Federal Court of Appeal | Cour d'appel fédérale

Date: 20170515

Docket: A-117-16

Citation: 2017 FCA 101

CORAM: **NADON J.A.**
RENNIE J.A.
DE MONTIGNY J.A.

BETWEEN:

CANADA (MINISTER OF HEALTH) and THE ATTORNEY GENERAL OF CANADA

Appellants

and

THE WINNING COMBINATION INC.

Respondent

Heard at Winnipeg, Manitoba, on November 16, 2016.

Judgment delivered at Ottawa, Ontario, on May 15, 2017.

PUBLIC REASONS FOR JUDGMENT BY: RENNIE J.A.

CONCURRED IN BY: NADON J.A.
DE MONTIGNY J.A.

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PUBLIC REASONS FOR JUDGMENT

RENNIE J.A.

[1] This is an appeal by the Attorney General of Canada and the Minister of Health from the Judgment of the Federal Court (2016 FC 381) per Russell J. In broad terms, the Judgment under appeal set aside a decision, and subsequent variations and reconsiderations of that decision, by the Minister of Health (the Minister) under the *Natural Health Products Regulations* (S.O.R./2003-196) (the *Regulations*). The effect of those decisions was to refuse a product

licence (Natural Health Product Licence) to the respondent, The Winning Combination Inc. (TWC), in respect of Resolve, a product that may assist in cessation from smoking. After finding that governmental officials involved in the regulatory review process were biased and that there had been multiple breaches of procedural fairness, the judge issued an order of *mandamus* compelling the Minister to issue a Natural Product Licence to the respondent. He granted costs of the application to TWC on a full indemnity basis.

[2] At the heart of the Attorney General's appeal lies the order of *mandamus*. The Attorney General contends that the judge erred in law in issuing *mandamus* and in so doing usurped a duty vested in the Minister under the *Regulations*. The Attorney General also contends that the judge erred in concluding that his findings of bias meant that there could be no fair and objective assessment of TWC's application, and in placing a burden on the Minister to demonstrate circumstances to the opposite effect. The Attorney General further contends that the judge erred in receiving and relying on evidence that was not before the Minister, erred in first striking and later relying on certain evidence and erred in principle in awarding solicitor and client costs.

[3] At the outset of the hearing of the appeal, the Attorney General conceded that the licensing decision and reconsideration process under the *Regulations* had not been reached in accordance with procedural fairness. However, the Attorney General maintained her position that the order of *mandamus* be set aside and that the question of whether a Natural Product Licence should be issued in respect of Resolve be remitted to the Minister for redetermination.

[4] This concession was appropriate. There was no error in the Federal Court's factual findings relevant to procedural fairness, nor in the application of the principles of procedural fairness to those findings. The judge found multiple breaches of procedural fairness throughout the licensing and subsequent reconsideration process, and was correct in doing so. The Court did not understand the Attorney General to be conceding bias, at least on a systemic level, given her position that the matter be returned to the Minister.

[5] Before the Federal Court, TWC advanced other grounds on which it claimed it was entitled to relief. To supplement its position that it was entitled to *mandamus*, TWC argued that once the Minister had decided that Resolve was classified as a natural health product, the doctrines of *functus officio* and estoppel precluded the Minister from reversing her decision. In light of his findings with respect to procedural fairness, bias and the unreasonableness of the decision, these grounds were not addressed by the judge but are raised again by TWC before this Court.

[6] For the reasons that follow, the appeal should be allowed, in part.

I. Legislative framework

[7] In order to set the stage for what is a rather extensive review of the history of this proceeding, a description of key elements of the regulatory scheme governing natural health products (NHPs) and its distinction from the regulatory scheme governing drugs is required.

[8] This Court, and the Federal Court, are familiar with the drug approval process under the *Food and Drugs Act* (R.S.C., 1985, c. F-27). Although there is similarity in some of the terms between the regulations governing drugs and NHPs, they do not necessarily share the same scientific or empirical regulatory requirements. The regimes for approval of drugs and NHPs are legally and operationally discrete. Subsection 3 of the *Regulations* makes this clear; unless expressly indicated, the *Food and Drug Regulations* (C.R.C., c. 870) do not apply to NHPs.

[9] The Minister of Health is responsible for the administration of the *Regulations*. The Health Products and Food Branch of Health Canada includes the Natural Health Products Directorate (NHPD, now the Natural and Non-prescription Health Products Directorate), responsible for the licensing of NHPs, and the Health Products and Food Branch Inspectorate (HPFBI), responsible for compliance and enforcement activities.

[10] Selling a NHP in Canada requires a licence, which is to be obtained by application to the Minister. The Product Licence Application (PLA) shall, pursuant to subsection 5(g) of the *Regulations*, include "information that supports the safety and efficacy of the natural health product". Section 6 directs the Minister to dispose of applications within 60 days in cases where safety and efficacy information submitted by an applicant is limited to that within the Department of Health's Compendium of Monographs. Subsection 7(d) provides that the Minister "shall" issue a licence if the product is "not likely to result in injury to the health of a purchaser or consumer."

[11] The *Regulations* provide the Minister with a wide range of powers to administer and enforce the regime. Sections 16 to 19 give the Minister the authority at any time to request information from a licence holder where reasonable grounds exist that the product may no longer be safe. The Minister may issue a direction to stop sales if no response is forthcoming. The Minister may suspend a licence where reasonable grounds exist that a licence holder has contravened the Act or *Regulations* or there has been a false or misleading statement in the information submitted under section 5 in a PLA. The Minister may also suspend a licence at any time, and without an opportunity for the licence holder to be heard, where there are reasonable grounds to believe it is necessary to prevent injury to the health of the consumer.

