies and standard operating procedures during the PLA consideration and reconsideration process;
4) Did Health Canada exhibit bad faith, bias, lack of independence, lack of impartiality, discrimination and/or conflict of interest in its decision-making;
5) Whether Health Canada was *functus* following the First Decision;
6) The legal relevance and effect of the reconsideration process; and
7) Whether any of the decisions satisfied the reasonableness standard.

## V. STANDARD OF REVIEW

[24] The Supreme Court of Canada in *Dunsmuir v New Brunswick*, 2008 SCC 9 [*Dunsmuir*] held that a standard of review analysis need not be conducted in every instance. Instead, where the standard of review applicable to a particular question before the court is settled in a satisfactory manner by past jurisprudence, the reviewing court may adopt that standard of review. Only where this search proves fruitless, or where the relevant precedents appear to be inconsistent with new developments in the common law principles of judicial review, must the reviewing court undertake a consideration of the four factors comprising the standard of review analysis: *Agraira v Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36 at para 48 [*Agraira*].

[25] All of the procedural fairness issues (bad faith, bias, lack of independence and impartiality, discrimination and/or conflict of interest) will be reviewed on a standard of correctness and in accordance with the tests and jurisprudence applicable to those issues.

[26] TWC submits that the standard of correctness should apply to the interpretation of the *NHP Regulations* in this case. In the alternative, should reasonableness be applied, TWC says that should the ordinary tools of statutory interpretation lead to a single reasonable interpretation that differs from that adopted by the Minister, his or her interpretation will necessarily be unreasonable and no degree of deference will justify its acceptance: *British Columbia (Securities Commission) v McLean*, 2013 SCC 67.

[27] The Respondents submit that where scientific knowledge is a factual component of the decision, reasonableness will apply: *Apotex Inc v Canada (Health)*, 2012 FCA 322 at para 41. The courts have accorded particular deference to Health Canada in drug submissions, given that the approval process is a complex and technical area of public administration: *Hospira Healthcare Corporation v Canada (Attorney General)*, 2010 FC 213 at para 33.

[28] The jurisprudence is clear that reasonableness is the proper standard to be applied for both the Minister's interpretation of the *NHP Regulations* and the decisions regarding TWC's PLA: *Canadian Pharmaceutical Technologies International (CPT) Inc v Canada (Attorney General)*, 2007 FC 708. These issues will therefore be reviewed on the reasonableness standard.

[29] When reviewing a decision on the standard of reasonableness, the analysis will be concerned with "the existence of justification, transparency and intelligibility within the decision-making process [and also with] whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law." See *Dunsmuir*, above, at para 47, and *Khosa v Canada (Minister of Citizenship and Immigration)*, 2009 SCC 12 at para 59. Put another way, the Court should intervene only if the Decisions were unreasonable in the sense that they fall outside the "range of possible, acceptable outcomes which are defensible in respect of the facts and law."

## VI. STATUTORY PROVISIONS

[30] The following provisions of the *NHP Regulations* are relevant in this proceeding:

| **Interpretation** | **Définitions** |
|---|---|
| "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; | (*b*) à la restauration ou à la correction des fonctions |

Or

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

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. 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.

**Licence Application**

5. An application for a product licence shall be submitted to the Minister and shall contain the following information and documents:

(*a*) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

(*b*) if the address submitted under paragraph (*a*) is not a Canadian address, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant's representative in Canada to whom notices may be sent;

(*c*) for each medicinal ingredient of the natural health

**Demande**

5. La demande de licence de mise en marché est présentée au ministre et comporte les renseignements et documents suivants :

(*a*) le nom, l'adresse, le numéro de téléphone et, le cas échéant, le numéro de télécopieur et l'adresse électronique du demandeur.

(*b*) si l'adresse visée à l'alinéa (*a*) est un lieu situe à l'extérieur du Canada, le nom, l'adresse, le numéro de téléphone et, le case échéant, le numéro de télécopieur et l'adresse électronique du représentant du demandeur au Canada à qui les avis peuvent être expédies;

(*c*) pour chacun des ingrédients médicinaux contenus dans le

product,

(i) its proper name and its common name,

(ii) its quantity per dosage unit,

(iii) its potency, if a representation relating to its potency is to be shown on any label of the natural health product,

(iv) a description of its source material, and

(v) a statement indicating whether it is synthetically manufactured;

(*d*) a qualitative list of the non-medicinal ingredients that are proposed for the natural health product and for each ingredient listed, a statement that indicates the purpose of the ingredient;

(*e*) each brand name under which the natural health product is proposed to be sold;

(*f*) the recommended conditions of use for the natural health product;

(*g*) information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use;

(*h*) the text of each label that is

produit :

(i) son nom propre et son nom usuel,

(ii) sa quantité par unité posologique,

(iii) son activité si l'une des étiquettes du produit comporte une déclaration à l'égard de celle-ci,

(iv) une description de sa matière d'origine,

(v) une mention indiquant s'il s'agit d'un ingrédient fabriqué synthétiquement;

(*d*) une liste qualitative des ingrédients non médicinaux qu'on se propose d'incorporer au produit de santé naturel ainsi que, pour chacun de ces ingrédients, une mention indiquant à quelle fins l'ingrédient serait incorpore au produit;

(*e*) chacune des marques nominatives sous lesquelles le produit est destiné à être vendu;

(*f*) les conditions d'utilisation recommandées du produit;

(*g*) les renseignements montrant l'innocuité et l'efficacité du produit lorsqu'il est utilisé selon les conditions d'utilisation recommandées;

(*h*) le texte à utiliser sur

proposed to be used in conjunction with the natural health product;

chacune des étiquettes du produit;

(*i*) a copy of the specifications to which the natural health product will comply; and

(*i*) un exemplaire des spécifications auxquelles le produit devra se conformer;

(*j*) one of the following attestations, namely,

(*j*) l'une des attestations suivantes :

(i) if the natural health product is imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3, or

(i) dans le cas d'un produit de santé naturel importé, une attestation du demandeur établissant que le produit de santé naturel sera fabriqué, emballé, étiqueté, importé, distribué et entreposé conformément aux exigences prévues à la partie 3 ou à des exigences équivalentes,

(ii) if the natural health product is not imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, distributed and stored in accordance with requirements set out in Part 3.

(ii) dans le cas d'un produit de santé naturel qui n'est pas importé, une attestation du demandeur établissant que le produit de santé naturel sera fabriqué, emballé, étiqueté, distribué et entreposé conformément aux exigences prévue à la partie 3.

…

…

**Issuance and Amendment**

**Délivrance et Modification**

7. The Minister shall issue or amend a product licence if

7. Le ministre délivre ou modifie la licence de mise en marché si les conditions suivantes sont réunies :

(*a*) the applicant submits an application to the Minister that is in accordance with section 5 or subsection 11(2), as the case

(*a*) le demandeur présente au ministre une demande conforme à l'article 5 ou au paragraphe 11(2), selon le cas;

| | |
|---|---|
| may be; | |
| (*b*) the applicant submits to the Minister all additional information or samples requested under section 15; | (*b*) le demandeur fournit au ministre les renseignements complémentaires ou les échantillons demandes en vertu de l'article 15; |
| (*c*) the applicant does not make a false or misleading statement in the application; and | (*c*) le demandeur ne fait pas de déclaration fausse ou trompeuse dans sa demande; |
| (*d*) the issuance or amendment of the licence, as the case may be, is not likely to result in injury to the health of a purchaser or consumer. | (*d*) la délivrance ou la modification de la licence ne risque pas de cause un préjudice à la santé de l'acheteur ou du consommateur. |

## VII. ARGUMENTS

### A. *Applicant*

#### (1) Procedural Fairness

[31] TWC submits that this licence application has been plagued by procedural unfairness since January 2007 and that the RESOLVE PLA review was not conducted in a fair and impartial manner. TWC was denied the basic elements of procedural fairness in relation to both the First Decision and the Second Decision, including notice and the opportunity to be heard. NHPD deviated from its standard procedure and TWC's legitimate expectations. NHPD's decisions demonstrate bias, pre-judgment, a closed mind and bad faith.

[32] TWC references a series of procedurally unfair actions taken and omissions made by the NHPD in relation to the RESOLVE PLA that render the administrative decisions in question *void ab initio*:

- The issuing of the May 4, 2007 warning letter even after questioning whether it made sense to do so and without giving TWC any prior notice or opportunity to respond;
- Creating a "moving target" by way of new allegations and reasons to take compliance action or to reject the PLA every time TWC responded to allegations;
- The admission of Mr. Gustafson, HPFBI inspector, on June 28, 2007 that TWC was not going to get a license no matter what information it provided;
- Dr. Marles' unauthorized intrusion into and effective management of the PLA process notwithstanding his conflict of interest as the author of the HHEs and resulting severe compliance action;
- Setting aside the initial Safety and Efficacy Assessment Report [SEAR] of June 19, 2007 which supported safety and should have been the end of any safety issues;
- Issuing both rejections (First Decision and Second Decision) without prior information request notices and therefore not caring what further evidence might have been available as to safety, efficacy or classification;
- Issuing HHE #6 based on three new and unfounded safety allegations without giving TWC any prior notice or opportunity to respond;
- Disregarding a toxicology report when it confirmed safety, without any toxicology evidence to the contrary, but then mistakenly relying on it to allege a new safety issue;
- Using the Adverse Reaction Reports as one of the reasons to justify HHE #6 and the rejection decision when it was highly tenuous and based on an erroneous assumption in regards to passionflower, without giving TWC proper opportunity to respond;
- Misinforming the Associate Deputy Minister, other senior officials of Health Canada, HPFBI and TWC regarding the status of the PLA and specifically, failing to advise that the initial SEAR had supported safety;
- Basing the First Decision on HHE #6 rather than a completed SEAR in accordance with standard procedure and then issuing the NOR before the SEAR was even complete;
- Overzealously pursuing the classification issue even after the First Decision and issuing the Second Decision without giving TWC notice that classification was now an issue;

- Issuing the Second Decision even though the Active Ingredient was still listed as a natural substance by NHPD and by the DNP reference as of that date;
- Taking the unprecedented step of lobbying DNP to remove the Active Ingredient from its list of natural substances;
- Issuing a Public Advisory when no "imminent" risk of "serious or irreversible" injury existed and after TWC had already agreed to recall the product.

(2) Classification

[33] In addition to considerations of procedural fairness, TWC submits that the Second Decision should be quashed on grounds including bootstrapping, *functus officio*, exhaustion of discretion, estoppel and lack of delegated authority.

[34] TWC argues that the Second Decision was an attempt to bolster the previous license denial in anticipation of the damages that TWC was likely to claim.

[35] TWC stresses that the Second Decision's conclusion in regards to classification did not result from any scientific evidence or testing. The Second Decision was issued by NHPD entirely as a result of an alleged DNP error without contacting DNP or TWC. TWC submits that it filled the evidence gap that NHPD alleged existed by providing overwhelming evidence, including scientific testing and reports from two different laboratories, as well as a peer-reviewed published article. NHPD, however, continued to criticize TWC's evidence, filed and retained its own reports and repeatedly refused to reverse the classification NOR of the Second Decision throughout the reconsideration process.

