Court File No. CV-09-390846 CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

MARA MICEVIC

Plaintiff

-and-

JOHNSON & JOHNSON, ORTHO-McNEIL-JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON INC., JANSSEN-ORTHO INC., COLBAR LIFESCIENCE LTD., and CANDERM PHARMA INC.

Defendants

Proceedings under the Class Proceedings Act, 1992

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 an Ontario lawyer acting for you must prepare a Statement of Defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the Plaintiff's lawyer or, where the Plaintiff does not have a lawyer, serve it on the Plaintiff, and file it, with proof of service, in this court office, **WITHIN TWENTY DAYS** after this Statement of Claim is served on you, if you are served in Ontario.

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

Instead of serving and filing a Statement of Defence, you may serve and file a Notice of Intent to Defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten (10) more days within which to serve and file your Statement of Defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date November 9, 2009 Issued by.....
Local Registrar S. Chandradat Registrar

Address of court office
10th Floor,
393 University Avenue
Toronto, Ontario

TO: JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933 USA

AND TO: ORTHO-McNEIL-JANSSEN PHARMACEUTICALS INC.
1125 Trenton Harbourton Rd.
Titusville, NJ 08560 USA

AND TO: JOHNSON & JOHNSON INC.
185 The West Mall
West Metro Corporate
Suite #860
Etobicoke, Ontario, Canada M9C 5L5

AND TO: JANSSEN-ORTHO INC.
19 Green Belt Drive
Don Mills, Ontario, Canada M3C 1L9

AND TO: COLBAR LIFESCIENCE LTD.
9 Hamenofim Street
Ackerstein Tower A,
Herzliya, 46733 Israel

AND TO: CANDERM PHARMA INC.
5353 Thimens Boulevard
Montreal, Quebec, Canada H4R 2H4

1. The plaintiff claims:

a. an order certifying the herein action as a class proceeding pursuant to the *Class Proceedings Act*, 1992;

b. an order appointing the plaintiff as Representative Plaintiff for the class in the herein pursuant the *Class Proceedings Act*, 1992;

c. damages in the sum of $10,000,000.00;

d. special damages on account of, inter alia, all, medical and other expenses for testing and treatment (including the subrogated claims of all Provincial and Territorial governmental providers of medical services) in such amount as is proven at trial;

e. in the alternative to the claim for damages, payment of the revenues realized by the defendants from their sale of Evolence;

f. aggravated damages in the amount of $2,500,000.00;

g. punitive damages in the amount of $2,500,000.00;

h. an interim interlocutory and permanent order, pursuant to s.101 of the Courts of Justice Act and Rule 40 of the Rules of Civil Procedure, compelling the defendants to fund a medical monitoring programme supervised by the Court for the review and monitoring of the health of the putative Class Members by medical and other experts and to make recommendations regarding the treatment of the said Class Members;

i. pre-judgment interest pursuant to section 130 or, in the alternative, section 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C-43;

j. post judgment interest pursuant to section 130 or, in the alternative, section 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C-43;

k. costs on a complete indemnity basis;

l. such further and other relief as this Honourable Court deems just.

THE PARTIES

2. The plaintiff resides in the City of Burlington, in the Province of Ontario.

3. The defendant Johnson & Johnson ("J&J") is a corporation incorporated pursuant to the laws of the State of New Jersey in the United States of America with its registered head office located in the City of New Brunswick in the State of New Jersey. J&J is a publicly traded company whose shares trade on the New York Stock Exchange.

4. The defendant Ortho-McNeil-Janssen Pharmaceuticals Inc. ("OMJ") is a corporation incorporated pursuant to the laws of the State of Pennsylvania in the United States of America with its registered head office located in the City of Titusville in the State of New Jersey. OMJ is a wholly-owned subsidiary of J&J. OMJ is, or at material times was, the owner, and a directing mind, of the defendant, ColBar LifeScience Ltd. At material times, the Ortho Dermatologics division of OMJ, formerly called the OrthoNeutrogena division of OMJ, markets the medical

device Evolence in the United States of America.

5. The defendant Johnson & Johnson Inc. ("J&J Canada") is a corporation incorporated pursuant to the laws of the Dominion of Canada with its registered head office located in the City of Montreal in the Province of Quebec, and with a principal place of business in Ontario in Etobicoke, now part of the City of Toronto. J&J Canada is a wholly-owned subsidiary of J&J.

