AMENDED PURSUANT TO
RULE 24 (1) (a)

NO. C954330
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

HELEN HARRINGTON, as representative Plaintiff

PLAINTIFFS

AND:

DOW CORNING CORPORATION
DOW CORNING CANADA INC.
THE DOW CHEMICAL COMPANY
DOW CORNING-WRIGHT CORPORATION

McGHAN MEDICAL CORPORATION
McGHAN NUSIL CORPORATION
MINNESOTA MINING AND MANUFACTURING COMPANY (3M)
INAMED CORPORATION
UNION CARBIDE CHEMICALS AND PLASTICS COMPANY INC.
UNION CARBIDE CORPORATION

BAXTER INTERNATIONAL INC,
BAXTER HEALTHCARE CORPORATION, and
MENTOR CORPORATION

BRISTOL-MYERS SQUIBB COMPANY
MEDICAL ENGINEERING CORPORATION
THE COOPER COMPANIES, INC.

DEFENDANTS

Proceeding under the ***CLASS PROCEEDINGS ACT***, 1995

AMENDED STATEMENT OF CLAIM

TABLE OF CONTENTS

PLAINTIFF

1. The Plaintiff, HELEN HARRINGTON, is a secretary and resides at 313-4989 47th Avenue, in the City of Delta, in the Province of British Columbia, Canada.

2. The Plaintiff undertakes this action on behalf of herself and all women who have been implanted with one or more breast implant mammary prosthetic devices and are resident in Canada, anywhere other than Ontario or Quebec, or were implanted in Canada, anywhere other than Ontario or Quebec.

3. In addition, the Plaintiff undertakes this action on behalf of all other persons or entities, including but not limited to, executors, administrators, personal representatives, spouses, relatives and "significant others" that because of a relationship to the women in paragraph 2 have an independent or derivative claim based on the breast implants.

THE "DOW" DEFENDANTS

4. The Defendant, **DOW CORNING CORPORATION** is a company incorporated under the laws of Michigan, in the United States of America, and is registered as an extra-provincial company under the laws of the Province of British Columbia. The Defendant, Dow Corning Corporation, has a head office in Midland, Michigan, in the United States of America and has an office within the Province of British Columbia at 2800 Park Place, 666 Burrard Street, Vancouver, British Columbia, V6C 2Z7.

5. The Defendant, **DOW CORNING CANADA INC.**, is a company incorporated under the laws of Canada, and has its registered office at 6747 Campobello Road, Mississauga, Ontario, L5N 2M1.

6. The Defendant, **THE DOW CHEMICAL COMPANY** (hereinafter Dow Chemical), is a foreign corporation incorporated pursuant to the laws of Delaware, in the United States of America, and has its head office in Michigan with an address for service at 2030 Dow Center, Midland, Michigan, in the United States of America, 48667.

7. The Defendant, **DOW CORNING-WRIGHT CORPORATION** (hereinafter Dow Corning Wright), is a company incorporated under the laws of Tennessee, United States of America, with its head office at CO 1222, Midland, Michigan, United States of America, 48686-0995.

8. The **Defendants Dow Chemical, Dow Corning, Corning Incorporated & Dow Corning-Wright** (hereinafter the Dow Defendants) at various times since the 1960s were engaged in the business of designing, patenting, marketing, researching, testing, manufacturing, compounding, assembling, developing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling to wholesalers, distributors, and retailers for resale to physicians, hospitals, medical practitioners, and the general public a product known as the breast implant, for use in breast surgery to enhance or augment the shape and size of the breast.

9. The **Dow** Defendants have, and/or had business relationships and connections with each other for their mutual profit. Each of these Defendants, or one or more of them, acted in concert in a joint venture, to carry out the activities described in paragraph 8. Interrelationships or transactions occurred among these Defendants whereby each and every one of these Defendants either participated in the activities described in paragraph 8, or assumed or became responsible for the liabilities of those Defendants who did so participate in the aforesaid activities.

THE "MCGHAN" DEFENDANTS

10. The Defendant, **McGHAN MEDICAL CORPORATION**, is a foreign corporation incorporated pursuant to the laws if the United States of America, and has its head office in California with an address for service at 1035 Cindy Lane, Capenteria, California, United States of America, 93013.

11. The Defendant, **McGHAN NUSIL CORPORATION** (hereinafter McGhan NuSil), is a foreign corporation incorporated pursuant to the laws of California, in the United States of America, and has its head office at 1035 Cindy Lane,

Carpenteria, California, in the United States of America, 93013 and an address for service at 303 W. Madison, Suite 1400, Chicago, Illinois, 60606.

12. The Defendant, **MINNESOTA MINING AND MANUFACTURING COMPANY** (hereinafter 3M), is a foreign corporation incorporated pursuant to the laws of Delaware, in the United States of America, and has its head office at 3M Center, 220-14W-06, St. Paul, Minnesota, United States of America, 55144.

13. The Defendant, **INAMED CORPORATION** (hereinafter Inamed), is a company incorporated under the laws of Florida, United States of America, with its head office at 1035 Cindy Lane, Carpenteria, California, in the United States of America, 93013.

14. The Defendant **UNION CARBIDE CHEMICALS AND PLASTICS COMPANY INC.**, (hereinafter Union Carbide Chemicals) is a company incorporated under the laws of New York, in the United States of America, with its head office at 39 Old Ridgebury Road, Danbury, Connecticut, in the United States of America, 06817-0001, and an address for service at 303 W. Madison, Suite 1400, Chicago, Illinois, 60606.

15. The Defendant **UNION CARBIDE CORPORATION.**, (hereinafter Union Carbide) is a company incorporated under the laws of New York, in the United States of America, with its head office at 39 Old Ridgebury Road, Danbury, Connecticut, in the United States of America, 06817-0001, and an address for service at 303 W. Madison, Suite 1400, Chicago, Illinois, 60606.

16. The Defendants, **MCGHAN, MCGHAN NUSIL, 3M , INAMED, UNION CARBIDE CHEMICAL and UNION CARBIDE** (hereinafter the **McGhan** Defendants) at various times since 1974 were engaged in the business of

designing, patenting, marketing, researching, testing, manufacturing, compounding, assembling, developing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling to wholesalers, distributors, and retailers for resale to physicians, hospitals, medical practitioners, and the general public a product known as the silicone breast implant, for use in breast surgery to enhance or augment the shape and size of the breast.

17. The **McGhan** Defendants have and/or had business relationships and connections with each other for their mutual profit. These Defendants, or one or more of them, acted in concert in a joint venture, to carry out the activities described in paragraph 16. Interrelationships or transactions occurred among these Defendants whereby each and every one of these Defendants either participated in the activities described in paragraph 16, or assumed or became responsible for the liabilities of those Defendants who did so participate in the aforesaid activities.

THE "BAXTER" DEFENDANTS

18. The Defendant, **BAXTER INTERNATIONAL INC,** (hereinafter Baxter International) is a foreign corporation incorporated pursuant to the laws of Delaware, in the United States of America, and has its head office at One Baxter Parkway, Deerfield, Illinois, in the United States of America, 60015-4633. The Defendant Baxter International Inc., is responsible for all legal liabilities of American Heyer-Schulte Corporation, Heyer-Schulte Corporation, American Hospital Supply Corporation.

19. The Defendant, **BAXTER HEALTHCARE CORPORATION,** (hereinafter Baxter Healthcare) is a foreign corporation incorporated pursuant to the laws of Delaware, in the United States of America, and has its head office at One

Baxter Parkway, Deerfield, Illinois, in the United States of America, 60015-4633. The Defendant Baxter Healthcare is a wholly-owned subsidiary of the Defendant Baxter International.

