NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Health Canada ordered to grant a Natural Health Product License for smoking cessation product

Case:	*The Winning Combination Inc. v Canada (Minister of Health)*, 2016 FC 381 (Court File No. T-1381-07)
Drug:	**RESOLVE®**
Nature of case:	Application for judicial review of Health Canada's decision refusing marketing authorization under the *Food and Drugs Act,* RSC 1985, c F-27 (***Act***) and *Natural Health Product Regulations,* SOR/2003-196 (***NHP Regulations***)
Successful party:	The Winning Combination Inc.
Date of decision:	April 4, 2016

Summary

The Winning Combination Inc. (**TWC**) marketed a smoking cessation aid in Canada with a confidential active ingredient under the brand name RESOLVE®. Through a series of decisions, Health Canada required that TWC remove RESOLVE from the Canadian marketplace and refused to grant a Product License for RESOLVE under the *NHP Regulations*.

The Court allowed TWC's application for judicial review, finding that Health Canada's refusal to grant a Product License Application (**PLA**) for RESOLVE was unjustified. The Court concluded that TWC had been denied procedural fairness and that the PLA and subsequent reconsideration processes were unreasonable and biased. Health Canada's decisions rejecting the PLA were quashed and Health Canada was ordered to grant a licence for RESOLVE within 30 days of the order.

Background

In 2004, the PLA for RESOLVE was submitted to the Natural Health Products Directorate (**NHPD**). The NHPD initially concluded, based on the authoritative Dictionary of Natural Products (**DNP**), that RESOLVE met the definition of a natural health product (**NHP**) under the *NHP Regulations.* RESOLVE entered the Canadian market in 2006. Later that year, Health Canada revisited its assessment of RESOLVE's PLA in response to allegations of health concerns and non-compliance with certain advertising standards pertaining to the product.

RESOLVE was marketed in Canada as a NHP until July 2007 when the NHPD issued two decisions rejecting TWC's PLA. The first decision, issued in July 2007, rejected TWC's PLA on the basis that there was insufficient evidence to support the safety and efficacy of RESOLVE. The first decision was followed by a public advisory, stop-sale and recall of RESOLVE. The second decision, issued in August 2007, rejected the PLA on a new and separate ground that RESOLVE was not a NHP but should be re-classified as a drug. Consequently, RESOLVE should be subject to the *Food and Drug Regulations.*

TWC filed for reconsideration of the NHPD's decisions and continuously submitted material to Health Canada between August 2007 and January 2012 in support of its PLA. A final letter was sent to TWC in January 2012 indicating that the PLA was rejected on the basis that the active ingredient in RESOLVE was not a NHP and that there was insufficient evidence to support the efficacy of the product.

TWC was not afforded procedural fairness

TWC alleged that it was denied procedural fairness in the PLA process, including the notice and the opportunity to be heard before the NHPD's decisions were released. TWC also alleged that the NHPD departed from the usual processes and procedures, resulting in decisions that demonstrated bias, pre-judgement, bad faith and a closed mind. Health Canada asserts that it provided ample opportunity for TWC to be heard.

With respect to both NHPD decisions, the Court found that TWC did not receive notice or the opportunity to address the issues of safety and efficacy, and classification until the decision to reject the PLA was issued. The evidence showed that the reconsideration of the NHPD decisions were "*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*." Justice Russell allowed the application for lack of procedural fairness, a reasonable apprehension of bias and unreasonableness.

TWC satisfied the requirements under the *NHP Regulations*

TWC argued that it had met the regulatory requirements with respect to the safety, efficacy and classification of RESOLVE as a NHP. TWC submits that the NHPD had no basis to reject the PLA based on efficacy. The standard under the *NHP Regulations* for supporting efficacy did not require TWC to submit substantive proof as required by the NHPD. With respect to classification, TWC argued that RESOLVE had been classified as a NHP on various occasions prior to the rejection of the PLA. Furthermore, the classification issue was not previously brought to the attention of TWC and was not based on any scientific evidence or testing.

The Court accepted TWC's argument. Justice Russell rejected Health Canada's demand that TWC meet an extremely high standard of conclusive proof in the form of clinical studies to support the efficacy of RESOLVE. With respect to classification, TWC had submitted expert evidence that the active ingredient in RESOLVE is a NHP. The evidentiary record showed that the active ingredient in RESOLVE was still listed as a natural substance in the DNP when the second decision to reject the PLA based on classification as a drug was issued. On these bases, the Court quashed both NHPD decisions rejecting the PLA and all subsequent decisions from reconsiderations.

Health Canada ordered to grant License for RESOLVE

Justice Russell refused to return the matter to Health Canada for reconsideration concluding 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*." The Court found no justifiable reason why RESOLVE was kept off the market for 8 years while the PLA and reconsideration process were under review, and as such ordered Health Canada to grant a license for RESOLVE to TWC. The Court awarded solicitor-client costs to TWC on a full indemnity basis.

Appeal sought

Health Canada has sought appeal of the Court's judgment (Appeal Court File No. A-117-16).

Link to decision:

The Winning Combination Inc. v Canada (Minister of Health), 2016 FC 381

Karen Sie

Financial institutions
Energy
Infrastructure, mining and commodities
Transport
Technology and innovation
Life sciences and healthcare

NORTON ROSE FULBRIGHT

For more information, please contact your IP/Life sciences and healthcare practice professional at Norton Rose Fulbright Canada LLP. For a complete list of our IP team, click here. For a complete list of our Life sciences and healthcare team, click here.