6. The defendant Janssen-Ortho Inc. ("Janssen-Ortho Canada") is a corporation incorporated pursuant to the laws of the Province of Ontario, with its registered head office located in Don Mills, now part of the City of Toronto. Janssen-Ortho Canada is a wholly-owned subsidiary of J&J.

7. The defendant ColBar LifeScience Ltd. ("ColBar") is a corporation incorporated pursuant to the laws of Israel, with its head office located in the City of Herzliya, Israel. ColBar is a wholly-owned subsidiary of J&J, or alternatively, a wholly-owned subsidiary of OMJ, which is a wholly-owned subsidiary of J&J. ColBar is the registered owner of the trademark in Canada for "Evolence". At all material times, ColBar was a biomaterial product company, engaged in development, manufacture, and commercialization of products for the biosurgical market. Evolence is one of ColBar's products.

8. The defendant Canderm Pharma Inc. ("Canderm") is a corporation incorporated pursuant to the laws of the Dominion of Canada with its registered head office located in the City of Montreal in the Province of Quebec. Canderm was at material times a marketer and distributor of Evolence in Canada.

9. J&J develops, manufactures, markets and distributes pharmaceuticals and medical devices throughout the world.

10. The plaintiff pleads that, by virtue of the acts described herein, each of the defendant companies, as set out above, is vicariously liable for the act and omissions of the others for the following reasons:

(a) Each was the agent of the other;

(b) Each defendant's business was operated so that it was inextricably interwoven with the business of the other;

(c) Each defendant entered into a common advertising and business plan with the other to distribute and sell Evolence;

(d) Each defendant operated pursuant to a common business plan to distribute and sell Evolence;

(e) Each defendant intended that the businesses be run as one business organization; and

(f) All or some of the defendants are related, associated or affiliated.

OVERVIEW

11. At all material times, the defendants researched, developed, tested, manufactured, marketed, distributed, and sold a porcine based collagen dermal filler for the use by patients throughout the world, including Ontario and the rest of Canada.

12. At all material times, the defendants manufactured, marketed, distributed and sold the said collagen dermal filler product throughout Ontario and Canada under the brand names Evolence and Evolence Breeze. Evolence was licensed by Health Canada as a Class 4 Medical Device for sale and distribution in Canada on November 22, 2005. Evolence Breeze was licensed by Health Canada as a Class 4 Medical Device for sale and distribution in Canada on July 14, 2006. The said collagen dermal filler products are hereinafter collectively referred to as "EVOLENCE."

13. Pursuant to the instructions, guidance, procedures and protocols provided by the defendants and, in particular, Canderm, the plaintiff was injected with Evolence in and around her lips at the Oakville Laser Clinic on or about January 18, 2007.

14. The plaintiff was not aware of the risk of injury, infection, scarring and disfigurement associated with and caused by the injection of Evolence. Equally, putative class members were not aware of the risk of injury, infection, scarring and disfigurement caused by the injection of Evolence.

15. The healthcare providers of the plaintiff and of putative class members were not aware of the risk of injury, infection, scarring and disfigurement associated with and caused by the injection of Evolence by virtue of the actions and conduct of the defendants.

16. The plaintiff's health care providers and the healthcare providers of putative class members would not have prescribed and injected Evolence had they known that Evolence could cause injury, infection, scarring and disfigurement.

17. The plaintiff and putative class members would not have purchased Evolence had the defendants properly disclosed the risks of injury, infection, scarring and disfigurement caused by the collagen dermal filler.

18. At the time the plaintiff and putative class members were injected with Evolence none of the product label, the package insert, the package containing the product, advertisements, promotional brochures, instructional materials and protocols provided any, or at least adequate, warnings that using Evolence carried a risk of experiencing injury, infection, scarring and disfigurement including such injuries and repeated complications as experienced by the plaintiff and putative class members.

19. Even now, as set forth below, the information on the drug label provides inadequate information and fails to properly warn consumers and medical professionals of the risks associated with using the drug.

EVOLENCE

20. Evolence is a porcine based collagen dermal filler used in the treatment and correction of moderate-to-deep facial wrinkles and folds, including nasolabial folds that appear from the nose to the corners of the mouth (commonly referred to as "laugh lines').

21. Prior to approval in Canada in 2005/06 and in the United States in 2008, Evolence has been available for use as a collagen dermal filler in certain international markets since 2004.