20. The Defendant, **MENTOR CORPORATION** (hereinafter Mentor), is a foreign corporation incorporated pursuant to the laws of Minnesota, in the United States of America, and has its head office at 5425 Hollister Avenue, Santa Barbara, California, United States of America, 93111, and an address for service at One Market Place, Spear Street Tower, San Francisco, California, 94105.

21. The Defendants, **BAXTER INTERNATIONAL, BAXTER HEALTHCARE, AND MENTOR** (hereinafter the **BAXTER** Defendants) at various times since 1968 were engaged in the business of designing, patenting, marketing, researching, testing, manufacturing, compounding, assembling, developing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling to wholesalers, distributors, and retailers for resale to physicians, hospitals, medical practitioners, and the general public a product known as the silicone breast implant, for use in breast surgery to enhance or augment the shape and size of the breast.

22. The **BAXTER** Defendants have and/or had business relationships and connections with each other for their mutual profit. These Defendants, or one or more of them, acted in concert in a joint venture, to carry out the activities described in paragraph 21. Interrelationships or transactions occurred among these Defendants whereby each and every one of these Defendants either participated in the activities described in paragraph 21, or assumed or became responsible for the liabilities of those Defendants who did so participate in the aforesaid activities.

THE "BRISTOL" DEFENDANTS

23. The Defendant, **MEDICAL ENGINEERING CORPORATION** (hereinafter M.E.C.), is a company incorporated pursuant to the laws of Delaware, United States of America, with its head office located in Wisconsin and carrying on business as a manufacturer of silicone breast implants, including breast implants manufactured under the trade name "Surgitek". The Defendant MEC is a subsidiary of the Defendant Bristol-Myers Squibb and Company and has an address for service at 4 Gateway Centre, 100 Mulberry Street, Newark, New Jersey, 0712-4096.

24. The Defendant, **BRISTOL-MYERS SQUIBB and COMPANY** (hereinafter Bristol) is a company incorporated pursuant to the laws of Delaware in the United States of America, with its head office located in New York and an office for service at 345 Park Avenue, New York, New York, 10154-0037.

25. The Defendant, **THE COOPER COMPANIES, INC.** (hereinafter Cooper) is a company incorporated pursuant to the laws of Delaware with its head office located in New York and an address for service at 250 Park Avenue, 6th Floor, New York, New York, 10177.

26. The Defendants **MEC** , **BRISTOL** and **COOPER** (hereinafter the Bristol Defendants) at various times since 1969 were engaged in the business of designing, patenting, marketing, researching, testing, manufacturing, compounding, assembling, developing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling to wholesalers, distributors, and retailers for resale to physicians, hospitals, medical practitioners, and the general public a product known as the silicone breast implant, for use in breast surgery to enhance or augment the shape and size of the breast.

27. The **Bristol** Defendants have, and/or had business relationships and connections with each other for their mutual profit. These Defendants, or one or more of them, acted in concert in a joint venture, to carry out the activities described in paragraph 26. Interrelationships or transactions occurred among these Defendants whereby each and every one of these Defendants either participated in the activities described in paragraph 26, or assumed or became responsible for the liabilities of those Defendants who did so participate in the aforesaid activities.

THE HISTORY OF THE DOW DEFENDANTS

28. The history of the Dow Defendants is outlined herein and includes, but is not limited to, the following matters.

29. The silicone used in silicone breast implants was first developed in the 1930s. Corning Glass Ware, which later became Corning Incorporated, developed silicone resin for use in insulating material. At approximately the same time Dow Chemical was developing silicones. When Dow Chemical discovered that Corning Glass Ware held patents on silicone the two companies jointly formed Dow Corning Corporation on February 9, 1943.

30. Dow Chemical and Corning Glass Ware each made all their data regarding organo silicone compounds available to Dow Corning. Corning Glass Ware provided the silicone technology while Dow Chemical provided the chemical processing and manufacturing technology. Dow Chemical regularly shared employees with Dow Corning.

31. Dow Corning did not have its own toxicologist or toxicology laboratory until 1969. Prior to 1969 research was carried out in the laboratories of Dow Chemical and Corning Glass Ware.

32. In 1944 Dow Chemical was concerned about the health of its plant workers involved in the production of silicones. They conducted a study entitled *Toxic Hazards Associated with the Manufacture of Dow Corning Silicone Polymers* which demonstrated that various forms of silicone can be very corrosive to human tissue and that skin contact or breathing of the vapours should be avoided.

33. In 1948 Dow Corning and Dow Chemical jointly released an article which asserted that silicone is inert and safe for biomedical applications. The article was authored by Dr. Rowe and Dr. Spencer, of Dow Chemical, and Dr. Bass of Dow Corning and was entitled *Toxicological Studies on Certain Commercial Silicones and Hydrolyzable Silane Intermediates*. The article was based on Dow Chemical's toxicological screening in a worker safety study. This article was promoted by Dow Chemical and Dow Corning and resulted in significant interest in the medical community in silicones as a biocompatible material. This article was published and promoted at a time when Dow Chemical and Dow Corning knew or ought to have known that silicone was toxic. This article has been quoted in over 100 articles since 1948.

34. In the early 1950s Dow Chemical did further toxicology testing and published articles intended to promote sales of silicone. In 1954 and 1955 Dow Chemical studied its workers and found a high order of toxicity from dust inhalation. An internal memo noted observable effects to the respiratory system, central nervous system, and neuromuscular co-ordination. In 1955 an internal memo noted that silica is capable of causing cellular infiltration and fibrotic changes. A 1956 study showed that silicone migrated to the major organs of mice. Intravenous injections of silicone were tested and resulted in the deaths of test animals. A 1957 a Dow Chemical study showed that exposure to silicone dust

caused the deaths of 74% of rats in the study. The remainder of the rats recovered when removed from the dust environment.

35. In 1954 Dr. Rowe, of Dow Chemical, wrote a letter to Dr. Hunter, of Dow Corning, re: *Results of Range Finding Toxicological Tests on Dow Corning 710 Fluid, Dow Corning 555 Fluid, Dow Corning 550 Fluid, Pa-type Fluid, Dow Corning 133-, Dow Corning 200 Fluid and Light Mineral Oil.* Dr. Rowe reported that one silicone fluid was very irritating to the eyes.

36. In 1956 a Dow Corning Study entitled *The Physiological Assimilation of Dow Corning 200 Fluid*, was conducted in Dow Chemical's labs and circulated to Dow Chemical employees. In the study Dow Corning 200 Fluid was injected or given orally to rats and dogs and resulted in concentrations of siloxane being found throughout the bodies of the animals.

37. On February 9, 1956 Dow Corning sent 9 silicone fluid samples to Dr. Rowe at Dow Chemical for testing: *Re Samples of Silicone Fluids for Determination of the Effect of Intravenous Injection.* The testing indicated that all the fluids were irriating to the eyes and skin. This included Dow Corning 360 Fluid which is chemically the same silicone formula used in breast implants.

38. On July 13, 1956 Dow Chemical reported to Dow Corning that silicone fluids have low levels of oral toxicity and are irritating to the eye: *Re Results of Range Finding Toxicological Tests on Octamethyl.* Octamethyl became the building block of silicone gel used in breast implants.

