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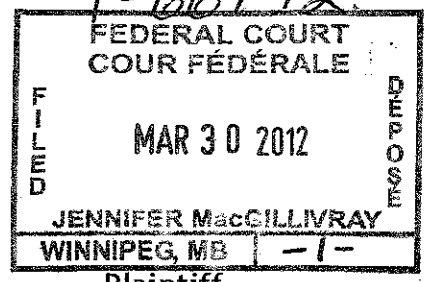
ORIGINAL

Court File No.

T-669-12.

FEDERAL COURT



BETWEEN:

THE WINNING COMBINATION INC.,

Plaintiff,

AND

HER MAJESTY THE QUEEN IN RIGHT OF CANADA, ATTORNEY GENERAL OF CANADA, PAUL GUSTAFSON, ROBIN MARLES, PHILLIP WADDINGTON, MICHELLE BOUDREAU, SCOTT SAWLER,

Defendants.

STATEMENT OF CLAIM

TAYLOR McCAFFREY LLP
Barristers and Solicitors,
9th Floor - 400 St. Mary Avenue,
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Client File No. 63339-34

Court File No.

FEDERAL COURT

BETWEEN:

THE WINNING COMBINATION INC.,

Plaintiff,

AND

HER MAJESTY THE QUEEN IN RIGHT OF CANADA, ATTORNEY GENERAL OF CANADA, PAUL GUSTAFSON, ROBIN MARLES, PHILLIP WADDINGTON, MICHELLE BOUDREAU, SCOTT SAWLER,

Defendants.

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or a solicitor acting for you are required to prepare a Statement of Defence in Form 171B prescribed by the *Federal Court Rules*, 1998, serve it on the plaintiffs' solicitor or, where the plaintiffs do not have a solicitor, serve it on the plaintiffs, and file it, with proof of service, at a local office of this Court, WITHIN THIRTY (30) DAYS after this Statement of Claim is served on you, if you are served within Canada.

If you are served in the United States of America, the period for serving and filing your Statement of Defence is forty (40) days. If you are served outside Canada and the United States of America, the period for serving and filing your Statement of Defence is sixty (60) days.

Copies of the *Federal Court Rules*, 1998, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or any local office.

IF YOU FAIL TO DEFEND THIS PROCEEDING, judgment may be given against you in your absence and without further notice to you.

March , 2012

Issued by ORIGINAL SIGNED BY JENNIFER MacGILLIVRAY DIRECTOR
(Registry Officer)

Federal Court
Winnipeg Local Office
4th Floor, 363 Broadway
Winnipeg, Manitoba
R3C 3N9

TO: Her Majesty the Queen in Right of Canada

AND TO: Attorney General of Canada
284 Wellington St.
Ottawa, Ontario
K1A 0H8

AND TO: Paul Gustafson
c/o Health Products and Food Branch Inspectorate
Manitoba and Saskatchewan Region
510 Lagimodiere Blvd.
Winnipeg, Manitoba
R2J 3Y1

AND TO: Robin Marles
c/o Natural Health Products Directorate
2936 Baseline Road
Basement - AL 3300B
Ottawa, Ontario
K1A 0K9

AND TO: Phillip Waddington
c/o Natural Health Products Directorate
2936 Baseline Road
Basement - AL 3300B
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AND TO: Michelle Boudreau
c/o Natural Health Products Directorate
2936 Baseline Road
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AND TO: Scott Sawler
c/o Natural Health Products Directorate
2936 Baseline Road
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CLAIM

1. The plaintiff claims from the defendants, jointly and severally:

   a) special damages;

   b) general damages;

   c) punitive, aggravated and exemplary damages;

   d) interest;

   e) a declaration that the actions of the defendants as herein described were unlawful and that the plaintiff was and is entitled to receive a natural health product licence for the product RESOLVE;

   f) a mandatory injunction requiring the withdrawal of all compliance and enforcement actions herein described, including stop sale orders, recalls and public health advisories, and the granting of a natural health product licence for the product RESOLVE;

   g) costs;

   h) such further and other relief as this Honourable Court may deem just.

