Amended without leave pursuant to Rule 24(1)(a) of the Supreme Court Rules.
Original filed March 9, 2001.

No. C954330
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

HELEN HARRINGTON AND BETTY GLADU, AS REPRESENTATIVE PLAINTIFFS

PLAINTIFFS

AND:

DOW CORNING CORPORATION, DOW CORNING CANADA INC., THE DOW CHEMICAL COMPANY, DOW CORNING-WRIGHT CORPORATION, MCGHAN NUSIL CORPORATION, MCGHAN MEDICAL 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, MENTOR CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, MEDICAL ENGINEERING CORPORATION, THE COOPER COMPANIES, INC.

DEFENDANTS

AMENDED STATEMENT OF DEFENCE OF THE DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY, MEDICAL ENGINEERING CORPORATION, and THE COOPER COMPANIES, INC.

1. The Defendants, Bristol-Myers Squibb Company ("BMS"), Medical Engineering Corporation ("MEC"), and The Cooper Companies, Inc. ("Coopers"), deny each and every statement of fact in the Amended Statement of Claim, unless expressly admitted in this Amended Statement of Defence.

2. In this Amended Statement of Defence, the Defendants MEC and Coopers will be collectively referred to as the "MEC Defendants".

3. In response to paragraphs 2 and 3 of the Amended Statement of Claim, this action has been certified as a class proceeding only with respect to those women who have been implanted with one or more silicone gel breast implants, have suffered an injury caused by a silicone gel breast implant and are either resident in Canada other than in Ontario or Quebec or have been implanted with one or more silicone gel breast implants in Canada other than in Ontario or Quebec.

The Defendant BMS, MEC and Coopers

4. The Defendant BMS is not and never was a manufacturer of breast implants. BMS has been the sole shareholder of MEC since 1982. In 1988 MEC purchased two other breast implant companies, Natural Y Surgical Specialties, Inc. and Aesthetech Corporation from Coopers. However, MEC and BMS have at all times remained legally separate corporate entities and BMS has never manufactured breast implants. A position as an owner or shareholder (whether direct, indirect or even controlling) in a manufacturer is an insufficient foundation in itself to impose a manufacturer's duty or any duty upon a mere owner such as BMS. Accordingly, the claim against BMS should be dismissed. In the alternative, BMS adopts the affirmative defences pleaded by the MEC Defendants in the subsequent paragraphs of this Defence.

Alleged Conspiracy and Joint Venture

5. In response to paragraphs 27 of the Amended Statement of Claim, as particularized by the Plaintiffs' Reply to Demand for Particulars dated February 1, 1996 and further to the Order of Mackenzie J. pronounced on April 11, 1996 and February 14, 1997, the claims in conspiracy and joint venture against the Defendants collectively or as defendant groups as defined in the Amended Statement of Claim are vague and devoid of the specificity required for those claims to stand. The allegations in paragraphs 27 of the Amended Statement of Claim are frivolous, vexatious and embarrassing and ought to be struck or, alternatively, stayed, pursuant to Rule 19(24)(a) – (c).

Purpose of Silicone Gel Breast Implants

6. In further response to paragraph 26 of the Amended Statement of Claim and paragraph 1 of the Plaintiffs' Reply to Demand for Particulars of the Defendants dated November 22, 2002, the MEC Defendants admit that silicone gel breast implants are for use in breast surgery to reconstruct the breast or enhance or augment the shape, size and appearance of the breast. In further response to paragraph 1 of the Plaintiff's Reply to Demand for Particulars of the Defendants dated November 22, 2002, the MEC Defendants deny that silicone gel breast implants are or were intended to last for the life of the patient.

Alleged Negative Effects of Silicone Gel Breast Implants

7. In further response to the Amended Statement of Claim, in 1992, the Food and Drug Administration in the United States instituted a moratorium on the sale of silicone gel breast implants in the United States in order to permit further studies on their safety to be conducted. Silicone gel breast implants remained available in the United States primarily to women who sought reconstructive surgery and mastectomy. A voluntary moratorium in Canada followed the American announcement. In or about 1998, the Canadian government introduced new medical devices regulations, SOR/98-282, s.32, Schedule 1, pursuant to which a manufacturer may apply to the Minister of Health for a licence to import or sell breast implants upon the Minister's evaluation.

