Court File No.:

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN

TAKWIHIN KIBALIAN and YEGHIA KIBALIAN

Plaintiffs

and

ALLERGAN PLC, ALLERGAN LIMITED, ALLERGAN, INC., ALLERGAN USA, INC. and ALLERGAN INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*, S.O. 1992, C.6

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the statement of claim served with this notice of action.

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 plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this notice of action 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 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 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,

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LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date MAY 23 2019 Issued by .....
Local registrar

Address of Court office: 393 University Avenue, 10th Floor, Toronto, Ontario, M5G 1E6

TO: ALLERGAN PLC
Clonshaugh Business and Technology Park
Coolock, Dublin, D17 E400,
Ireland

AND TO: ALLERGAN LIMITED
Marlow International
The Parkway
Marlow, Buckinghamshire,
SL7 1YI, UK

AND TO: ALLERGAN, INC.
2525 Dupont Drive
Irvine, CA, US, 92612

AND TO: ALLERGAN USA, INC.
5 Giralda Farms
Madison, NJ, US, 07940

AND TO: ALLERGAN INC.
85 Enterprise Blvd., Suite 500
Markham, ON, L6G 0B5

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CLAIM

1. The plaintiffs, on their own behalf and on behalf of the members of the Class and the Family Class claim:

(a) an order pursuant to the *Class Proceedings Act, 1992,* S.O. 1992, c.6 ("*CPA*") certifying this action as a class proceeding and appointing the plaintiffs as representative plaintiffs of the Class and the Family Class (as defined below);

(b) general, special and punitive damages in amounts to be determined at trial;

(c) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the defendants from the sales of their Allergan Implants (as defined below) in Canada;

(d) a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

(e) prejudgment and post judgment interest on the damages in accordance with the provisions of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

(f) the costs of this action on a full indemnity basis, or in an amount that provides substantial indemnity, plus, pursuant to s.26(9) of the *CPA* the costs of notices and of administering the plan of distribution of the recovery in this action; and

(g) such further and other relief as this Honourable Court deems just.

NATURE OF THE ACTION

2. This action relates to the pain and suffering and resulting pecuniary and non-pecuniary damages suffered by the plaintiffs herein and other members of the Classes as a result of the defendants' negligent research and development, design, testing, manufacturing, licensing,

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marketing, distribution, sale and post-market monitoring of breast implants in Canada (the "Allergan Implants").

3. The plaintiffs allege that the Allergan Implants are defective and inherently dangerous, that they have an unacceptably high failure rate and that they cause an unacceptably high rate of adverse health effects in patients who are implanted with them, including, but not limited to, the development of various autoimmune, neurological and musculoskeletal diseases, as well as chronic fatigue, cognitive impairments, chronic muscle weakness and pain and breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL").

4. In spite of knowing about these risks of serious harm associated with their Allergan Implants, the defendants failed to disclose the known risks of illness and/or injury to Class Members, their treating physicians and regulatory authorities in Canada in a timely way or at all. Further, the defendants knowingly misrepresented and/or concealed information related to the high failure rate of the Allergan Implants and the unacceptably high rate of illness and injury associated with their use.

THE PARTIES

a) The Plaintiffs

5. The plaintiff, Takwihin Kibalian ("Taky"), is an individual who resides in the City of Toronto, in the Province of Ontario. Taky had Allergan Implants surgically placed in her body on or about January 6, 2014.

6. The plaintiff, Yeghia Kibalian ("Yeghia"), is an individual who resides in the City of Toronto, in the Province of Ontario and is Taky's brother.

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b) The Defendants

7. The defendant, Allergan plc, is an Irish company which is listed on the New York Stock Exchange, with its head office located in Coolock, Dublin, and at all times material to this action, wholly owned and controlled the defendants Allergan Limited, Allergan, Inc., Allergan USA, Inc., and Allergan Inc. Allergan plc and/or its predecessor in interest made all world-wide decisions relating to the Allergan Implants and at all material times was involved in, and/or was responsible for, the research and development which led to the design, manufacturing, licensing, marketing and distribution of the Allergan Implants in Canada, whether directly or indirectly, through an agent, affiliate or subsidiary.