THE PARTIES

2. The plaintiff is a corporation duly incorporated pursuant to the laws of Manitoba and carries on business in Manitoba, throughout Canada and in the United States of America with its head office in the City of Winnipeg, in Manitoba.

3. The defendant, Her Majesty the Queen in Right of Canada, is the Government of Canada and is located in the City of Ottawa, in Ontario.

4. The defendant, Attorney General of Canada, is sued on behalf of the Government of Canada pursuant to the *Crown Liability and Proceedings Act*, R.S.C., 1985, c. C-50. The defendants, Her Majesty the Queen in Right of Canada and Attorney General of Canada, are hereinafter referred to collectively as "Canada".

5. The defendant, Paul Gustafson ("Gustafson") is or was, at all material times, employed by Canada and, to the best of the plaintiff's knowledge, resides in the City of Winnipeg, in Manitoba.

6. The defendant, Robin Marles ("Marles") is or was, at all material times, employed by Canada and, to the best of the plaintiff's knowledge, resides in the City of Ottawa, in Ontario.

7. The defendant, Phillip Waddington ("Waddington") is or was, at all material times, employed by Canada and, to the best of the plaintiff's knowledge, resides in the City of Ottawa, in Ontario.

8. The defendant, Michelle Boudreau ("Boudreau") is or was, at all material times, employed by Canada and, to the best of the plaintiff's knowledge, resides in the City of Ottawa, in Ontario.

9. The defendant, Scott Sawler ("Sawler") is or was, at all material times, employed by Canada and, to the best of the plaintiff's knowledge, resides in the City of Ottawa, in Ontario.

10. At all material times hereto:

a) Health Products and Food Branch ("HPFB") is a branch of Health Canada of the Government of Canada and Natural Health

Products Directorate ("NHPD") is a directorate within HPFB. Both are based in Ottawa, Ontario;

b) NHPD is responsible for the licensing of natural health products manufactured and sold in Canada. The Bureau of Clinical Trials and Health Sciences ("BCTHS") is a bureau within the NHPD and is involved in clinical trials, Health Hazard Evaluations ("HHE"), risk assessments, product classifications, natural health product databases, monographs concerning natural health products and in providing scientific advice on natural health products to other government directorates, inspectorates, branches and departments and to industry and consumers. It is based in Ottawa, Ontario;

c) the Health Products and Food Branch Inspectorate ("HPFBI") is an inspectorate within HPFB and is responsible for regulatory compliance and enforcement regarding natural health food products sold in Canada. It is based in Ottawa, Ontario and has offices in Winnipeg, Manitoba;

d) the defendant Gustafson was employed as a drug specialist in HPFBI and acting within the scope of his employment with Canada;

e) the defendant Marles was employed as the Director of BCTHS and acting within the scope of his employment with Canada;

f) the defendants Waddington, Boudreau and Sawler served, at different times, as Director General of NHPD and acted within the scope of their employment with Canada;

g) the manufacture and sale of natural health products in Canada were and are governed by the relevant provisions of the *Food*

and Drugs Act, R.S.C. 1985, c. F-27 and the *Natural Health Products Regulations*, S.O.R./2003-196 (the "Regulations") enacted pursuant to the *Food and Drugs Act* and which came into force on January 1, 2004;

h) the Regulations, under section 7, provide that the Minister of Health for Canada ("Minister") shall issue a natural health product licence if the applicant has submitted an application to the Minister that is in accordance with section 5 of the Regulations, the applicant has submitted to the Minister any additional information requested under section 15 of the Regulations, no false or misleading statements were made by the applicant in the application and the issuance of the licence is not likely to result in injury to the health of a purchaser or consumer;

i) section 15 of the Regulations provides that, if the information or documents submitted in respect of a product licence application under section 5 are insufficient to enable the Minister to determine whether the product licence should be issued, the Minister may request that the applicant provide such additional information as may be necessary to make the determination;

j) section 16 of the Regulations provides that, if the Minister has reasonable grounds to believe that a natural health product may not be safe, the Minister may request from an applicant or licensee information or documents demonstrating that the natural health product is safe;

