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No. C954330
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:	
HELEN HARRINGTON, as representative Plaintiff	
PLAINTIFF	
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.**	**REASONS FOR JUDGMENT** **OF THE HONOURABLE** **MR. JUSTICE K.C. MACKENZIE**
DEFENDANTS	

Counsel for the Plaintiff: Deborah A. Acheson, Q.C., David Klein, Mark R. Steven, K. Whitley

Counsel for the Defendant, Baxter Healthcare Corporation and

Baxter International Inc.:	Oleh W. Ilnyckyj, Mari A. Worfolk
Counsel for the Defendant, Inamed Corporation and McGhan Medical Corporation:	Bruce E. McLeod
Counsel for the Defendant, Union Carbide Corporation:	Marvin Storrow, Q.C., David Neave
Counsel for the Defendant, Bristol-Myers Squibb Company, Medical Engineering Corporation, The Cooper Companies, Inc.:	W.S. Beradino, Q.C., Allan P. Seckel
Counsel for the Defendant, Minnesota Mining and Manufacturing Company (3M):	J. Kenneth McEwan, Stacey Silber
Counsel for the Defendant, Dow Corning Corporation, Dow Corning Canada Inc., Dow Corning-Wright Corporation:	Derek J. Mullan, Q.C., D. Weinrath
Counsel for the Defendant, The Dow Chemical Company:	Robert G. Ward, Jonathan McLean
Counsel for the Defendant, McGhan Nusil Corporation:	R. Cooper, L. Martz
Place and Date of Hearing:	Vancouver, B.C. March 25-29, 1996

1 The plaintiff Helen Harrington applies for an order under s. 2 of the *Class Proceedings Act*, 1995 SBC c. 21, certifying a class action against certain manufacturers of breast implants and related companies. Ms. Harrington also applies to be designated as representative of the members of the class for the purposes of the litigation. Plaintiff's counsel indicate that nearly 1,000

women in British Columbia and others outside the province have contacted them to be included in the class. Class actions against breast implant manufacturers have been certified elsewhere, including Quebec, Ontario and several U.S. jurisdictions. Some U.S. state courts have refused certification orders.

2 In British Columbia s. 4 of the *Limitation (Amendment) Act*, 1994 S.B.C. c. 8 was passed as companion legislation to the *Class Proceedings Act,* suspending until December 31, 1995 the limitation on breast implant claims. By agreement among the parties to this litigation the suspension was extended to April 30, 1996. The approach of that date lends urgency to this application.

3 The central question on the application is whether there are common issues in this litigation amenable to class action proceedings. Plaintiff's counsel contend that there are common issues and that they can be defined either generally or more specifically. In ***Bendall*** v. ***McGhan Medical Corp. et al.*** (1993), 14 O.R. (3d) 374, Montgomery J. ordered class proceedings setting out 3 common issues; plaintiff's counsel would be content with an order which sets out those issues, with one addition. Alternatively, plaintiff's counsel have submitted a list of 18 questions which attempt to define issues more narrowly.

Defendants' counsel raised a variety of defences to certification. They are united in contending that there are no common issues and a class action should not be certified.

4 Class action and so-called "mass tort" litigation is evolving rapidly. Most of the jurisprudence is in the United States, and Canadian class action legislation borrows heavily from American precedent. The issues involving breast implants must also be viewed in the light of the recent judgment of the Supreme Court of Canada in ***Hollis*** v. ***Birch*** (1996), 2 W.W.R. 77.

5 There are two main elements of the plaintiff's general case against breast implants - their rupture or failure rate, and the alleged link between silicone and connective tissue disease. There are also complaints of local complications, including scar tissue or capsular contraction around the implant and calcification or hardening of the breast.

The Implications of *Hollis* v. *Birch*

6 ***Hollis*** is the first breast implant case to reach the Supreme Court of Canada, and the decision not only provides definitive guidance on important legal principles but it also illustrates the complexity of such cases. The plaintiff was injured by implant rupture from an undetermined cause. At trial, the

defendant Dow Corning was held liable in negligence for the manufacture and distribution of an implant which had an unreasonable risk of rupture, and was therefore defective. On appeal, both the B.C. Court of Appeal and the Supreme Court of Canada rejected liability on that ground but held, alternatively, that Dow Corning was liable for failing to warn the plaintiff that the implants involved a risk of rupture, and consequent injury, from undetermined non-traumatic causes. Thus, a case that was decided at trial to be one of liability for a defective product became, on appeal, a case of failure to warn of an inherent defect. The Supreme Court held that the manufacturer, Dow Corning, had a duty to provide doctors advising patients concerning implants with "clear, complete and current information about the dangers inherent in the ordinary use of their product" (para. 24).