8. The defendant, Allergan Limited, is a United Kingdom company with its head office and manufacturing facilities located in the town of Marlow, in South Buckinghamshire, England. Allergan Limited is a wholly owned subsidiary of Allergan plc and at all times material to this action, held medical device licenses issued by Health Canada for several of the Allergan Implants.

9. The defendant, Allergan, Inc., is an American company with its head office located in Irvine, California. Allergan, Inc. is a wholly owned subsidiary of Allergan plc and at all times material to this action held medical device licenses issued by Health Canada for several of the Allergan Implants.

10. The defendant, Allergan USA, Inc., is an American company registered in Delaware with its principal business address in Madison, New Jersey. Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc.

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11. The defendant, Allergan Inc., is a Canadian company, incorporated pursuant to the *Canada Business Corporations Act,* R.S.C., 1985, c. C-44, with its corporate offices located in Markham, Ontario and is a wholly owned subsidiary of Allergan plc. Allergan Inc.'s website includes the Allergan Implants in its products listing.

12. At all material times, the defendants each participated in and/or shared the common purpose of one or more of the following: designing, developing, manufacturing, testing, inspecting, licensing, marketing, labelling, supplying, exporting, importing and selling Allergan Implants in Canada for profit either directly or indirectly through an agent, affiliate or subsidiary.

13. The development of Allergan Implants for sale in Canada, the conduct of clinical studies, if any, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding the Allergan Implants and other actions central to the allegations in this lawsuit were undertaken by the defendants in Ontario and elsewhere.

14. At all material times, each defendant was the agent of the other and, as such, each defendant is individually, as well as jointly and severally, liable to the plaintiffs and other members of the Classes for their injuries, losses and damages because:

a) each company's business was operated so that it was inextricably interwoven with the business of the other;

b) each company entered into a common business plan and shared the common purpose of developing and manufacturing Allergan Implants for profit;

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c) each company owed a duty to the other and to each Class Member and Family Class Member by virtue of the common business plan to manufacture and sell Allergan Implants; and

d) each company intended that its business be run as one global business organization.

THE CLASSES

15. The plaintiffs bring this proposed class proceeding pursuant to the *CPA* against the defendants on behalf of the following two proposed Classes:

(a) All persons who were implanted in Canada with one or more breast implants which were variously designed, developed, tested, manufactured, licensed, assembled, labelled, marketed, instructed for use, distributed and/or sold by one or more of the defendants (collectively "the Allergan Implants"), and their estates, administrators or other legal representatives, heirs or beneficiaries (the "Class" or "Class Members");

and

(b) All persons who, by virtue of a personal relationship with one or more Class Member, have standing in this action pursuant to section 61(1) of the *Family Law Act,* R.S.O. 1990, c. f.3, as amended, or analogous provincial legislation or at common law (the "Family Class" or "Family Class Members").

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THE FACTS

Background - Breast Implants

16. Breast implants are medical devices that are used either to augment breast size, principally for cosmetic purposes, or in order to replace breast tissue that has been removed due to trauma or cancer or to correct the consequences of an underlying medical condition that may have caused the breast to not grow or to grow unevenly or abnormally.

17. Various methods for breast augmentation and reconstruction have been attempted dating back to the mid-1800s, with the precursor to today's breast implants being introduced in the early 1960s. There have been several iterations of the original breast prosthesis, with the two most common designs involving a silicone outer shell filled with either silicone gel or saline.

18. Currently, saline implants have three types of design, including one with a fixed volume of saline, one with an adjustable volume and one that is somewhat of a hybrid of the two. Silicone implants have a single design, namely fixed volume. The viscosity of the silicone used in a given implant varies by manufacturer and among a given manufacturer's product lines. Implants come in a variety of shapes and sizes and the silicone shells may have a smooth or a textured surface.

Rising Safety Concerns and the 14-Year Moratorium

19. In the late-1980s concerns began emerging about an increasing incidence of adverse health effects in common among patients with silicone breast implants, including autoimmune, neurological and connective-tissue diseases, along with reports of a constellation of debilitating physical and cognitive impairments and injuries.