39. In September 1956 Dr. Rowe, of Dow Chemical, at Dow Corning's request, arranged for the University of Miami to do toxicological studies on 6 different silicone compounds. The silicone compounds were injected into test

animals and resulted in the deaths of some animals. All six compounds resulted in silicone elements being found in the rats blood. With one compound, known as Z-4141, the rats' livers were found to be enlarged and significantly heavier than those of the control group which indicated stress to the rats' livers. In October 1957 these test results were reported to Dow Corning and Dow Chemical: This University of Miami report was published on October 5, 1957 by Dow Corning *but all references to the enlarged rat livers caused by Z-4141 were omitted from the report.* The report only mentioned 5 of the 6 silicone compounds tested.

40. In May 1957 a Dow Chemical study done for Dow Corning and marked "Not for outside distribution" found that silica dust is capable of cellular infiltration and caused fibrotic changes in the lungs and other organs of certain animals. 74% of rats exposed to the dust died. The remaining rats made a significant recovery when removed from the dust environment.

41. On June 13, 1957 Dow Chemical reported to Dow Corning that Dow Corning 200 Fluid was an eye irritant: *Results of Comparative Eye Tests on 200 Fluid.*

42. In August 1957 a Dow Corning study found that silicone fluid, known as DC 200 Fluid, was absorbed through the skin by the adrenal glands and kidneys of a rabbit.

43. On September 1, 1959 Dow Chemical reported to Dow Corning that testing confirmed that silicone fluids are an eye irritant: *Comparative Eye Irritation of Specially Prepared Dow Corning 200 Fluids.*

44. In 1959 Dow Corning established the Centre for Aid to Medical Research to promote the use of silicones and educate doctors in the use of silicones in

medical applications. Their bulletins referred to the 1948 and 1950 articles but did not mention the studies that showed silicone to be toxic.

45. The 1959 Dow Chemical Annual Report represented that silicones are safe, chemically inert and not toxic. This was in spite of Dow Chemical's knowledge that silicone was toxic.

46. In 1961 Dow Chemical conducted a study for Dow Corning, "*The Toxicity to Rats of Vapors Resulting from Heating of Silicon-Containing Fluids*", which noted liver, kidney and lung abnormalities in several rats that died. The deaths were "definitely uncomfortable to the animals".

47. In 1961 Doctors Cronin and Gerow contacted Dow Corning regarding developing silicone gel breast implants based on their understanding that silicone is biologically inert. In 1962 Dr. Gerow implanted the first silicone breast implant in a woman, without first testing on animals, based on his belief that silicone had been extensively studied

48. In February 1961 Dow Chemical reported to Dow Corning that silicone vapours were toxic: *The Toxicity to Rats of Vapors Resulting from Heating of Silicon Containing Fluids.*

49. In 1962 Dow Corning was the first company to introduce silicone gel breast implants to the public market. This was done without Food and Drug Administration (FDA) approval, and without adequate or proper testing on animals. This was done with Dow Chemical's knowledge and based on Dow Chemical's testing. As the controlling interest in Dow Corning and as owner of the tradename "Dow" Dow Chemical would profit from the sale of Dow Corning's breast implants.

50. On July 5, 1962 Dow Chemical reported to Dow Corning that rabbits injected with silicone fluid showed an inflammatory response: *Toxicity by Subcutaneous Injection of Dow Corning 200 Fluids and Dow Corning 555 and 550 Fluids.*

51. On May 14, 1964 a Dow Corning letter, copied to Dow Chemical, proposed a study of the toxicology of silicone: *Discussion of Program for Study on the Toxicology of Silicones.*

52. In the Dow Corning Advisory Committee Meeting re "Silicone Injection Committee Meeting" held May 16 and 17, 1964 in was noted that silicone fluid was studied in reverse, it was used in human patients before it was completely evaluated in animals. A Dr. Rees stated that Dow Corning was in deep water due to the unknown fate of the fluid. The problem of migration on silicone was discussed. Two of five women injected with silicone were suffering from silicone migration which proved to be impossible to remove. A Dr. Goulian reported that silicone was attractive as a material because it is a soft material. He also noted that one rat that was injected with silicone developed a cancerous tumour that is rare in rats. Other doctors noted of women complaining bitterly about pain during pregnancy from injected silicone and of the difficulty of removing silicone that had migrated into the pectoral muscle. Dr. Rees stated, referring to silicone augmentation, that "The horse if out of the barn. There is no question of controlling it nor even stopping it now... I feel that we have to be terribly careful about what we say about it at the moment". A Dr. Oser stated that FDA approval should have been applied for long before this. He stated that they had proceeded far beyond the point at which they are legally justified.

53. An October 27, 1965 Dow Corning internal memo states "There are still a number of questions concerning our breast unit that have not been

answered. We know that a quantity of low molecular weight material is exuding from the bag, but that is all".

54. From 1965 to 1970 Dow Corning's Bioscience Research Department was housed in the Dow Chemical building where Dow Chemical's research labs were located. Dow Corning did not pay rent.

55. At a June 6, 1966 meeting attended by the FDA, Dow Corning and others, the FDA asked Dow Corning why it had stopped shipments of DC 555, a silicone fluid. Dow Corning replied that tests on rabbits showed that it caused testicular shrinkage. This was after it had been on the market for 10 years. The same test results were found in monkeys. These problems had been discovered by Dow Corning in 1964 but not reported to the FDA until this meeting.

56. On January 10, 1967 Dr. Rowe, of Dow Chemical, sent a memo to Mr. McHard, of Dow Corning, expressing concern over the legal liability involved in a proposed testing schedule involving humans and silicone.

57. The minutes of a Dow Corning executive meeting, held on February 1, 1967, show that a joint research agreement with Dow Chemical pertaining to certain silicone products was formed. The agreement was a joint development agreement relating to the physiological effects resulting from the ingestion or injections of particular physiologically active silicones where Dow Chemical and Dow Corning were to jointly share the profits and losses of any commercialization of silicones.

58. A February 16, 1967 memo entitled *Discussion of Toxicology of Various Dow Corning Products*, detailed a meeting of Dow Chemical and Dow Corning employees where silicone toxicity was discussed.

59. In 1967 Dow Chemical took over majority ownership of Lepetit, a European corporation, which was responsible for European, Austrailian, Central and South American sales of Dow Chemical and Dow Corning products. Lepetit received many complants regarding breast implant rupture and adverse reactions to the implants. Through Lepetit Dow Chemical was aware of complaints regarding Dow Corning's breast implants. Dow Chemical transferred Charles Hinman from a Dow Chemical subsidiary, Pitman-Moore, to Lepetit to act as technical advisor. For his two year term with Lepetit his salary and expenses were paid by Dow Chemical. Dow Chemical's R. William Caldwell, Assistant Director of Dow Chemcal's Bioproducts Divisions, became the "Administratore Delegato" of Lepetit. He had the right to buy, sell, or trade Lepetit. He reported to Dow Chemical. Mr. Caldwell has stated that he always viewed himself as a Dow Chemical employee although his position was at Lepetit. Many of Lepetit's directors were Dow Chemical officers and directors. Scientists from Dow Chemical and Lepetit freely exchanged research, information, and personnel.

60. The minutes of a March 7, 1968 Dow Corning directors meeting show that Dow Corning created a stock purchase plan for its employees to buy shares in Dow Chemical.

61. The same minutes state that an agreement was formed on December 5, 1967 with Dow Chemical providing for joint research, development, evaluation and commercialization programs on the physiological effects of organosilicone compounds.

62. Dr. Rowe, of Dow Chemical, wrote a letter to the President of Dow Corning on Arpril 26, 1968 proposing that Dow Corning create its own toxicology lab and hire its own toxicologist. Until this time Dow Corning did not have its own lab but relied totally on Dow Chemical for all of its toxicological testing.