8. In further response to the Amended Statement of Claim, and in particular and paragraphs 2 and 3 of the Plaintiffs' Reply to Demand for Particulars of the Defendants dated November 22, 2002, the MEC Defendants specifically deny that any breast implant or, in the alternative, any breast implant which it designed, developed, manufactured, distributed or marketed caused or is capable of causing the alleged "Silicone Syndrome" or other alleged or any systemic disease or condition, or any of the following alleged diseases or conditions, whether classical or atypical:

(a) Atypical Connective Tissue Disease;

(b) Undifferentiated Connective Tissue Disease;

(c) Mixed Connective Tissue Disease;

(d) Raynaud's Syndrome or Raynaud's Disease;

(e) Sjogren's Syndrome;

(f) Dermatomyositis-Polymyositis;

(g) Chronic Fatigue Syndrome;

(h) Fibromyalgia;

(i) Myasthenia Gravis;

(j) Multiple Sclerosis;

(k) Amytrophic Later Sclerosis (ALS);

(l) Systemic Sclerosis;

(m) Scleroderma;

(n) lupus or systemic lupus;

(o) Erythemathosus;

(p) cancer;

(q) autoimmune disorder or disease;

(r) autoimmune reaction;

(s) local or systemic inflammatory reaction;

(t) rheumatoid arthritis;

(u) joint pain;

(v) pain or stiffness in muscles;

(w) tingling in fingers or other extremities;

(x) swollen feet;

(y) fevers or night sweats;

(z) sleep disturbances;

(aa) bruising or constant bruising;

(bb) skin rashes on the face or neck;

(cc) fatigue or severe fatigue;

(dd) headaches or severe headaches;

(ee) bowel problems;

(ff) bladder problems;

(gg) dry mouth or trouble swallowing;

(hh) dry eye syndrome; or

(ii) extreme mental anguish, stress or depression.

9. In further response to paragraphs 174, 179 and 192 of the Amended Statement of Claim and paragraph 2 of the Plaintiffs' Reply to Demand for Particulars of the Defendants dated November 22, 2002, the MEC Defendants admit that the implantation of breast implants may in some individual instances be associated with scarring, infection, discomfort, firmness of tissue and/or capsular contracture but says that at all material times they appropriately warned physicians, hospitals, medical practitioners, and/or recipients of breast implants of this risk.

10. In further response to paragraph 174 of the Amended Statement of Claim, the MEC Defendants deny that any breast implant or, in the alternative, any breast implant which it designed, developed, manufactured, distributed or marketed, caused or is capable of causing scarred breasts, painful breasts, capsular contracture, or hard, misshapen breasts as elements or symptoms of the alleged "Silicone Syndrome" or other alleged or any systemic disease or condition.

11. In further response to paragraph 2 of the Plaintiffs' Reply to Demand for Particulars of the Defendants dated November 22, 2002, the MEC Defendants deny that silicone gel breast implants or, in the alternative, silicone gel breast implants which it designed, developed, manufactured, distributed or marketed:

(a) rupture at an unreasonable rate;

(b) form capsular contracture at an unreasonable rate;

(c) bleed silicone gel at an unreasonable rate;

(d) become infected at an unreasonable rate;

(e) migrate out of the breast area at an unreasonable rate; and

(f) cause disease as alleged or at all.

12. In further response to paragraphs 169 – 171 and 174 – 176, 183 – 184, 206 and 208 of the Amended Statement of Claim, the MEC Defendants deny that the Plaintiffs Helen Harrington or Betty Gladu suffered the alleged or any damage, loss or expense or, in the alternative, that the alleged or any damage, loss or expense was caused by breast implants.

13. In the alternative, in further response to paragraphs 169 – 171, 174, 181 – 184, 192 – 193 and 208 of the Amended Statement of Claim, the MEC Defendants deny that at any material time they knew or ought to have known that breast implants cause the conditions alleged, which are denied, or do so at the rates alleged, which are also denied.

Alleged Negligence

14. In further response to paragraphs 178 – 179, 183 – 184 and 192 – 193 of the Amended Statement of Claim, the MEC Defendants deny that they owed a duty of care to the Plaintiffs or members of the public who did not receive implants designed, developed, manufactured distributed or marketed by the MEC Defendants.

15. Further, or in the alternative, in further response to paragraphs 178 – 179, 183 – 184 and 192 – 193 of the Amended Statement of Claim, the MEC Defendants state that at all times they used reasonable care in all their activities respecting breast implants, including but not

limited to researching, testing, manufacturing, compounding, assembling, developing, analyzing, recommending, merchandising, advertising, promoting, supplying and/or selling breast implants.