k) section 9 of the Regulations provides a right of reconsideration from any decision to refuse the issuance of a natural health product licence and section 10 of the Regulations provides that,

after reconsideration, the Minister shall issue said licence if the requirements of section 7 are met. The plaintiff says that pursuant to the Regulations, or otherwise at law, such reconsiderations must be conducted reasonably and fairly and by independent and unbiased persons who have not been involved in previous decisions relating to the licensing or reconsideration in question;

l) the law and the relevant Regulations concerning the compliance, enforcement and licensing of natural health products including those relating to stopping the sale of, or recalling, natural health products require that advance notice and an opportunity to respond be given to an applicant or licensee before such decisions are made or actions taken;

m) although the Regulations came into force on January 1, 2004, natural health product vendors such as the plaintiff had the tacit and de facto approval of Health Canada to manufacture and sell natural health products in Canada, even without a licence, as a result of a lengthy phase-in period and the large backlog of natural health product licence applications which existed within Health Canada from 2004 until 2009. In the result, natural health products, including the plaintiff's natural health product herein described, were not prohibited from sale in Canada simply as a result of not being licensed;

n) in all matters relating to the licensing (including reconsiderations), compliance, enforcement and regulation of such natural health products, the defendants, and each of them, owed to product licence applicants and natural health product vendors, including the plaintiff, a duty of good faith, a duty to

observe all requirements of natural justice and/or procedural fairness and a duty to act fairly, independently, reasonably and without negligence, bias, conflict or discrimination;

o) Canada is liable for the conduct and actions of its servants, including Gustafson, Marles, Waddington, Boudreau, Sawler and other federal government employees and agents involved in the matters referred to herein and is directly liable for its own conduct and actions in relation to said matters. The plaintiff pleads and relies on sections 1, 2, 3 and 23 of the *Crown Liability and Proceedings Act* aforesaid; and

p) although most or all of the actions and decisions of the defendants as herein described were initiated in the City of Ottawa, in Ontario, those actions and decisions take effect and adversely impact the plaintiff in each province of Canada and outside of Canada.

BACKGROUND

11. On October 4, 2004, Applied Food and Specialties Inc. ("AFS") filed a Product Licence Application ("PLA") for a natural health product originally named "NicCess" (Cesteminol-350). The product name was changed to "RESOLVE" in April, 2006. The active ingredient in RESOLVE is a trade secret natural compound X (hereinafter "Compound X") of which the defendants are aware. The identity of the compound will be disclosed in a confidential Schedule "A" and as soon as a Protective Order issues in this proceeding. Compound X is derived from natural sources, specifically, passionflower and can also be manufactured synthetically. Compound X and RESOLVE are natural health product substances and natural health products as defined in the Regulations. In addition, compound X has long

been recognized as a safe natural substance and product and has been used a food additive by Pfizer and other parties since the 1970s. It enjoys "Generally Regarded As Safe" (GRAS) status with the U.S. Food and Drug Administration and has been studied as a smoking cessation aid since at least 1982.

12. AFS sold and assigned all of its rights and ownership in NicCess Cesteminol-350 (RESOLVE), including all of its rights in the PLA, to the plaintiff on April 12, 2006. The defendants were given notice of the plaintiff's status as the owner of RESOLVE and the PLA.

13. In or about December, 2004 NHPD accepted the PLA and granted it submission no. 103119. This acceptance included the acceptance of RESOLVE (Compound X) as a natural health substance and product.

14. Pursuant to the Regulations and to the guidelines and policies of NHPD, acceptance of the PLA and granting it a submission number constituted a representation, express or implied, by the defendants that the PLA was "complete" as to all required information concerning the classification, safety and efficacy of the natural health product in question. Further representations to this effect were made by representatives of the defendants between March and June, 2006 including an e-mail from Neil Yeates, Assistant Deputy Minister, NPFB, which indicated that the product had reached the level 3 assessment category which was "towards the end of the review process".