7 Under the learned intermediary rule which the court approved, the manufacturer was entitled to warn the doctor of the risk of rupture without warning the patient directly. The manufacturer was under a duty to warn once it had tangible evidence that there were ruptures from unexplained causes, and before it reached its own definitive conclusions with respect to the cause and effect of the unexplained ruptures. The duty to warn by manufacturers of breast implants and other similar medical products is stringent. In ***Hollis*** the evidence indicated

that the risk of unexplained rupture was less than 1 in 1,000 but adequate warning of the risk to learned intermediaries was, nonetheless, required.

8 Whether the patient would have heeded the warning had it been given is an issue that is subjective and personal to each patient in determining the manufacturer's liability. The Supreme Court approved the test previously accepted by the Ontario Court of Appeal in ***Buchan*** v. ***Ortho Pharmaceutical (Canada) Ltd.*** (1986), 25 D.L.R. (4th) 658. As against the doctor, the test to be applied in determining whether the patient would have heeded the warning is the objective test adopted by the Supreme Court in ***Reibl*** v. ***Hughes*** [1980] 2 S.C.R. 880. In cases which raise a failure to warn issue, the doctor normally will be a key participant, both in terms of evidence as to the warning, if any, that the patient was actually given, and as a potential defendant for failing to discharge an independent duty to warn. It was not necessary for Ms. Hollis to prove that a warning from the manufacturer would have been passed along by the learned intermediary doctor to her in order to succeed against the manufacturer. However, if the learned intermediary had given Ms. Hollis an adequate warning of the risk of unexplained rupture, then presumably there would be no causal nexus between the manufacturer's failure to warn and any injury sustained by Ms. Hollis attendant on an unexplained rupture. Thus the issues will

fall to be decided on evidence specific to each patient's circumstances.

9 There may also be important timing differences between cases. Ms. Hollis received her first breast implants in 1983. The Supreme Court concluded that instances of unexplained rupture first came to Dow Corning's attention about 1977 and similar instances continued to be brought to its attention over the next several years. Dow Corning did not include a warning of a risk of unexplained rupture with its products until 1985. The Supreme Court, upholding the Court of Appeal, concluded that in 1983 when Ms. Hollis received her implants, Dow Corning had sufficient evidence of unexplained rupture to be required to warn. In the case of the particular model of Dow Corning breast implant at issue in ***Hollis***, implants sold and distributed before 1977 would not have required a warning because Dow Corning apparently was unaware of the risk. After 1985, Dow Corning's warning with respect to unexplained rupture was apparently adequate and, therefore, there would be no liability in these circumstances for implants distributed after 1985. At some point between 1977 and 1983, when Ms. Hollis received her implants, Dow Corning received some credible evidence of an increase in risk of unexplained rupture and should have started warning. The precise date by which that warning should have been given may be a critical date for determination of liability in particular cases and it must to

some degree be an arbitrary determination. Should that question be answered in the abstract as a general question, or as it was in ***Hollis*** in the context of the circumstances of a particular plaintiff?

10 The conclusions flowing from ***Hollis*** are that actions against breast implant manufacturers may turn on the issue of failure to warn of inherent risk rather than product defect and that the claims will succeed or fail depending on a number of factors that can be determined only with regard to the particular circumstances of individual claimants. The role of doctors as learned intermediaries will be a factor in virtually every failure to warn case. There will be the question of whether an adequate warning would have been heeded if given, and the Supreme Court has decided that the test is subjective. La Forest J. referred to a category of breast implantees that could be described as "pre-sold" and sufficiently determined on implantation to have not heeded any adequate warning of risk (para. 48). Ms. Hollis did not fall into that category, but others may and the answer will turn on evidence specific to the particular plaintiff. Further, the duty to warn may vary with the risk involved in a particular product and the state of the manufacturer's reasonable knowledge of the risk involved at the particular time a product is distributed and finds its way to each implantee.