[36] The PLA was concluded subject only to TWC's right to request reconsideration. Therefore, TWC says that the Minister was *functus* with respect to the PLA as the *NHP Regulations* do not provide for a unilateral right of the Minister to reconsider a decision. The Minister was without jurisdiction to issue a further rejection of the PLA based on classification (as was done in the Second Decision) or on any other grounds*: Canadian Association of Film Distributors and Exporters v Society for Reproduction Rights of Authors, Composers and Publishers in Canada (SODRAC) Inc*, 2014 FCA 235 at paras 58, 68-75; *CHUM Ltd v Canada (Attorney General),* 2005 FCA 142; *Baudisch v Civil Aviation Tribunal*, [1997] 129 FTR 241.

[37] In the alternative, even if *functus* does not apply, it should be noted that as of August 21, 2007, DNP still listed the Active Ingredient as a natural substance. DNP was adopted by NHPD as the definitive standard for NHP classification and it is therefore submitted that the Minister was bound by the DNP classification as it existed on July 19, 2007 and August 21, 2007 and at the time of the prior NHPD classification decisions. The Minister was estopped or precluded from reversing these decisions or issuing the Second Decision. Alternatively, the abandonment of the DNP standard was discriminatory and a gross deviation from accepted procedure and the legitimate expectations of TWC.

(3) Safety

[38] RESOLVE had been designated an NHP on three occasions prior to the denial of its PLA in the First Decision. Even though the classification of the Active Ingredient had been questioned prior to July 19, 2007, the First Decision was issued solely on the basis of safety and efficacy.

[39] While it is clear, and Health Canada has admitted, that safety concerns should not have been relied on in denial of the PLA in the first place, TWC submits that it had no opportunity to address the alleged safety concerns of the First Decision until after it was released.

[40] Following the release of the First Decision, TWC says it provided specific responses to each of the three safety allegations of Health Canada, and the decision was subsequently reversed.

(4) Efficacy

[41] TWC says that the standard demanded by the NHPD with respect to efficacy exceeded any reasonable interpretation of the *NHP Regulations*, which do not require any substantive proof for efficacy. The practices of Health Canada cannot create additional or more onerous standards or tests.

[42] Section 7 of the *NHP Regulations*, which provides that the Minister shall issue a licence if the requirements of subsections (a) through (d) are met, sets out a substantive test for safety. Therefore, s 5(g) which simply requires "information which supports safety and efficacy" should only be interpreted as administrative in nature as it only addresses materials that should be included in the PLA. This interpretation is consistent with the authorities on statutory interpretation, including the "presumption of coherence." *Bell ExpressVu Ltd Partnership v Rex*, 2002 SCC 42 at paras 26-27, 30; *R v Ulybel Enterprises Ltd*, 2001 SCC 56 at paras 28-30; *Gordon v Taylor*, 2014 ABQB 11 at paras 9-11. Furthermore, Health Canada's "Decision

Making Framework" recognizes that sometimes no evidence of "benefit" is necessary for safe products, even prescription drugs.

[43] Even if s 5(g) can be interpreted as a threshold substantive test, it must be less onerous than the standard of proof required for safety under s 7(d): the information required for efficacy does not have to prove that the product "likely" is efficacious, and no minimum standard of scientific proof is required.

[44] TWC's PLA simply claimed that the product "may" help with smoking cessation (not that it "will"). Therefore, any substantive test for efficacy must be very modest and information that falls short of establishing a likelihood that a product may help with smoking cessation should be considered sufficient. Furthermore, even if the information provided does not support the claims made for the product, the PLA is not automatically denied. Steps such as market studies and/or the amending of product labels can be applied as conditions for granting the license.

[45] TWC submits that on the reasonable interpretation of the *NHP Regulations* and of the evidence, Health Canada had no basis to reject the PLA on efficacy-related grounds. Even if the *NHP Regulations* are interpreted as requiring a substantive test for efficacy, TWC was only required to adduce information that supported the modest claim in the PLA that RESOLVE "may" help with smoking cessation.

[46] The PLA complied with s 5(g) by including information that supports efficacy, including a phase 1 human clinical study along with university-conducted *in vitro* and animal studies, a statistical analysis of phase II human clinical study, U.S. patent information and various papers, articles and testimonials. Health Canada acknowledged this by accepting the PLA and deeming it complete.

[47] TWC further submits that the information provided by TWC in both the PLA and the reconsideration processes was more than sufficient to prove even the likelihood that RESOLVE may help with smoking cessation. Therefore, it certainly satisfied a standard less than that. NHPD nonetheless critiqued it based on technical scientific standards, imposing a standard that went beyond the simple "information to support" requirement under the *NHP Regulations* towards one of "conclusive proof" of efficacy.

(5) The Reconsideration Process Generally

[48] TWC says that the reconsideration process in this case did not constitute an adequate alternative remedy and failed to address fundamental deficiencies of the First and Second Decisions, such as whether procedural fairness had been afforded and whether the Second Decision had issued after the Minister was *functus*.

[49] TWC says that the Subsequent Decisions of the reconsideration process are legally irrelevant and need not be considered by the Court. In the alternative, it is submitted that if the reconsideration process is relevant, then it was not fair or impartial, suffering from the same procedural unfairness as the First and Second Decisions.

[50] Because the review of the PLA was not done by an independent tribunal outside of Health Canada, as requested repeatedly by TWC, there could be no reasonable expectation that the reconsideration would occur fairly or cure the defects present in this case. Whereas DNP was prepared to accept evidence from TWC's experts as sufficient proof that the Active Ingredient was naturally occurring, NHPD held TWC to an unprecedented standard of scientific certainty. No matter what evidence was offered by TWC, it was not going to succeed in the reconsideration.

B. *Respondents*

(1) Procedural Fairness

[51] The Respondents submit that TWC was afforded procedural fairness beyond what is required by law. It was not necessary for Health Canada to provide notice or an opportunity to be heard prior to the issuing of the public advisory on July 27, 2007, but it did so. Furthermore, TWC was given the chance to submit additional documents within ten days of the June 28, 2007 meeting. Determinations of procedural fairness must be balanced with the reality that Health Canada was addressing what could only have been assessed as a serious and immediate safety risk based on the information available to the NHPD at the time. Following the Second Decision regarding the classification of RESOLVE, TWC took advantage of numerous opportunities to continually submit further evidence to show that its Active Ingredient is an NHP. This evidence was accepted and considered until October 2011.

[52] The Respondents say that because TWC was regularly engaged by Health Canada about its product throughout the regulatory decision-making process, only a minimal amount of procedural fairness is owed with respect to the classification decision in the Second Decision. Furthermore, when it comes to matters of public health and safety, procedural guarantees will be adjusted according to the degree of risk and urgency, which the decision-maker will enjoy considerable latitude in assessing: *Miel Labonté Inc v Canada (Attorney General)*, 2006 FC 195.

[53] The NHPD was in possession of information from a reliable source relating to safety risks. It was reasonable for the NHPD to believe this information and take corresponding enforcement measures, including public advisories and stop sale and recall orders.

(a) *Reconsideration*

[54] Health Canada accepted new information from TWC, including seven volumes of material plus additional supporting correspondence in the reconsideration process. NHPD not only followed all of the prescribed rules under ss 7 through 10 of the *NHP Regulations* but went beyond the normal scope of reconsideration in granting TWC a second reconsideration. When the evidence adduced by TWC was determined to be inadequate, the First Decision was upheld. TWC submitted an additional request for reconsideration. Notwithstanding the stated general practice of Health Canada to terminate reconsideration processes when a judicial review has been filed (as it was on July 27, 2007), to give TWC every opportunity to address outstanding issues, NHPD continued the reconsideration process.

(b) *Bias*

[55] Dr. Marles was at all material times the senior science advisor to the NHPD. TWC accuses NHPD staff, including Dr. Marles, of bias, pre-judgment, having a closed mind and bad faith. TWC has not submitted any logical explanation as to why he might be antagonistic towards TWC or RESOLVE and there is no evidence that Dr. Marles had any interest in a competing product or was at any point entrenched in any position regarding RESOLVE.

[56] The Respondents say that the classification of the Active Ingredient as a drug rather than an NHP was not, as alleged by TWC, an attempt to bootstrap the First Decision. It was not unprecedented that the DNP was contacted and the DNP reached its own conclusion that the Active Ingredient is not a natural product. Contrary to what TWC suggests, it has not re-listed the Active Ingredient as a natural substance.

[57] The Respondents submit that its decisions to refuse the PLA and the subsequent reconsideration applications were reasonable and made through reliance upon valid scientific evidence with respect to the classification, safety and efficacy of the Active Ingredient. TWC was given an exceptional opportunity to provide fresh evidence during the reconsideration process, which the NHPD considered even after the commencement of the judicial review application, and has failed to demonstrate that its product is "natural."

(2) Classification

[58] NHPD's internal and external experts concluded that there is no evidence in the peer-reviewed scientific literature that the Active Ingredient occurs in nature. Where a product contains an active ingredient that does not occur in nature, it does not fall within the scope of the definition of an NHP. When this occurs, the NHPD is statutorily prohibited from issuing a license under the *NHP Regulations*. While a 2005 article may have alleged the presence of the Active Ingredient in mangoes [Mango article], the DNP, which the NHPD considers to be an authoritative database of natural health products, was never updated to include the Active Ingredient subsequent to the article. The Respondents submit that it was entirely reasonable for the NHPD to issue the Second Decision to reflect the operation of the *NHP Regulations* because the Active Ingredient is a synthetic substance that does not occur naturally.

(3) Safety and Efficacy

[59] The Respondents say that the NHPD, as a federal health regulator, reasonably took compliance and enforcement measures in accordance with the information it received concerning safety and efficacy. NHPD's information relating to a safety risk was from a reliable source and included information from a peer-reviewed article as well as the HHEs themselves. It was therefore reasonable and necessary that the NHPD took enforcement measures like public advisories and stop sale and recall orders in order to limit consumer risk.

[60] The Respondents disagree with TWC's submission that a substantive requirement of efficacy is not mandatory under the *NHP Regulations*. Subsection 7(a) incorporates the

requirements of s 5, including paragraph (g), which necessitates "information which supports safety and efficacy." The Respondents assert that this is not merely an administrative requirement but also a substantive one. A substantive review of the RESOLVE PLA was conducted under the regulations for the various requirements prescribed by s 7 which includes information that supports efficacy. The PLA was analyzed in light of efficacy concerns identified in the HHE and it was determined that it did not meet the threshold for granting a licence under s 8.

## VIII. ANALYSIS

### A. *Introduction*

[61] In addition to general charges of acting unreasonably, TWC accuses Health Canada in this application of egregious misconduct including bad faith, lack of procedural fairness, bias, appearance of bias, acting without authority, bootstrapping, shoring up of evidence, and acting with a closed mind contrary to standard policy and outside the legitimacy of delegated authority.