15. The plaintiff relied to its detriment on said acceptance and representations and continued to develop and prepare for the sale of the RESOLVE product which commenced in or about October, 2006. Also based on said representations, the plaintiff understood that, should there be any

concerns or questions regarding the classification, safety or efficacy of the product, it would receive advance notice of such matters and be given an opportunity to respond and to provide further information prior to any decision being made or adverse action taken with respect to said product.

16. In December, 2006, Pfizer Canada Inc. ("Pfizer"), or its representatives on behalf of Pfizer, acting with malice and in bad faith and with the intention of injuring the plaintiff, wrote to Health Canada falsely alleging that the product RESOLVE was unsafe as a result of it containing passionflower and balsam fir residue.

17. In fact, RESOLVE did not contain any passionflower or balsam fir residue and this information was readily available. Accordingly, not only was Pfizer's allegation false, it could have been determined as false with very little effort. Notwithstanding this, and without any notice to the plaintiff, the defendants, through Marles, issued an HHE in January, 2007 which was based essentially on the false allegations made by Pfizer. There was no *bona fide,* reasonable or any effort on the part of the defendants to ascertain whether these allegations were true. In addition, the defendants, through Marles, incorrectly alleged in the HHE that no PLA had been filed with respect to RESOLVE and that no PLA submission number existed for said product. In any event, the defendants, and in particular Marles, failed to have any regard to the substantial documentation and information that was filed with the PLA.

18. Concurrently with the issuance of said HHE, RESOLVE was improperly designated by the defendants as a "type II health hazard" and subjected to a heightened and stricter assessment both from a licensing and compliance perspective. The plaintiff says that, had it not been for the wrongful or negligent conduct of the defendants as herein described, the product

RESOLVE, which by this time was enjoying substantial market acceptance, would have been licensed as a natural health product in the normal course, likely in 2007.

19. Prior to May 4, 2007, notwithstanding the initial HHE from January, 2007 and subsequent revisions of said HHE, the defendants failed to advise the plaintiff of the HHE or of the alleged health concerns relating to RESOLVE and requested no information from the plaintiff in relation to such matters. Instead, without any forewarning, the plaintiff received on May 4, 2007 an official "Warning" from the defendant Gustafson, on behalf of the defendants, which ordered the plaintiff to stop selling and advertising RESOLVE and to recall any RESOLVE from the Canadian marketplace. This warning letter was purportedly based on the false Pfizer allegations and erroneous HHE aforesaid.

20. On May 9, 2007, the plaintiff received a Processing Deficiency Notice ("PDN") from the NHPD relating to some minor administrative matters in the PLA which had nothing to do with safety, efficacy or classification. The plaintiff quickly responded to the PDN and provided the necessary information. This was the first and only request for information that the plaintiff received with respect to the PLA itself. The plaintiff was also told by representatives of the defendants that the PLA assessment and the compliance and HHE matters aforesaid were separate and distinct processes.

21. Between May 4 and June 28, 2007, the plaintiff provided further information to the defendants demonstrating and re-confirming not only were the initial allegations made by Pfizer false but that the product was, in fact, safe. This was over and above the information already contained in the original PLA to which the defendants had little or no regard.

22. On June 28, 2007, the plaintiff met with Gustafson in person and with Marles and other representatives of the defendants on a conference call at which time the defendants, through Marles, admitted that the allegation that RESOLVE contained passionflower and balsam fir residue was false. However, the defendants then asserted new allegations to justify their actions and to designate RESOLVE as a health hazard. Specifically, even though the plaintiff had received no advance notice or forewarning as to these matters, the defendants now alleged wrongfully that Compound X itself was a safety risk and purported to rely on an Adverse Reaction Report ("ARR") which alleged that an individual who had taken RESOLVE had suffered elevated liver enzymes.

23. The defendants, through Gustafson, refused to provide the plaintiff with any further information regarding this ARR. Subsequently, Gustafson told the plaintiff that if it wanted any further information regarding this ARR, it would have to submit an "access to information" request. This was improper in that the plaintiff was not seeking any confidential information as to the identity of the individual involved in the ARR but only "scrub data" which would give no identifying information about the individual but merely provide particulars as to the individual's condition, other medications being taken, and other information relevant to the issue of causation. In fact, the defendants knew that there was no evidence of any relationship between RESOLVE and the individual's elevated liver enzymes.