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20. Ultimately, in or about April of 1992, the health regulators in North America ordered that these products be removed from the market however, both the Food and Drug Administration ("FDA") in the U.S. and Health Canada allowed their continued use in limited circumstances.

21. In the years following the 1992 market withdrawal, silicone implants continued to be available in Canada through Health Canada's special access program and as of October, 2006, there was an average of 8,000 cases approved every year.

2006 Market Return

22. In or about October of 2006, following extensive lobbying by breast implant manufacturers, and on condition that extensive long-term post-market studies be undertaken, Health Canada (and in November, 2006, the FDA) removed the limited restrictions on the use of silicone breast implants and allowed for broad marketing of these products.

23. The conditions imposed by Health Canada and the FDA on the manufacturers of silicone breast implants included, *inter alia,* conducting large long-term post-market case control health safety studies intended to follow 40,000 patients, along with device failure analyses. However, it is now known that less than five years after these studies were ordered, they had failed; the defendants' long-term case control study had lost almost 40% of the breast augmentation study subjects to follow-up by just the two year mark.

Breast Implants Continue to Cause Complications

24. Complaints similar to those that were the precursors to the 1992 market withdrawal have continued to increase in number in both anecdotal and scientific reporting since the 2006 market reintroduction of silicone breast implants. In spite of this continued reporting, the defendants

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have consistently denied the association between these adverse health effects and the Allergan Implants.

25. In particular, symptoms of Breast Implant Illness ("BII") have long been reported to the FDA's Medical Device Reporting ("MDR") system. The MDR system is considered to be a "passive" or spontaneous reporting system because it relies upon the consumer (or their physician) to independently submit a report and the FDA has no ability to actively solicit or otherwise proactively obtain or fully analyze such reports. Many countries, including Canada, have similar passive reporting systems for adverse reactions to drugs and medical devices and such systems have been demonstrated to reflect reporting rates as low as 5%.

26. Recently, the FDA indicated that between 2008-2018, there had been over 1,300 such reports made in association with breast implants and that the top five symptoms and medical conditions reported were fatigue, brain fog, rash, joint pain and memory loss.

27. In addition to the above, many patients with breast implants report a broad array of symptoms and conditions, many of which, while not permitting the diagnosis of a defined or currently known disease, reflect systemic inflammatory and/or autoimmune responses.

28. In this regard, a clinical entity associated with various medical implants called "Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA)" has been studied extensively since the term was introduced in 2011.

29. The proposed diagnostic criteria for ASIA include the presence of at least two major criteria while the presence of one major criterion and two minor criteria would also tend to suggest the condition.

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30. Major criteria for ASIA include:

a) exposure to external stimulus prior to clinical manifestations;

b) the appearance of "typical" clinical symptoms:

- myalgia, myositis or muscle weakness;
- arthralgia and/or arthritis;
- chronic fatigue, un-refreshing sleep or sleep disturbances;
- neurological manifestations (especially associated with demyelination);
- cognitive impairment, memory loss;
- pyrexia, dry mouth;

c) removal of inciting agent induces improvement; and

d) typical biopsy of involved organs.

31. Minor criteria for ASIA include:

a) the appearance of autoantibodies or antibodies directed at the suspected adjuvant;

b) other clinical manifestations (i.e. irritable bowel syndrome);

c) specific human lymphocytic antigens (HLA) (i.e. HLA DRBI, HLA DQBI); and

d) evolvement of an autoimmune disease (i.e. multiple sclerosis, scleroderma and systemic sclerosis (SSC)).

32. In terms of the relationship between ASIA and breast implants specifically, studies have reflected a strong correlation, with one review of 622 women reporting that 75.4% experienced improvement in their symptoms after removal of the breast implants. However, of those who had developed a specific autoimmune disease diagnosis, only 56% experienced improvement after explant, with many requiring immunosuppressive therapy to achieve improvement.

33. Among the most recent studies on the association between breast implants and the most clinically relevant autoimmune/rheumatological diseases was a cross-sectional study that used a

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large, population-based database which included up to twenty (20) years of data on 2 million members.