16. In further response to paragraph 179 of the Amended Statement of Claim, the MEC Defendants deny that they or any of their servants or agents was guilty of the alleged or any negligence and specifically denies the following:

(a) that breast implants which they designed or manufactured contained substandard, inappropriate or inadequate materials as alleged in any of subparagraphs 179(a) - (b), in the alternative, that they negligently designed or manufactured implants including such materials;

(b) that breast implants which they designed or manufactured rupture during ordinary usage either generally or as alleged in subparagraph 179(a) or are prone to rupture as alleged in paragraph 192;

(c) that silicone gel from implants which they designed or manufactured bleeds through the envelope during ordinary usage either generally or as alleged in subparagraph 179(b) or is prone to leak as alleged in paragraph 192;

(d) that silicone is toxic in the human body or has toxic effects, inherent dangers, risks or adverse side effects either generally or as alleged in any of subparagraphs 179(c), (d), (m), (p), (r), (t);

(e) in the alternative to subparagraph (d), that the MEC Defendants knew or ought to have known that silicone is toxic in human body. Indeed, it is denied that silicone is in fact toxic;

(f) further, or in the alternative to subparagraphs (d) or (e), that the MEC Defendants negligently designed or manufactured the implants which use silicone in the envelope or as filling;

(g) that breast implants produced by the MEC Defendants were incapable of standing the stress of ordinary or foreseeable usage either generally as alleged in subparagraph 179(f);

(h) in the alternative to subparagraph (h), that the MEC Defendants negligently selected, manufactured or assembled component parts of breast implants either generally or as alleged in subparagraph 179(f);

(i) that filling designed or manufactured by the MEC Defendants, if any, was made with substandard, inappropriate or contaminated materials either generally or as alleged in subparagraph 179(g) or at all or, in the alternative, that any such materials were included negligently;

(j) that the MEC Defendants negligently designed or manufactured breast implants which generally or inevitably cause scarring either generally or as alleged in subparagraph 179(h), although the MEC Defendants admit that in some instances scarring may occur after implantation;

(k) that silicone gel breast implants which the MEC Defendants designed or manufactured interfere with mammography either generally or as alleged in subparagraph 179(i) or, in the alternative, that they designed or manufactured such implants negligently;

(l) that the MEC Defendants failed to employ advanced and/or available design or manufacturing techniques, including any such techniques which may have reduced the likelihood that breast implants would rupture or bleed after implantation either generally or as alleged in subparagraph 179(j), or, in the alternative, that any such failure, which is denied, was negligent;

(m) that the MEC Defendants had a duty to warn the Plaintiffs, their physicians, other medical personnel or the public of any of the matters alleged in subparagraphs 179(k), (l), (n) or (o), paragraphs 192 – 193;

(n) that the MEC Defendants failed to warn if it had a duty to do so of the matters alleged in subparagraphs 179(k), (l), (n) or (o), paragraphs 192 – 193 or at all;

(o) further, or in the alternative to subparagraph (o) insofar as it relates to subparagraph 179(k), that there are complications attendant upon rupture or bleed as alleged in subparagraphs 179(k) or (p) or at all;

(p) further, or in the alternative to subparagraphs (o) and (p) insofar as they relate to subparagraphs 179(k), that the MEC Defendants knew or ought to have known of the alleged or any chances for rupture or bleed or the alleged or any complications;

(q) that the MEC Defendants failed to test breast implants or rushed them to market in the manner alleged in subparagraph 179(p) or at all;

(r) that a significant number of failures or injuries occurred or were caused by implants since breast implants were first manufactured or distributed as alleged in subparagraphs 179(q), (s) or at all, or, in the alternative, that the MEC Defendants knew or ought to have known of the alleged failures or injuries;

(s) that the MEC Defendants had a duty to recall and/or cease the manufacture and distribution of breast implants as alleged in subparagraphs 179(q), (r), (s), (t) or at all; and

(t) in the alternative, that the MEC Defendants continued the design, manufacture or distribution of breast implants after obtaining or after they ought to have obtained the knowledge alleged in any of subparagraphs 179(c), (d), (l), (q), (r), (s) or (t), paragraph 192 or at all.

17. In further response to paragraphs 183 and 184 of the Amended Statement of Claim, the MEC Defendants deny that breast implants necessarily were implanted in class members in the same condition as when they left its control and says that the doctrine of *res ipsa loquitur* does not apply.