[12] Save in circumstances where suspension is necessary to prevent injury, sections 19 and 20 of the *Regulations* require the Minister to give the licence holder both notice and an opportunity to be heard before a suspension takes effect and, once suspended, before taking administrative action to reinstate or cancel a suspended licence. So too at the application stage; section 9 requires that reasons for refusal (Notice of Refusal or NOR) to issue a licence be given, and provides a process by which an applicant may request reconsideration with the associated opportunity to be heard.

[13] There is a threshold question that must necessarily be answered to determine the applicability of the *Regulations* to a particular product, and that is whether the product that is the subject of an application is a NHP. "Natural health product" is defined in subsection 1(1) as a substance listed in Schedule 1 of the *Regulations*. Schedule 1 states that, *inter alia*, a natural health product substance is, "[a] plant or a plant material, an alga, a bacterium, a fungus or a non-

human animal material" (Item 1). Item 2 of the Schedule provides that a natural health product substance includes "[a]n extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation".

[14] The question of classification of a substance, either as a NHP or as a drug, determines which regulatory scheme is engaged and, in consequence, the nature of the evidence that must be provided in support of the licence application. There is an inherent logic to this. If natural health products were to be subject to the same regulatory requirements and standards as drugs, a separate regulatory regime would not have been required.

II. History of the proceeding

A. *The licence application for Resolve*

[15] The *Regulations* came into force in January 2004. The series of events under review began with the 2004 application by the then-owner of Resolve to the NHPD for a Natural Product Licence. Consistent with departmental practice, as the Active Ingredient in Resolve was listed in the Dictionary of Natural Products (DNP), the NHPD concluded on December 2, 2004, that Resolve fell within the definition of a NHP within Schedule 1 to the *Regulations*. The application for Resolve was given a PLA submission number.

[16] TWC purchased the rights to Resolve in 2006 and began to sell the product in Canada in October of that year. However, in December of 2006, Health Canada received a complaint from Pfizer Canada Inc. (Pfizer), alleging health and safety concerns related to Resolve. The complaint asserted that the description of the pharmacology of the product suggested that it

should be regulated as a drug. This complaint triggered an internal inquiry by the HPFBI, that part of Health Canada responsible for regulatory compliance. Responsibility for the inquiry was assigned to Mr. Paul Gustafson.

[17] Five months later, on May 4, 2007, Mr. Gustafson sent TWC a warning letter, requesting that it stop the sale and advertising of Resolve and recall the product from the market. This request was based on an alleged contravention of the Act and *Regulations* and a determination that Resolve posed a risk to health. The letter stated that, as Resolve was a NHP subject to the *Regulations*, it could not be sold or advertised without a licence. Further, a Health Hazard Evaluation (HHE) requested as part of the investigation had resulted in classification of the product as a Type II Health Hazard. A Type II Health Hazard is defined as "a situation in which the use of, or exposure to, a product may cause temporary or mild to moderate adverse health consequences or where the probability of serious adverse health consequences is remote." Health Canada concluded, among other things, that Resolve contained a substance that was derived from passion flower and that there was a risk of at least a temporary or mild adverse health consequence.

[18] In its response TWC noted that it was taken by surprise, particularly with respect to the safety and efficacy concerns raised by Health Canada. TWC took the position that the requests to stop sale, advertising and the recall of Resolve were unwarranted, but indicated its willingness to meet and work with Health Canada to resolve the situation.

[19] Approximately one month later, on June 20, 2007, in response to information submitted by TWC, Health Canada issued a revised HHE which confirmed the Type II Health Hazard classification and alleged regulatory contravention. Health Canada requested once again that TWC immediately stop the sale and advertising of, and recall, Resolve.

[20] This triggered a meeting between TWC and Health Canada officials on June 28, 2007. At that meeting, TWC was provided with another revised HHE which confirmed that there was no residual passion flower in Resolve, but noted a report of an adverse reaction (Adverse Reaction Report or ARR) as establishing a "serious" case with a "possible" causality between the use of Resolve and symptoms reported by a patient. The judge determined that neither the classification of Resolve as a NHP nor its efficacy was raised as a concern at the meeting.

[21] At the close of the meeting, TWC agreed, on an interim basis, to comply with the stop sale and advertising requests made by Health Canada, but the issue of a recall was left in abeyance. Correspondence was exchanged by the parties on the issue, and TWC submitted written materials, along with 16 attachments and a subsequent expert opinion, in order to address the issues raised in the investigation. Health Canada was not satisfied. It ultimately issued a public advisory, which stated that Resolve was not authorized for sale, TWC had not complied with Health Canada's recall request, and advised Canadians not to use Resolve because of its potential health risk.

[22] At the risk of disrupting the chain of events, I will jump forward in the chronology to note that, by September 18, 2008, Health Canada conceded that it had no safety concerns with respect to Resolve.

[23] On July 19, 2007, the NHPD issued a Notice of Refusal (the July NOR). TWC's application was rejected on the basis of subsections 7(a) and (d) of the *Regulations*, including in particular a lack of sufficient evidence to support the safety and efficacy of the product. The July NOR expressed concerns over the Active Ingredient's potential effects on the liver, the scientific evidence submitted in support, the therapeutic benefit of Resolve and its recommended dosage. It cited the ARR noted in the prior HHE as establishing a "possible" causality between the use of Resolve and the symptoms reported by a patient. No mention was made in the July NOR of any concern as to whether Resolve was properly classified as a NHP.