[62] The history of this litigation is long and bitter and the record is voluminous. The dispute is rendered particularly convoluted by the interactions between the HPFBI, responsible for compliance and enforcement, and the NHPD (now the Natural and Non-Prescription Health Products Directorate – NNHPD), both of which were called into play following TWC's assumption of the PLA that Applied Food and Specialties Inc had commenced in October 2004, and after Pfizer's submission of a trade complaint about the sale and marketing of TWC's RESOLVE product in December 2006. From that point on, TWC was obliged to deal with

Health Canada from both a licencing and a compliance perspective, and it is in the interplay between these two distinct, but inevitably related, processes that the dispute is pitched.

[63] In order to provide some sense of direction through the interactive maze that developed between the initial PLA in 2004 and NHPD's final negative reconsideration decision of January 30, 2012, it helps to bear in mind that NHPD made two (2) major decisions with regard to TWC's PLA.

[64] The First Decision occurred on July 19, 2007 when NHPD rejected TWC's PLA outright based upon safety and efficacy concerns, but not upon classification concerns. This decision was underscored by HPFBI's decision on the same day to issue a "Stop Sale, Stop Advertising and Recall" direction, and to release a revised HHE classifying RESOLVE as a Type II health hazard.

[65] The Second Decision by NHPD, which occurred on August 21, 2007, rejected the same PLA on the basis that RESOLVE was not an NHP and was thus subject to regulation under the *Food and Drug Regulations* and not the *NHP Regulations*. In effect, this Second Decision rendered the First Decision moot, but NHPD continued thereafter to consider and invite reconsideration applications by TWC that questioned both decisions (one based upon safety and efficacy issues, and the other based upon classification), thus indicating, ostensibly at least, that NHPD was open to changing its mind on both grounds of refusal.

[66] TWC says that, in fact, NHPD had made the decision long ago to deny TWC a PLA, and that NHPD's purposes in going through the reconsideration process was to build a case to support and shore up the two refusal decisions that it had already made in error and in total disregard of procedural fairness.

[67] The two major decisions I have referred to cannot be disconnected because TWC alleges that the classification decision of August 21, 2007 (the Second Decision) was an unjustified and cynical ploy by NHPD to cut the ground out from under TWC after TWC asked for reconsideration of the safety and efficacy decision of July 19, 2007 (the First Decision), a decision that, according to TWC, had no basis in law or fact to support it.

[68] So, we are dealing with allegations of individual and institutional bias and bad faith in addition to the more usual grounds for reviewable error based upon unreasonableness and procedural unfairness.

B. *Evidentiary Issues*

[69] TWC has raised a considerable number of objections to affidavit evidence filed by the Respondents, as well as certain paragraphs contained in the Respondents' Memorandum of Fact and Law. These objections were brought as formal motions that the Court heard together with the underlying application for judicial review.

[70] In general, TWC's objections to the affidavit evidence filed by the Respondents (the Marles and Arnason affidavits) and the report of Dr. Foster that is attached to the Marles' affidavit of January 30, 2012, are that:

a) The affidavits filed on behalf of the Respondents, or portions therein, contain facts outside of the deponents' personal knowledge, inadmissible hearsay, opinions, arguments, conclusions and irrelevant information;

b) The affidavits filed on behalf of the Respondents, or portions therein, contain inadmissible supplemental reasons for denying TWC a NHP license which attempt to add to the denial reasons that are the subject of this application;

c) The affidavits filed on behalf of the Respondents, or portions therein, contain inadmissible opinions and conclusions from experts which lack independence and impartiality;

d) The offending affidavits filed on behalf of the Respondents, or portions therein, directly relate to controversial issues to be argued in this application; and

e) The Applicant will be unfairly prejudiced by the inclusion of the offending affidavits, or portions therein.

[71] As regards the objections to the Respondents' Memorandum of Fact and Law, TWC objects to paragraphs 40, 85 and 108 on the grounds that:

a) The Memorandum of Fact and Law in the Respondents' Motion Record improperly contains alleged evidence and statements not included in any affidavit material filed with the Court;

b) The Memorandum of Fact and Law in the Respondents' Motion Record contains an evidentiary objection which is not permissible as a result of the Respondents' failure to file motion materials making evidentiary objections by August 31, 2015, as directed by the Court; and

c) The Applicant will be unfairly prejudiced by the inclusion of the offending alleged evidence and the untimely objection.

[72] It is impossible to deal with the detailed substance of these evidentiary objections separate and apart from the full context and merits of the judicial review application. Consequently, I will deal with evidentiary objections as they arise on the merits.

C. *Classification*

[73] The August 21, 2007 NOR (Second Decision) denied TWC's PLA on the ground that the Active Ingredient of RESOLVE was not a natural substance.

[74] The previous July 19, 2007 NOR (First Decision) was based on efficacy and safety issues which means that, by implication, NHPD did not regard classification as a problem at that time. Indeed, relying upon the definitive DNP listing of the Active Ingredient as a natural substance, NHPD had already made three classification decisions (December 2, 2004, January 25, 2007 and June 18, 2007) which accepted that the Active Ingredient in RESOLVE was a natural product based upon the DNP listing. So what happened to make NHPD change its mind and decide to deny the PLA on the separate classification ground in the Second Decision? The motivation and the sequence of events here are murky.

[75] The issue of classification was, in fact, raised within Health Canada prior to the First Decision based upon efficacy and safety. Prior to the July 19, 2007 NOR, Paul Gustafson, who was the investigator at HPFBI dealing with the Pfizer complaint, emailed Dr. Marles and challenged the previous classification of RESOLVE's Active Ingredient as a natural substance. On July 10, 2007, Dr. Marles replied to Mr. Gustafson and confirmed that the Active Ingredient was an NHP according to the definitive DNP reference. This is why the First Decision is based

solely on safety and efficacy. And even after the First Decision, Dr. Marles made it clear in a July 25, 2007 email that "everyone internally knows it is an NHP".

[76] Dr. Marles' advice, however, did not deter Mr. Gustafson. The evidence suggests that he researched the scientific articles that DNP had relied upon and cited to list the Active Ingredient as an NHP. Mr. Gustafson then emailed Dr. Marles on August 16, 2007 and raised the issue again. This time Dr. Marles was convinced that the classification could and should be questioned and he took decisive action to ensure that it was.

[77] It was Dr. Marles who arranged for the August 21, 2007 NOR (the Second Decision), which denied TWC's PLA on the separate ground of classification. The issuance of the Second Decision and the refusal of the PLA on this new ground was a complete surprise to TWC, because classification had never been previously raised and there was no reason to believe that it could be a problem. The First Decision makes it clear that safety and efficacy were the only concerns.

[78] There are certain telling facts surrounding the issuance of the Second Decision that give rise to serious legal issues:

a) There was no evidence before Dr. Marles or anyone at NHPD or HPFBI that RESOLVE's Active Ingredient was not an NHP. At the time of the NOR, it was still listed as an NHP by DNP, which Health Canada regards as definitive;

b) All that Dr. Marles could know at the material time was that the articles cited and relied on by DNP could be questioned and, even if these articles, in Dr. Marles' opinion, did not support the DNP listing, this did not mean that the Active Ingredient was not an NHP. So, without evidence and without even consulting with DNP over the issue, Dr. Marles took it upon himself to make a crucial and far-reaching decision that had no evidence to support it; and

c) Dr. Marles made this crucial and far-reaching decision that, in effect, kicked RESOLVE out of the *NHP Regulations* and into the *Food and Drug Regulations* without any notice to TWC that there was a classification issue to be resolved, and without any opportunity for TWC to address it with either NHPD or DNP.

[79] In my view, this evidence alone supports the allegations of a serious breach of procedural fairness and the unreasonableness of the August 21, 2007 NOR. But there is also evidence to suggest something more serious took place during this process.

[80] Having made and orchestrated the decision behind the August 21, 2007 NOR, Dr. Marles then contacted DNP and, on August 27, 2007, he made a submission to DNP that the Active Ingredient at issue in this case should be removed from DNP's list of natural substances. He pointed out that an article relied upon by DNP for the listing did not actually confirm that the Active Ingredient was a natural substance. TWC was not informed of these submissions, and was given no opportunity to address this important issue.

[81] On September 11, 2007, DNP said it would remove the Active Ingredient from the list. This gives rise to further concerns that emerged during the reconsideration process and which I will come to later. However, in his affidavit of July 2, 2013, sworn on behalf of TWC, Shazad Bukhari, who is the Chief Operating Officer of TWC [Bukhari July 2, 2013], says that DNP later agreed to re-list the Active Ingredient as a natural substance after reviewing the expert opinions of scientists retained by TWC. In its written Memorandum of Fact and Law, NHPD says that such a re-listing has not occurred. This remains a mere assertion in argument and has no evidence to back it up. This is one of the evidentiary matters raised by TWC and the Court has been asked to strike paragraph 108 of NHPD's written Memorandum. NHPD says that a listing,

or lack thereof, in DNP, is something of which I can take judicial notice. However, although I agree with TWC that NHPD cannot reply upon assertions in legal argument for which there is no evidentiary base, I do not think this disagreement between the parties really goes to the issue before me. All the Court knows at this point is that the Active Ingredient was de-listed from DNP but that DNP has said it will be re-listed. The present state of thinking at DNP on this issue is not in evidence. What is clear from the record is that the de-listing of the Active Ingredient by DNP occurred at the instigation of Dr. Marles, who made submissions to DNP after the August 21, 2007 NOR had been issued and at a time when the Active Ingredient was still listed in DNP and when Dr. Marles and DNP had no evidence to suggest that it was not a natural substance. While subsequent evidence produced by TWC during the reconsideration process suggests that there is ample proof that the Active Ingredient in RESOLVE is a natural substance, TWC was never given an opportunity to produce submissions on point before the August 21, 2007 NOR issued. As I will discuss later, reconsideration does not correct the procedural unfairness that TWC suffered as a result of the Second Decision.

[82] There is no reason why Dr. Marles needed to hurriedly orchestrate the Second Decision without input from TWC. On August 21, 2007, the PLA license had already been denied by virtue of the First Decision, RESOLVE had been recalled and a Public Health Advisory had been issued. The August 21, 2007 NOR was made at the instigation of Dr. Marles and was based upon his own unsupported conclusions that the Active Ingredient should not be listed as a natural substance. Dr. Marles also made sure that this momentous decision, from the perspective of TWC's interests, was made without any input from TWC and without TWC even knowing that it was a possibility. Having made an unreasonable and procedurally unfair decision, Dr. Marles

then – and once again, without notice to TWC – set about enlisting the support of DNP in an attempt to legitimize an unacceptable decision he had already made. Further attempts were also made to use the reconsideration process to legitimize a legally erroneous decision, but the reviewable error had already occurred.

D. *Classification Reconsideration*

[83] Health Canada takes the position that it afforded more than ample procedural fairness to TWC with respect to RESOLVE, both prior to the licensing decision and throughout the three reconsideration decisions.