22. Despite having knowledge of severe side effects and risks of injury, infection, scarring, and disfigurement associated with the use of Evolence based on experience with the product internationally, the defendants nevertheless marketed and promoted Evolence in Canada as follows:

a) Are you ready to look as young as you feel?

b) Evolence is a safe treatment;

c) Evolence is a natural treatment you can trust;

d) Evolence is based on collagen, which throughout two decades of use has maintained an excellent safety record as an injectable beauty treatment;

e) Evolence has undergone additional extensive safety testing;

f) Evolence is a natural product and is able to mimic the properties of the natural collagen found in skin;

g) Allergic reaction is extremely rare;

h) Evolence is a unique natural product in a class of its own, natural and long lasting;

i) Evolence restores your true beauty naturally;

j) Evolence is injected just below the skin surface where it replenishes lost collagen and adds support to the skin's own remaining collagen network;

k) Evolence restores shape and smoothes away wrinkles, lines and folds, quickly and effectively, giving the skin texture a soft even tone;

l) Evolence restores the skin's tone for a period of at least 12 months and the visible effect of the improved facial contour is maintained throughout the 12 month period;

m) Evolence provides immediate results and long-lasting effect;

n) Evolence is a truly novel dermal filler that can immediately improve and refresh the appearance of the skin by smoothing out and softening unwanted wrinkles and folds;

o) Evolence dermal filler can help to enhance and maintain the structure, volume, and naturally younger-looking appearance of the skin;

p) Evolence achieves immediate, natural-looking results, so that one can walk out of the aesthetic professional's office looking beautifully refreshed;

q) Evolence does not require a skin pre-test so that people can acquire results in just 1 visit;

r) Evolence has been used extensively in Europe and Isreal.

23. The sale of Evolence has generated millions of dollars of sales in Canada for the defendants.

24. On November 3, 2009 the defendants announced their intention to immediately discontinue the manufacture, marketing and sale of Evolence. The plaintiff pleads that the

substantial reason behind the defendants' decision to discontinue the manufacture, marketing and distribution of Evolence is their knowledge that Evolence is not a safe product and not fit for its intended purpose. Prior to the discontinuance of the manufacture, marketing and sale of Evolence, the defendants attempted to sell the Evolence product line to others. The defendants' efforts in this regard failed.

25. Well before the discontinuance of Evolence concern was being expressed about nodule formation following lip augmentation using Evolence. A scholarly article published in the June 2008 edition of the Journal of Drugs in Dermatology, noted that, over one year post-injection, six patients still had nodules in their lips. Reference was made to one patient who had obvious nodules of the lips 15 months post-Evolence injections. The authors pointed out that the words "nodule" or "small, round bumps under the skin" do not appear in the Evolence website or in the product monograph for consumers or physicians. Further, there was no mention of any potential problems by using Evolence in the body of the lip.

26. In a further study reported in the September 2009 edition of the Journal of Drugs in Dermatology, Jean and Alastair Carruthers noted that Evolence should not be injected in the lips or infraorbital region due to the high incidence of nodule formation.

CAUSES OF ACTION

Negligence

27. The defendants owed the plaintiff and putative class members a duty of care as follows:

a. to ensure that Evolence was thoroughly and appropriately tested so as to determine if there were any potentially adverse side affects associated with the dermal filler;

b. to ensure that Evolence was fit for its intended or reasonably foreseeable use;

c. to warn the plaintiff and the putative class members that injection of Evolence carried significant specifically enumerated risks of injury, infection, scarring and disfigurement;

d. to conduct adequate tests and clinical trials to determine the degree of risk associated with injection of Evolence;

e. to ensure that prescribing physicians and aesthetics professionals were apprised and fully and regularly informed of all of the health risks associated with the injection of Evolence;

f. to conduct ongoing tests and clinical trials with long term follow-up to determine the long-term effects and risks associated with the injection of Evolence;

g. to inform Health Canada and other regulatory agencies fully, properly, and in a timely manner of the health risks, complaints and adverse events associated with the injection of Evolence;

h. to ensure that prescribing physicians and aesthetics professionals were apprised and fully and regularly informed and trained as to specifically where Evolence should and should not be injected;

i. to monitor the post-market effects of Evolence.