63. When Dow Corning did create its own toxicology laboratory It hired Ken Olson, a Dow Chemical scientist, to head the lab. He later returned to Dow Chemical. The Dow Corning toxicology lab was housed in the same building as Dow Chemical's and accessed Dow Chemical's equipment, facilities, lab animals, and personnel.

64. Several Dow Chemical scientists transferred to Dow Corning and later returned to Dow Chemical. These scientists researched silicones and breast implants. When Olson returned to Dow Chemical in 1973 he had specific knowledge of the toxicological studies on breast implants and had knowledge of potential estrogenic effects and gel migration to tissues and organs.

65. In 1968 Dow Corning and Dow Chemical tested silicone as an insecticide. DC 360 fluid was found to have insect attractant and inseticidal properties. In a study of cockroaches it was found to be very effective at attracting and killing them. DC 200 did not yield useful effects in this study but a different study of DC 200 showed that when it was sprayed on plants it reduced the aphid population by 50%. It was not known why the silicone fluids had these properties.

66. The minutes of a December 4, 1969 Dow Corning directors meeting show that Dow Corning employees had participated in the Dow Chemical Pension and Profit Sharing Plan since 1948.

67. The same minutes show that there was a confidentiality agreement dated August 14, 1969 between Dow Chemical, Dow Corning, and Lepetit relating to the biological activity of organosilicon compounds.

68. In 1970 several Dow Corning and Dow Chemical memos discuss the development of an "inflatable mammary implant" because of concern over the effects of migrating silicone. The problems with leakage by diffusion, rupture or any other means were discussed. It was noted that several ruptured implants had been returned to them. At the same time the problems of capsular contraction (hardness) were discussed. Dow Corning continued to represent to the public that breast implants were safe.

69. An April 20, 1970 report entitled *Two-Year Studies with Miniature Silastic Mammary Implants (TX202A and TX202B) in Dogs* was submitted to Dow Corning and showed that one dog died for unknown reasons and the rest showed inflammatory reactions to the silicone.

70. A December 2, 1970 Dow Chemical Study, requested by Dow Corning, and entitled *Pathology Report on the Effects of Dow Corning 360 Fluid, 350 Centistokes after Administration to Rats Intraperitoneally or Subcutaneously*, showed that silicone was present in the internal organs of the rats studied.

71. In 1970, after Dow Corning had been marketing breast implants for six years, the only toxicology tests on file at Dow Corning's library regarding the silicone gel used in breast implants were ones that had been conducted by Dow Chemical. Dow Chemical, primarily through Dr. Rowe, performed toxicological tests on silicone compounds, directed outside research on behalf of Dow Corning, and made recommendations to Dow Corning regarding future testing.

72. Dow Chemical's scientists learned that low molecular weight silicones were not wholly inert but had some biologically active properties. Studies specifically revealed that low molecular weight silicones could affect the immune system and that certain silicone fluids, including the gel making up

about 80% of breast implants, had estrogen effects. Despite finding these reactions to silicones, Dow Chemical scientists continually notified Dow Corning that the adverse reactions were due to other forces.

73. A July 1972 study, "*DC 360 Medical Fluid Distribution and Disposition in Rats Following Subcutaneous Injection*" found migration of silicone throughout the body. The study suggested migration via the lymphatic system which forewarns of dangers to the immune system.

74. A 1973 Dow Corning project to develop artificial skin using silicones was abandoned when it was found that there was a reaction in the tissue culture to the silicone.

75. On June 7, 1973, G.C. Jersey, of Dow Chemical, sent a letter to Wayne Statt of Dow Corning, *Report of Histopathological Examination*, which detailed a study, conducted by Dow Chemical, of rabbits which showed an inflammatory reaction to silicone implants.

76. The 1973 Dow Chemical Annual Report to shareholders represented that Dow Corning's breast implants were the standard of the industry. This was in spite of Dow Chemical's knowledge of silicone toxicity, rupture and capsular contracture of breast implants.

77. The 1974 Dow Corning "*Bioscience Research Quarterly Status Report*" showed silicone to be an analgesic in some mice and rats, to increase pituitary gonadotropni and to have anti-parkinsonism-like activity and anti-ulcer activity.

78. An October 2, 1974 Dow Corning study, *"Immunological Enhancing Activity of Organosilicon Compounds and Non-Functional Fluids*", reported that DC

200 fluids showed enhanced autobody production comparable to standard adjuvants. An adjuvant is used to stimulate the immune system.

79. A 1975 Dow Corning internal memo to sales representatives notes that the silicone gel implants appear oily after manipulation. The memo states that "our technical people assure us that the doctor in the O.R. will not see any appreciable oiling on the product removed from the package. The oily phenomenon seems to appear the day following manipulation. You should make plans to change demonstration samples often. Also, be sure samples are clean and dry before customer detailing. Two easy ways to clean demonstration samples while traveling, 1) wash with soap and water in nearest washroom, dry with hand towels, 2) carry a small bottle of IPA and rag."

80. A February 1975 internal Dow Corning memo noted inflammatory reactions (indicating an immune response) in animal studies at 7, 14 and 21 days. Despite concerns, Dow Corning distributed implants to doctors that same month.

81. In March, 1975 a Dow Corning task force reported "the possible migration of gel noted in one of the test monkeys."

82. In May, 1975, a Dow Corning engineer wrote a memo on the problem that demonstration breast implant samples "bleed profusely after they have been flexed vigorously".

83. In 1975, a trade name and trademark agreement between Corning Glass Ware, Dow Chemical and Dow Corning states that since the formation of Dow Corning in 1943 Dow Chemical and Corning Glass Ware have continuously owned and controlled its operations including quality of its goods and services. The agreement required that Dow Corning's products be acceptable to Corning

Glass Ware and Dow Chemical and allowed on-sight inspections. The agreement required that Dow Corning's products not damage the reputation or goodwill associated with the name "Dow" and permited Dow Chemical to inspect the quality of Dow Corning's products. Dow Chemical maintained the right to withdraw its consent to the use of its name.

84. The 1975 Dow Chemical Annual Report referred to an agreement regarding Dow Chemicals' continuous control of the management structure of Dow Corning and Lepetit.

85. On November 3, 1975 Dow Chemical and Dow Corning entered into an agreement entitled *Secrecy Agreement -Technological Interchanges.* This agreement provided that Dow Chemical and Dow Corning would share information and testing on existing and future silicones and polymers. On November 7, 1985 Dow Chemical and Dow Corning terminated the agreement.

86. In June, 1976 a Dow Corning clinical research specialist wrote "I have proposed again and again that we must begin an in-depth study of our gel, envelope, and bleed phenomenon. Capsular contracture isn't the only problem. Time is going to run out for us if we don't get underway."

87. In 1976 the distributorship agreement with Lepitit, as European distributor of breast implants, states that when Dow Chemical and Dow Corning are sued for defective products Dow Corning and Dow Chemical will cooperate to protect Dow Chemical from liability.

88. In 1977 a Dow Corning marketing executive told surgeons that studies of contractures and gel bleed were underway when he knew that they were not. He wrote to Dow Corning "the black clouds were ominous and should be given more attention."

89. In December, 1977 a Dow Corning memo noted the problem of four Ohio and Michigan doctors who reported ruptures in 11 to 32 percent of annual breast implant procedures.

90. In 1977 Dow Corning purchased Wright Manufacturing Corporation and merged it with Dow Corning Medical Products division under the name Wright Manufacturing. In 1984 the name of Wright Manufacturing was changed to Dow Corning-Wright Corporation.