The Difference Between This Case and *Hollis*

11 Plaintiff's counsel in their submissions emphasized the problem of implant rupture or leak, but not in ***Hollis*** terms although failure to warn is pleaded. The plaintiff's emphasis here is that the elastomer envelope of most implants will rupture or disintegrate within several years and release silicone gel into the body with attendant consequences. The plaintiff will assert that the implants are generally defective because they will not maintain their structural integrity for the life of the implantee.

Silicone and Connective Tissue Disease

12 The other main assertion is that the silicones contained in breast implants, including the silicone gel filler and the silicone components of the outer shell, are disease causing agents. The shell is in contact with body tissue and all silicone gel filled implants are said to bleed small quantities of silicone into the body even in the absence of a rupture or leak. It will be alleged that the silicone in implants causes a variety of diseases which are loosely referred to as auto-immune or connective tissue diseases.

13 The patient consent form prepared by the Canadian Society of Plastic Surgeons in 1994 described the then state of knowledge with respect to these diseases as follows:

> *Connective tissue disorders:* These are a group of relatively rare disorders in which the body reacts. Some cases of these disorders have been reported in women with breast implants.
>
> These disorders can cause long-term, serious health problems. Symptoms include pain and swelling of joints; tightness, redness or swelling of the skin; swollen glands or lymph nodes; unusual and unexplained fatigue; swelling of the hands and feet; and unusual hair loss.
>
> Some women have reported a reduction in symptoms after their implants were removed. More research needs to be done to determine if women with implants have higher rates of these diseases than women without implants. Due to concern about a possible link between breast implants and connective tissue disorders, manufacturers are sponsoring large-scale scientific studies. Such studies, to be effective and reasonably conclusive, take time and the results are expected no sooner than 1997.

14 There have been a number of scientific studies investigating possible links between breast implants and connective tissue diseases. Most of the studies so far have found no significant link between breast implants and connective tissue diseases. However, the report of a study by Charles H. Hennekens and others in the February 28, 1996, issue of the Journal of the American

Medical Association (JAMA) suggests at least the possibility of an association, although its conclusions are carefully qualified.

15 I asked counsel whether this issue would be limited to a "battle of experts" providing opinions on the proper inference to be drawn as to causation from the various scientific studies. Counsel were essentially agreed that the issue of causation could not be neatly confined to the scientific studies and opinions of epidemiologists. First, while some connective tissue diseases such as rheumatoid arthritis and scleroderma have generally recognized medical definitions, there are others which do not and are referred to as atypical. The Hennekens report explains the problem in these terms:

> It is difficult to study any relation of breast implants with these atypical diseases or syndromes, because currently these conditions possess no validated classification criteria. Investigating subjective symptoms that are largely unverifiable are likely to yield spurious results.

The injury alleged by the plaintiff Helen Harrington falls within this atypical category with her condition being described, inter alia, as silicone syndrome and atypical connective tissue disease.

16 Even if the definitional problem could be overcome, counsel are agreed that evidence as to causation would extend beyond general scientific data to evidence related to individual claimants including pre-existing conditions, genetic and other pre-dispositions, and other potential causes. Counsel for the plaintiff suggested that the issue of causation might be divided, with the scientific data being canvassed first as a general issue and the individual circumstances addressed later. I will return to this suggestion later in these reasons, but it is clear that any ultimate determination of the issue of causation for any particular member of the class will have to consider factors specific to that individual.

17 I should note that virtually all aspects of the plaintiff's theory are disputed by the defendants and the merits of the opposing cases are not before me on this application. It is sufficient that I am satisfied there is some evidence which supports each side and, consequently, there is a triable issue.

American Mass Tort Litigation Experience

18 American courts have been wrestling with the problems of litigating mass tort claims for some time. Recently the United States Court of Appeals for the 6th Circuit in ***Re American Medical Systems Inc.***, 6th Cir. No. 95-3303, February 15, 1996,

granted mandamus to decertify a products liability class proceeding involving penile protheses, reversing the decision of Judge Rubin in the District Court. In so doing, the 6th Circuit commented, "We find that the District judge's total disregard of the requirements of Rule 23 [of the Federal Rules of Civil Procedure] in this case, and his similar rulings in other medical products liability actions, warrant issuance of the writ of mandamus on these extreme and limited facts." (At p. 36). ***Dante***, the breast implant class action certified by Judge Rubin, was one of the other medical liability actions referred to, and criticism of the ***Dante*** certification is thus implied. The 6th Circuit opinion added (at p. 26):

> A single litigation addressing every complication in every model of prosthesis, including changes in design, manufacturing, and representation over the course of twenty-two years, as well as the unique problems of each plaintiff, would present a nearly insurmountable burden on the district court. By contrast, an individual case of this type is relatively simple to litigate if narrowly focused on a claim regarding a specific model, a specific component, or specific statements made to a particular urologist during a particular period of time.