28. The defendants breached their duty of care owed to the plaintiff and putative class members. The particulars of the defendants' negligence are as follows:

(a) They failed to ensure that Evolence was not dangerous to consumers and that the product was fit for its intended purpose and of merchantable quality;

(b) They failed to conduct appropriate testing to determine whether and to what extent the injection of Evolence poses health and aesthetic risks;

(c) They failed to adequately test Evolence in a manner that would fully disclose the side effects and the magnitude of the risks associated with its injection;

(d) They failed to conduct any or adequate follow-up studies on the efficacy and safety of Evolence;

(e) They failed to provide the plaintiff and putative class members and their physicians and aesthetic professionals with any or adequate warnings of the inherent risks associated with Evolence;

(f) They failed to provide any or adequate updated and current information to the plaintiff and putative class members and their physicians and aesthetic professionals respecting the risks and effects of Evolence as such information became available;

(g) They failed to provide prompt warning of potential risks and adverse side effects associated with Evolence on the product monograph, in the product labelling, and instruction manuals and protocols;

(h) They failed to warn the plaintiff and putative class members and their physicians and aesthetic professionals about the need for comprehensive regular medical monitoring to ensure early discovery of potentially adverse events;

(i) After receiving actual or constructive notice of problems associated with Evolence, they failed to issue adequate warning, withdraw or recall the product, publicize the problems and otherwise act properly and in a timely manner to alert the public, the plaintiff and putative class members and their physicians and aesthetic professionals of the product's inherent dangers;

(j) They failed to establish any adequate procedures to educate their sales representatives, marketers and distributors as well as prescribing physicians

and aesthetic professionals respecting the usage of Evolence and the risks associated with the product;

(k) They falsely stated and or implied that Evolence was safe and fit for its intended purpose when they knew or ought to have known that these statements were false;

(l) They misstated the state of research, opinion and medical and other literature pertaining to the purported benefits of Evolence and its associated risks;

(m) They failed to cease the manufacture and or distribution of Evolence earlier than they did when they knew or ought to have known that this product caused or could cause significant injury, infection, scarring and disfigurement;

(n) They disregarded reports of symptoms of adverse events among patients who participated in clinical trials of Evolence;

(o) They failed to instruct employees to properly monitor and record complaints of adverse effects of Evolence;

(p) They failed to accurately and promptly disclose to Health Canada information relating to the risks associated with Evolence and to modify the product monograph and product labelling accordingly in a timely manner or at all;

(q) They failed to monitor and to initiate a timely review, evaluation, and investigation of reports of adverse events associated with Evolence in Canada and around the world;

(r) They marketed and sold Evolence when they know or ought to have known of the adverse events associated with its use;

(s) They failed to provide any or adequate warning to the health profession, aesthetic professionals and to the plaintiff and putative class members;

(t) They failed to properly investigate cases of adverse events and reactions caused by Evolence;

(u) They failed to conform with applicable disclosure and reporting regulations;

(v) They hired incompetent personnel and appointed incompetent officers;

(w) They failed to instruct their servants, agents, officers, and directors to act ethically and responsibly;

(x) They failed to properly supervise their employees, their subsidiaries, and their related, associated and affiliated corporations;

(y) They encouraged their employees to increase sales volumes while neglecting to inform consumers (including the plaintiff and putative class members), retailers, physicians, clinics and aesthetic professionals of the risks of adverse events associated with Evolence;

(z) They failed to withdraw or recall Evolence in a timely manner because of the cost, loss of profit, and the negative publicity to them. For the same reasons,

they failed to market and sell Evolence with adequate and appropriate monograph warnings;

(aa) They falsely understated the risks of Evolence, while at the same time falsely overstating the safety and efficacy of the product; and

(bb) The plaintiff's and putative class members' healthcare providers and aesthetic professionals were not made aware of the risk of injury, infection, scarring and disfigurement associated with and caused by Evolence.

Conspiracy

29. At all material times, the defendant companies, by their directors, officers, servants and agents, wrongfully, unlawfully, and maliciously conspired and agreed together and with persons unknown as set out below.

30. The plaintiff pleads that the defendants' conspiracy involved both lawful and unlawful means with the predominant purpose of causing the plaintiff and putative class members to use Evolence in circumstances where they knew or ought reasonably to have known that such use would cause harm to the plaintiff and putative class members.

31. The defendants conspired to unlawfully market, distribute, advertise and sell Evolence and thereby derived substantial revenues from the conspiracy.

32. As a result of the said conspiracy, the plaintiff and putative class members were injected with Evolence and thereby have suffered damage and loss.

33. The defendants engaged in the said conspiracy for the purpose, inter alia, of:

(a) maximizing profit from the sale of Evolence;

(b) increasing or maintaining their market share;

(c) avoiding adverse publicity;

(d) placing their economic interests above the safety of the plaintiff and putative class members;

(e) maintaining their brand and corporate image;

(f) keeping the plaintiff and putative members, their physicians, their aesthetic professionals and Health Canada in the dark regarding the dangerous properties and effects of Evolence; and

(g) causing the plaintiff and putative class members to be injected with Evolence.