91. In March, 1978 a Dow Corning salesman reported an excessive number of ruptures and one doctor who had four consecutive ruptures.

92. In September, 1981 a Las Vegas surgeon (Vinnik) wrote to the Dow Corning vice-president to report problems with ruptures (5% failure rate) and considerable silicone reaction of one patient.

93. A 1982 study, reported to Dow Corning, indicated giant cell formation in response to silicone and migration to the lymph nodes.

94. In a September 15, 1983 letter Bill Boley, of Dow Corning, mentioned the FDA requirement to show that silicone gel was "medical grade". He stated "I want to emphasize that, to my knowledge, we have no valid long-term implant data to substantiate the safety of gels for long-term implant use."

95. February, 1984 Dr. Vinnik advised Dow Corning that breast massaging recommended by most surgeons could cause ruptures. Dow Corning did nothing to notify other surgeons.

96. In September, 1985 Dr. Vinnik advised Dow Corning that silicone gel from ruptured implants becomes "terribly runny" and that Dow Corning has a

moral obligation to notify others. Dow Corning did nothing to notify other surgeons.

97. In October, 1985 a Florida surgeon wrote to the Dow Corning president terminating his consignment agreement due to two years of recurring "spontaneous unexplainable rupture".

98. Between 1985 and 1987 Dow Corning conducted a rat study which showed fibrosarcoma tumours in one quarter or the rats. Of those one half were fatal.

99. In 1985 a Dow Corning memoranda warned that their testing has not been sufficiently thorough and described the situation as "ominous".

100. For more than two years after the FDA expressed concerns regarding cancer from breast implants in1988, Dow Corning fought efforts to have study documents made public.

101. In 1989 an internal Dow Corning study was leaked which showed "an increased incidence of fibrosarcomas at the implant site".

102. A Dow Corning investigation showed that "there were manufacturing problems that had been covered up by fabricating test results". In 1987 Dow Corning discovered that some lots of breast implants were not properly cured and technicians altered the records "to make it appear that there was no problem.

103. In December, 1990 a Dow Corning interoffice memo stated that two company officials were attempting to destroy internal reports analyzing implant complication rates.

104. An internal Dow Corning study indicated 30.3% of women with implants had experienced problems and 13% had implants replaced within 5 years.

105. In 1991 an internal Dow/Corning-Wright memo mentioned the "cover-up" of the implant controversy, discussions with the four main breast implant manufacturers, and the establishment of a committee and networks to orchestrate strategies. The memo was written by Dan Hayes, the President and CEO of of Dow Corning Wright and specifically mentioned the cooperation of Keith McKennan who was with Dow Chemical.

106. In January 1992 the American Food and Drug Administration and, in Canada, the Department of Health and Welfare put a moratorium on the sale of silicone gel breast implants because of safety concerns.

107. By April 1992 the Dow Defendants ceased the manufacturing and selling of breast implants.

108. The Report of the American House of Representatives entitled "The FDA's Regulation of Silicone Breast Implants" (FDA Report) was released on April 17, 1993. The report noted that Dow Corning failed to publish or disclose to the FDA their own research results when they showed problems. Because of this the FDA was unable to judge the true risk of implants. When the FDA demanded that Dow Corning provide the study documents Dow Corning refused. The report states that Dow Corning fabricated test results to cover up manufacturing problems.

THE HISTORY OF THE McGHAN DEFENDANTS

109. The history of the McGhan Defendants is outlined herein and includes, but is not limited to, the following matters.

110. McGhan Corporation was formed by Donald McGhan on November 28, 1974 for the purpose of designing, marketing, manufacturing and distributing medical products including silicone breast implants.

111. Donald McGhan, T. Jan Varner, Richard Compton, Clark Pool and Charles Haynes formed the board of directors of McGhan and, along with several employees, all came from either the Dow Defendants or Heyer-Schulte Corporation (the Baxter Defendants). Their knowledge of silicone toxicity came from their experience with the Dow Defendants and the Baxter Defendants.

112. McGhan started selling breast implants to the public without first conducting proper or adequate testing on the toxicity of silicone.

113. From approximately 1974 to 1976 McGhan purchased silicone gel for use in breast implants from General Electric.

114. From approximately 1976 to 1977 McGhan purchased silicone gel for use in breast implants from the Defendant Dow Corning Corporation.

115. In June 1977 McGhan Corporation was purchased by the Defendant 3M and continued to operate under the name McGhan.

116. From approximately 1977 to 1984 McGhan Corporation produced its own silicone gel for use in breast implants.

117. On or about December 31, 1980 McGhan was merged into 3M as an unincorporated division, McGhan/3M.

118. In 1980 3M's due diligence revealed that the Defendant McGhan had not done adequate testing of the breast implants before introducing them to the market.

119. In a memo known as the "Broadman memo" the Defendant 3M's lawyers discussed the failure to conduct proper testing and research and considered 3M's exposure to liability for punitive damages.

120. In 1984 3M sold the McGhan/3M division to the original owner of McGhan, Donald McGhan. The new McGhan Corporation acquired all of the Defendant 3M's plastic surgery product line including the inventory of silicone gel breast implants that 3M had purchased in 1977.

121. In May of 1980 Donald McGhan and Richard Compton and others purchased the Defendant McGhan Nusil. Donald McGhan was president until 1984.

122. In 1984 the Defendant McGhan Nusil began to provide silicone gel for breast implants produced by McGhan Corporation. Richard A Compton, a director of the Defendant McGhan, became the President of the Defendant McGhan Nusil. McGhan Nusil continued to provide the silicone gel until approximately 1990.

123. In August 1984 McGhan Corporation became a wholly owned subsidiary of First American Corporation whose name was later changed to the Defendant Inamed Corporation. The Defendant Inamed agreed to defend the Defendant 3M in all claims or lawsuits involving silicone gel breast implants sold in the United States.

124. The Defendants McGhan, Inamed and McGhan Nusil have shared corporate officers throughout their history. For example, in 1993 the corporate officers of the Defendant McGhan and the Defendant Inamed were exactly the same people: Donald K. McGhan and Michael D. Farney. In 1988 the corporate officers of the McGhan and McGhan Nusil included Donald McGhan and Richard Compton

125. From 1976 to 1984 the Defendant Union Carbide sold raw silicone materials to McGhan Medical with the knowldege that the raw silicone would be used in breast implants.

126. From 1984 to 1991 the Defendant Union Carbide sold raw silicone materials to McGhan Nusil with the knowledge that the raw silicone would be used in breast implants.

127. In marketing brochures the Defendant Union Carbide represented that the silicone they supplied was designed for use in silicone rubber implants and other medical devices.

128. In 1990 the Defendant Union Carbide Chemicals and Plastics Company and the Defendant Union Carbide Corporation purchased their former silicone customer, McGhan Nusil Corporation. In conducting due diligence the defendants Union Carbide Chemicals and Union Carbide became aware of possible liability for personal injury caused by the breast implants.

129. In January 1992 the American Food and Drug Administration and, in Canada, the Department of Health and Welfare put a moratorium on the sale of silicone gel breast implants because of safety concerns.

130. On October 15, 1992 Union Carbide sold their shares in McGhan Nusil.

131. Since that time McGhan Medical has continued to produce and market saline breast implants.

THE HISTORY OF THE BAXTER DEFENDANTS

132. The history of the Baxter Defendants is outlined herein and includes, but is not limited to, the following matters.

133. In 1968 Heyer-Schulte Inc., a Delaware corporation, began designing, manufacturing and marketing medical products, including silicone gel breast implants.