[84] As set out above, the facts are clear that Health Canada provided TWC with no procedural fairness at all with regard to the classification ground for denial and the Second Decision. That decision was hurriedly instigated by Dr. Marles without notice or warning to TWC that classification was a concern to Health Canada, and after previous internal decisions by Health Canada that suggest that classification was not a concern and that NHPD accepted the Active Ingredient of RESOLVE as an NHP. I fail to see how this can be described as "ample" procedural fairness, as Health Canada now asserts.

[85] If Health Canada means that the reconsideration process undertaken with respect to classification somehow rectified the lack of procedural fairness that lies behind the Second Decision, then I think Health Canada is mistaken on both legal and factual grounds.

[86] Section 9 of the *NHP Regulations* allows PLA license applicants to challenge license refusals by way of reconsideration, and in this case TWC asked the Minister to reconsider both the First Decision based upon safety and efficacy concerns, and the Second Decision based upon classification.

[87] It is important to bear in mind that administrative decisions made in the absence of procedural fairness cannot be cured by a reconsideration process. As indicated by the Supreme Court of Canada in *Newfoundland Telephone Co v Newfoundland (Public Utilities Board)*, [1992] SCR 623 [*Newfoundland Telephone*], a decision "which denied the parties a fair hearing cannot be simply voidable and rendered valid as a result of the subsequent decision of the tribunal" (at para 40). Administrative decisions made without procedural fairness are *void ab initio*. See also *Agraira*, above, at paras 93-96.

[88] Strictly speaking, then, the Court does not need to examine the reconsideration process with regard to the August 21, 2007 NOR for its impact upon the lack of procedural fairness behind that decision. However, the reconsideration process does have some relevance for this judicial review application because it throws some light upon the bootstrapping, closed mindedness and bias that TWC alleges have characterized NHPD's whole approach to dealing with the PLA and, indeed, HPFBI's compliance actions.

[89] NHPD, relying upon and following the directions of Dr. Marles, based the August 21, 2007 NOR upon a lack of evidence that RESOLVE's Active Ingredient was an NHP. Consequently, TWC set about providing authoritative evidence that it was an NHP.

[90] My review of the evidence on this aspect of the reconsideration process leads me to the conclusion that NHPD was both unreasonable in its reconsideration decisions and, once again, procedurally unfair in its dealings with TWC.

[91] To begin with, in violation of policy and assurances given by NHPD to TWC, the reconsideration process significantly involved individuals responsible for the Second Decision. In particular, Dr. Marles was heavily involved and, in effect, defended his own prior decisions at a time when NHPD knew it was facing legal action and possible heavy liabilities for its negative PLA decisions. Further, it was Dr. Marles who effected HHE #6 and advised HPFBI to issue the public advisory and recall which had removed TWC's ability to market RESOLVE in the first place.

[92] TWC had requested independent experts for reconsideration, including an opportunity for its own expert panel to meet with the panel considering its reconsideration. NHPD had initially refused to involve outside experts but provided assurances that reconsideration would not involve any person in the original PLA assessment, the issuance of the HHEs or the July 19, 2007 NOR (see Bukhari December 2007 at paras 18-19, 93, 97-102 and EXHS. 40-43; Sitar November 2011 at paras 21 and 29; Marles Cross, at 248-250 and EXHS. 35; Bukhari Cross at 116). It is true that NHPD did enlist the services of Dr. John Arnason and Dr. Brian Foster to critique TWC expert evidence from two laboratories. However, Dr. Foster's independence and qualifications for the task are somewhat in doubt because he is an employee of Health Canada in the therapeutic drug branch and appears to have had no experience with NHPs. Dr. Arnason, on the other hand, appears to be qualified for the task. However, he is a biologist

and not an analytical chemist. He is a professor of Biology at the University of Ottawa and Associate Director of the Biopharmaceutical Science Program. He has a phytochemistry lab at the University of Ottawa and has trained over 50 graduate students in the field and published more than 250 peer-reviewed papers. In addition, he is a former president of the Phytochemical Society of North America and a founding member of the Natural Health Product Research Society of Canada. These are impressive qualifications, but the evidence also shows that Dr. Arnason has close affiliations with Dr. Marles, Dr. Foster, Health Canada and the Federal Government. He has received substantial grants and funding from Health Canada and its associated agencies. Significantly for this application, the Court cannot ignore that Dr. Arnason was Dr. Marles' post-doctoral supervisor and he has co-authored a significant number of articles with Dr. Foster and/or Dr. Marles. This is extremely problematic in an application where Dr. Marles' conduct has come under close scrutiny and the need for truly objective evidence is crucial. In a matter like this, it doesn't help to go to colleagues and associates for support. This is particularly the case when, as I shall discuss, even prior to Health Canada retaining Dr. Arnason, Dr. Marles stated that any experts Health Canada might retain would not accept TWC's expert evidence. The inference is unavoidable, in my view, that Dr. Marles could say this because he knew who those experts would be and he knew they would support him.

[93] TWC asserts a connection between Dr. Marles and Dr. Arnason which, in my view, would not normally call into question Dr. Arnason's objectivity. However, according to TWC witnesses (and I do not see this evidence questioned or challenged anywhere) Dr. Marles himself acknowledged that NHPD would have to conduct its own laboratory testing if it was going to refute the evidence from TWC experts, and this was not done. In addition, Dr. Marles indicated

that any experts retained by NHPD would reject TWC's expert opinion (see Bukhari Cross at 116-117; Marles April 2008, EXH. P; Supplementary Affidavit of Shazad Bukhari Affidavit, July 30, 2008 [Bukhari July 2008], at paras 3-8 and EXH. B). This gives rise to a serious concern that Dr. Marles knew who to go to secure the expert opinions he needed to support his own conclusions and past decisions.

[94] These concerns become even more troublesome when the reports from Dr. Arnason and Dr. Foster are reviewed. To begin with, there is no independent laboratory testing to support their conclusions and to refute the stringent testing that supports TWC's expert evidence. Both NHPD experts engage in the kind of armchair sniping and speculation that is frowned upon in the jurisprudence by straying from the duties to be fair, objective and non-partisan. See *White Burgess Langille Inman v Abbott and Haliburton Co*, 2015 SCC 23 at paras 2, 10 and 46; *R v Mohan*, [1994] 2 SCR 9 at para 24. Standards are asserted – and then changed – and strategic mistakes are made. For instance, in his report of October 7, 2008, Dr. Arnason says that he has conducted a literature search of the American Chemical Society which he says "has one of the most authoritative databases," and that he has failed to find any articles confirming the natural occurrence of RESOLVE's Active Ingredient. However, TWC did its own research of the American Chemical Society database and found information in the Mango article that confirmed the Active Ingredient as a natural substance (see Bukhari July 2013 and EXHS. A (extracts), and B-F). So we have an article confirming the Active Ingredient as a natural substance published in the prestigious journal that Dr. Arnason himself cites. The article meets the standards of publication that NHPD's expert says is required, yet NHPD has not changed its mind on classification.

[95] Over and above these evidentiary issues, NHPD's handling of the reconsideration process is, once again, fraught with procedural fairness problems. For example, one need only look at the final reconsideration decision of January 30, 2012, in which NHPD produces a new affidavit from Dr. Marles, a report from Dr. Foster, and a new affidavit from Dr. Arnason – all of which set out new allegations and new arguments relied upon by NHPD, but not shown to TWC – all the while telling TWC that it would not consider any further correspondence, thus foreclosing any response to the new evidence relied upon for the decision.

[96] In short, the reconsideration decisions on classification are irrelevant for the reviewable errors I have found on the August 21, 2007 NOR. However, they themselves also contain reviewable errors. They make mistakes of fact and process that render them unreasonable, they are lacking in procedural fairness and, I think at this point I have to conclude, they provide evidence of a reasonable apprehension of bias in accordance with the *Baker* test: *Baker v Canada (Citizenship and Immigration)*, [1999] 2 SCR 817 at paras 45-47. Dr. Marles orchestrated the August 21, 2007 NOR and he continued to influence the reconsideration process to an unacceptable degree, a process in which his own earlier decision was supposed to be examined objectively and independently.

E. *Safety*

[97] The First Decision was based upon safety and efficacy concerns. As with the classification process discussed above, the record shows serious procedural fairness errors and the improper interference by Dr. Marles in the PLA process that, once again, support a finding of a reasonable apprehension of bias.

[98] In particular, TWC received no notice of HHE #6 which contained the new reasons relied upon to designate RESOLVE as a Type II health hazard, and TWC was given no opportunity to respond until after the PLA was rejected on July 19, 2007.

[99] We also, once again, see Dr. Marles dominating and interfering with the PLA process in ways that suggest his main objective was to ensure that TWC would not be granted a PLA license. For example, on July 17, 2007, Dr. Marles sent an email to several NHPD staff, including Mr. Zeshawn Awan, who was the Bureau of Product Review and Assessment [BPRA] assessment officer who prepared the SEAR for RESOLVE. Mr. Awan's SEAR of June 19, 2007 confirmed that safety was supported and he recommended a routine Information Request Notice [IRN] to deal with efficacy. At this point, as Dr. Marles has conceded in evidence for this application, a license for RESOLVE likely would have been issued upon TWC providing further information to satisfy the efficacy requirement (see Marles Cross at164-165). Normal procedure would mean that the PLA would then go to the BPRA unit head and manager for approval, and then to the NHPD Director for a final decision. This normal procedural was not followed (see Marles Cross at 122-127, 133 and 135).

[100] Mr. Awan's decision that RESOLVE was safe contradicted the HHEs that Dr. Marles had been issuing to support a Type II health hazard. It is at this point that the HPFBI complaint investigation became inextricably intertwined with the PLA process as a result of the intervention of Dr. Marles.

[101] Dr. Marles advised BPRA of the HHE he had prepared for HPFBI. I see no problem with Dr. Marles drawing his safety concerns to the attention of BPRA so that they could be examined as part of the PLA process, provided the integrity of both processes is maintained. However, that is not what happened here.

[102] A crucial meeting occurred on June 28, 2007 at which HPFBI officials met with TWC to deal with the HHE that had been issued as part of the inspectorate process. Health Canada argues in the context of this judicial review application that the meeting of June 28, 2007 provided TWC with all of the procedural fairness required to deal with the safety concerns raised in the PLA:

> Much has been said against Dr. Marles by the applicant in its memorandum. The meeting of June 28, 2007 between TWC and NHPD and the [*sic*] afforded [*sic*] TWC to file additional documentation prior to the final licensing decision conclusively proves otherwise.