34. The findings included an adjusted odds ratio of 1.22 between having a silicone breast implant and developing any autoimmune/rheumatic disorder, and adjusted odds ratios of 1.58, 1.63 and 1.98, respectively for Sjögern's syndrome, systemic sclerosis and sarcoidosis. A multivariate Cox regression model yielded a hazard ratio of 1.45 for being diagnosed with at least one autoimmune/rheumatic disorder in women with silicone breast implants compared with those without such implants. These striking findings are in addition to several smaller studies conducted in the Netherlands and the U.S. which reached similar conclusions.

35. In addition to the prior and on-going complaints of connective-tissue, neurological, chronic musculoskeletal, cognitive and autoimmune diseases and disorders, as well as chronic pain and fatigue, since 1997, case reports have continued to accumulate in the scientific literature of what has become known as breast implant-associated anaplastic large cell lymphoma, or BIA-ALCL.

36. ALCL is a rare type of non-Hodgkin lymphoma, namely a T-cell lymphoma. ALCL generally is more common among children and young adults and affects more men than women. The incidence of ALCL in the background population at all sites in the body has been reported to be in the range of 0.5%-3% of all non-Hodgkin lymphomas in adults.

37. ALCL has two types: ALK1 positive ALCL has an average age of onset of 34 years, is fast growing and generally responds well to chemotherapy. ALK1 negative ALCL has an average onset of 54 years and typically has worse outcomes than the ALK1 positive form of the disease. BIA-ALCL is more commonly of the ALK1 negative nodal type. Clinically, BIA-

ALCL typically originates directly adjacent to the breast implant, in the capsule around the breast implant and presents as a fluid collection (seroma) or a tumor.

38. Estimates as to the incidence of BIA-ALCL are challenging because there is inadequate and incomplete information as to the total number of implants worldwide. Nonetheless studies going back at least as far as 2008 suggest that, although the absolute number of known cases was low at that time, the increased risk of developing ALCL associated with breast implants was very high when compared with the background population.

39. While the incidence calculated in 2008 suggested that persons with breast implants had a more than eighteen (18) times higher risk of developing ALCL in the breast than persons in the general population, more recent studies have revealed significantly higher rates.

40. For example, calculations based on one powerful population-based case-control study reported a relative risk for ALCL in the breast in persons with breast implants at 421.8 and another population study that was focused on textured implants reported an incidence of 2.03 per million women per year, which is 67.6 times higher than the risk of ALCL in the breast in persons without a textured implant.

41. In Australia and New Zealand, there had been fifty-six (56) cases of confirmed BIA-ALCL by September of 2017, yielding an estimated incidence of 1 in 300,000, however 26 new cases were diagnosed between January, 2017 and April, 2018, increasing the estimated incidence to 1 in 1,000-10,000.

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2018-2019 Regulatory Action

42. In or about July of 2018, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom advised that, subsequent to their efforts at having healthcare professionals report cases of BIA-ALCL, they had received 48 reports up to December, 2017, 40 of which met the World Health Organization's ("WHO") diagnostic criteria. By February of 2019, the number of reports had increased to 62 of which 52 met the WHO criteria and among which there were 3 deaths, with 1 meeting the WHO criteria.

43. In or about December of 2018, the European certification (CE marking) for textured breast implants manufactured by the defendants expired and rather than approve the essentially automatic renewal of the CE marking for another five years, the regulator declined to grant the certification, following which, Allergan suspended sales of textured breast implants and tissue expanders in CE marking countries.

44. In addition, the defendants were required by the Agence Nationale de Sécurité du Médicament (ANSM) to withdraw any remaining supply of its macro-textured implants in European markets. By February of 2019, there had been 56 confirmed cases of BIA-ALCL in France and by March, 2019 that number had increased to 59. As of March, 2019, the textured Allergan Implants had been recalled in the 33 European countries, as well as in Israel and Brazil.

45. As of March, 2019, the FDA advised that the American Society of Plastic Surgeons reported 673 known cases of BIA-ALCL worldwide as of January 16, 2019 with 16 disease-related deaths.

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46. The FDA's own data, while acknowledging reliability issues arising from the MDR system being a passive or spontaneous system, reflected a total of 457 distinct reports of BIA-ALCL in the U.S. alone, involving 9 deaths (out of an original 660 reports which had been vetted for duplicates). The FDA calculations were based on data received as of September, 2018 and also noted that the number of unvetted reports of BIA-ALCL had increased by 246 cases between September, 2017 and September, 2018.