19 Those comments are pertinent here. Not only does this case involve changes in models and variations among the different manufacturers, but there are also varied medical conditions allegedly caused by the implants and individual issues of

causation. Those varied questions realistically cannot be addressed in a single lawsuit. The American experience makes it abundantly clear that neither class actions nor pre-trial co-ordination of multiple individual actions is a panacea for the scale and complexity of mass tort claims. There is no simple, elegant solution.

20 In an asbestos case, in ***Re Fibreboard Corporation,*** 893 F.2d 706 (5th Cir. 1990), the U.S. Court of Appeals for the 5th Circuit rejected certification for trial of issues of causation and damages involving about 3,000 asbestos personal injury plaintiffs through the expedient of trying the causation and damages issues for 41 members of the group and then using those results to determine the remaining cases without further trials. The 5th Circuit concluded:

> This proof for 2,990 class members will be supplied by expert opinion regarding their similarity to 41 representative plaintiffs. Plaintiffs deny that they will be extrapolating a total universe from a sample. While we are skeptical of this assertion, plaintiffs' characterization is of little moment. The inescapable fact is that the individual claims of 2,990 persons will not be presented. Rather, the claim of a unit of 2,990 persons will be presented. Given the unevenness of the individual claims, this Phase II process inevitably restates the dimensions of tort liability. Under the proposed procedure, manufacturers and suppliers are exposed to liability not only in 41 cases actually tried with success to

> the jury, but in 2,990 additional cases whose claims are indexed to those tried.
>
> . . .
>
> Commonality among class members on issues of causation and damages can be achieved only by lifting the description of the claims to a level of generality that tears them from their substantively required moorings to actual causation and discrete injury. Procedures can be devised to implement such generalizations, but not without alteration of substantive principle.

21 At the same time, the 5th Circuit did approve conducting "phase I" of the trial, addressing common defences and punitive damages, as a common trial in the manner ordered by the district court, with evidence restricted to the small sample of plaintiffs. Thus the case supports the proposition that if a threshold issue can be identified which is common to all claims, that issue can be litigated in a class action format, leaving individual issues to be dealt with later in separate trials if necessary, depending on the outcome of the threshold issue.

22 I find support for this approach in the history of proceedings before the judicial panel on multi-district litigation which assigned silicone gel breast implant litigation to Judge Pointer of the U.S. District Court for the Northern District of Alabama: In ***Re Silicone Gel Breast Implants Product Liability Litigation*** 793 F.Supp. 1098 (1992). Judge Pointer was

charged with the responsibility of coordinating the litigation of what has grown to approximately 20,000 separate breast implant cases. In 1994, Judge Pointer certified a class action for settlement purposes only under Federal Rule 23(b)(3). He later approved a settlement referred to as the "Global Settlement".

23 The Global Settlement subsequently collapsed, apparently for two main reasons. Many more women gave notice of intention to participate in the settlement than had been anticipated, and a larger number of women than anticipated invoked the "opt out" provisions of the settlement. Dow Corning's petition for relief under Chapter 11 of the U.S. Bankruptcy Code in 1995 followed the collapse of the Global Settlement.

24 While Judge Pointer was prepared to certify a class action for settlement purposes, he did not certify a class action for litigation purposes and his most recent order dated March 26, 1996, Order No. 30, in ***Re Silicone Gel Breast Implants Product Liability Litigation*** (MDL-926) case No. CV92-P-10000-S, United States District Court, Northern District of Alabama, notes that, "Discoveries should be conducted on the assumption that there may be a separate trial of each case." Judge Pointer's role is to coordinate the pre-trial management of the vast number of cases in the system and it is not clear how the litigation will ultimately proceed. However, it does appear that Judge Pointer

has concluded for pre-trial purposes, in contrast to settlement, the cases raise individual issues that cannot be disposed of by a common issues trial.