[103] This assertion is not born out by the record. As TWC points out in this application, what the record does reveal is as follows:

- TWC had requested this meeting to address the safety concerns alleged in the HHEs and Warning Letters from HPFBI;
- Dr. Marles attended the meeting because he had issued the HHEs for HPFBI;
- TWC was presented, for the first time, with HHE #5 dated June 27, 2007;
- TWC requested an opportunity to respond to the safety allegations in HHE #5. No mention was made of any efficacy issues;

- Although HHE #5 referred to the Adverse Reaction Reports [ARR], it was not, at that time, relied on as a reason for designating RESOLVE as a Type II health hazard;

- TWC requested details of the ARR so that it might have an opportunity to respond. It was told that such details would be provided;

- This meeting was not called for the purpose of discussing the PLA submission and no representative of BPRA was present;

- BPRA had not issued any Information Request Notice [IRN] with respect to the RESOLVE PLA nor had BPRA requested any information from TWC regarding safety or efficacy. TWC has not been informed of any safety or efficacy deficiencies in its PLA submission;

- TWC was not told that this meeting was in lieu of an IRN pertaining to its PLA;

- TWC did not give permission for its pending responses to HHE #5 to be used for the PLA assessment. If mention of the PLA was made at the meeting, TWC would have advised that any PLA issue should be dealt with through its consultant Dicentra in the normal course.

(Bukhari December 2007 at paras 47-49 and 51-56, Marles Cross at 51-57, 170-187, 204-205, 209 and 210; Bukhari Cross at 65-67 and 69-76, emphasis in original)

[104] Following the June 28, 2007 meeting, TWC prepared and submitted a binder of response materials addressing the four safety concerns alleged in HHE #5, but it could only respond to the Adverse Reaction Reports in a preliminary way because it did not have the details it was promised. In fact, on July 5, 2007, TWC was told that if it wanted the Adverse Reaction Reports details, it would have to submit a formal Access to Information request. This meant that TWC was not given an opportunity to fully respond to the Adverse Reaction Reports before the PLA was denied on July 19, 2007. This is important because it meant that TWC did not know until after the First Decision that the Adverse Reaction Reports were based upon the false assumption

that RESOLVE contained passionflower (see Marles January 2008, extracts of EXH D; Marles Cross at 180-182, 186, 187, 210-211 and 227; Bukhari December 2007 at paras 51-55, 59-61, 91 and 93; Marles Cross, EXH 23).

[105] TWC points out in this application – and the Respondents have not refuted this evidence – that, as of July 15, 2007, the status of the PLA was as follows:

- All of the safety issues relied on in HHEs #1 to #5 (January 25, 2007 to June 27, 2007) had been addressed by TWC;
- No issues relating to efficacy has been raised in any context;
- TWC had not received an IRN or any other form of notice that there were any concerns or deficiencies in its PLA relating to safety or efficacy;
- The NHPD Director had advised the ADM that, as of June 28, 2007, there was no information upon which to deny a license for RESOLVE;
- The only SEAR in existence to that point in time was the SEAR of June 19, 2007 prepared by Mr. Awan which indicated that safety was supported and that a routine IRN should be issued with respect to efficacy.

[106] In addition, on July 12, 2007, TWC provided HPFBI with Dr. Mike Dutton's report that confirmed RESOLVE to be a safe product.

[107] Against this background, Dr. Marles issued HHE #6 on July 17, 2007 which rendered HHEs #1 to #5 irrelevant and relied upon three new reasons to designate RESOLVE as a Type II health hazard. This means that TWC had no opportunity to respond to HHE #6 before NHPD issued the First Decision. This would not have happened if the integrity of the licensing and the

inspectorate processes had been maintained, and it is here that Dr. Marles' interference in the PLA process becomes crucial.

[108] Before looking at the details of Dr. Marles' interference in the PLA process, the following must be borne in mind regarding the three new reasons he gave in HHE #6 for designating RESOLVE as a Type II health hazard:

a) Dr. Marles completely disregarded the expert opinion from Dr. Dutton that RESOLVE is a safe product in its daily dosage. Dr. Dutton is an expert toxicologist. Dr. Marles is not a toxicologist and he has conceded in evidence for this application that he did not consult with a toxicologist. See Bukhari December 2007 at para 75; Marles Cross, 11, 223-227. In other words, against the expert evidence, Dr. Marles simply decided to substitute his own opinion on the safety of the daily dosage;

b) HHE #6 also relied on the Adverse Reaction Reports – that TWC has not been able to respond to in full – and the Adverse Reaction Reports were based on the false assumption that RESOLVE contained passionflower. Dr. Marles knew about this error but failed to correct it;

c) HHE #6 also relied upon an alleged risk of hemolytic anemia referred to in Dr. Dutton's expert report. But Dr. Dutton's report, as Dr. Marles must have known, clearly states that RESOLVE is a safe product, so that Dr. Marles' remarks about hemolytic anemia in his report are simply a misinterpretation of what Dr. Dutton says.

[109] These are serious errors for someone in Dr. Marles' position to make, and they create the impression that, after TWC had satisfied all of the safety concerns raised in HHEs #1 to #5, Dr. Marles relinquished his objectivity and was simply grasping at anything to justify a determination that he had already made to have RESOLVE designated as a Type II health hazard. The bizarre aspect of this conclusion is that there is some evidence before me in this application that Mr. Gustafson confided to a TWC representative at the June 28, 2007 meeting referred to above that TWC would not get a PLA license for RESOLVE and "it did not matter" what information TWC provided (see Bukhari December 2007 at para 50, Bukhari Cross at 83).

[110] The Respondents object to this evidence in their written Memorandum of Fact and Law:

> 40. TWC falsely alleges that Mr. Gustafson advised one of TWC's representatives at the June 28 meeting that "TWC was not going to get a license no matter what information it provided." Mr. Gustafson never made any such statement. TWC has not filed any direct evidence from the person who allegedly heard Mr. Gustafson make such a statement. Such false allegations are highly prejudicial and ought to be struck from the record as pure hearsay.

[111] The strange thing is that it would have been very easy to refute the disputed evidence with an affidavit from Mr. Gustafson himself. But the Respondents have filed no such refutatory evidence and they have not given any reason for not doing so. The denial remains a mere assertion in a Memorandum of Fact and Law before the Court, which is not evidence at all, particularly on a point such as this one. Health Canada must be aware that this is extremely damaging evidence against the Respondents. It is strong support for TWC's position that it was dealing with a closed and biased mind and that the whole subsequent reconsideration process was a sham.

[112] Even stranger is the fact that on July 24, 2015, Prothonotary Aalto directed that either party wishing to raise evidentiary objections must file a Notice of Motion to that effect by no later than August 31, 2015. TWC filed and served its motion on August 28, 2015. The Respondents did not file any motion. Motion Records were to be filed by September 30, 2015 and Responding Records were to be filed by October 30, 2015. In accordance with Prothonotary Aalto's Direction, TWC filed its Motion Record with respect to its motion regarding evidentiary objections on September 30, 2015. Accordingly, the Respondents were to have filed their Responding Record by October 30, 2015. At the close of business on Friday, October 23, 2015,

TWC received the Respondents' Memorandum of Fact and Law for the judicial review which was the only material provided to TWC in the Respondents' Record. Upon initial review, it was noted that certain paragraphs, specifically paragraphs 40, 85, 106, 107 and 108, contained factual allegations which do not appear in any affidavit or other evidence filed with the Court. Furthermore, the paragraphs contained an objection to TWC's evidence despite the Prothonotary's Direction that the parties must file motions to make evidentiary objections on or before August 31, 2015.

[113] This is an important issue that, on TWC's evidence, weighs heavily against the Respondents. It confirms TWC's position that it was dealing with bias, a closed mind and bootstrapping. It is evidence that would have been extremely easy to refute with direct evidence from Mr. Gustafson, and it is obviously evidence that the Respondents should have addressed in accordance with Prothonotary Aalto's Direction. Yet, the Respondents have done none of these things and have not offered the Court any explanation as to why.

[114] I agree with the Respondents that none of this prevents them from pointing out to the Court that TWC's evidence is hearsay. It is clear, however, that I can consider hearsay evidence using the principled approach clearly established in the jurisprudence. See *R v* Smith, [1992] 2 SCR 915; R *v Khan*, [1990] 2 SCR 531 at paras 35-36, 42, 48-49 and 61; *Eli Lilly Canada v Apotex Inc*, 2015 FC 875 at para 195; *Ottawa Athletic Club Inc v Athletic Club Group Inc*, 2014 FC 672 at paras 117-119. Hearsay excludes evidence that cannot be tested, but the fact of Mr. Bukhari having heard that Mr. Gustafson had made such comments was testable, and Health Canada could easily have refuted the truth value of the evidence by having Mr. Gustafson

provide direct evidence on point. And the Respondents could easily have objected in the way directed by Prothonotary Aalto.

[115] Pointing out that this evidence is hearsay does not allow the Respondents to assert in their written Memorandum that "Mr. Gustafson never made any such statement," or that "such false allegations are highly prejudicial and ought to be struck from the record as pure hearsay," because there is no evidence before me that the hearsay evidence is false or that Mr. Gustafson never made such a statement. Consequently, these bald assertions by the Respondents in their Memorandum are struck, but I take the point that I am dealing with hearsay evidence on this issue.

[116] In adopting a principled approach to this evidence, I think I have to pay particular note to the fact that the Respondents have made no attempt to file refutatory evidence on a crucial factual issue and have failed to explain to the Court why not. They have also failed to object to the evidence in the way directed by Prothonotary Aalto. I think I have to draw an adverse inference from these facts that this is not evidence the Respondents can refute. Having been given the opportunity and direction by Prothonotary Aalto to object to this evidence, they chose to leave it on the record for the review hearing. Any hearsay objections should have been raised in accordance with the Court's directions. However, even if I were to exclude this piece of evidence, I would still reach the same conclusions on reasonable apprehension of bias.

[117] It is against this background (the problems associated with HPFBI's process and Dr. Marles' role in that process) that we have to examine Dr. Marles' overwhelming intervention in the PLA process and the First Decision.

[118] The starting point is that, before that intervention, Mr. Awan, a BPRA assessment officer, had not only confirmed that RESOLVE met the regulatory definition of an NHP but also, on June 19, 2007, had prepared the initial SEAR for RESOLVE confirming that there were no concerns regarding safety, and recommending a routine IRN for efficacy. See Marles Cross, 122-127, 133-135 and 164-165 and extracts of EXH.14.

[119] It was at this point that Dr. Marles intervened and advised BPRA of the HHEs he had prepared for HPFBI, which were then used by NHPD in reaching its conclusions that there were safety concerns with RESOLVE. NHPD did not, however, conduct its own investigation into this issue. It simply took what Dr. Marles said at face value and, in fact, allowed Dr. Marles to direct that Mr. Awan's SEAR be set aside and substituted with a SEAR that was consistent with his own HHEs.

[120] It is worth repeating that, at this point, TWC had not been able to respond to the three new reasons relied upon in the July 17, 2007 HHE #6. Dr. Marles says that BPRA used HHE #6 – which TWC had not seen – as well as the TWC July 3, 2007 binder response to HHE #5 – no longer relevant on its PLA assessment. See Marles Cross, 185-187 and 199.

[121] As I have said above, I see no problem with Dr. Marles communicating that the Inspectorate had safety concerns to NHPD, but if NHPD simply adopts those concerns and allows its own processes to be subsumed, it must realize that it inherits all of the reviewable errors that I have identified were made as a result of Dr. Marles' role in the HPFBI process. We can see the extent of Dr. Marles' role in the PLA process from the July 17, 2007 email he sent to NHPD staff members, including Mr. Awan, in which he says that the NOR will be ready for signing "tomorrow morning" and that Mr. Awan should ensure that the NOR "adequately captured" the reasons set out in HHE #6, which TWC had not seen. BPRA simply followed Dr. Marles' instructions and drafted the SEAR and the July 19, 2007 NOR, and neglected to follow the normal process of first issuing an IRN. An email of July 18, 2007 confirms that the NOR was ready on that date.