34. In furtherance of the conspiracy, the following, inter alia, are some of the acts carried out by the defendants:

(a) they submitted false, inaccurate and misleading information to Health Canada for the purpose of obtaining approval to market and sell Evolence in Canada;

(b) they concealed and disguised information about the dangerous properties and effect of Evolence from Health Canada, from health practitioners, from aesthetic professionals and from the plaintiff and putative class members;

(c) they misled the plaintiff and putative class members, health practitioners, aesthetic profesionals and others about the efficacy, safety and effect of Evolence;

(d) they refused to issue warnings and to make monograph changes regarding the use of Evolence or to stop selling the product even after its harmful effects and properties became manifest;

(e) they developed and used marketing and promotional strategies that covered up the truth about the dangerous properties and side effects of Evolence.

Sale of Goods Act

35. The defendants are strictly liable for some or all of the damages suffered by the plaintiff and putative class members by virtue of breaches of the Ontario Sale of Goods Act and similar provincial and territorial legislation in Canada. Specifically, it is alleged that:

(a) they manufactured, marketed and sold Evolence;

(b) Evolence is a Type 4 medical device that is inherently dangerous;

(c) the plaintiff and the putative class members had no opportunity to inspect or test Evolence to ensure its safety;

(d) the plaintiff and putative class members were injected with Evolence,

(e) Evolence failed to satisfy certain reasonable expectations of the plaintiff and putative class members;

(f) Evolence was not reasonably fit for its intended purpose;

(g) The plaintiff and putative class members relied on the defendants' skill and judgment when purchasing Evolence;

(h) Evolence was a product which clearly was in the course of the defendants' business to supply; and

(i) Evolence was not of merchantable quality certainly when compared to comparable products available in the market.

Consumer Protection Act

36. The defendants engaged in unfair practices in the development, distribution, marketing, and sale of Evolence. They made, or had others make, false, misleading, or deceptive

representations regarding the characteristics, qualities, benefits, and risks associated with Evolence. The defendants exaggerated the benefits to be derived from Evolence.

37. The defendants arranged for and paid scholars and researchers to "author" scholarly articles misrepresenting the benefits of Evolence. In some or all of these cases, the said articles were actually "ghost written" by agencies or individuals employed, contracted by, or otherwise engaged by the defendants. The said articles consisted of unconscionable representations to the extent that the opinions expressed therein regarding Evolence were misleading in such a way as to cause consumers of Evolence to rely on such representations to their detriment.

Breach of Warranty

38. The defendants expressly or impliedly warranted to the plaintiff and the putative class members that Evolence was of merchantable quality and fit for use and safe for human use. The defendants breached the said warranty by designing, testing, researching, formulating, developing, manufacturing, producing, labelling, advertising, promoting, distributing and selling Evolence which was inherently dangerous to users and which the defendants knew or ought to have known would lead to injury, infection, scarring and disfigurement.

Waiver of Tort

39. The plaintiff and the putative class members are entitled to waive the tort and require the defendants to account for all the revenue they received from the sale of Evolence in Canada.

40. The plaintiff pleads that waiver of tort may be appropriate for the following reasons, among others:

(a) Such revenue was acquired in such circumstances that the defendants cannot in good conscience retain it:

(b) The integrity of Health Canada's regulations and the marketplace would be undermined if the court did not require an accounting:

(c) Evolence could not have been marketed, and the defendants would not have received any revenue from its sale in Canada, absent their egregious conduct;

(d) The defendants engaged in wrongful conduct by putting into the marketplace a product which causes or has the potential to cause injury; and

(e) The defendants would be unjustly enriched if they were permitted to retain revenues realized from the sale of Evolence.

Breach of Section 52 of the *Competition Act*, R.S. 1985, c. C-34

41. The defendants knowingly or recklessly made material false representations to the plaintiff and putative class members for the purposes of promoting the supply and use of Evolence.

Breach of the *Food and Drugs Act*, R.S. 1985, c. F-27

42. The defendants engaged in unfair trade practices. Such practices included making false or misleading representations or advertisements, knowingly or with reason to know, as to the characteristics, efficacy, and risks associated with Evolence

Unjust enrichment

43. The defendants voluntarily accepted and retained profits and benefits, derived from the plaintiff and putative class members, with full knowledge and awareness that, as a result of its conscious and intentional wrongdoings, the plaintiff and putative class members did not receive a product of the quality, nature or fitness that had been represented by the defendants or reasonably expected by the plaintiff and putative class members.