The Bankruptcy Proceedings

25 In the Dow Corning bankruptcy proceedings, several manufacturers, including Dow Corning, took the position that there was a "core issue" of whether silicone gel breast implants cause the diseases claimed (see the affidavit of Candace Wall sworn herein March 11, 1996, exhibits K to O inclusive). The District Court in bankruptcy decided that it had jurisdiction over all of the personal injury claims against Dow Corning but it left pre-trial case management with Judge Pointer in Alabama: In ***Re Dow Corning Corp***. 187 B.R. 919 (E.D. Mich. 1995). It reserved to its jurisdiction all trial venue questions and concluded (at p. 929):

> The Court agrees with the finding in *A.H. Robins* that the Bankruptcy Court should first estimate the unliquidated, contingent tort injury claims before a trial is held. As the Claimants argue, the estimation process can be accomplished in a short period of time. The Debtor has the information needed to value the unliquidated tort injury claims.
>
> The Court notes that both the Debtor and the Claimants agreed during oral arguments the one causation trial will not resolve all the issues between the Debtor and the Claimants.

> Issues including individual liability, rupture of implants, mechanical causation, and disfigurement would not be addressed if only one causation trial were held. Further trials will be needed to resolve these issues.

26 Bankruptcy proceedings have their own imperatives relating to the reorganization of the debtor and it is clear that the estimation process contemplated by the court would not determine issues in the tort actions. The conclusion that individual issues are raised is consistent with the conclusions in the other U.S. cases referred to above. The estimation process is important because it will influence assessment of the viability of any reorganization and the availability of assets to satisfy tort claims, but it is not the same process as in adjudication of liability and quantum of those claims in the normal tort process.

Implications of Breast Implant Settlement Agreements

27 I have been referred to several comprehensive settlement agreements or proposals involving various breast implant manufacturers in other jurisdictions. It should be noted first, as defendants' counsel have stressed, that these agreements and proposals from manufacturers all have been advanced with a denial of liability, and the settlement funds, no doubt, not only reflect the calculation of the risk of an adverse finding, but

also the staggering cost of pursuing litigation. Dow Corning's petition for Chapter 11 bankruptcy relief was based on the estimated cost of defending all the lawsuits against it, which threatened to swamp the financial resources of an otherwise viable company. The settlements provide, by agreement, various means of summary adjudication of individual claims in a manner which may be practical and efficient but would not be within the power of a court to order independently. An analogy may be drawn with structured settlements in personal injury cases in this jurisdiction. Parties to a structured settlement may agree to a stream of periodic payments in substitution for a lump sum award of damages in circumstances where the court would have no authority to order anything but a lump sum award following trial, absent agreement of the parties. The settlement agreements to which I have been referred therefore cut both ways. They hold out the hope that multiple breast implant claims can be settled in practical ways, but the manner of disposition involves a summary determination with arbitrary elements that a court could not otherwise impose in place of trial of the issues.

The Efficacy of the *Bendall/Dante* Questions

28 This application comes down to the critical question of whether "the claims of the class members raise common issues,..." as required by s. 4(1)(c) of the *Class Proceedings Act.*

Plaintiff's counsel urge upon me the decision in ***Bendall*** v. ***McGhan Medical Corp.*** (1993), 14 O.R. (3d) 374, as a precedent for certification which I should follow. In one of the first certifications under the Ontario *Class Proceedings Act,* Montgomery J. of the Ontario Court, General Division, followed ***Dante*** v. ***Dow Corning,*** 143 F.R.D. 136 (S.D. Ohio, 1992), which certified a national breast implant class action in the United States. The common issues determined by Montgomery J. were identical to the common issues contained in the order of Judge Rubin in ***Dante*** as follows:

> (A) What information did the Defendants have regarding adverse effects of silicone gel breast implants and when was that knowledge available to them?
>
> (B) Are silicone gel breast implants likely to cause specific medical conditions?
>
> (C) Were adequate notices of either of the foregoing given by the Defendants?

29 Plaintiff's counsel ask that, if I were to follow the common issues stated in ***Bendall*** and ***Dante,*** a fourth common issue should be added as follows:

> Are breast implants fit for their intended purpose?

30 Alternatively, plaintiff's counsel submits a list of 18 more detailed questions as set out in appendix 1 to these Reasons. Question 11 on the detailed list repeats the question counsel proposes to add to the ***Bendall/Dante*** questions.