[122] The evidence placed before me in this application reveals that it was really Dr. Marles' decision to ignore the IRN process and to go directly to a NOR. He did this fully aware of the problems with his own HHE #6 outlined above, and that TWC had been given no opportunity to respond to HHE #6. In other words, I think we have confirmation here of Mr. Gustafson's reported words that a decision had already been made that TWC was not going to get a PLA license, and we see Dr. Marles intervening in the PLA process to ensure that this occurs. Mr. Awan and his colleagues were rushed into preparing the SEAR and July 19, 2007 NOR to reflect the safety concerns in the HHE #6 and to support a decision that Dr. Marles had already made in error.

[123] Dr. Marles has admitted that what occurred was contrary to standard policy because he says that PLAs and HHEs are separate processes. See Marles Cross at 122-127, 133 and 135.

[124] Another email of July 18, 2007 which was sent to everyone concerned (including the NHPD Acting Director) shows Dr. Marles directing the steps to be followed. He directs the BPRA manager to sign off on the SEAR and the Acting Director to sign off on the NOR, which are required formalities. The Acting Director signed the NOR on July 19, 2007, and the NOR was served on TWC together with HHE #6 and a new stop sale and recall notice. See Marles Cross, 238-240 and EXH 30; Bukhari December 2007 at paras 63-65 and EXHS 25 and 26.

[125] This meant that, as far as HPFBI was concerned, TWC had received no prior notice of the three new safety concerns that were used to justify HHE #6, and as far as NHPD was concerned, TWC had received no prior notice of any safety or efficacy concerns raised by BRPA.

[126] Yet NHPD continues to allege that TWC was afforded procedural fairness beyond the requirements of the law and that Dr. Marles behaved appropriately throughout the process. Apart from these general assertions, however, the Respondents have not addressed the detailed points of fact raised by TWC concerning the PLA process and the HPFBI process which, in my view, establish procedural unfairness, unreasonable decisions and, at the very least, a reasonable apprehension of bias. The Respondents, however, assert that:

> TWC has not put forward any logical explanation why Dr. Marles would be antagonistic towards TWC or RESOLVE. Dr. Marles has had a long and distinguished career at Health Canada, there is no evidence of [*sic*] with no prior complaints of bias or bad faith by any other license applicants or industry stakeholders.

[127] This kind of assertion is irrelevant and unhelpful. It does not answer the detailed points of evidence referred to above, or much else contained in TWC's judicial review application. TWC does not have to establish *mens rea* to prove procedural unfairness, unreasonableness or a reasonable apprehension of bias. The strange thing is that the Respondents have done so little to explain or justify the detailed points of evidence that support TWC's application.

[128] The Respondents also say that:

> The Refusal Decision and Classification Decision were based on transparent communications between Health Canada and TWC. At each step of the way TWC was notified of the reasons its PLA was subject to refusal and provided with participatory rights to be heard.

[129] Yet the evidence is clear that TWC was never given any opportunity to respond to the three new safety reasons alleged in HHE #6 that were the basis for the compliance decision, and TWC received no prior notice that there were any safety or efficacy concerns in relation to the PLA and the July 19, 2007 NOR. As regards classification, TWC was given no prior notice of classification concerns in the July 19, 2007 NOR, and was given no prior notice of classification concerns prior to the August 21, 2007 NOR. The bald assertions of the Respondents in this application are not evidence to the contrary.

F. *Safety Reconsideration*

[130] As with a lack of procedural fairness and/or bias behind the Second Decision, the First Decision cannot be cured by the reconsideration process. See *Newfoundland Telephone*, above, at paras 38-41. The decision is *void ab initio*. The Respondents have not acknowledged any

defects in either decision. Once again, therefore, the reconsideration process on the issue of safety has little relevance for my decision. In any event, Health Canada has subsequently conceded that there are no health and safety concerns with RESOLVE.

G. *Efficacy*

[131] The First Decision also denied TWC a license on the basis of efficacy. As with safety, the handling of the efficacy issue gives rise to concerns about procedural fairness, the appearance of bias, and the reasonableness of the First Decision. Because safety and efficacy were both cited in the July 19, 2007 NOR to deny the license, it is difficult to separate reviewable errors related to efficacy from reviewable errors related to safety.

[132] The evidence is clear that TWC did not receive prior notice from NHPD about either efficacy or safety concerns under the PLA process. The first notice was the July 19, 2007 NOR (First Decision) itself. It also has to be remembered that TWC did not receive the routine IRN recommended in the initial SEAR and that, under Dr. Marles' direction, NHPD went directly to the July 19, 2007 NOR. So there was no opportunity for TWC to respond to efficacy concerns before the NOR was issued. It also appears from the evidence before me that this was a deviation from standard procedures. There is also the troubling issue of Mr. Gustafson's admission at the June 28, 2007 meeting that TWC would not be granted a license. However, even without this admission, I think TWC has established procedural unfairness and a reasonable apprehension of bias with regard to the efficacy issues. That finding is reinforced by what occurred during the reconsideration process when it became clear that Health Canada was demanding "conclusive proof" of efficacy in the form of unimpeachable human clinical studies. As TWC points out, this

extremely high standard has been rejected by this Court as a minimum mandatory requirement for drug submissions. See *Wellesley Therapeutics Inc v Canada (Health)*, 2010 FC 573, at paras 40-45, 61-62, 66-69, 72; *Epicept Corp v Canada (Health)*, 2010 FC 956 at paras 13-14, 41-46, 67-72. So it is difficult to see why Health Canada would insist upon such a standard for RESOLVE in the context of the more relaxed regime under the *NHP Regulations*. Even more significant, the Respondents have placed no evidence before me that Health Canada has ever used this standard in any other PLA. This gives rise to issues of procedural fairness, apprehension of bias, legal errors in interpretation, and reasonableness. These issues are significantly complicated in the present case by a lack of clarity in the governing regulations and a lack of jurisprudence on the applicable standard for efficacy under those regulations.

[133] As regards efficacy, the *NHP Regulations* provide as follows:

| | |
|---|---|
| 5. An application for a product licence shall be submitted to the Minister and shall contain the following information and documents: | 5. La demande de licence de mise en marché est présentée au ministre et comporte les renseignements et documents suivants : |
| … | … |
| (*g*) information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use; | (*g*) les renseignements montrant l'innocuité et l'efficacité du produit lorsqu'il est utilisé selon les conditions d'utilisation recommandées; |

[134] Section 7 of the *NHP Regulations* then provides as follows:

| | |
|---|---|
| **Issuance and Amendment** | **Délivrance et Modification** |
| 7. The Minister shall issue or | 7. Le ministre délivre ou modifie la licence de mise en |

| | |
|---|---|
| amend a product licence if | marché si les conditions suivantes sont réunies : |
| (a) the applicant submits an application to the Minister that is in accordance with section 5 or subsection 11(2), as the case may be; | (*a*) le demandeur présente au ministre une demande conforme à l'article 5 ou au paragraphe 11(2), selon le cas; |
| (b) the applicant submits to the Minister all additional information or samples requested under section 15; | (*b*) le demandeur fournit au ministre les renseignements complémentaires ou les échantillons demandes en vertu de l'article 15; |
| (c) the applicant does not make a false or misleading statement in the application; and | (*c*) le demandeur ne fait pas de déclaration fausse ou trompeuse dans sa demande; |
| (d) the issuance or amendment of the licence, as the case may be, is not likely to result in injury to the health of a purchaser or consumer. | (*d*) la délivrance ou la modification de la licence ne risque pas de cause un préjudice à la santé de l'acheteur ou du consommateur. |

[135] TWC has put forward detailed submissions as to how these two sections should be interpreted:

> 128. As discussed, the first position of TWC is that the Regulations do not provide any substantive test for efficacy. The requirement under section 5(g) for "information that supports" efficacy is administrative only. Alternatively, even if the Regulations can be interpreted as creating some sort of threshold substantive test, that test should be less onerous than the "likely" test expressly set out for safety in section 7(d).
>
> 129. Section 5(g) does not call for evidence to prove but rather information to support. This indicates that the information can come in many forms and need not rise to the level of evidence. Unlike the new drug regulations, the NHP Regulations do not specify the need for any clinical evidence. It must also be kept in mind that the information to support efficacy must be assessed in relation to the product claims set out in the PLA. In this case, the only claim in the PLA is that it "may" help with smoking

> cessation. Accordingly, TWC was only required to adduce information which supported that modest claim even if that information fell short of proving the likelihood that it may help.
>
> 130. In this case, the PLA did comply with section 5(g) by including information that supports efficacy. Health Canada acknowledged this by accepting the PLA and granting it a submission number. Under Health Canada's own policy, this PLA was deemed to be complete otherwise it would have been rejected at the outset or in 2006 under the new backlog policy. The efficacy information in the PLA included a phase I human clinical study along with *in vitro* and animal studies all conducted by Purdue University, a statistical analysis of a phase II human clinical study, U.S. patent information and various papers, articles and testimonials.
>
> 131. TWC submits that this information was more than sufficient to prove even the likelihood that RESOLVE may help with smoking cessation. Therefore, it certainly satisfied a standard less than that, whatever the standard might be. The sufficiency of this efficacy information is confirmed by the evidence including statements made by a former NHPD Director at sessions held for industry.
>
> [footnotes omitted]

[136] Health Canada, on the other hand, argues that a substantive requirement for efficacy can be made out from the *NHP Regulations*:

> 86. Contrary to the applicant's submission, the Regulations do impose a substantive requirement of efficacy in subsection 5(g) and s.7. Section 7 sets out the requirements for a licence to issue. Paragraph 7(a) incorporates the requirements of section 5 in full, including the requirement in paragraph 5(g) of "information which supports safety and efficacy". This is not merely an administrative requirement but rather a substantive requirement. All of the information required by section 5 for a PLA must be reviewed and considered in order to determine whether a licence will issue. This is the plain and obvious meaning of subsection 5(g) and s.7. Here, the review bureau conducted a substantive review of the RESOLVE PLA submission for the various requirements prescribed by section 7, including information which supports efficacy. The information in the PLA submission was examined in light of the concern as to efficacy identified in the HHE, and it was

> determined the application did not meet the threshold for granting a licence under section 7.
>
> 87. The review bureau conducted a review of the RESOLVE PLA submission for the various requirements prescribed by section 7, including information which support efficacy. The information in the PLA submission was examined in light of the concern as to efficacy identified in the HHE, and it was determined the application did not meet the threshold for granting a licence under section 7[.]