47. The Australian Therapeutic Goods Administration ("TGA") has also been investigating the science related to BIA-ALCL and convened its expert working group on April 9, 2019, at which time it noted that the TGA had confirmed 76 reports of BIA-ALCL and it made formal requests of all manufacturers of textured implants for further information and product data.

48. In the Canadian context, Health Canada reported on February 12, 2019, that as of January 1, 2019, it had received reports of 22 confirmed and 22 suspected Canadian cases of BIA-ALCL. Then, in early April, 2019 Health Canada reported that it had been notified of 28 confirmed cases of BIA-ALCL of which 86% involved textured Allergan Implants.

49. The number of BIA-ALCL cases reported in Canada up to November, 2017 for the previous 10 years was only five cases, four of which involved textured implants, demonstrating that, as in Australia, there was a significant increase in the number of case reports over a short period of time.

50. In or about March, 2019, the Quebec health ministry requested that all women who had received textured implants in the province since 1995 (an estimated 15,000 patients) be contacted by the health centres where the implant surgeries had taken place and be notified of the potential risk of BIA-ALCL.

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51. On April 4, 2019, Health Canada issued a public advisory of its intention to suspend Allergan's licences for its macro-textured implants as a precautionary measure to protect Canadian patients from the risk of BIA-ALCL. It provided Allergan with fifteen (15) calendar days within which to provide any new evidence and advised that, if a satisfactory response was not received by then, Health Canada's intention was to suspend the product licenses. In an update provided on April 25, 2019, Health Canada advised that it had received a response from Allergan and that the response was being reviewed. No final determination by Health Canada has yet been made public.

52. It should be noted that although the regulatory activity described above is focused on the textured implants, the fact remains that both BIA-ALCL and the constellation of connective-tissue, neurological and autoimmune diseases and symptoms as well as chronic fatigue, pain and cognitive impairments have been reported both anecdotally and in the scientific literature with both textured surface and smooth surface implants and involve both silicone and saline implants which, as noted, both use silicone shells.

53. Notwithstanding the regulatory actions around the world, as of April 18, 2019, Allergan's Canadian website for the Natrelle line of the Allergan Implants continued to include the following under the FAQ section:

> **Anaplastic large cell lymphoma (ALCL)**
>
> Anaplastic large cell lymphoma (ALCL) is an extremely rare type of cancer that begins in the cells of the immune system. It can occur in children and adults, including women with or without breast implants. Over the last two decades, there have been rare reports of ALCL occurring in women with breast implants. This has led the medical community to recognize a new and different type of ALCL, referred to as Breast Implant-Associated ALCL or BIA-ALCL for short.

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BIA-ALCL should not be confused with breast cancer, and recent studies have found no causal link between breast implants and the development of primary breast cancer

Since BIA-ALCL was first identified, **fewer than 200 total cases have been reported globally.** In addition, most cases of BIA-ALCL resolve after a surgical procedure to remove the breast implant. **Very rarely, chemotherapy or radiation treatment may be needed.** For more information consult your doctor. (Emphasis added)

54. This information that was being provided to Canadian consumers and patients in April of 2019, advised Canadians that there had been fewer than 200 cases reported worldwide, which was grossly inaccurate and misleading when compared with the information reported by various regulatory authorities including the FDA which reflected that there were known to be at least 673 cases worldwide as of January, 2019, including 16 disease-related deaths.

55. Further, the defendants knew or ought to have known, since at least 2011, that many cases of BIA-ALCL do not have a benign course but, instead, involve recurrent disease and do require chemotherapy and/or radiation therapy in addition to the surgical removal of the implant. The website information emphasizing the typically benign nature of the disease was thus also inaccurate and misleading.

56. In the meantime, the worldwide breast implant business has been exceptionally lucrative, exceeding $1 billion annually in revenue with more than 1.6 million women receiving breast implants in 2017 and with breast enlargement surgery being the most common cosmetic surgery in the world.

57. With respect to the defendants' market-share of this highly profitable business, after the defendants' suspension of sales of textured breast implants in Europe in December, 2018, it

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reported on its global website that on a fiscal year basis for 2018, sales of just textured implants in only the CE marking countries represented approximately $60 million in net revenues.