31 The litigation in ***Bendall*** has not proceeded beyond the certification order. The ***Dante*** litigation does not appear to have moved ahead either. The questions remain untested and I think they require re-evaluation in the light of ***Hollis*** and the more recent American cases **discussed above.**

32 Issue (A) above does not admit of a simple comprehensive answer. The inference from ***Hollis*** is that at some point between 1977 and 1983 Dow Corning had sufficient information about instances of unexplained ruptures of that model of implant that it should have informed patients through their doctors. Information available to other defendant manufacturers and the resulting duty to warn may vary from manufacturer to manufacturer and perhaps from model to model; later models of implants may have reduced incidents of rupture. Other risks imposing a duty to warn, and the warnings given, are likely to vary from manufacturer to manufacturer and model to model.

33 Issue (B) raises problems of definition as well as causation related to "specific medical conditions". As discussed above,

there are apparently a number of atypical connective tissue diseases or syndromes potentially involved as well as more generalized complaints, such as chronic fatigue and chronic pain syndromes, which resist definition. Definitions used for various settlement agreements are practical expedients but would not be adequate for trial purposes. Localized medical conditions can be caused by the rupture of a breast implant, as ***Hollis*** demonstrates, but such complications will also be varied.

34 Issue (C) raises issues both of timeliness and adequacy of notice which are likely to vary from manufacturer to manufacturer, product to product and risk to risk.

35 Thus the three ***Bendall/Dante*** issues inevitably will dissolve into a variety of more specific questions. The answer to each of the questions may be of significance to some members of the class but not to all. With one exception, the 18 questions submitted by plaintiff's counsel as an alternative to the ***Bendall/Dante*** questions also fail the test of commonality. The exception is the same issue which plaintiff's counsel submitted should be added to the ***Bendall/Dante*** issues, were I to certify them. That is, "Are breast implants fit for their intended purpose?"

The Fitness Issue

36 The plaintiff's case is that breast implants are unfit because of their rate of failure, the association of silicone with connective tissue disease, and localised complications. It also has been alleged that breast implants may be a factor in breast cancer, either as a cause of cancer or as an impediment to mammography thereby interfering with the timely diagnosis of breast cancer. Cancer was not stressed in the certification proceedings, and most of the attention was directed to the other categories.

37 It is alleged that breast implants were not properly tested before they were marketed and the variety of health risks they present to women remained undetected or were ignored. Breast implants did not receive any regulatory evaluation or approval in Canada or the United States.

38 On the plaintiff's theory, all women with implants face an unreasonable risk of harm. The question which troubles thousands of women who have silicone gel breast implants is - Are my implants safe? That question extends to the whole range of models of silicone gel breast implants distributed by the various manufacturers.

39 This theory goes far beyond the underpinnings of liability in ***Hollis*** where, following the plaintiff's unfortunate experience

with her first implants, the evidence disclosed that she was re-implanted with a later model of silicone gel filled Dow Corning implants about which there were no complaints. Fitness is not a question that ***Hollis*** addressed comprehensively because that case went forward on limited evidence. The appellate courts rejected the trial judge's conclusion of negligent manufacture on the ground that he misapprehended certain evidence of the relationship between two models of breast implants manufactured by Dow Corning. Neither appellate court explored the issues of negligent manufacture or fitness for the purpose beyond that limited context.

40 Plaintiff's counsel want to attack the fitness of both silicone gel and saline implants. Notwithstanding that saline breast implants contain a silicone in the implant shell, I am not satisfied that the issues of fitness are common to both silicone gel and saline implants. The challenge of addressing the fitness of silicone gel breast implants as a generic issue will be sufficiently formidable without complicating it further by adding saline implants. Saline breast implants are still being routinely implanted into patients. Neither Health and Welfare Canada nor the Food and Drug Administration in the United States have imposed moratoriums on saline implants as they have for silicone gel implants. I am not aware of any class action certification in any other jurisdiction involving saline

implants. The common issue should be limited to breast implants containing silicone gel.

41 I am satisfied that the question: Are silicone gel breast implants reasonably fit for their intended purpose? - raises a threshold issue which is common to all intended members of the class who have been implanted with silicone gel breast implants and to the several manufacturers of such implants. If the plaintiff succeeds on this issue, then it moves the class a long way to a finding of liability. Quantum of damages would still have to be individually assessed but s. 7(a) of the Act makes clear that individual assessment of damages is not a barrier to certification.