24. The plaintiff says that the true intention of the defendants was to contrive and assert any unfounded or arbitrary excuse to prevent the plaintiff from selling RESOLVE in the Canadian marketplace. The defendant Gustafson admitted this on June 28, 2007 when he indicated

that it did not matter what the plaintiff did in response to the HHE's or what material it supplied, its PLA was not going to be approved.

25. Following the discussion of June 28, 2007, the plaintiff continued to provide the defendants with further information to confirm the safety of RESOLVE and to demonstrate that there was no basis for the compliance and enforcement actions taken by the defendants. In spite of this, the defendants, through Gustafson and Marles, further revised the HHE (now in its sixth version) to continue asserting that RESOLVE constituted a health hazard. Specifically, the final version of the HHE issued on July 17, 2007, again prepared without any advance notice or opportunity to respond being given to the plaintiff, designated RESOLVE as a health hazard based on three reasons. The first reason was the unfounded ARR referred to above. In addition, two new and also improper reasons were advanced; namely, a baseless allegation concerning the daily dosage of RESOLVE and certain unfounded and irrelevant allegations relating to monitoring the use of RESOLVE.

26. On July 19, 2007, the defendant Waddington, on behalf of the defendants, issued a Notice of Refusal rejecting the PLA for RESOLVE. This refusal was purported to be based upon alleged concerns relating to the safety of Compound X itself and to the efficacy of RESOLVE. The plaintiff had never received any advance notice or requests for information regarding product safety or efficacy as part of the PLA assessment process. Furthermore, the plaintiff had never received any notice or questions regarding the efficacy of RESOLVE in any context whatsoever. The refusal of July 19, 2007 was the first indication that the plaintiff had received to suggest any concerns or questions as to the efficacy of RESOLVE.

27. Also on July 19, 2007, a further recall demand was issued by Gustafson, on behalf of the defendants, notwithstanding all of the information previously provided by the plaintiff which demonstrated that there was no safety risk associated with RESOLVE. Furthermore, even though the plaintiff agreed on a without prejudice basis to cooperate in an orderly recall, the defendants, through Gustafson, issued on July 27, 2007 a public health advisory to the public and industry generally containing false information as to alleged lack of cooperation on the part of the plaintiff and false information regarding the safety of RESOLVE.

28. On August 21, 2007, the defendants, through Waddington, issued a further Notice of Refusal of the RESOLVE PLA this time falsely and wrongfully alleging that RESOLVE (Compound X) was not a natural health substance and product but rather a synthetic drug. This was said to be a further reason to refuse the issuance of a natural health product licence for RESOLVE. The plaintiff had received no prior indication whatsoever as to any question regarding the classification of Compound X as a natural health substance or product. As stated, RESOLVE and Compound X are natural health products and substances and had been accepted by the defendants as such immediately following the PLA in October, 2004. The plaintiff had relied on this acceptance, and the representation implicit in such acceptance, and understood that RESOLVE and Compound X would be treated as a natural health products and substances by the defendants.

29. On July 26, 2007, the plaintiff sent a formal request for reconsideration of the July 19, 2007 Notice of Refusal pursuant to section 9(2) of the Regulations. On September 18, 2007, the plaintiff formally requested a reconsideration of the August 21, 2007 Notice of Refusal pursuant to section 9(2) of the Regulations. The defendants Boudreau and

Sawler served as Director-General of NHPD during the reconsideration processes.

30. Since the filing of the requests for reconsideration as aforesaid, the plaintiff has been frustrated in its efforts to obtain proper reconsiderations of both Notices of Refusal as a result of the continuing wrongful and/or negligent conduct of the defendants described below. After numerous delays and difficulties, the plaintiff received a final decision on January 30, 2012 wrongfully rejecting the requests for reconsideration of both the July 19, 2007 and August 21, 2007 Notices of Refusal. During the course of the reconsideration process, the defendants finally admitted that there were no safety concerns regarding RESOLVE and have abandoned that as a ground for refusing to license RESOLVE as a natural health product. However, the defendants continue to purport to rely on alleged efficacy concerns and their refusal to recognize Compound X as a natural health substance and product both of which reasons lack any merit or validity whatsoever.