44. By virtue of the conscious wrongdoings alleged, the defendants have been unjustly enriched at the expense of harm to plaintiff and putative class members.

DAMAGES

45. The Ontario Ministry of Health and Long-Term Care provided coverage for healthcare services to the plaintiff and putative class members residing in Ontario through OHIP. Similar government programs provided coverage for healthcare services to putative class members residing elsewhere in other provinces and territories in Canada.

46. The plaintiff and putative class members required hospitalization and other medical services as a result of the conduct of the defendants as aforesaid. These medical services were paid for by OHIP and other provincial and territorial health insurers.

47. OHIP and other provincial and territorial health insurers will continue to provide treatment in the future to the plaintiff and putative class members.

48. The subrogated interest of OHIP and all other provincial and territorial health insurers includes the cost of all past and future insured services for the benefit of the plaintiff and putative class members on account of being injected with Evolence.

49. Putative class members who paid for their own Evolence seek a full refund of the purchase price as well as the full cost of having same injected and all follow-up treatments, examinations, and clinic visits. The plaintiff and putative class members are entitled to recover from the defendants as special damages the cost of purchasing Evolence and all services related thereto. But for the defendants' wrongdoing, as particularized above, the plaintiff and putative class members would not have incurred the expense(s) of being injected with Evolence.

50. As a result of the defendants' negligence and other actionable conduct as set out above, the plaintiff and putative class members have suffered and will continue to suffer damages and loss including:

(a) personal injury;

(b) out of pocket expenses including, but not limited to, those connected with medical care and treatment, medications, and the cost of Evolence paid for directly by the plaintiff and putative class members;

(c) cost of past medical and other care and services;

(d) cost of future medical and other care and services; and

(e) past loss of income and future loss of income.

51. The plaintiff pleads that the defendants' conduct, as particularized above, in the research design, development, testing, manufacturing, licensing, distribution, marketing, production, and sale of Evolence and the failure to warn the public at large about the risks associated with the use of Evolence was high-handed, outrageous, reckless, egregious, deliberate, disgraceful, wilful, callous, and in wanton disregard of the rights and safety of the plaintiff and of putative members of the class. The defendants took active steps to suppress the public voicing of safety concerns surrounding Evolence. The defendants' conduct was indifferent to the consequences and motivated by economic considerations such as the maintaining of profits and market share. Such conduct constitutes separate actionable wrongs and renders the defendants liable to pay punitive damages to the plaintiff and putative members of the class.

52. The defendants' conduct, as aforesaid, was injurious to the feelings of pride, dignity and self-respect of the plaintiff and putative class members and, therefore, the defendants are liable to the plaintiff and putative class members for aggravated damages.

THE PROPOSED REPRESENTATIVE PLAINTIFFS

53. The plaintiff is a 53 year old woman who was injected with Evolence in her lips and the borders of her lips in or about January 2007.

54. Since being injected with Evolence, the plaintiff has and continues to have visible nodules in her lips; as a consequence of which her lips have been disfigured. She has and continues to suffer numerous infections in her lips. She has and continues to suffer abscesses in her lips during which a yellowish substance has leaked out. The plaintiff suffered these symptoms as a consequence of being injected with Evolence.

55. The plaintiff did not discover that the aforesaid symptoms were caused by Evolence until

March 2008.

56. The plaintiff will fully and adequately represent and protect the interests of the proposed class. Neither the plaintiff nor her solicitors have interests which are contrary to or conflicting with the interests of the proposed class.

DEFINITION OF THE CLASS

57. The plaintiffs seek certification of the following class:

(a) All persons throughout Canada who were injected with Evolence and who claim damages as a result; and

(b) Such sub-classes as may be defined on the motion for certification herein.

COMMON ISSUES

58. The plaintiff and putative class members have issues in common in that each suffered injury and loss as a consequence of, directly or indirectly, being injected with Evolence.

59. The plaintiff and putative class members have issues in common in that each suffered damages, directly or indirectly, as a consequence of being injected with Evolence.

60. Individual putative class members do not have a significant need to individually control the prosecution of their claims. Individual actions would present the potential for varying, inconsistent and contrary judgments and would magnify the delay and expense to all parties. The inherent cost of pursuing individual actions concerning the herein claim would effectively deny individual claimants' access to justice.