42 The common issue of fitness would require that silicone gel breast implants would have to be considered generically as a group, ignoring differences among the particular models of the various manufacturers. In practical terms, the plaintiff would be required to establish unfitness against the model of silicone gel breast implant which has the strongest claim to fitness. Only as against that standard could the issue be said to be common to all manufacturers and all models. Warnings of risk would be irrelevant if no silicone gel filled breast implants should have been manufactured and distributed, and liability would attach to the unfit product.

43 To a degree, the common issue will raise the same medical problems of causation and definition that are contained in more specific questions I have rejected. However, the issue will be raised in the context of an assessment of the overall risk, presumably through expert opinion. This should permit some appraisal of the incidence and severity of atypical conditions which may be caused by the silicones involved without requiring precise definition of atypical conditions. Essentially it is the same risk assessment that a manufacturer ought to undertake before putting the product on the market. The difficulties inherent in the assessment of risk are not an excuse for declining to make such an assessment.

The Class Proceedings Act Requirements

44 The requirements for certification of a class are set out in s. 4 of the Act. Section 4(1) provides as follows:

> **4.** (1) The court must certify a proceeding as a class proceeding on an application under section 2 or 3 if
>
> (a) the pleadings disclose a cause of action,
>
> (b) there is an identifiable class of 2 or more persons,
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members,
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, and
>
> (e) there is a representative plaintiff who
>
> (i) would fairly and adequately represent the interests of the class,
>
> (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
>
> (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

45 I am satisfied that the pleadings disclose a cause of action and there is an identifiable class of 2 or more persons as required in s. 4(1)(a) and (b).

46 Mr. Beradino contended that a common issue can only meet the test of a "common issue" required by s. 4(a)(c) if it is determinative of liability, or provides a ground for some relief. The common issue under consideration in this case would fail such a test because a finding that silicone implants were unfit would still leave open the question of whether the manufacturer was careless in failing to appreciate the risk or adequately test the implants before they were marketed. The evidence and conclusion could vary from manufacturer to manufacturer, model to model, and time to time. Thus an answer favourable to the plaintiff would not lead automatically to relief.

47 The Act defines common issues. Section 1 states:

> **"common issues"** means
>
> (a) common but not necessarily identical issues of fact, or
>
> (b) common but not necessarily identical issues of law that arise from common but not necessarily identical facts;

Under this definition the common issue need only be an issue of fact. Presumably such a factual issue should involve a material fact in the case in order for the finding to advance the proceedings. In addition, the finding would be binding on all members of the class and other parties to the case. But there is nothing in the definition that requires that a common issue of fact be sufficient in itself to support relief, and such a restrictive view of "common issue" could undermine the needed flexibility of class action proceedings. No class action case was cited to me in support of Mr. Beradino's submission. I am satisfied that the common issue set out above meets the test of a common issue as defined in the Act.

48 As a condition of certification, s. 4(1)(d) requires that "a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues". Section 4(2) outlines factors to be considered in that determination as follows:

> **4.** (2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, the court must consider all relevant matters including
>
> (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members,

> (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions,
>
> (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings,
>
> (d) whether other means of resolving the claims are less practical or less efficient, and
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.

The general fitness of silicone gel breast implants is an overriding issue affecting all women with such implants who would constitute the members of the class.

49 Some individuals may have claims which they may wish to pursue based on failure to warn or other grounds that would likely have to be tried separately. ***Hollis*** is an illustration of individual circumstances which may lead to a finding of liability apart from the common issue. Women "who have a valid interest in individually controlling the prosecution of separate actions" may opt out of the class and pursue separate claims, if they are resident in British Columbia, or not opt in if non-resident. There are likely to be a number of opt-out claims separately pursued, involving individual circumstances and larger potential damages. However, I think that is unavoidable. Such claims

should not be forced into a common mold, but neither should they preclude class proceedings by others for whom a class action is the only practical avenue for relief. Class proceedings will still remain the only practical and efficient means of resolution for women whose claims have modest damage potential and for whom separate proceedings would not be feasible. Greater difficulties would be experienced in administering separate proceedings for modest claims unless those claims were simply not pursued at all, which would defeat the whole purpose of class proceedings. For those prospective class members the common issue should be the predominant issue. I am satisfied that the plaintiff meets the standard set by s. 4(1)(c) and (d) of the Act.