134. During the years 1969 to 1976 the silicone gel for the filling of the implants and silicone polymers for the envelopes of the implants manufactured, designed and/or marketed by Heyer-Schulte were provided by the General Electric Co. In approximately August of 1976 the Defendant Dow Corning began to supply the silicone gel and silicone polymers for Heyer-Schulte.

135. Heyer-Schulte introduced their breast implants onto the public market without proper testing of the toxicity of silicone.

136. On or about August 20, 1974 American Hospital Supply Corporation purchased Heyer-Schulte Inc and continued to manufacture, design and market breast implants under the name Heyer-Schulte Corporation.

137. On or about June 23, 1980 Heyer-Schulte Corporation changed its name to American Heyer-Schulte Corporation.

138. On or about December 16, 1982 American Heyer-Schulte Corporation dissolved and thereafter was known as American Heyer-Schulte, an unincorporated division of American Hospital Supply Company.

139. On or about March 30, 1984 the Defendant Mentor Corporation acquired Heyer-Schulte from American Hospital Supply Company.

140. On or about November 25, 1985 the Defendant Baxter Healthcare Corporation, then known as Baxter Travenol Laboratories purchased American Hospital Supply. In conducting due diligence Baxter was aware of the product liability exposure because of the breast implant product line.

141. The Defendant Baxter International is the parent corporation of the Defendant Baxter Healthcare.

142. In 1987 the Defendant Baxter Travenol Laboratories changed its name to Baxter Healthcare Corporation.

143. In January 1992 the American Food and Drug Administration and, in Canada, the Department of Health and Welfare put a moratorium on the sale of silicone gel breast implants because of safety concerns.

144. At that time the Baxter Defendants ceased manufacturing and marketing silicone gel breast implants.

THE HISTORY OF THE BRISTOL DEFENDANTS

145. The history of the Bristol Defendants is outlined herein and includes, but is not limited to, the following matters.

146. The Defendant MEDICAL ENGINEERING CORPORATION (MEC) was formed in 1969 for the purpose of manufacturing medical products and devices.

147. In 1972 MEC began producing and marketing breast implants to the public. This was done without first conducting proper testing to establish the safety of their product.

148. Between the years 1972 and 1982 MEC produced and marketed breast implants using silicone gel provided by General Electric and the Defendant Dow Corning.

149. Between 1972 and 1991 MEC produced and marketed Meme, Replicon, and Surgitek breast implants.

150. In 1982 the Defendant BRISTOL-MYERS SQUIBB and COMPANY (Bristol) purchased MEC and made it a subsidiary of its Zimmer subsidiary. Before this purchase took place Bristol conducted extensive due diligence review that included information regarding legal liability for injury caused by capsular contracture, rupture, and gel bleed.

151. In 1988 Bristol expanded its breast implant business by purchasing Natural Y Surgical Specialties and Aesthetech Corporation from the Cooper Companies , Inc (Cooper). The purchase was executed in the name of MEC but was negotiated by Bristol and the purchase price was paid by Bristol. The due diligence which indicated liability with respect to breast implants was conducted jointly by MEC and Bristol. As early as 1972 MEC was aware of rabbit tests that

showed that the polyurethane foam implants, designed and manufactured by Natural Y, were toxic.

152. Natural Y Surgical Specialties, Inc. (Natural Y) was formed in 1976. The Natural Y patent was registered in 1969 by Edward Weck, Company and was sold and distributed by Markham Medical International, Inc. In 1972. In 1976 Markham Medical formed the company Natural Y. In 1981 Aesthetech was formed as a manufacturing facility for Natural Y. In 1987 Natural Y and Aesthetech were acquired by the Cooper Surgical Division of Cooper Companies

153. Natural Y designed and marketed Vogue, Optimam, Meme, and Replicon implants.

154. Natural Y introduced its implants onto the market without adequate pre-market testing. Natural Y did not conduct any formal clinical studies before introduction of the product.

155. In 1982 Natural Y promoted the Meme implant which was coated with polyurethane foam, the same foam used in furniture upholstery. The polyurethane foam was intended to bond with breast tissue and reduce capsular contracture.

156. As early as 1977 Natural Y was aware that polyurethane degrades in the human body and releases Toluenediamine (TDA), a known carcinogen. A 1964 study showed that the TDA released from polyurethane caused cancer in rats.

157. Natural Y and Aesthetech did not conduct any studies on the toxic effects of polyurethane foam before introducing the foam implants onto the market.

158. In 1988 MEC was losing breast implant sales to Natural Y's polyurethane foam implants. Bristol and MEC investigated purchasing Natural Y. In conducting due diligence Bristol and MEC expressed concern regarding the increased product liability exposure because of the foam implant line. Bristol lawyers advised against the Natural Y purchase for that reason. However, Bristol did a cost/benefit analysis and decided the increased sales from the foam implant line would outweigh the risks of increased liability costs.

159. Bristol conducted research into the hazards of breast implants and polyurethane foam. Bristol provided the funding for testing and a subsidiary of Bristol, ConvaTec assisted MEC in developing its premarket approval application for the FDA. Bristol's Technical Evaluation and Service Department (TESD) performed auditing and review functions for MEC once or twice per year and performed all Good Manufacturing Practices audits for MEC. TESD found a number of conditions regarding the production of breast implants that needed corrective action.

160. MEC had a board of three directors, two of them being Bristol executives, including the Vice President. MEC's budgets were subject to Bristol's approval. Bristol maintained MEC's bank accounts and provided loans to MEC as necessary and Bristol had to approve any MEC capital acquisitions.

161. Bristol's name and logo appeared on package inserts and promotional products regarding breast implants.

162. On April 17, 1991 Bristol's executive vice president suspended MEC's sales of breast implants when it failed to comply with Class III safety and efficacy testing required by the Medical Device Amendment to the American *Food Drugs and Cosmetics Act.*

163. Later that year MEC ceased all operations by selling is urology division. Proceeds from the sale were turned over to Bristol.

THE REPRESENTATIVE PLAINTIFF'S HISTORY

164. The Plaintiff began to suffer from multiple cysts in both breasts in approximately 1970. In 1978 the Plaintiff was diagnosed by a physician as having fibrocystic disease. The Plaintiff's physician recommended that she undergo bilateral mastectomies and reconstruction with silicone breast implants.

165. On or about April 3, 1981 the Plaintiff underwent bilateral mastectomies by Dr. Kergin at the Surrey Memorial Hospital. During the operation the Plaintiff's breasts were reconstructed by Dr. Quayle using Heyer-Schulte silicone gel implants designed and manufactured by the Baxter Defendants. These implants were identified as 200cc Round 7000, Catalog No. 350-7200, Lot No. 208497.

166. Within months of the implantation the Plaintiff suffered capsular contracture (tightening of scar tissue around the implant causing hard and painful breasts) and severe stabbing pains in her breasts.

167. On or about July 18, 1985 Dr. Quayle performed surgery to the right breast to relieve the capsular contracture. During this surgery the right implant was replaced with a silicone gel Meme implant with a polyurethane envelope designed and manufactured by the Bristol Defendants and identified as Meme, Catalog No. 4-190, size 4, Weight 190 grams, Control No. 430550.

168. Again within months the Plaintiff began suffering capsular contracture and severe pains in the right breast.

169. In addition to these symptoms, from approximately 1985 and continuing today, the Plaintiff has suffered from joint paints, tingling in her fingers, and pain and stiffness in her muscles.