[24] TWC sought recourse. It filed both a request for reconsideration on July 26, 2007 under subsection 9(2) of the *Regulations* (Request for Reconsideration), and an application for judicial review of the July NOR.

[25] Approximately one month following the Request for Reconsideration, on August 21, 2007, NHPD wrote to TWC "adjusting" the grounds for the July NOR (the Adjustment Letter). Resolve was no longer considered to be a NHP, but rather a drug, and therefore subject to regulation under the *Food and Drug Regulations*. The letter stated that NHPD relied, in part, on the DNP for classification, but that a review of the DNP's sources led the NHPD to determine that its inclusion of the Active Ingredient was in error. NHPD took the position that the Active

Ingredient "is in fact a synthetic substance that does not occur naturally". TWC accordingly amended its Notice of Application to include judicial review of the Adjustment Letter.

[26] The grounds upon which the Adjustment Letter relied represented the first time that NHPD had directly addressed the question of the classification of Resolve as a NHP with TWC. The judge found that the licence application had proceeded up to that date on the basis that Resolve was classified as a NHP, a determination that he found to have been confirmed on December 2, 2004, January 25, 2007 and June 18, 2007.

[27] There was evidence before the judge that the DNP was the authoritative reference in North America for natural health products. It was at the time, the definitive reference source used by the NHPD with respect to classification of natural health products. It was on the basis of the DNP that Resolve had originally been classified as a NHP. However, on September 11, 2007, the Active Ingredient in Resolve was removed from the DNP.

[28] The judge found that this de-listing occurred at the instigation of Dr. Robin Marles, the Director of the Bureau of Clinical Trials and Health Sciences at NHPD, and the official who oversaw the HHE process. While the "motivation and sequence of events were murky" leading up to the Adjustment Letter, the judge found it was clear at that time that the Active Ingredient was still listed in the DNP and that neither Dr. Marles nor Health Canada had evidence to suggest that it was not a natural product. No notice had been given to TWC of this change in position, nor was it given an opportunity to make submissions on the point before the Adjustment Letter was issued.

B. ***Reconsideration process – August 2007 to January 30, 2012***

[29] I turn now to the reconsideration process, a regulatory review or appeal mechanism established under subsection 9(2) of the *Regulations*.

[30] Beginning in late August 2007 and continuing throughout the lengthy reconsideration process, TWC provided NHPD with written submissions, additional scientific data and expert analysis regarding its conclusions related to classification, safety and efficacy. TWC requested that the reconsideration process be conducted by different officials than those involved in the original PLA assessment. NHPD gave TWC assurances throughout the process that it had consulted individuals who were not involved in the original PLA process; however, the judge questioned the independence of the experts retained by Health Canada in its review.

[31] On April 7, 2008, the NHPD rendered its first decision in the reconsideration process, responding to TWC's requests for reconsideration related to both classification and safety and efficacy at once. NHPD maintained that Resolve did not meet the definition of a NHP. It found the additional data submitted by TWC to support its position that the Active Ingredient was naturally occurring was inconclusive. As a result, safety and efficacy could only be addressed pursuant to an application under the *Food and Drug Regulations*.

[32] Five months after its initial refusal to reconsider, on September 18, 2008, NHPD rendered a second refusal. On the basis of its review of additional information submitted by TWC, it reversed its prior decision on safety. However, it maintained its position that there was insufficient evidence of efficacy as a smoking reduction/cessation aid. Despite abandoning its

position that the product was not safe, no change was made by Health Canada to the requirement that Resolve be recalled from the Canadian market. NHPD indicated that it would be willing to further reconsider its findings related to efficacy.

[33] NHPD rendered its "final" reconsideration decision regarding classification and efficacy on July 22, 2009, concluding once again that the evidence was insufficient to classify Resolve as a NHP. NHPD stated that it drew this conclusion on the basis of its review of all of the evidence that TWC had submitted throughout the licensing and reconsideration processes. Given its classification decision, NHPD considered the outstanding efficacy issue to be "moot". Nonetheless, NHPD confirmed its previous findings relating to the efficacy of Resolve. NHPD gave "final notice" pursuant to subsection 10(2) of the *Regulations* that the product did not meet the definition of a NHP and that its conclusion on efficacy was final.

[34] Though the NHPD communicated to TWC that the July 22, 2009 decision was final, it subsequently accepted further submissions related to Resolve. Further additional reconsideration decisions were communicated to TWC on October 19, 2009; September 20, 2011; and January 30, 2012. On January 30, 2012, the NHPD stated that additional evidence had been considered, but it maintained its position on both classification and efficacy. The letter stated that the refusal was final and the reconsideration process concluded.

C. *The Federal Court decision*

[35] The judicial review and reconsideration proceedings moved in parallel. As decisions were rendered in the reconsideration process, the original judicial review application was amended.

But the proceedings were not separate – independent laboratory reports and expert opinions submitted in the reconsideration process were filed in the judicial review. The reconsideration process lasted four years, the judicial review, much longer. The reconsideration process was poorly managed. There was no finality. Even Health Canada's "final" decision was not final in practice, as it continued to receive, review and respond to further submissions. These, as well as Health Canada's responses, all found their way into the court record. As will be seen, this was not without consequence for the judicial review.