[137] I think it has to be acknowledged that the appropriate standard for efficacy under the PLA regime has not yet been authoritatively determined. There is no guidance in the *NHP Regulations* themselves and there is no jurisprudence on point to assist. However, in my view, the standard cannot be the excessively high standard that Health Canada eventually decided to impose in this case. Besides arguing that s 5(g) imports a substantive requirement for efficacy, Health Canada has provided no evidence or authority for the standard that was applied in this case under the First Decision or for the "conclusive proof" standard that it eventually articulated, nor has Health Canada provided evidence of the standard that has been used in other PLAs. This lack of an established standard, and the application of a strict test to TWC's PLA, lends credence to the argument that Health Canada was simply applying any standard that would deny TWC's PLA.

[138] TWC's argument is that, because s 7 expressly sets out a substantive test for safety, s 5(g) should not be interpreted as creating a substantive test. TWC says that this means that s 5(g) requires an applicant to provide only materials supporting efficacy, which TWC did in this case. In other words, TWC says it provided a complete application in this case, so that the Minister, under the s 7 language ("shall"), was obliged to issue the license, provided, in accordance with s (g), it was not likely to result in injury to the health of a purchase or consumer.

[139] On the face of it, the ordinary meaning of these two regulations suggests that this is the appropriate way to read them together, except that it still leaves open the issue of what, even in an administrative sense, is needed to support efficacy under s 5(g), and what discretion does NHPD have under s 5(g) to assess any information provided.

[140] It seems to me that the use of the term "information" requires an applicant to provide some meaningful and acceptable documentation that "supports" efficacy and that, if this is not done – either because no information is provided or because the information provided is not adequate to support some degree of efficacy – then, even from an administrative perspective, an application would not be complete and NHPD would, in the normal course, notify an applicant of the deficiency and allow a reasonable time for a response.

[141] In the present case, TWC was never notified that its efficacy information was deficient in any way before the First Decision was issued, and it was certainly never informed as to *why* its efficacy information was deficient, or what would be required to rectify the situation. In this regard, the efficacy aspect of the July 19, 2007 NOR was procedurally unfair and, in the full context of the evidence presented in this case, it also gives rise to a reasonable apprehension of bias. No standard was articulated to TWC at the material time, and no reason was given as to why TWC's "information" did not "support" efficacy.

[142] It seems to me, then, that under s 5(g), an applicant is required to provide "information" that, reasonably speaking, supports some degree of efficacy in terms of the product claims set out in the PLA which, in this case, were that RESOLVE "may" help with smoking cessation. Health

Canada has put forward no argument as to why the information submitted by TWC in its PLA did not meet this test. Instead, Health Canada, as revealed by the reconsideration process, has simply adopted a very strict test that would appear to be higher than that required under the *Food and Drug Regulations*. No legitimate reason has been put forward by Health Canada as to the need for such a strict test in the context of NHPs and there is no evidence of Health Canada ever applying such a strict test for any PLA other than TWC's application for RESOLVE. In my view, the test applied by Health Canada was both incorrect as a matter of statutory interpretation and unreasonable in the full context of the manner in which efficacy was dealt with. My own review of the information submitted by TWC with its PLA is that it does provide some objective and legitimate authoritative "information" to "support" that RESOLVE "may" help with smoking addiction. On a plain reading of the *NHP Regulations* in their full context, it seems to me that TWC clearly satisfied the efficacy requirement, and the decision to reject the PLA on this basis was both contrary to the legal requirements and unreasonable.

H. *Efficacy Reconsideration*

[143] As with classification and safety, the reconsideration process with regard to efficacy could not cure the First Decision that, because of a lack of procedural fairness and a reasonable apprehension of bias, was *void ab initio*. See *Newfoundland Telephone*, above, at paras 38-41.

I. *Other Issues*

[144] TWC has raised a number of other issues in its submissions which I do not reject. However, I do not think that an exhaustive analysis is required to deal with this application. A

finding for TWC on the issue of, for example, *functus* would not change the result or the remedies that I think are appropriate for this application. On the basis of my review and my findings so far, it is clear that the application must be allowed for lack of procedural fairness, a reasonable apprehension of bias, and unreasonableness.

J. *Motions on Evidence*

[145] As I mentioned above, both sides have raised objections to some of the evidence filed in this application. I have referred to what I regard as some of the more important points of evidence in the body of my reasons. For the most part, I think that the facts that establish procedural unfairness, incorrect statutory interpretation, unreasonableness and a reasonable apprehension of bias are clear and the Respondents, while making general assertions, have not really answered the specifics of the evidence that support the reviewable errors that occurred in this case.

[146] By formal motion, TWC asks that paragraphs 40, 85 and 108 of the Respondents' Memorandum of Fact and Law be struck. For the reasons given by TWC, I agree that, for the most part, these paragraphs must be struck. However, as indicated in the body of my reasons, I have noted the hearsay aspects of Mr. Bukhari's evidence on the issue of what Mr. Gustafson said at the June 28, 2007 meeting. As previously stated, what I find most troublesome is the fact that the Respondents have filed no denial by Mr. Gustafson and have provided no explanation as to why such a denial could not have been filed. At the same time, they have failed to challenge this evidence as directed by the Court, and so have left it on the record.

[147] As regards paragraph 85, I think that the first sentence can be supported by the record, but the sentences that refer to the DNP have to be struck for a lack of supporting evidence. I have indicated in my reasons what I think can be ascertained about the DNP from the records.

[148] Paragraph 108 must be struck in its entirety for reasons given by TWC.

[149] As regards the affidavit evidence of Dr. Marles, I think the reality has to be acknowledged that he was the prime decision-maker of the decisions that are at the heart of this application. I have already indicated in my reasons that the integrity of both the PLA process and the enforcement and compliance process was compromised by the role that Dr. Marles took upon himself to play and, to be fair, that those who should have been overseeing the process and making the decisions, allowed him to play. Normal PLA processes were abandoned and those with the authority and responsibility to make the decision simply followed Dr. Marles' directions, whose directing mind appears to have lost all sense of objectivity and procedural fairness as he attempted to shore up his own misconceived conclusions. For example, Dr. Marles has conceded that he had no evidence that the Active Ingredient in RESOLVE was not an NHP. All he had was his own opinion that the articles relied upon by DNP to support the listing did not, in fact, support it. And yet Dr. Marles actively sought to have the Active Ingredient de-listed from DNP without giving any notice to TWC that classification was a problem and without giving TWC the opportunity to provide him and/or DNP with expert evidence to show that the Active Ingredient does, in fact, occur in nature. In my view, a reasonable person knowing the facts of this case would conclude that Dr. Marles was not acting fairly or objectively and that his

aim was to thwart the TWC PLA. I must conclude that there is a reasonable apprehension of bias in this case.

[150] Because he was the prime decision-maker for the decisions under review and directed others to do what was needed in a way that led them to abandon standard practices, Dr. Marles probably does have more direct knowledge than anyone else as to how and why these decisions were made. However, and as TWC points out, the fact that he can play the managing role in providing the overall picture from Health Canada's perspective is itself an indicator of the extent to which Health Canada's own practices and procedures relating to TWC's PLA were overrun and abandoned by the actions of one man with the result that procedural fairness and reasonable decision-making became impossible.

[151] This also leads to problems with Dr. Marles' evidence for this application. He is in the position of the effective decision-maker defending his own actions. This means that he is the sole fact witness put forward by Health Canada, but a fact witness who is defending his own decisions. He is an advocate for himself. Health Canada remains firmly in the hands of Dr. Marles and is apparently unwilling to provide the Court with reliable factual evidence from others in the system who were involved. As a consequence, although he is put forward as a fact witness, there is a great deal in his evidence, as TWC once again points out, that must be considered inadmissible opinion evidence, inadmissible arguments, inadmissible supplemental reasons and/or inadmissible conclusions, and bootstrapping.

[152] I accept TWC's submissions that the following portions of the affidavits of Dr. Marles and Dr. Arnason should be struck:

| *A. Affidavit of Robin Marles, January 22, 2008* | *Reasons for Striking* |
|---|---|
| Paragraph 14 | Argument, and interpretation of legislation |
| Paragraph 15 | Hearsay and argument |
| Paragraph 16 (sentences 2 and 3) | Hearsay, opinion, argument and improper expert opinion |
| Paragraph 17 (sentences 1 and 2) | Hearsay, opinion and argument |
| Paragraph 30 (sentences 2 and 3) | Hearsay |
| Paragraph 33 (sentences 1 and 2) | Argument and hearsay |
| Paragraph 34 (sentences 2, 3, 4, 5, 6, 7, 8, 9 and 12) | Hearsay, opinion, argument, improper expert opinion and bootstrapping |
| Paragraph 35 (sentence 3) | Hearsay and argument |
| Paragraph 38 | Hearsay and argument |
| Paragraphs 39 and 40 | Hearsay, argument and opinion |
| Paragraph 43 | Hearsay, argument and opinion |
| Paragraph 44 | Hearsay, argument and opinion |
| Paragraphs 47 - 50 | Hearsay and argument |
| Paragraphs 51-53 | Hearsay |
| Paragraph 54 | Hearsay and argument |
| Paragraph 56 | Hearsay and argument |
| Paragraphs 58-63 | Hearsay and argument |
| Paragraphs 64-68 | Opinion, argument, interpretation of legislation, improper expert opinion and bootstrapping |
| Paragraphs 69-71 | Hearsay and bootstrapping |
| Paragraph 72 | Hearsay, argument, interpretation of legislation and bootstrapping |
| Paragraph 73 (sentences 1 and 2) | Hearsay, argument and bootstrapping |
| Paragraph 74 (the word "erroneously") | Hearsay, argument, opinion and bootstrapping |
| Paragraphs 75-77 | Hearsay, argument, opinion and bootstrapping |
| Paragraph 78 | Opinion, argument, hearsay, improper expert opinion and bootstrapping |
| Paragraph 79 | Hearsay, argument and opinion |
| Paragraph 80 | Hearsay and bootstrapping |
| Exhibits C, H, I, J, K, N and O | Hearsay and bootstrapping |

| *B. Affidavit of Robin Marles, April 10, 2009* | *Reasons for Striking* |
|---|---|
| Exhibit P | Hearsay (not admissible to prove truth of content), improper expert opinion and bootstrapping |

| *C. Affidavit of Robin Marles, October 7, 2008* | *Reasons for Striking* |
|---|---|
| Exhibit Q | Hearsay (not admissible to prove truth of content) and improper expert opinion) |

| *D. Affidavit of John Arnason, October 7, 2008* | *Reasons for Striking* |
|---|---|
| Entire affidavit and Exhibit B | Bootstrapping, hearsay and improper expert opinion |

| *E. Affidavit of Robin Marles, January 30, 2012* | *Reasons for Striking* |
|---|---|
| Paragraphs 4 and 5 | Argument |
| Paragraph 6 | Argument, hearsay, opinion and improper expert opinion |
| Paragraphs 7, 8 and 9 | Hearsay, opinion and argument |
| Paragraph 10 | Argument, opinion and bootstrapping |
| Paragraphs 11 and 12 | Argument, hearsay and bootstrapping |
| Paragraphs 13-15 | Hearsay, argument and opinion |
| Paragraph 16 and 17 | Hearsay, bootstrapping, improper expert opinion and argument |
| Paragraphs 18-20 | Hearsay and argument |
| Paragraph 21 | Hearsay, argument, improper expert evidence and bootstrapping |
| Paragraphs 22 and 23 | Hearsay, argument and opinion |
| Exhibits C and D | Hearsay |
| Exhibits E and F | Hearsay, improper expert opinion and bootstrapping |

| *F. Affidavit of John Arnason, January 27, 2012* | *Reasons for Striking* |
|---|---|
| Paragraphs 3-6 | Bootstrapping and improper expert opinion |

[153] As I indicate in my reasons, the essential facts for procedural unfairness, incorrect statutory interpretation, unreasonableness and reasonable apprehension of bias are clearly established in this case.