58. In spite of all the widely reported health concerns expressed at the patient level, in the scientific community and most recently at the regulatory level internationally, the defendants have failed or refused to behave as responsible corporate citizens and voluntarily withdraw their products from the Canadian stream of commerce and, instead, are continuing to allow their products to be implanted in Canadian patients, to the patients' detriment and to the defendants' profit.

The Plaintiffs' Circumstances

59. On or about January 6, 2014, Taky had two Allergan Implants surgically placed in her body. Specifically, she was implanted with two Natrelle INSPIRA®-TSF implants which are silicone implants with Biocell textured surface shells. Taky decided to have implants for cosmetic reasons as she had lost a significant amount of weight which had resulted in changes to the shape and size of her breasts that she wished to change.

60. Taky was advised by her implanting surgeon that her Allergan Implants would stay intact for longer, would be more natural in appearance and feel, were less likely to move or rupture than other models of implants and would generally last longer than saline implants. Taky was not told that she was at risk of developing serious adverse health effects as a result of having the Allergan Implants inserted and she was not educated about the risk of developing BIA-ALCL either.

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61. Since shortly after receiving her Allergan Implants, Taky has experienced a variety of physical, psychological and cognitive symptoms including, but not limited to, hair loss, hypothyroidism requiring pharmaceutical therapy, depression requiring pharmaceutical therapy, debilitating fatigue, cognitive changes, memory loss, anxiety, difficulty concentrating and various musculoskeletal ailments. The full extent of the adverse effects of the Allergan Implants on Taky's body are not yet known.

62. By July of 2014, Taky's symptoms had become so debilitating, particularly her fatigue, depression, concentration problems and musculoskeletal pain, that she could not get out of bed and go to work and she therefore had to take a leave of absence from the job she had held since 2006.

63. By that time, Taky had lost interest in life, was suffering from low self-esteem, anxiety, had been diagnosed with Major Depressive Disorder and suffered from serious difficulties with her concentration and memory, along with significant physical pain. She was prescribed medication for her depression in the summer of 2014 and for her hypothyroid problems in 2015.

64. Taky's employer asked her to return to work in or about July of 2015, however Taky was unable to do so until November of 2015, after which she returned to a different position that she worked at on an accommodated basis until she had to resign in March, 2019.

65. In or about March of 2019, Taky learned of Health Canada's concerns related to the Allergan Implants and the associated risk of developing BIA-ALCL. As a result of understandable concerns about her risk of developing BIA-ALCL, as well as her on-going complaints of post-implant symptoms, Taky intends to have her implants removed, thereby requiring further invasive medical procedures.

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66. Yeghia has a very close relationship with Taky and has been very concerned about her medical state since she had her Allergan Implants inserted. He has provided and will continue to provide ongoing emotional support, attendant care and other services that Taky may require in the future. He is also prepared to provide financial assistance as needed for the costs associated with any surgeries Taky may require and such other expenses that may not be covered by OHIP.

CAUSES OF ACTION

Negligence

67. The Allergan Implants were designed, developed, tested, manufactured, licensed, assembled, distributed, imported and/or exported, marketed, and/or sold by the defendants. At all material times the defendants owed a duty of care to the plaintiffs and to the Classes to provide a safely designed and manufactured product. The defendants breached the standard of care expected in the circumstances.

68. The defendants also owed a duty to the plaintiffs and other Class Members to:

a) initiate appropriate scientific studies to assess the possible association between the Allergan Implants and the development of various medical conditions including, but not limited to, BII, ASIA and BIA-ALCL;

b) carefully monitor the safety and post-market performance of the Allergan Implants;

c) ensure meaningful and consistent follow-up with Class Members and their surgeons;

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d) proactively seek information on and advise Health Canada and other international health regulators about reports received by them relating to adverse events associated with the Allergan Implants;

e) preserve data and physical evidence related to Allergan Implant failure rates and adverse health effects associated with the Allergan Implants;

f) provide Taky and other Class Members with information that a reasonable implant patient would want to know about the risk of developing adverse health effects after implantation with the Allergan Implants; and

g) warn Taky and other Class Members, their health care professionals and the Canadian and international regulators of the defective nature of the Allergan Implants and to recall them from the Canadian market when they knew or ought to have known that the Allergan Implants could not be safely used, thereby causing risk of or actual serious personal injury and/or death to Taky and other Class Members.