[36] It is useful to recapitulate the key findings in the Federal Court insofar as they underlie the judge's legal analysis and bear on the appropriateness of the remedy.

(1) Classification

[37] First, from December 2, 2004 to the August 21, 2007 Adjustment Letter, the judge found that Health Canada had concluded, on the basis of its own criteria, that Resolve was properly classified as a NHP. It had confirmed that conclusion on more than one occasion between those dates. For example, the judge noted that the issue of classification was raised when Mr. Gustafson, the investigator assigned to the Pfizer complaint, emailed Dr. Marles to challenge the previous classification of Resolve. Dr. Marles responded to Mr. Gustafson by confirming that the Active Ingredient was a NHP according to the DNP (Reasons for Judgment, para. 75).

[38] The judge found that, based on the structure of the *Regulations*, the reliance on safety and efficacy concerns for the July NOR necessarily implied that NHPD did not consider classification to be at issue when it rendered its decision. Put otherwise, if it were not a NHP, the

findings on efficacy and safety would be immaterial given that those criteria would have to be evaluated under the standards and methodologies governing drug submissions.

[39] The judge found that, even after the first decision was made, Dr. Marles made it clear by way of email on July 25, 2007 that "everyone internally knows [the Active Ingredient] is an NHP". Despite this correspondence, Mr. Gustafson conducted his own research into the scientific articles relied upon by the DNP and raised the issue again with Dr. Marles, who was now convinced that the classification of the product should be questioned. The judge found that Dr. Marles directed that the Adjustment Letter on classification be issued (Reasons for Judgment, paras. 75-77).

[40] In October 2008, TWC received a report by Dr. Arnason, an expert retained by Health Canada for the purposes of the judicial review. Dr. Arnason opined that "there is no convincing evidence of [the Active Ingredient naturally occurring] that would be acceptable in a peer reviewed phytochemical journal". Based on this report, the judge noted this to be evidence that the standards upon which Resolve was evaluated as a NHP were "asserted – and then changed" during the reconsideration process. Dr. Arnason's evidence was subsequently struck from the record as improper expert opinion.

(2) Safety and efficacy

[41] Safety was raised as an issue on May 4, 2007, when the first warning letter was issued to TWC. The letter attached a revised HHE which demonstrated that Resolve had been classified as a Type II Health Hazard. By September 18, 2008 safety had been conceded.

[42] The judge noted that the efficacy and safety issues were intricately connected, as they both formed part of the July NOR. The lack of prior notice and deviation from standard practices were equally concerning for the judge on the issue of efficacy (Reasons for Judgment, paras. 131-132).

[43] The judge also took issue with NHPD's interpretation of the efficacy requirements, which seemed to demand "conclusive proof of efficacy in the form of unimpeachable human clinical studies" (Reasons for Judgment, para. 132). The judge concluded that section 7 and subsection 5(g) of the *Regulations* only require an applicant to provide information that reasonably supports some degree of efficacy as claimed in the PLA (Reasons for Judgment, para. 142).

[44] TWC claimed in its PLA that Resolve "may" help with smoking cessation, and the judge found that the information submitted supported such a claim. The judge determined that the NHPD's reading of the *Regulations* was both "incorrect as a matter of statutory interpretation and unreasonable in the full context of the manner in which efficacy was dealt with" (Reasons for Judgment, para. 142).

[45] The judge correctly noted the demarcation between the regulatory standards for the assessment of the safety and efficacy of drugs and the regulatory standards for the assessment of the safety and efficacy of NHPs. Subsection 5(g) of the *Regulations* requires "information that supports the safety and efficacy" of NHPs in contrast with Regulation C.08.002(2) of the *Food and Drug Regulations* which requires that a submission for a Notice of Compliance for a new drug contain:

[…]	…
(f) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;	f) le détail des épreuves qui doivent être effectuées pour contrôler l'activité, la pureté, la stabilité et l'innocuité de la drogue nouvelle;
(g) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;	g) les rapports détaillés des épreuves effectuées en vue d'établir l'innocuité de la drogue nouvelle, aux fins et selon le mode d'emploi recommandés;
(h) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;	h) des preuves substantielles de l'efficacité clinique de la drogue nouvelle aux fins et selon le mode d'emploi recommandés;
[…]	…

[46] I also agree with the judge's conclusion that, given the breaches of procedural fairness, the reconsideration process related to efficacy did not rectify the shortcomings of the PLA process (Reasons for Judgment, para. 143).

(3) Procedural fairness / Bias

[47] As noted, the Attorney General has conceded that there were breaches of procedural fairness plaguing this series of events. However, I have summarised some of the key facts which underlie this concession as they inform the judge's approach to remedy:

i. Dr. Marles instigated removal of the Active Ingredient by enlisting the support of the DNP in an effort to legitimize his unacceptable decision (Reasons for Judgment, para. 82);

ii. The reconsideration process involved individuals responsible for the Adjustment Letter, despite assurances given to the contrary (Reasons for Judgment, para. 91);

iii. The NHPD responded to TWC's request for independent experts with Drs. Arnason and Foster, whose impartiality was called into question (Reasons for Judgment, para. 92);

iv. The NHPD did not conduct its own laboratory testing, as Dr. Marles admitted would have been necessary to refute the evidence provided by TWC's experts (Reasons for Judgment, para. 93);

v. There was evidence sufficient to raise a concern that Dr. Marles knew which expert opinions to secure in order to support his own conclusions and past decisions (Reasons for Judgment, para. 93);

vi. Though Dr. Arnason stated that he conducted a literature search of "one of the most authoritative databases", he did not find any articles confirming the natural occurrence of the Active Ingredient, despite the existence of one such article (Reasons for Judgment, para. 94); and

vii. The final reconsideration decision of January 30, 2012, which referenced the reports of Health Canada's experts Drs. Arnason and Foster, set out new allegations and arguments not previously disclosed to TWC and did not provide TWC with an opportunity to respond (Reasons for Judgment, para. 95).