CAUSES OF ACTION

31. Following the Notices of Refusal aforesaid, the plaintiff commenced judicial review proceedings in this Court seeking to review and set aside the Notices of Refusal so as to allow for the licensing and continued sale of RESOLVE. These judicial review proceedings are still pending. Pursuant to the Federal Court of Appeal decision in *Canada vs. Grenier*, [2006] 2 F.C.R. 287, the plaintiff was precluded from commencing the within action for damages and other relief until such time as said judicial review proceedings were concluded. This prohibition was removed by virtue of the Supreme Court of Canada's decision in *Attorney General of Canada vs. Telezone Inc.*, [2010] 3 S.C.R. 585 which was issued in December, 2010.

32. The plaintiff says that, at all material times, the requirements of section 7 and section 10 of the Regulations were satisfied with respect to the PLA and therefore, the Minister was obliged to issue a natural health product licence for RESOLVE.

33. Alternatively, based on the representations made by the defendants as aforesaid, including the representations expressly or implicitly contained in the acceptance of the PLA, the granting of a PLA submission number and in the acceptance of RESOLVE as a natural health product, and as a result of the plaintiff relying on said representations to its detriment as aforesaid, the defendants were and are estopped or otherwise precluded at law from refusing to grant a natural health product licence for RESOLVE and from taking the compliance and enforcement actions described herein based on any grounds related to safety, efficacy or classification.

34. The plaintiff states that the said Notices of Refusal, compliance and enforcement actions, and rejections of the requests for reconsideration were and are a result of malice, misfeasance in public office, bias, abuse of authority and/or bad faith on the part of some or all of the defendants which the defendants knew and intended to result in injury, loss and damage to the plaintiff. Particulars of this malice, misfeasance, bias, abuse and/or bad faith include the following:

a) conspiring among themselves and/or with Pfizer or other unknown parties to injure the plaintiff by taking such actions or making such refusals and rejections based on allegations or grounds which they knew to be false, improper and unlawful;

b) relying on allegations or grounds in respect of said matters which they knew to be false, improper and unlawful. Alternatively,

being reckless or willfully blind as to the truth, propriety or legality of said allegations and grounds;

c) repeatedly asserting improper or baseless reasons to conduct or continue compliance and enforcement proceedings against the plaintiff and to refuse to licence RESOLVE as a natural health product without giving the plaintiff any prior notice or opportunity to address such issues;

d) issuing warning letters, public health advisories and orders requiring the plaintiff to stop selling and advertising RESOLVE and to recall all RESOLVE product from the Canadian Marketplace when the defendants knew that such actions were unlawful, improper, discriminatory and unreasonable. Alternatively, being reckless or willfully blind as to such matters;

e) imposing standards, requirements and burdens of proof on the plaintiff with respect to compliance, licensing and reconsideration which the defendants knew to be unlawful, improper, discriminatory and unreasonable. Alternatively, being willfully blind or reckless as to such matters;

f) making a predetermination that the plaintiff would not receive a natural health product licence no matter what information or evidence was provided by the plaintiff;

g) purporting to reject the status of RESOLVE (Compound X) as a natural health substance and product in or about August, 2007 when they knew that there was no legal or scientific basis for doing so or being reckless or willfully blind as to such matters; and

h) failing to provide the plaintiff with independent, unbiased and fair reconsideration processes using persons who were not involved at previous stages of the application or reconsideration procedures.