170. From approximately 1987 and continuing today, the Plaintiff has also suffered extreme fatigue, swollen feet, dry mouth and eyes, fevers and night sweats.

171. From approximately 1990 and continuing today, the Plaintiff has also suffered from bowel and bladder problems, constant bruising and skin rashes.

172. In 1994 blood tests revealed a positive ANA result.

173. On or about June 26, 1995 the Plaintiff underwent explantation of both implants conducted by Dr. Urve Kuusk at UBC Hospital. The right implant (Meme) had a 2 inch rupture and the left implant (Heyer-Schulte) had a massive rupture. Both implants had released silicone gel into the surrounding breast tissue.

174. As a consequence of the matters referred to, the Plaintiff has suffered and continues to suffer physical injury, loss and damage sometimes referred to as "Silicone Syndrome" as follows:

a) Silicone Syndrome;
b) Atypical Connective Tissue Disease;
c) Raynauds Syndrome;
d) scarred breasts;
e) painful breasts;
f) capsular contractures;
g) hard, misshapen breasts;
h) joint pain;
i) pain and stiffness in muscles;
j) tingling in her fingers;

k) swollen feet;

l) fevers and night sweats;

m) sleep disturbances;

n) constant bruising;

o) skin rashes on the face and neck;

p) severe fatigue;

q) severe headaches;

r) bowel problems;

s) bladder problems;

t) dry mouth and trouble swallowing;

u) dry eye syndrome;

v) extreme mental anguish, stress and depression.

175. The Plaintiff has suffered special damages, losses and expenses. Without limiting the generality of the foregoing the Plaintiff has suffered the loss of past and future income, loss of sick leave and employment benefits, and loss of opportunity.

176. The Plaintiff continues to undergo medical treatment so the eventual condition of the Plaintiff is not known and many not be known for some time.

THE DEFENDANTS' NEGLIGENCE

177. The Plaintiff adopts each and every foregoing paragraph of this Statement of Claim.

178. The Defendants, or each of them, owed the Plaintiff, and the public, a duty to use reasonable care in the researching, testing, manufacturing, compounding, assembling, developing, analyzing, recommending, merchandising, advertising,

promoting, supplying and/or selling breast implants. The Defendants failed to meet this duty.

179. Particulars of the negligence of the Defendants, or each of them, are as follows:

a) negligently designing and/or manufacturing the implants of substandard or inappropriate materials which were inadequate to protect against the rupture of breast implants during ordinary usage;

b) negligently designing and/or manufacturing the implants of substandard or inappropriate materials which were inadequate to protect against the bleeding of silicone gel through the envelope during ordinary usage;

c) negligently designing and/or manufacturing the implants using silicone in the silicone polymer envelope when the Defendants knew or ought to have known that the silicone is toxic in the human body;

d) negligently designing and/or manufacturing the implants using silicone in the silicone-gel filling when the Defendants knew or ought to have known that the silicone is toxic in the human body;

e) negligently designing and/or manufacturing the implants using polyurethane foam when the Defendants knew or ought to have known that polyurethane foam is toxic in the human body

f) negligently selecting, manufacturing and assembling the component parts of the product, including but not limited to envelope and the filling itself, thus producing a final product incapable of standing the stress of ordinary and foreseeable usage;

g) negligently designing and/or manufacturing the filling of the implants, silicone-gel or saline, with substandard, inappropriate, and/or contaminated materials;

h) negligently designing and/or manufacturing implants that cause the formation of hard and painful scar tissue (encapsulation) around the implants;

i) negligently designing and/or manufacturing implants that interfere with mammography making the detection of cancer or other breast tissue diseases more difficult;

j) failing to employ advanced yet available design and manufacturing techniques which would have reduced the likelihood that implants would rupture or bleed after implantation;

k) failing to warn the Plaintiff and/or her physicians of the likelihood that such implants could rupture or bleed;

l) failing to warn the Plaintiff and/or her physicians of the complications attendant upon rupture or bleed despite the fact that Defendants knew or ought to have known of the chances for rupture or bleed and the foreseeable complications which could result therefrom;

m) failing to warn the Plaintiff, her physicians, other medical personnel, and the public of the inherent dangers from the toxic effects of silicone or polyurethane;

n) failing to warn the Plaintiff, her physicians, other medical personnel, and the public of the true statistical rate of rupture of the implant shell;

o) failing to warn the Plaintiff, her physicians, other medical personnel, and the public of the true statistical rate of encapsulation caused by fibrotic tissue;

p) failing to test the silicone or polyurethane implants in a manner that would fully disclose the magnitude of the risks associated with leaking silicone gel in the body, the frequency of capsular contracture, rupture, leakage, or other adverse side effects of silicone. The Defendants rushed the breast implants to market without conducting reasonable testing including long-term testing of their product as to the safety and efficacy of breast implants.

q) failing to recall the breast implants when they knew, or ought to have known, that a significant number of failures had occurred since the product was first manufactured and distributed and prior to the implantation in the Plaintiff's body;

r) failing to recall the implants when they knew, or ought to have known, that the silicone and polyurethane used in the implants was toxic;

s) failing to cease manufacture and distribution of the implants when they knew, or ought to have known, that a significant number of injuries had been caused by the implants since they were first manufactured;

t) failing to cease manufacture and distribution of the implants when they knew, or ought to have known, that the silicone and polyurethane used in the implants was toxic;

PARTICULARS OF DEFENDANTS' BREACH OF WARRANTY

180. The Plaintiff adopts each and every foregoing paragraph of this Statement of Claim.

181. The Defendants, or each of them, warranted, either express or implied, that the breast implants were reasonably fit for their intended use when the fact is that the implants when used in a normal manner and for their intended purpose, caused the Plaintiff's injury. The Plaintiff pleads and relies upon the Sale of Goods Act. R.S.B.C. 1979 and amendments thereto, and in particular Section 18 thereof.

182. Further, or in the alternative, the Defendants or each of them, designed manufactured and distributed the breast implants in a defective and unsafe condition, and placed the products in the normal stream of commerce with the knowledge and expectation that they would be sold and ultimately used without further inspection of their condition and/or without inspection which would reveal latent defects in the implants, and the Plaintiff pleads and relies upon the Sale of Goods Act,, R.S.B.C. 1979 and amendments thereto. The Plaintiff claims damages for breach of a contractual warranty and/or condition as to merchantability and/or quality or fitness for a particular purpose.

RES IPSA LOQUITUR

183. The facts regarding the researching, testing, manufacturing, assembling, developing, analyzing, recommending, merchandising, advertising, promoting and supplying are peculiarly within the knowledge of the Defendants. The Plaintiff has no means of ascertaining the method or manner in which the breast implants were manufactured and designed. The implants came into the Plaintiff's possession in the same condition as they were in when they left the control of the Defendants. The injury to the Plaintiff, as described above, was

one which, in the ordinary course of events, would not have occurred without negligence on the part of the Defendants.

184. The Plaintiff pleads and relies upon the doctrine of res ipsa loquitur.

PARTICULARS OF THE DEFENDANTS' MISREPRESENTATIONS

185. The Plaintiff adopts each and every foregoing paragraph of this Statement of Claim.

186. The Defendants, or each of them, their servants, agents and employees, made negligent, reckless and fraudulent misrepresentations regarding the quality and character of the implants, by implication or otherwise, through advertising or otherwise that the implants were safe for use in the human body.

187. These misrepresentations were made with the intent that the general public, including the plaintiff, would rely on them.

188. These misrepresentations were made when the Defendants knew, or ought to have known, of the falsity of the representations or with reckless disregard for the truth.