[48] The judge also found a reasonable apprehension of bias arising from consideration of the safety of Resolve. For example, he noted that safety had been confirmed within Health Canada in June 2007 (Reasons for Judgment, para. 99). This was in contradiction to the HHEs, including

HHE#6, which contained new reasons supporting Resolve's designation as a Type II Health Hazard that appeared to be unsupported by the evidence. TWC was given no opportunity to respond to these new allegations (Reasons for Judgment, paras. 98 and 108).

[49] The judge noted in particular the statement made by Mr. Gustafson to a TWC representative to the effect that, no matter the information provided by TWC, a PLA was not going to be granted (Reasons for Judgment, para. 109). I note however, that this finding was challenged as hearsay. In fact, TWC had provided Health Canada with an expert report confirming its safety in July 2007, prior to the issuance of the July NOR (Reasons for Judgment, para. 106).

[50] The judge detailed further Dr. Marles' involvement in the PLA process. He noted that, before his intervention, an official within the Bureau of Product Review and Assessment (BPRA) within NHPD had confirmed that the product was safe. The judge found that BPRA took Dr. Marles' concerns at face value without conducting its own review or analysis, and allowed Dr. Marles to direct that the initial Safety and Efficacy Assessment Report be set aside and replaced by an assessment taking greater account of his safety concerns (Reasons for Judgment, para. 119). The judge concluded that Dr. Marles influenced BPRA to deviate from its standard licensing practices (Reasons for Judgment, para. 121).

[51] The judge concluded that Dr. Marles' orchestration of the Adjustment Letter and his influence in the reconsideration process in particular led to a reasonable apprehension of bias in

accordance with the test laid out in *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817, 174 D.L.R. (4th) 193, at paras. 45-47 (Reasons for Judgment, para. 96).

(4) Evidentiary issues

[52] What began as a discrete judicial review of the July NOR metamorphasized into a six-year inquiry into the merits of the licence application, with the applicant and respondent before him filing competing evidence, each vying to win a scientific debate before the applications judge. The evidence before the Federal Court for the purposes of the judicial review included those expert reports and opinions exchanged throughout the reconsideration process. Both NHPD and TWC adduced further expert evidence that was not before the Minister. For example, TWC tendered a report from a pharmacologist retained to review the manner in which the PLA was dealt with by NHPD and Health Canada tendered evidence in response. This led, as might be expected, to a flurry of motions and objections to evidence at the hearing of the judicial review, as the parties tried to disentangle the factual from the opinion, hearsay from first-hand evidence.

[53] The judge was concerned with Dr. Marles' role as the sole fact witness of Health Canada, given the extent of his influence and participation in the PLA and reconsideration processes. The judge considered Dr. Marles to be advocating for himself in his affidavit evidence and criticized Health Canada for not putting forth any reliable factual evidence from other individuals who may have been involved in the process. As such, Dr. Marles' evidence was not given much weight and a significant portion of it was struck from the record.

[54] The judge also struck most of the evidence of Health Canada's experts, Drs. Arnason and Foster, on the basis of improper expert opinion, "bootstrapping" and hearsay. Given the involvement of Dr. Marles in the PLA process, the judge noted that the need for "truly objective evidence" was warranted (Reasons for Judgment, para. 92). As Dr. Foster was an employee of Health Canada in the therapeutic drug branch with no experience with natural health products, the judge doubted his independence and qualifications. He struck his entire report. Although Dr. Arnason "appear[ed] qualified for the task", the judge noted close personal and professional affiliations with Health Canada, Dr. Marles and Dr. Foster. He struck the majority of Dr. Arnason's evidence.

[55] Before the Federal Court in 2015, TWC tendered evidence in the form of a peer-reviewed article published in the *Journal of Agricultural and Food Chemistry* [redacted] which established, according to the authors and TWC, that the Active Ingredient was naturally occurring in mangos (the Mango article). Before this Court, the Attorney General objects to the judge's reliance on this paper to support the award of *mandamus*. [redacted]

[56] Viewed in light of how the judicial review proceedings unfolded, I have considerable sympathy for the judge. The entire proceeding and conduct of the parties were directed to put the judge in a position to decide the substantive question which, by regulation, was for the Minister to make. Both parties sought to shape the record with dueling and evolving reports and evidence.

In light of this, the Attorney General's complaint that the judge erred in receiving new evidence rings hollow.

III. The standard of review

[57] The issues raised in this appeal orbit around decisions made by the judge himself and not his review of decisions made by the respondent Minister. Accordingly, the applicable standard of review is the appellate standard of review stated in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. In consequence, to succeed on this appeal the Attorney General must persuade us that the Federal Court erred on a pure question of law or on a question of law that can be extracted from a question of mixed fact and law. In the absence of this sort of legal error the appellant can succeed only if he demonstrates palpable and overriding error in his assessment of the evidence: *Blank v. Canada (Justice)*, 2016 FCA 189, at para 25.