18. In further response to paragraph 192 of the Amended Statement of Claim, the MEC Defendants deny that breast implants which it designed, manufactured, marketed or sold were defective.

Alleged Breach of Warranty

19. In further response to paragraphs 180 – 182 of the Amended Statement of Claim, the MEC Defendants did not contract with the Plaintiffs or any other member of the class and state that further to the Order of Mackenzie J. pronounced on April 11, 1996 and February 14, 1997, any claims in contract are not appropriate for class action determination.

20. Further, or in the alternative, in further response to paragraph 181 of the Amended Statement of Claim, the MEC Defendants state that breast implants which they designed, developed, manufactured, distributed, or marketed were reasonably fit for their intended purpose.

21. Further, or in the alternative, in further response to paragraph 182 of the Amended Statement of Claim, the MEC Defendants deny that breast implants which they designed, manufactured or distributed were:

(a) designed, manufactured or distributed in a defective or unsafe condition;

(b) sold or used without further inspection of their condition or, in the alternative, without inspection which would reveal latent defects in the breast implants, which are denied;

(c) not of merchantable quality; or

(d) not fit for a particular purpose.

Alleged Fraud and Misrepresentation

22. In further response to paragraphs 185 – 189 of the Amended Statement of Claim and further to the Order of Mackenzie J. pronounced on April 11, 1996 and February 14, 1997, the claims in fraud and misrepresentation against the Defendants collectively are vague and devoid of the specificity required for those claims to stand. The allegations are frivolous, vexatious and embarrassing and ought to be struck or, alternatively, stayed, pursuant to Rule 19(24)(a) – (c).

General

23. In further response to paragraphs 194 – 195 of the Amended Statement of Claim, the MEC Defendants deny any disregard for the public or the Plaintiffs, as alleged.

24. In the alternative, and in further response to the Amended Statement of Claim as a whole, if any risks of injury or damage were associated with breast implants, which is denied, then class members with full knowledge of the nature and extent of the risk of injury or damage involved voluntarily and freely consented to accept that risk and to waive any claim for injury or damage resulting from the risk.

25. In further response to the Amended Statement of Claim as a whole, the BMS and MEC Defendants plead and rely upon the *Limitation Act*, R.S.B.C. 1996, c. 266, s.3 and any applicable predecessor legislation and amendments thereto. The cause of action, if any, of certain or all members of the class arose more than two years prior to the commencement of these proceedings, and the claim is therefore barred except insofar as the *Limitation Amendment Act*, 1994, S.B.C. 1994, c.8, s.4 applies.

26. Further, and in further response to the Amended Statement of Claim as a whole, the MEC Defendants plead and rely upon the *Negligence Act*, R.S.B.C. 1996, c.333 and any applicable predecessor legislation and amendments thereto.

27. The MEC Defendants further plead the substantive law of each other jurisdiction, including the law of limitations and contributory negligence, applicable to the claims of class members who did not receive their implants in British Columbia and/or to whom the substantive law of British Columbia otherwise does not apply, including but not limited to the *Limitation of Actions Act*, R.S.A. 1980, c. L-15, the *Contributory Negligence Act*, R.S.A. 2000, c. C-27, *The Limitations of Actions Act*, C.C.S.M. c. 150, *The Tortfeasors and Contributory Negligence Act*, C.C.S.M. c. T90 and any applicable predecessor legislation and amendments thereto. Further particulars of this pleading will be provided once the requisite information about class members is made known to the MEC Defendants.

WHEREFORE the Defendants Bristol-Myers Squibb Company, Medical Engineering Corporation, The Cooper Companies, Inc. submit that the Plaintiff's claim should be dismissed with costs to these Defendants.

Dated at Vancouver, British Columbia, on June 6, 2003.

FASKEN MARTINEAU DuMOULIN LLP

Solicitors for the Defendants Bristol-Myers Squibb Company, Medical Engineering Corporation, The Cooper Companies, Inc.

The Solicitors for the Defendants Bristol-Myers Squibb Company, Medical Engineering Corporation, The Cooper Companies, Inc. are Fasken Martineau DuMoulin LLP, whose office address and address for delivery is 2100 - 1075 West Georgia Street, Vancouver, B.C. V6E 3G2 Telephone: (604) 631-3131 Facsimile: (604) 631-3232. (Reference: Andrew D. Borrell/STE12690)