50 The claims in conspiracy, fraud, misrepresentation, and joint venture against defendants collectively are vague and devoid of the specificity required for those claims to stand: Rule 19(11) and ***Can-Dive Services Ltd***. v. ***Pacific Coast Energy Corp. (No.2)*** (1993), 96 B.C.L.R. (2d) 156. Any claims in contract are not appropriate for class action determination because they could apply only to a limited number of individuals in special circumstances.

Helen Harrington as Representative of the Class

51 Turning to the requirements of s. 4(1)(e), I am satisfied that Ms. Harrington does not have, on the common issues, an interest which is in conflict with other class members. I find that she will fairly and adequately represent the interests of the class, with one possible qualification. Ms. Harrington does not allege personal experience with breast implants of several manufacturers and some defendants contend that she cannot represent claims against those manufacturers. The primary cause of action to which the common issue relates is negligent manufacture and distribution. Negligence is a cause of action which involves the manufacturers severally and it may be appropriate to divide the class into subclasses by manufacturer, with separate representatives for each subclass. That appears to have been the procedure adopted in ***Bendall***. I will hear further submissions on this aspect of class representation after counsel have had an opportunity to consider their position in the light of the common issue set.

52 The workable plan presented in support of the certification application is sketchy, but I think it is sufficient at this stage of the proceedings when the parties and issues are still being settled.

Claims Against Non-manufacturer Defendants

53 The claims against the defendants Union Carbide and McGhan Nusil rest on the supplying of raw or semi-processed silicone materials to other defendants to be used in the manufacture of breast implants. On the pleadings as they stand, I do not think that limited involvement imposes a duty as manufacturer. There are no particulars of any representations by those defendants associated with the use of their products, usually reprocessed by others, in breast implants. A position as shareholder, even a controlling shareholder, in a manufacturer is an insufficient foundation in itself to impose a manufacturer's duty. Accordingly, the defendants Inamed Corporation, Baxter International Inc., Union Carbide Corp., Union Carbide Chemicals and Plastics Company Inc., and McGhan Nusil Corporation will be excluded from any certification order.

54 The position of the Dow Chemical Company has not been fully argued, in part because of a problem in communication between counsel, and in part because of time constraints at the certification hearing. The status of the Dow Chemical Company with respect to the certification order will therefore have to be reargued.

55 By agreement between counsel, the defendant Mentor Corporation did not participate in the certification application and its status has not been addressed.

56 Issues involving prospective class members not resident in British Columbia also were deferred.

57 I am satisfied that a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issue. With the reservation referred to above, I am satisfied that the plaintiff Helen Harrington would fairly and adequately represent the interests of the class, and that the other requirements of s. 4(1) of the Act have been met.

"K.C. MACKENZIE, J."

Vancouver, B.C.
11 April 1996

Harrington v. Dow Corning et al,

Common Questions:

1. Do silicons or saline breast implants cause systemic disease, including those diseases included in Exhibit E to the "Breast Implant Litigation Settlement Agreement" in MDL 926 attached hereto as Schedule 1.

2. Do breast implants rupture at an unreasonable rate and thereby cause injury?

3. Do breast implants bleed silicone into the body and thereby cause injury?

4. Does silicone migrate in the human body and thereby cause injury?

5. Do breast implants cause capsular contracture at an unreasonable rate?

6. Do breast implants interfere with mammography so as to cause a health hazard?

7. Do polyurethane implants cause systemic disease?

S. Did the Defendants adequately test silicone, breast implant components or breast implants?

9. Were the suppliers of silicone negligent in failing to ensure that their product was safe for human implantation?

10. Did the suppliers of silicone owe a duty to the ultimate user? If so, was that duty breached? If so, did that breach cause harm?

11. What knowledge did the Defendants possess concerning the adverse or harmful effects of silicone, breast implant components or breast implants and when was that knowledge available to each of them?

12. Were breast implants fit for their intended purpose?

13. Was there a continuing duty to warn? If so, were adequate warnings of any of the foregoing given by the Defendants?

14. Did any of the Defendants conspire to sell defective breast implants thereby causing injury?

15. Did any of the Defendants misrepresent the safety of silicone, breast implant components or of breast implants so as to induce the Plaintiffs to use breast implants thereby causing harm?

16. Can a failure to disclose a lack of testing in law amount to an actionable misrepresentation?

17. Did Dow Chemical owe a duty of care to the Plaintiffs? If so, was the duty breached? If so, did the breach cause harm to the plaintiffs?

18. Can saline solution maintain its sterile quality so as to be safe for implantation in the human body?

March 25, 1996