IV. *Analysis*

A. *Mandamus*

[58] The primary responsibility of the Minister under the *Food and Drugs Act* and the *Regulations* is the health and safety of Canadians. Like the *Food and Drugs Act*, the purpose of the *Regulations* is "to encourage bringing safe and effective medicines to market to advance the nation's health": *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at para. 12. When the Minister exercises her discretion under section 7 of the *Regulations* to issue a Natural Product Licence, she must be satisfied that the product is safe and effective, albeit to different standards than in the assessment of new drugs. Thus, where the

safety and efficacy of products are concerned, natural or otherwise, a court should be cautious about issuing *mandamus*. These are matters for the Minister to decide.

[59] This is not to be taken as authority for the proposition that *mandamus* cannot issue where the question relates to whether drugs or natural health products comply with safety and efficacy requirements. There is no doubt that the Federal Court has the authority to compel the Minister to issue a Notice of Compliance or a Natural Product Licence. See, for example, *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742, [1993] F.C.J. No. 1098 (*Apotex*), aff'd [1994] 3 S.C.R. 1100, [1994] S.C.J. No. 113. However, the question at the heart of this appeal is whether the judge erred in ordering *mandamus* in the particular circumstances of this case.

[60] This Court in *Apotex*, and more recently in *Lukacs v. Canada (Transportation Agency)*, 2016 FCA 202, at para. 29, set out criteria to guide the issuance of a *mandamus* order:

> (1) there must be a legal duty to act;
>
> (2) the duty must be owed to the applicant;
>
> (3) there must be a clear right to performance of that duty;
>
> (4) where the duty sought to be enforced is discretionary, certain additional principles apply;
>
> (5) no adequate remedy is available to the applicant;
>
> (6) the order sought will have some practical value or effect;
>
> (7) the Court finds no equitable bar to the relief sought; and
>
> (8) on a balance of convenience an order of *mandamus* should be issued.

[61] The judge held that the conditions for *mandamus* were satisfied. He found the PLA review of TWC's product to be dysfunctional and biased, such that remitting the matter back for reconsideration would simply result in more litigation. He thus ordered that the Natural Product Licence be granted on the basis that there were no outstanding safety concerns, the test for efficacy under the *Regulations* had been satisfied, and the evidence before him confirmed that the Active Ingredient was naturally occurring, referencing specifically to the Mango article.

[62] In my view, the judge erred in granting *mandamus*. I say this for two reasons.

(1) The finding of systemic bias

[63] The first error relates to the principal justification for the decision to grant *mandamus*. The judge concluded that there would be "no point in directing reconsideration" of TWC's application for a licence (Reasons for Judgment, para. 158). He observed that the "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" (Reasons for Judgment, para. 155). He also concluded that it was "by no means clear that totally independent people with the necessary qualifications can be found within Health Canada" (Reasons for Judgment, para. 157). Although not explicitly addressed by the judge in terms of the *Apotex* criteria, these factors underscore his conclusion that no adequate remedy was available to TWC.

[64] The judge's findings of individual bias had a solid foundation in the extensive record. It is, however, of an entirely different order to extrapolate those findings to an entire department of government. The judge noted that "[t]o 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" (Reasons for Judgment, para. 155). While I note the judge's concerns, I am not satisfied that there was evidence upon which it could be concluded that the responsible branches within Health Canada, or its senior management, were incapable of discharging their regulatory obligations in a fair and impartial manner in light of the reasons of the Court.

[65] Further, in placing an evidentiary onus on Health Canada to affirmatively prove that it could conduct a fair and objective redetermination, the judge erred. If any presumptions are to be made they would be that a statutory decision maker will act fairly and in accordance with its legal obligations, including being scrupulously faithful to both the letter and spirit of the reasons of the Court when it remits a matter for redetermination. The finding of bias on the part of officials did not, in the absence of further evidence, justify the conclusion that the Department as a whole was systemically incapable of making a fair assessment of TWC's application. As the judge predicated his decision to grant *mandamus* on an inference which cannot be sustained on the evidence, the order must be set aside.

(2) Fresh Evidence on Appeal

[66] I turn to the second ground of error. The Attorney General advances an argument relating to the evidence on which the decision to grant *mandamus* was based. The judge considered the Mango article to be determinative of the question of classification. The Attorney General takes issue with the fact that the Mango article was not before the Minister and therefore not properly

part of the record. As previously noted, the Attorney General has submitted fresh evidence on appeal which appears to call into question the conclusions of the Mango article.

[67] I will address the question of admissibility and then turn to the use of the Mango article by the judge.

[68] The record on judicial review is generally restricted to that which was before the decision maker: *Association of Universities and Colleges of Canada v. Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22. There are exceptions to this principle which include evidence directed to proof of an allegation of bias. The Mango article was admissible and relevant in respect of the bias issue and was relied on by the judge for that purpose. To that extent, it falls within the scope of the exception.

[69] I turn now to the use to which the evidence was put.

[70] The judge also relied on the Mango article to find that the Active Ingredient should be classified as a NHP such that TWC had a clear right to issuance of a licence on the record before him.

[71] In reaching the conclusion that the Mango article was determinative of classification, the judge noted the evidence of Health Canada's expert, Dr. Arnason, which he interpreted as setting out a new standard that only a peer-reviewed article evidencing natural occurrence of a substance would be sufficient to meet Health Canada's classification requirements. The Mango article met

that standard, and accordingly the judge relied on it to determine the substantive, scientific question.