69. The circumstances of the defendants being in the business of designing, manufacturing, and placing the Allergan Implants into the Canadian stream of commerce are such that the defendants were in a position of legal proximity to the plaintiffs and the Class Members and therefore under an obligation to be fully aware of and concerned for their safety when designing, manufacturing, assembling and marketing products such as the Allergan Implants.

70. It was reasonably foreseeable that a failure by the defendants to design and manufacture a reasonably safe product, and thereafter to monitor its performance following market introduction

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(and to take corrective measures when required) would cause, materially contribute to, or materially increase the risk of harm to Taky and the other members of the Classes.

71. The defendants knew, or ought to have known about the association between the Allergan Implants and the development of various medical adverse effects including, but not limited to, various autoimmune, neurological and musculoskeletal diseases and symptoms, chronic fatigue, chronic muscle weakness and pain, cognitive impairments and BIA-ALCL and failed to advise, adequately or at all, Canadian and international government regulators of the incidents reported to them, failed to advise, adequately or at all, the implanting medical community and failed to provide adequate or any warnings to Canadians who, without being apprised of such risks, elected to have the Allergan Implants placed in their bodies to the detriment of their health and well-being.

72. In designing, manufacturing, marketing and distributing the Allergan Implants in Canada, the defendants breached their duty of care to the plaintiffs and other members of the Classes. Specifically, the defendants:

a) failed to ensure the Allergan Implants were safe for use by Class Members, fit for their intended purposes and of merchantable quality;

b) failed to adequately test the Allergan Implants in a manner that would fully disclose the various side effects and the magnitude of the risks associated with their use;

c) failed to conduct any or any adequate follow-up studies on the efficacy and safety of the Allergan Implants;

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d) failed to provide Taky and other Class Members and implanting physicians with any or any adequate warning of the serious risks of adverse medical effects associated with the Allergan Implants;

e) failed to investigate, research and warn Taky, other Class Members, and physicians and others of the propensity of the Allergan Implants to cause or materially increase the risk of developing various serious medical adverse effects including, but not limited to, various autoimmune, neurological and musculoskeletal disorders, chronic fatigue, chronic muscle weakness and pain, cognitive impairment as well as BIA-ALCL, when they knew or ought to have known about such risks from existing scientific evidence;

f) failed to provide any or any adequate updated and current information to Taky, other Class Members and their physicians respecting the risks of the Allergan Implants as such information became available;

g) failed to warn Taky, other Class Members and their physicians about the need for regular monitoring to ensure that any adverse medical effects associated with their Allergan Implants were detected and addressed as early as possible;

h) failed to establish any adequate procedures to educate sales representatives and implanting physicians about the risks associated with the Allergan Implants;

i) falsely stated and/or implied that the Allergan Implants were safe and fit for their intended purpose(s) when they knew or ought to have known that these representations were false;

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j) misstated the state of research, opinion and medical literature pertaining to the purported benefits of the Allergan Implants and their associated risks;

k) failed to cease the manufacture and distribution of the Allergan Implants when they knew or ought to have known that these devices caused or could cause significant harm;

l) disregarded reports of symptoms among patients who had Allergan Implants;

m) failed to monitor and to initiate a timely review, evaluation and investigation of reports of adverse medical effects associated with the use of the Allergan Implants in Canada and around the world;

n) after receiving actual or constructive notice of the side effects experienced from the use of the Allergan Implants, failed to accurately and promptly disclose this information to Health Canada, cause adequate warnings to be issued, appropriately modify the product information available to patients and implanting physicians, withdraw or recall the Allergan Implants, publicize the problems and otherwise act properly and in a timely manner to alert Taky and other Class Members of all the known risks associated with the Allergan Implants;

o) aggressively marketed the Allergan Implants as safe and effective when they knew or ought to have known of the increased risk of various adverse medical effects; and

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p) encouraged their employees to increase sales volumes while neglecting to inform patients, physicians and health regulators of the increased risk of developing adverse medical effects associated with the Allergan Implants.