35. Further, or in the alternative, the plaintiff says that the defendants, or some of them, were grossly negligent or negligent with respect to the said compliance and enforcement actions, Notices of Refusal and reconsideration proceedings. Particulars of such negligence include the following:

a) relying on allegations or grounds in respect of said matters which they ought to have known were false, improper and unlawful;

b) failing to take reasonable steps to determine whether said allegations and grounds were true, proper and lawful;

c) designating RESOLVE (Compound X) as a "type II health hazard" without any reasonable basis for doing so;

d) failing to have regard or proper regard to the PLA and the information contained in the PLA;

e) failing to have regard or proper regard to the information provided by the plaintiff which demonstrated that RESOLVE (Compound X) was not a safety risk;

f) failing to have regard or proper regard to the information provided by the plaintiff which demonstrated the efficacy of RESOLVE (Compound X);

g) imposing on the plaintiff standards, requirements and burdens of proof with respect to compliance, licensing and reconsideration

which the defendants ought to have known were unlawful, improper, discriminatory and unreasonable;

h) failing to have fair, independent and reasonable systems, policies and processes, along with properly trained, skilled and unbiased employees, with respect to the compliance, enforcement, licensing and reconsideration of natural health products so as to ensure compliance with the Regulations and all duties owed to industry members including the plaintiff;

i) failing to follow fair, independent and reasonable processes with respect to compliance, enforcement, licensing and reconsideration regarding natural health products;

j) issuing warning letters to the plaintiff and requiring the plaintiff to stop selling and advertising RESOLVE and to recall all RESOLVE product from the Canadian market without reasonable, proper or lawful grounds to take such actions;

k) issuing and publishing a public health advisory which the defendants knew or ought to have known contained false and inaccurate information regarding the plaintiff's cooperation and the safety of RESOLVE;

l) erroneously rejecting the status of RESOLVE (Compound X) as natural health substances and products when they knew or ought to have known there was no legal or scientific basis for doing so; and

m) imposing on the plaintiff reconsideration procedures and requirements which the defendants ought to have known were unfair, unreasonable, unlawful, biased and discriminatory and in

failing to have proper or any regard to the information provided by the plaintiff in relation to said reconsiderations.

36. The plaintiff further says that the defendants, or some of them, have unlawfully interfered with the plaintiff's economic relations and have acted in breach of the Regulations and their statutory duties and in breach of their duty to comply with the requirements of natural justice and due process and/or their duty to act reasonably, fairly and without discrimination or bias. The plaintiff relies on the same particulars as set out in paragraphs 34 and 35 herein.

PAST AND CONTINUING INJURY, LOSS AND DAMAGE

37. The plaintiff says that the misfeasance, abuse, bad faith, bias, negligence, interference and/or breaches of duty as aforesaid are continuing with the plaintiff still being improperly prohibited from selling RESOLVE as a natural health product throughout Canada and from selling RESOLVE in other jurisdictions as a consequence of the Canadian circumstances described herein.

38. As a result of the matters aforesaid, the plaintiff has suffered and continues to suffer severe injury, loss and damage including:

a) costs and expenses incurred in relation to its PLA and in relation to the compliance and enforcement actions taken by the defendants;

b) costs and expenses incurred in relation to the extensive reconsideration processes;

c) costs incurred to develop and to prepare the RESOLVE product for sale, including substantial advertising costs;

d) loss of RESOLVE sales in Canada and in the United Stated from July, 2007 until the present;

e) loss of income and profit with respect to RESOLVE from July, 2007 until the present;

f) loss of future sales, income and profit relating to RESOLVE; and

g) injury and damage to its reputation and goodwill.

39. The defendants' actions constitute a malicious, wanton and contumelious attempt to injure the plaintiff and its business for which the plaintiff is entitled to an award of aggravated, punitive and exemplary damages.

40. The plaintiff further says that, unless granted injunctive relief against the defendants as herein requested, it will continue to suffer irreparable harm including injury to its business relations, reputation and goodwill and a permanent loss of custom and trade.

DATED at Winnipeg, Province of Manitoba, Canada, this 30th day of March, 2012

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Court File No.
FEDERAL COURT

B E T W E E N:

THE WINNING COMBINATION INC.,

Plaintiff,

-and-

HER MAJESTY THE QUEEN IN RIGHT OF CANADA, ATTORNEY GENERAL OF CANADA, PAUL GUSTAFSON, ROBIN MARLES, PHILLIP WADDINGTON, MICHELLE BOUDREAU, SCOTT SAWLER,

Defendants,

STATEMENT OF CLAIM

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Solicitors for the plaintiff