61. Hundreds, if not thousands, of putative class members were injected with Evolence in circumstances similar to the plaintiff; namely, without being informed or sufficiently informed that the injection of Evolence is harmful and unsafe.

62. There are common legal and factual issues which may be determined without reference to the individual circumstances of the putative class members. These include, inter alia:

a. whether the defendants properly and adequately researched, manufactured, marketed, sought government approval for, labelled, and sold Evolence;

b. whether the defendants fully and properly disclosed the results of all testing and other information in their possession regarding the side effects associated with the injection of Evolence, both to Health Canada and the public;

c. whether the defendants misrepresented the safety and efficacy of Evolence;

d. whether the defendants were negligent in failing to act as a reasonable and prudent manufacturer of collagen based dermal filler;

e. whether the defendants intentionally or negligently exaggerated the efficacy of Evolence, on the one hand, and downplayed or minimized the risks of side effects, on the other;

f. whether the defendants properly and adequately warned Health Canada, the medical and aesthetics community, and the general public, including the putative class members, of the full array of risks associated with Evolence;

g. whether the defendants conspired to do any or all of the foregoing;

h. whether this is an appropriate case for the award of punitive damages;

i. whether this is an appropriate case for the award of aggravated damages;

j. whether Evolence was reasonably fit for its intended purpose;

k. whether the defendants properly and adequately tested Evolence;

l. whether the defendants conducted follow-up studies on the efficacy of and risks associated with Evolence; and

m. whether the defendants reported the results of the studies referred to in (k) to the healthcare and aesthetics community, Health Canada, and the public at large.

63. The claim of the plaintiff is typical of that of the putative class members.

64. At all material times, the plaintiff and putative class members were uninformed as to the hazards and risks associated with using Evolence.

65. The only notable difference among putative class members involves the extent of damages suffered. The question of damages can readily be determined through individual assessment and ought not to be a bar to certification of this action as a class proceeding.

STATUTES

66. The plaintiff pleads and relies upon s.101 of the Courts of Justice Act, R.S.O. 1990, c.43, Rule 40 of the Ontario Rules of Civil Procedure and, *inter alia,* upon the following legislation:

Ontario

- *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;
- *Consumer Protection Act,* 2002 S.O. 2002, c.30, Sched. A;
- *Courts of Justice Act,* R.S.O. 1990, c.43;
- *Family Law Act*, R.S.O. 1990, c. F.3;
- *Health Insurance Act,* R.S.O. 1990, c. 11.6;
- *Sale of Goods Act,* R.S.O. 1990, c. S.1;
- *Trustee Act*, R.S.O. 1990, c. T.23

Alberta

- *Domestic Relations Act*, R.S.A. 2000, c. D10.5, was repealed by R.S.A. 2003, c. F-4.5 [*Family Law Act*]
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8
- *Hospital's Act*, R.S.A. 2000, c. H-12
- *Sale of Goods Act*, S-2 R.S.A 2000
- *Tort Feasors Act,* R.S.A. 2000, c. T-5

British Columbia

- *Business Practices and Consumer Protection Act,* S.B.C. 2004, c.2
- *Hospital's Insurance Act*, R.S.B.C. 1996, c. 204 [en. 1994, c. 37, s. 4; am. 1996, c. 24, s. 1(3)]

- *Sale of Goods Act*, R.S.B.C. 1996, c.410
- Current to Gazette Vol. 49:19 (October 20, 2006)

Manitoba

- *Fatal Accidents Act*, C.C.S.M. c. F50, as amended
- *Manitoba Public Insurance Corporation Act*, C.C.S.M. c. P215
- *Sale of Goods Act,* C.C.S.M. c. S10
- *The Consumer Protection Act*, C.C.S.M. c. C200
- *The Health Services Insurance Act*, R.S.M. 1987, c. H35
- *Trustee Act*, C.C.S.M. c.T160
- Current to Gazette Vol. 135:44 (November 4, 2006)

New Brunswick

- *Consumer Product Warranty and Liability Act*, Chap. C-18.1
- *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9
- *Sale of Goods Act*, RS.N.B. 1973, c.S-1
- Current to Gazette Vol. 164:1901 (November 29, 2009)

Newfoundland

- *Consumer Protection Act,* R.S.N.L. 1990 c. C-31
- *Fatal Accidents Act,* R.S.N.L. 1990, c. F-6
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990, c. H-7
- *Medical Care Insurance Act*, 1999 S.N. 1999, c. 5.1
- *Sale of Goods Act*, R.S.N.L. 1990, c.S-6