K. *Remedies*

[154] Remedies are problematic in this case. The usual remedy for judicial review is to quash the decision at issue and to return the matter for reconsideration by a differently constituted tribunal that will pay attention to the reasons and avoid similar mistakes in its decision-making. It is not clear that such an approach is even possible in the present case.

[155] Much of what I've said about reviewable error has focussed upon the conduct of Dr. Marles, but Dr. Marles was supposed to be no more than a scientific advisor in a whole system that had its recognized procedures and checks and balances. That system did not function as it should have in this case, and there is no evidence that it is likely to if this matter is returned for reconsideration. As the record shows, the reconsideration that TWC went through was far from impartial or fair. Information was deliberately withheld from TWC, targets were moved, standards were changed and, despite promises, personnel were involved who had given rise to the problems, thus preventing any true independent assessment. TWC has not been able to market RESOLVE for eight years while this dispute has dragged on, for no justifiable reason that I can find. To simply return the matter for reconsideration to a system that has shown itself to be so dysfunctional might simply plunge TWC back into the quagmire and trigger more litigation.

[156] For these reasons, TWC argues that if reconsideration is ordered then it should be conducted by an external panel whose compensation and procedure will be agreed upon and settled by the Court or, alternatively, by individuals within Health Canada who will be totally free of association with the present dispute. TWC also requests detailed directions from the

Court concerning what facts and information, and what law, will govern the reconsideration process.

[157] In my view, TWC's suggestions in this regard are extremely cumbersome and are likely to lead to further Court involvement as disputes arise over the proper interpretation of the Court's direction. Also, it is by no means clear that totally independent people with the necessary qualifications can be found within Health Canada, or that an independent panel could be given the necessary authority under the governing legislation. This Court cannot usurp the Minister's legislative authority to administer the Act and the *NHP Regulations*. So this approach looks like another quagmire to me.

[158] On the other hand, the evidence before me in this application suggests that there is really very little to be gained from ordering a full reconsideration process. Both sides have been involved in a protracted and bitter dispute and I see no point in directing reconsideration when the evidence clearly established the following:

a) There are no outstanding safety concerns over RESOLVE. Health Canada accepts that the product is safe for its prescribed uses and we have Dr. Dutton's objective expert report that confirms this.

b) I have settled what I believe is the appropriate efficacy test under the *NHP Regulations* and I have satisfied myself that information submitted by TWC to support efficacy meets that test. If Health Canada disagrees with me then it can appeal this decision and the Federal Court of Appeal will correct any mistakes I have made and direct accordingly. If Health Canada accepts my ruling on efficacy, then there is no efficacy dispute between the parties.

c) As regards classification, there is evidence before me that the Active Ingredient is an NHP. This evidence is found in the Mango article of 2005 that appeared in the Journal of Agricultural and Food Chemistry, a copy of which was provided to Health Canada in Mr. Bukhari's affidavit. Health Canada has not before questioned or objected to confirmation of what this article provides. This is the journal that Dr. Arnason, Health

> Canada's own expert says provides the kind of standing needed in the circumstances. Hence, I cannot see how Health Canada can disagree with its own expert and not accept the Mango article as establishing the Active Ingredient as an NHP.

[159] In legal terms, what I am saying is that, on the evidence before me, I see nothing that could justify withholding a PLA licence for RESOLVE, and that the conditions for *mandamus* are satisfied. Under s 7 of the *NHP Regulations*, the Minister "shall issue… a product licence" if the conditions under ss (a) to (d) are satisfied. In my view, those conditions are satisfied here and have been for some time, and yet the Minister has refused to issue the licence. On the evidence before me, it would be pointless to return this matter for further reconsideration and, given the protracted and bitter nature of this dispute, I see no point in further wasting public and private resources.

[160] This is not an interference with the legislative powers and discretion given to the Minister under the legislation to ensure that NHPs are safe and efficacious. If conditions change in the future and the Minister is provided with new evidence that calls into question classification, safety or efficacy, the Minister is free to take whatever action is necessary and allowable under the statutory scheme.

L. *Costs*

[161] TWC has asked for enhanced costs and feels that solicitor and client costs are justified:

> 36. With respect to costs, TWC respectfully submits that it should never have been put through the reconsideration process in the first place. Nor should it have been required to prosecute these judicial review proceedings. It asserts that the fundamental defects, including lack of procedural fairness and *functus officio*, ought to have been obvious to the Minister at the outset. Accordingly, the

> Minister should have immediately rescinded both NORs and either granted the license or ordered a completely fresh PLA assessment with all of the safeguards necessary to ensure that TWC received a full and fair consideration of its license application and that appropriate standards and tests were adopted in accordance with the Regulations. Instead, TWC was subjected to multi-year reconsideration and Court proceedings which involved continually moving goal posts and enormous expenses including expert fees. For these reasons, TWC respectfully requests payment of all its costs for both proceedings on a full indemnification basis.

[162] The Respondents naturally take a different view:

> 33. The award of costs is governed by Rules 400 and Tariff B according to the *Federal Courts Rules*. The Supreme Court of Canada recognizes that full indemnification or solicitor – client costs are awarded only on very rare occasions, for example when a party had displayed reprehensible, scandalous or outrageous conduct. The Federal Court of Appeal has found that because of the exceptional nature of solicitor – client costs, a trial judge should generally provide some explanation as to why such an award is made. The record does not demonstrate that the circumstances of this case warrant such an exceptional award.
>
> [footnote omitted]

[163] My own feeling is that TWC has been subjected to a dysfunctional licensing process during the course of which normal and procedurally fair safeguards were abandoned and Dr. Marles was allowed to pursue a course of action aimed at denying a PLA licence to TWC on spurious grounds. Any safety concerns with RESOLVE were put to rest in September 2008, when Health Canada finally accepted that safety was not an issue. Health Canada was provided with an article published in 2005 which was authoritative evidence (the Mango article) that the Active Ingredient in RESOLVE occurs in nature and has not sought to question the validity of that evidence in these proceedings. As regards efficacy, Health Canada has provided no evidence that would suggest that the high standard used to deny TWC a licence has ever been used before

or since, or that Health Canada truly believes that such a high standard is required for an NHP. With some objectivity and supervision, any concerns that arose under TWC's original licence application either were resolved, or could easily have been resolved, years ago. Instead, Health Canada has allowed Dr. Marles, who was primarily responsible for the original problems and who, as I have found, demonstrated a closed mind and a reasonable apprehension of bias in his interventions in the PLA process, to in effect use the public purse to defend his own conduct (by making himself the principal fact witness in this case) which, in my view, should have been objectively assessed by Health Canada itself. This has also put TWC to tremendous trouble and expense to bring conduct before the Court that Health Canada should have questioned and rectified instead of wasting public and private resources in a vain and misguided attempt to further shore up inappropriate conduct by the officials involved in dealing with TWC.

[164] As the Respondents point out, solicitor-client costs are awarded only in exceptional circumstances. The jurisprudence tells us that such costs should only be granted when a party or parties have demonstrated reprehensible, scandalous or outrageous conduct. In this context, reprehensible behaviour means acts deserving of censure or rebuke; scandalous means causing general public outrage or indignation and outrageous means behaviour that is deeply shocking, unacceptable, immoral and offensive: *Louis Vuitton Malletier SA v Singga Enterprises (Canada) Inc*, 2011 FC 776 at para 56; *Hamilton v Open Window Bakery*, 2004 SCC 9 at 26; *Microsoft Corp v 9038-3746 Quebec Inc*, 2007 FC 659 at para 16.

[165] Based on what is now before the Court, it can be said that Health Canada engaged in behaviour that rises to the level of reprehensible. The evidence that has been adduced has

described incidents and actions on the part of Health Canada that not only repeatedly denied TWC procedural fairness, but also led to a protracted and convoluted dispute during which TWC was forced to keep its product off the market, while incurring substantial costs as it pursued reconsideration and judicial review.

[166] Health Canada strayed from its established processes, demonstrated bias and pre-judgment and prevented TWC from ever fully comprehending the standard to which its NHP was being held. Both the PLA and HHE processes were carried out without TWC being permitted the ability to fully and fairly participate and make its case for RESOLVE. This essentially disallowed a reasonable decision from ever occurring. All of this should have been obvious to Health Canada without the need for these judicial review proceedings.

[167] Here, the Respondents' behaviour is worthy of rebuke and merits an award of solicitor-client costs against them. However, I am dealing solely with the judicial review application. I agree with TWC that it should never have been required to prosecute these judicial review proceedings and that it should be reimbursed for the costs of having to do so, on a full indemnity basis.

## JUDGMENT

**THIS COURT'S JUDGMENT is that**

1. Both of the NORs (the First Decision of July 19, 2007 and the Second Decision of August 21, 2007) together with all of the reconsideration decisions (Subsequent Decisions) are hereby quashed;
2. An order for *mandamus* shall issue and the Minister shall grant to TWC a PLA licence for RESOLVE within 30 days of the date of this order;
3. Nothing in the above shall restrict the Minister from taking any action in the future that is permissible in accordance with the governing Act and Regulations should the Minister, in her discretion and acting reasonably and with procedural fairness, conclude that RESOLVE has ceased to qualify as an NHP; and
4. TWC shall have the costs of this application calculated on a solicitor and client, full indemnity basis.

"James Russell"

Judge

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-1381-07 |
| **STYLE OF CAUSE:** | THE WINNING COMBINATION INC. v MINISTER OF HEALTH AND THE ATTORNEY GENERAL OF CANADA |
| **PLACE OF HEARING:** | WINNIPEG, MANITOBA |
| **DATE OF HEARING:** | NOVEMBER 17-18, 2015 |
| **JUDGMENT AND REASONS:** | RUSSELL J. |
| **DATED:** | APRIL 6, 2016 |

**APPEARANCES:**

| | |
|---|---|
| John Myers<br>Rod C. Roy | FOR THE APPLICANT |
| Eric Peterson<br>Abigail Browne | FOR THE RESPONDENTS |

**SOLICITORS OF RECORD:**

| | |
|---|---|
| Taylor McCaffrey LLP<br>Barrister & Solicitors<br>Winnipeg, Manitoba | FOR THE APPLICANT |
| William F. Pentney<br>Deputy Attorney General of Canada<br>Winnipeg, Manitoba | FOR THE RESPONDENTS |