Waiver of Tort

73. In the alternative to damages, the plaintiffs plead an entitlement to waive the torts and claim an accounting, or other such restitutionary remedy, for disgorgement of all revenues generated by the defendants from their unlawful conduct. It would be unconscionable for the defendants to retain the revenues generated by the conduct set out herein.

VICARIOUS LIABILITY

74. Allergan plc is vicariously liable for the actions and omissions of its subsidiaries, affiliates, partners, officers, directors and employees, including but not limited to, Allergan Limited, Allergan, Inc., Allergan USA, Inc. and Allergan Inc.

75. Similarly, Allergan Limited, Allergan, Inc., Allergan USA, Inc. and Allergan Inc. are vicariously liable for the actions and omissions of their subsidiaries, affiliates, partners, officers, directors and employees.

DAMAGES

76. As a result of the negligence and/or intentional acts of the defendants, the plaintiffs and other members of the Classes have suffered damages, including serious pain and suffering and, in some cases death, losses of guidance, care and companionship as well as losses of income and other special damages, the amounts and values of which will be particularized prior to trial.

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77. The plaintiffs plead that the defendants have acted in such a deliberate, high-handed, wanton and reckless manner, without regard to the lives, health and safety of the plaintiffs and other members of the Classes, and were motivated by economic incentives, so as to warrant a claim for punitive and aggravated damages.

78. The defendants' conduct in concealing the risks of various serious adverse medical effects associated with the Allergan Implants and their failure to provide adequate, complete and timely warnings to Taky and other Class Members exacerbated their injuries and damages, thus entitling them to aggravated damages. Taky and other Class Members would not have had their Allergan Implants placed in their bodies had they been properly and adequately warned about the increased risks associated with the devices.

79. Similarly, had the defendants provided adequate and timely warnings about the associations between the Allergan Implants and the multiplicity of serious adverse health effects associated with them, Taky and other Class Members could have made informed decisions to have their Allergan Implants explanted sooner, thereby shortening the time during which they had to suffer from their ongoing serious adverse health effects.

80. Further, the defendants' failure to provide adequate, complete and timely warnings to Taky and other Class Members was high-handed and motivated by malice, driven principally by the financial incentives offered by the lucrative cosmetic surgery industry, thus warranting an award of punitive damages. In particular, the defendants continued to promote, market, distribute and derive substantial profit from the Allergan Implants despite their increasing but undisclosed knowledge of the risks of serious adverse medical effects.

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LEGISLATION

81. The plaintiffs plead and rely upon, *inter alia*, the following statutes and the regulations made thereunder, and their provincial and territorial equivalents (all as amended):

a) *Class Proceedings Act, 1992*,S.O. 1992, c.6;

b) *Consumer Protection Act 2002*, S.O. 2002, c. 30, Schedule A;

c) *Family Law Act*, R.S.O. 1990, c. f.3;

d) *Food and Drugs Act*, R.S.C. 1985, c. F-27;

e) *Negligence Act*, R.S.O. 1990, c. N.1; and

f) *Sale of Goods Act*, R.S.O. 1990, c. S.1.

REAL AND SUBSTANTIAL CONNECTION

82. There is a real and substantial connection between the subject matter of this action and the Province of Ontario for the following reasons:

a) the defendants carry on business in Ontario, either directly or through a subsidiary and/or affiliate;

b) the defendants manufacture, distribute and sell the Allergan Implants in Ontario and derive substantial income in Ontario from such sales;

c) the Allergan Implants are approved for sale in Ontario; and

d) the plaintiffs' damages, and those of other Class Members resident in Ontario, were sustained in Ontario.

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SERVICE EX JURIS

83. This statement of claim may be served without court order outside Ontario because 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 however committed (rule 17.02 (h));

c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and

d) against a person carrying on business in Ontario (rule 17.02(p)).

PLACE OF TRIAL

84. The plaintiffs propose that this action be tried in Toronto.

May 23, 2019

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Court File No.:

ONTARIO
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PROCEEDING COMMENCED IN TORONTO

STATEMENT OF CLAIM

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