- Current to Gazette Vol. 81:46 (November 17, 2006)

Northwest Territories

- *Consumer Protection Act*, R.S.N.W.T. 1988, c. C-17
- *Fatal Accidents Act,* R.S.N.W.T. 1988, c. F-3
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- *Sale of Goods Act*, R.S.N.W.T. 1988, c. S-2
- Current to Gazette Vol. XXVII:10 (October 31, 2006)

Nova Scotia

- *Consumer Protection Act*, R.S., c.92
- *Fatal Injuries Act,* R.S.N.S. 1989, c. 163, amended 2000, c. 29, ss 9-12
- *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197
- *Sale of Goods Act*, R.S., c.408
- Current to Gazette Vol. 30:21 (November 10, 2006)

Nunavut

- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- Current to Gazette Vol. 8:10 (October 31, 2006)

Prince Edward Island

- *Consumer Protection Act*, R.S.P.E.I. 1988, c. C-19
- *Fatal Accidents Act,* R.S.P.E.I. 1988, c. F-5, as amended
- *Hospital and Diagnostic Services Insurance Act,* R.S.P.E.I. 1988, c H-8

- *Sale of Goods Act*, R.S.P.E.I. 1988, c. S-1
- Current to Gazette Vol. 132:47 (November 25, 2006)

Quebec

- *Civil Code of Quebec* Book 5
- *Consumer Protection Act*, R.S.Q. chapter P-40.1

Saskatchewan

- *Department of Health Act,* R.S.S. 1978, c. D-17
- *Fatal Accidents Act,* R.S.S. 1978, c. F-11 as amended
- *The Consumer Protection Act*, 1996, c. C-30.1
- *The Sale of Goods Act*, R.S.S. 1978, c. S-1
- Current to Gazette Vol. 102:44 (November 3, 2006)

Yukon

- *Consumers Protection Act*, R.S.Y. 2002, c. 40
- *Hospital Insurance Services Act,* R.S.Y. 2002, c. 112
- *Sale of Goods Act*, R.S.Y. 2002, c. 198
- Current to Gazette Vol. 25:10 (October 15, 2006)

and all relevant amendments thereto.

67. The plaintiff pleads and relies on the legal doctrine known as *res ipsa locquitur*.

THE REAL AND SUBSTANTIAL CONNECTION

68. There is a real and substantial connection between the subject matter herein and the Province of Ontario among others for the following reasons:

(a) J & J Canada and Janssen-Ortho carry on business in Ontario;

(b) The plaintiff and numerous putative class member reside in Ontario;

(c) The plaintiff and numerous putative class members used Evolence in Ontario and suffered damages in Ontario; and

(d) The regulatory approval in Canada for Evolence was granted in Ottawa, Ontario.

SERVICE OUTSIDE ONTARIO

69. This originating process may be served without court order outside Ontario in that the claim is:

(a) In respect of a tort committed in Ontario (Rule 17.02(g));

(b) In respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (Rule 17.02(h));

(c) In respect of property in Ontario (Rule 17.02 (a));

(d) Against a person outside Ontario who is a necessary or proper party to a proceeding

properly brought against another person served in Ontario (Rule 17.02 (o)); and

(e) Against a person carrying on business in Ontario (Rule 17.02 (p)).

70. The plaintiffs proposes that this action be tried at the City of Toronto.

– 9 NOV

Date: November 6, 2009

McPHADDEN, SAMAC, TUOVI
Barristers and Solicitors
Suite 300 – 8 King Street East
Toronto, Ontario M5C 1B5

Zoran Samac (LSUC #28637T)
Bryan C. McPhadden (LSUC #28160K)
Peter E. Tuovi

Tel: (416) 363-5195
Fax: (416) 262-7485

Solicitors for the Plaintiff

MICEVIC

PLAINTIFFS

- and -

JOHNSON & JOHNSON, ET AL.

DEFENDANTS

CV-09-390846 00CP

(Short title of proceeding)

Court File No.

ONTARIO

SUPERIOR COURT OF JUSTICE

(Proceeding Commenced at Toronto)

STATEMENT OF CLAIM

McPhadden, Samac, Tuovi
Suite 300, 8 King Street East
Toronto, Ontario M5C 1B5

Zoran Samac LSUC#: 28637T
Bryan McPhadden LSUC#: 28160K
Peter Tuovi LSUC#: 31328E
Tel: (416) 363-5195
Fax: (416) 363-7485

Solicitors for the Plaintiff.