[72] TWC contends that there is a distinction between consideration of the safety and efficacy of a product and the threshold question as to whether it is a NHP. TWC submits that the question of whether Resolve is a NHP is a factual determination, devoid of discretionary or policy considerations. The definition of a natural health product substance in Schedule 1 is clear. TWC argues that classification, unlike safety and efficacy, is not an elastic concept. Classification only opens the door to the appropriate regulatory review. The twin requirements of safety and efficacy remain to be determined by the Minister.

[73] I do not agree. The evidence before the Federal Court and the fresh evidence on appeal, demonstrate the opposite. The parameters of Schedule 1 and the definition of what is a natural health product can be, in some but not all cases, a matter of legitimate scientific debate.

[74] The fresh evidence tendered on appeal is first in the form of a comment submitted to the *Journal of Agricultural and Food Chemistry* in rebuttal to certain claims in the Mango article.

[redacted]

[redacted]

[75] There is, on the record before this Court, fresh evidence on appeal of what appears to be a debate on a scientific question, the resolution of which is central to the question of which regulatory regime is applicable. This evidence undermines the basis on which the judge determined that TWC had a clear right to the licence on the record before him in 2016. There is, therefore, no clear right, in 2017, to performance of the duty. In sum, the judge erred insofar as he relied on the Mango article to answer the question of classification. Recognizing that the relief under subsection 18(1) of the *Federal Courts Act*, R.S.C. 1985, c. F-7 is discretionary, I would not, given the fresh evidence on appeal, confirm the decision to grant *mandamus*: *MiningWatch Canada v. Canada (Fisheries and Oceans)*, 2010 SCC 2, [2010] 1 S.C.R. 6.

[76] TWC points to the excessive delay in processing its application, and notes that *mandamus* is available in such circumstances to compel a specific exercise of discretion.

[77] The circumstances of this case do not warrant this exercise of discretion. There is a dispute on a substantive, scientific question, the answer to which determines the legal rights and obligations of both TWC and the Minister. TWC's argument in this regard is best addressed through an expedited redetermination, not a directed verdict.

[78] For completeness, I turn to TWC's argument that the Minister was precluded from making the decisions that she did based on the doctrines of *functus officio* and estoppel.

B. *The other grounds – functus officio and estoppel*

[79] TWC contends that the doctrine of promissory estoppel prevents the Minister from revisiting the July NOR as the Minister had maintained and confirmed the position over three years that Resolve is a NHP. It contends the doctrine of *functus officio* is engaged because the Minister's regulatory power was spent having made, on July 19, 2007, her regulatory decision.

[80] As noted above, TWC submits that the question of whether Resolve is a natural health product is a factual determination, devoid of discretionary or policy considerations which limit the scope and the application of the doctrine of *functus officio*. TWC contends that the *functus* argument in this case is more compelling than *Mount Sinai Hospital Center v. Quebec (Minister of Health and Social Services)*, 2001 SCC 41, [2001] 2 S.C.R. 281, where the Minister attempted to reverse his decision before issuance of a permit. TWC contrasts that with the situation here, where the Minister attempted to alter the grounds for her decision after the July NOR had been issued.

[81] As a practical matter, it should be recalled that there was never a decision to issue a licence. The licence application was refused at various times and in various forms over a period of at least six years, albeit not according to law. The licensing power, and the affirmative decision to grant a licence, remained extant – subject to TWC engaging the reconsideration process. Safety remained in dispute until September 2008, although not for any reason that the

judge found to be justified. While the Minister never conceded efficacy, the court found that there was no reasonable basis for withholding approval on either safety or efficacy.

[82] The extent to which the doctrines of *functus officio* and estoppel apply is necessarily informed by the nature of the decision and the legislative context in which the doctrines are said to operate. Here, the *Regulations* give the Minister significant authority to revisit decisions with respect to NHPs. Following the issuance of a licence, section 16 allows the Minister to request further information "[i]f the Minister has reasonable grounds to believe that a natural health product may no longer be safe". Sections 17 to 19 give the Minister the authority to stop the sale of a natural health product, provided there exist reasonable grounds for a concern that the product may no longer be safe, or where it appears that false or misleading information was filed in support of the original application. This would include information in respect of safety and efficacy.

[83] It is clear that the doctrine of *functus officio* is limited in the context of the Minister's mandate to ensure the safety of licenced products to be consumed by Canadians. The doctrine has been displaced or constrained by the regulatory scheme. There is nothing in the regulatory scheme that supports the position that the Minister may not revisit all licensing requirements. In conclusion, the principles of *functus officio* have limited application in the context of regulatory approval of products where use may have deleterious impacts on the health of the consumer. The door must always be open for the Minister, in light of evolving science and information, to determine whether a product, natural or otherwise, should be made available to the public at large.

[84] As a corollary of the *functus* argument, TWC seeks to limit the scope of the reconsideration to only the matters which it puts in issue. The Minister was bound by the July NOR on classification and, to be precise, the Minister could reconsider only the issues of safety and efficacy. On the other hand, the Attorney General notes that section 10 allows for reconsideration of "the application", suggesting that if the applicant engages the reconsideration process, all matters are in issue.

[85] I am not prepared to read the limitation on the scope of reconsideration into section 10 as urged by TWC. To do so would be inconsistent with the governing principle of statutory interpretation that legislation is to be given its plain and obvious meaning, informed by its context, and consistent with its purpose: see, Ruth Sullivan, Statutory Interpretation, 3rd ed. (Toronto: Irwin Law, 2016).