189. The Plaintiff purchased the breast implant in reliance on the aforesaid misrepresentations.

PARTICULARS OF THE DEFENDANTS' CONSPIRACY

190. The Plaintiff adopts each and every foregoing paragraph of this Statement of Claim.

191. The Defendants participated with each other in a common plan and conspired to design, manufacture and market breast implants when they knew or ought to have known that injury to women with implants, including the Plaintiff, would result.

192. From the 1960s to the present results from clinical tests together with reports from physicians indicated silicone breast implants were prone to rupture, leakage, severe and constant capsular contracture, and linked to a variety of autoimmune disorders including but not limited to scleroderma, various forms of lupus, rheumatoid arthritis, cancer, and related medical problems as described herein that could result in severe and substantial injury. Despite this knowledge, the Defendants continued to design, manufacture, market and sell their defective silicone breast implants to the public without disclosing the known dangers.

193. The Defendants participated with each other in a common plan, or by tacit agreement, to oppose reclassification of breast implants into Class III status by the United States FDA as this would require proof of their safety. The Defendants also worked to prevent regulation of the breast impants by other U.S. Government agencies and other governments. As well, the Defendants participated in a common plan to prevent public awareness of the hazards of breast implants. To further these plans the Defendants concealed and minimized the evidence of the risks of breast implants. These plans included, but were not limited to, agreements in 1977, 1982, 1983 and 1988.

THE DEFENDANTS' RECKLESS DISREGARD

194. The Plaintiff adopts each and every foregoing paragraph of this Statement of Claim.

195. The conduct of the Defendants, or each of them, as stated herein showed reckless disregard for the well-being of the public, including the Plaintiff. The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety or welfare of the Plaintiff and the Plaintiff hereby claims for exemplary and punitive damages.

PARTICULARS REGARDING DOW CHEMICAL

196. The Plaintiff herein adopts each and every foregoing paragraph of this Statement of Claim, in particular paragraphs 28 to 108.

197. Dow Chemical owed a duty of care to the ultimate users of breast implants manufactured by Dow Corning due to a sufficient relationship of proximity. Dow Chemical knew or ought to have known that negligence on their part would cause injury to the end users of breast implants. Therefore, all references herein to negligence by Dow Corning also apply to Dow Chemical.

198. Additional particulars of the negligence of the Defendant Dow Chemical are as follows:

a) Dow Chemical provided the scientific basis for the use of silicone in medical devices. This scientific foundation was relied on, to some extent, by all the Defendants herein;

b) Dow Chemical performed experiments and studies which contraindicated the use of silicone in medical devices and showed that breast implants were hazardous to those who received them;

c) Dow Chemical provided scientific assistance, testing, facilities, personnel, and knowledge to Dow Corning;

d) Dow Chemical was in constant communication with Dow Corning through testing, facilities and personnel such that Dow Chemical was fully aware of Dow Corning's negligence;

e) Dow Chemical had authority, power, and duty to stop Dow Corning from designing, manufacturing and marketing defective products but failed to do so;

f) Dow Chemical failed to warn of the dangers of silicone when breast implants were first introduced to the market;

g) Dow Chemical failed to warn of the dangers of breast implants throughout the history of Dow Corning's marketing of breast implants;

199. Dow Chemical made misrepresentations concerning the safety of silicone which induced manufacturers to use silicone in medical devices, induced physicians to use breast implants and induced the public to use breast implants. The Plaintiffs relied on Dow Chemical's misrepresentations and suffered injury as a result.

200. The particulars of Dow Chemical's misrepresentations:

a) Dow Chemical misrepresented to the public, the medical and scientific community in published and unpublished reports that silicone was an appropriate product for breast implants when they knew or ought to have known that silicone was toxic;

b) Dow Chemical made misrepresentations regarding Dow Corning's products, including breast implants, by allowing Dow Corning to use the name and mark "Dow".

c) Dow Chemical made misrepresentations regarding Dow Corning's products, including breast implants, in their annual reports to shareholders and the public.

201. Dow Chemical and Dow Corning pursued a common tortious act in a joint venture. Dow Chemical actively participated in research and testing of silicones for Dow Corning, aided Dow Corning and offered encouragement to Dow Corning. Dow Chemical benefited from the sale of breast implants as a shareholder of Dow Corning and as a owner and user of the name "Dow".

202. Dow Chemical dominated and controlled Dow Corning's silicone breast implant operations such that Dow Chemical was the de facto operating mind or alter ego. Dow Chemical created Dow Corning for the purpose of designing, manufacturing and marketing silicone products, including breast implants. Therefore Dow Chemical is at law responsible for the liabilities of Dow Corning with respect to breast implants.

203. Dow Chemical conspired with Dow Corning to study the effects of silicone in a secretive and deceptive manner.

PARTICULARS REGARDING THE DEFENDANTS McGHAN, McGHAN NUSIL AND INAMED

204. The Defendants McGhan, McGhan Nusil and Inamed pursued a common tortious act. The three Defendants actively participated in each others breast implant businesses sharing knowledge, expertise and personnel. The corporate directors of all three Defendants were the same so as to form one operating mind for all three Defendants. The three Defendants operated their breast implant business as one enterprise

PARTICULARS REGARDING SILICONE SUPPLIERS DOW CORNING, UNION CARBIDE AND MCGHAN NUSIL

205. The Defendants Dow Corning, Union Carbide and McGhan Nusil owed a duty of care to the ultimate users of breast implants due to a sufficient relationship of proximity. These Defendants knew or ought to have known that negligence on their part, in supplying toxic silicone, would cause injury to the end users of breast implants. Therefore, all references herein to negligence by the Manufacturing Defendants also apply to the Defendants Dow Corning, Union Carbide and McGhan Nusil as suppliers of silicone.

PARTICULARS OF THE PLAINTIFF'S DAMAGES

206. Particulars of the loss and damage suffered by the Plaintiff as a result of the matters aforesaid which were caused by or contributed to by the negligence of the Defendants or any of them are as follows:

a) shock, pain and suffering;

b) future pain and suffering;

c) loss of enjoyment of life;

d) loss of earnings past and prospective;

e) economic loss and loss of opportunity;

f) future care, medical necessities and contingencies.

g) special damages, loss and expense and will be put to further loss and expense in the future;

207. The Plaintiff pleads and relies upon the provisions of the Court Order Interest Act, R.S.B.C. 1979 and amendments thereto, and the Negligence Act, R.S.B.C. 1979 and amendments thereto.

208. **WHEREFORE** the Plaintiff claims against the Defendants, jointly and severally, as follows:

a) General damages;

b) Punitive damages;

c) Special damages;

d) The Costs of this action;

e) Interest pursuant to the Court Order Interest Act;

f) Such further and other relief as this Honourable Court may deem just.

DATED at the City of Vancouver, in the Province of British Columbia, this 1st day of August, 1995.

PLACE OF TRIAL: Vancouver, British Columbia

"DA Acheson"
Solicitor for the Plaintiff

"D. Klein"
Solicitor for the Plaintiff

"Mark A. Steven"
Solicitor for the Plaintiff

THIS AMENDED STATEMENT OF CLAIM is filed and delivered by Deborah A. Acheson, Q.C., of the law firm of Acheson & Company, Victoria, David A. Klein of the law firm of Klein Lyons, Vancouver, and Mark R. Steven of the law firm of Connell Lightbody, Vancouver. The address for service is C/O Mark R. Steven, Connell Lightbody, 1900 - 1055 West Georgia, Vancouver, British Columbia, V6E 4J2.