[86] The power to reconsider all issues is not, however, unlimited. It must be exercised according to law and the principles of procedural fairness. Here, the reconsideration process was tainted by breaches of procedural fairness, such that the judge deemed it to be a nullity.

[87] Thus, the reconsideration process, while opening the door to all issues, did not cure the procedural breaches that had plagued the original PLA assessment process: *Newfoundland Telephone Co. v. Newfoundland (Board of Commissioners of Public Utilities)*, [1992] 1 S.C.R. 623, at paras. 38-41.

C. ***Remedy***

[88] The judge erred in directing the Minister to issue a Natural Product Licence in respect of Resolve. The judge erred in extrapolating his findings of bias to the entirety of Health Canada, and in relying on the Mango article to ground his finding that there was a clear right to the issuance of a Natural Product Licence in 2016.

[89] It is axiomatic that the Court should respect the role of statutory decision makers to discharge their responsibility and obligations under the *Regulations*. This principle should not be lightly displaced. The judge made significant and damaging findings related to the behaviour of senior Health Canada officials, administrative confusion, deliberate cherry-picking of evidence, shifting standards of evaluation, bias and an admitted denial of procedural fairness. While I maintain and rely upon the presumption that statutory decision makers will act fairly and in accordance with their legal obligations, circumstances such as these have the potential to compromise public confidence in the licensing system for NHPs.

[90] Despite his findings, the proper remedy was for the judge to remit the matter back to the decision maker for redetermination. The redetermination shall be completed within 90 days of the date of this decision, unless extended on consent.

D. ***Costs***

[91] The judge awarded costs on a solicitor-client, full indemnity basis. In reaching this decision, he considered relevant principles under Rule 400 of the *Federal Courts Rules* (S.O.R./98-106) and the case law with respect to awards of solicitor-client costs. He listed, with

precision, the conduct that he felt required sanction. An award of costs is highly discretionary, and I am not convinced that the judge misdirected himself to either the relevant principles or mischaracterised the conduct of the appellant.

[92] With respect to costs in this Court, the parties have had divided success. The Attorney General was successful on the principal ground of appeal that the order of *mandamus* be set aside. She was also successful in the argument that the reconsideration process included all elements of the licensing process. The Attorney General also conceded that the decisions had violated procedural fairness, although this concession came at the hearing, after all related costs had been incurred. The favourable outcome for the Attorney General arose in part because of the fresh evidence tendered on appeal. TWC, while unsuccessful in maintaining the *mandamus* order, did preserve the factual foundation of the Judgment.

[93] In the ordinary course costs are awarded to the successful party. Costs are, however, discretionary, and there are considerations relevant to the exercise of that discretion in this case which warrant a departure from the usual course. The concession that there had been breaches of procedural fairness came only on the eve of the hearing before this Court, following nearly a decade of litigation and nearly a year after the Federal Court decision. The concession on procedural fairness was confirmation of that which was obvious to the judge, there was bias on the part of officials, shifting regulatory standards and interpretations, objections on the grounds of safety which were not substantiated and from which the department resiled, lack of notice and disclosure.

[94] Parliament has given the Minister a mandate to ensure that Canadians have access to natural health products that are safe and efficacious. The provisions of the regulatory scheme, which I have reviewed in some detail, demonstrate that the discretionary powers vested in the Minister are to be exercised on the basis of objective scientific considerations, and in a fair and transparent manner. Public confidence in the products they consume, of whatever origin, is dependent on the understanding that decisions are made on the foundation of these principles. In this case, they were not, and for that reason I would award costs of this appeal to TWC on a solicitor-client basis.

[95] In sum, I would allow the appeal in part and set aside paragraphs (2) and (3) of the Judgment of the Federal Court. Making the judgment that the judge should have made, TWC's licence application will be remitted to the Minister for redetermination in accordance with these reasons. Given the circumstances, the Minister is directed to make the redetermination within 90 days of the date of this decision, unless the parties consent to an extension of the time. It will be for the Minister to devise a process by which her regulatory decision-making responsibilities in respect of TWC's application can be discharged in a manner consistent with these reasons.

"Donald J. Rennie"

J.A.

"I agree
M. Nadon, J.A."

"I agree
Yves de Montigny, J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

APPEAL FROM A JUDGMENT OF THE FEDERAL COURT DATED APRIL 6, 2016, DOCKET NUMBER T-1381-07 (2016 FC 381)

DOCKET:	A-117-16
STYLE OF CAUSE:	CANADA (MINISTER OF HEALTH) and, THE ATTORNEY GENERAL OF CANADA v. THE WINNING COMBINATION INC.
PLACE OF HEARING:	WINNIPEG, MANITOBA
DATE OF HEARING:	NOVEMBER 16, 2016
REASONS FOR JUDGMENT BY:	RENNIE J.A.
CONCURRED IN BY:	NADON J.A. DE MONTIGNY J.A.
DATED:	MAY 15, 2017

APPEARANCES:

Peter Southey Glynis Evans	FOR THE APPELLANTS
Rod C. Roy John A. Myers	FOR THE RESPONDENT

SOLICITORS OF RECORD:

William F. Pentney Deputy Attorney General of Canada Winnipeg, Manitoba	FOR THE APPELLANTS
Taylor McCaffrey LLP Barristers & Solicitors Winnipeg, Manitoba	FOR THE RESPONDENT