IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
TRIAL DIVISION

Citation: *Doucette v. Eastern Regional Integrated Health Authority* 2007NLTD138
Date: 2007 07 20
Docket: 2006 01T 2966 CP

BETWEEN:

VERNA DOUCETTE

PLAINTIFF

AND:

EASTERN REGIONAL INTERGRATED HEALTH AUTHORITY

DEFENDANT

Before: The Honourable Mr. Justice Carl R. Thompson
Rendered orally on May 28, 2007

Place of hearing:	St. John's, Newfoundland and Labrador
Summary:	This action was certified as a class proceeding.

CLASS ACTION - CERTIFICATION

Appearances:

Chesley F. Crosbie, Q.C.	For the Plaintiff.
Daniel M. Boone and Janie L. Bussey	For the Defendant.

Authorities Cited:

CASES CONSIDERED: Western Canadian Shopping Centre Inc. v. Dutton, [2001] 2 S.C.R. 534; **Wheadon et al v. Bayer Inc**., [2004] N.J. No. 147 SCTD; **Hollick v. City of Toronto**, 2001 3 S.C.R. 158; **McInerney v. MacDonald** 1992 Carswell NB 63 (S.C.C.); **Brenda Rideout v. Health Labrador Corp.**, 2005 NLTD 116; **Ordon Estate v. Grail** (1998) 166 D.L.R. (4th) 193 (S.C.C.); **Hodder et al v. Waddletom and Waddleton's Store Ltd.**, 1993 Carswell Nfld. 373 (SCNL); **Mustapha v. Culligan of Canada Ltd.**, 2006 Carswell Ont. 7937; **Fidler v. Sun Life Assurance Company of Canada**, 2006 SCC 30; **Heward v. Eli Lilly & Co.**, [2007] O.J. 404 (S.C.J.); **Ragoonan v. Imperial Tobacco Inc.**, 2005, 78 O.R. (3d) 98 (S.C.J.); **Rumley v. British Columbia**, [2001] 3 S.C.R. 184; **Cloud v. Canada (Attorney General)**, 2004 Carswell Ont. 5026, Ont. C.A; **Chada v. Bayer Inc.**, 2003 Carswell 49, Ont. C.A.

STATUTES CONSIDERED: *Rules of the Supreme Court, 1986, Class Actions Act*, SNL 2001 c. C-18.1, as amended.

REASONS FOR JUDGMENT

THOMPSON, J. (ORALLY):

Introduction

[1] I want to start where I finished on Friday and that is by thanking counsel for what really were very comprehensive briefs and what were also very helpful and cogent arguments in their oral presentation. Had it not been for both these features, I don't think I would be in a position to be able to provide an oral judgment today.

[2] I had noted to counsel on Friday that I felt it important that all concerned parties know the status of this action as soon as possible. Given the nature of the illness, and that some members of the perspective class may be suffering, I felt that as a early response to this application as was feasible should occur.

[3] I will start with the affidavit of Heather Predham filed in this matter February 9, 2007, in which she deposes through paragraphs 14-23:

> 14. THAT in May 2005 a patient, who has been diagnosed in 2002 with a lobular carcinoma of the breast and had been determined to be negative after ER/PR testing using the DAKO semi-automated system, converted to positive after further ER/PR testing using the Ventana automated platform.
>
> 15. THAT in June of 2005 Eastern Health conducted a case review of negative ER/PR tests that it obtained in 2002. Of the 25 cases retested, 12 converted from negative to positive. An additional 32 negative ER/PR tests were retested in July 2005 and 25 of the 32 cases converted.
>
> 16. THAT in early July 2005 Eastern Health decided to retest all negative ER/PR tests performed between May 1997 and August 8, 2005.
>
> 17. THAT in late July 2005 Eastern Health stopped reporting ER/PR in its laboratory and arranged for an independent, external laboratory to complete the retesting. In August 2005 Mount Sinai Hospital agreed to perform the retesting. All new cases were sent to Mount Sinai for ER/PR testing.
>
> 18. THAT in October 2005 Eastern Health received the first results from Mount Sinai Hospital. A Tumor Board was constituted and was composed of two oncologists, two surgeons, two pathologists, myself as the Quality Initiatives representative and one secretary. Its mandate was to review the results, assess the impact on patients and make treatment recommendations.
>
> 19. THAT in late January 2006 the final samples were forwarded to Mount Sinai Hospital for retesting and the final results were received from Mount Sinai in February, 2006. Between February and May 2006 the Tumour Board continued to review results and make treatment recommendations.

20. THAT Eastern Health reviewed 2760 ER/PR tests conducted between 1997 and August 2005. Of those cases reviewed, 939 of the tests were originally reported as ER-negative. The negative test samples were sent to Mount Sinai Hospital to be retested. Results were obtained and reviewed for 763 patients.

21. THAT of the 763 patients whose samples were retested and results obtained, 433 patients saw no change in their ER/PR results and therefore no change in treatment was recommended. Specifically,

    (a) 341 patients were confirmed negative by Mount Sinai;
    (b) 28 patients were confirmed negative by the Tumor Board;
    (c) 12 patients were confirmed positive; and
    (d) 52 patients were determined to have ductal carcinoma in situ, and therefore no form of treatment would have been recommended.

22. THAT a further 12 patients saw no change in their ER/PR test results but a change in treatment was recommended as the standard for interpretation of what constituted an ER-positive test result had changed between the time of original testing and the Tumor Board's review.

23. THAT the ER/PR test results were different for 317 patients following retesting. Of the 317 patients, 104 patients required a change in treatment. Ninety-six of these patients were recommended for treatment with Tamoxifen or another aromatase inhibitor; 4 of these patients saw a change in their original diagnosis and; and 4 of these patients originally had a degree of ER positivity but were negative on retesting.

[4] I then go to the affidavit of Dr. Charles Hutton which was filed with the interlocutory application and I would reference firstly paragraphs 8-13:

8. The high Estrogens produced by the placenta have a profound effect on the breast. The ducts enlarge and the cells at the end of the ducts begin to sprout glands which will eventually produce breast milk.

9. The ducts not only enlarge, but Estrogen induces the cells at the end of the ducts to sprout buds which after months of high Estrogen levels, will turn into glands. Estrogens also induce Progesterone receptors on the nuclei of the gland cells. This future development and growth of the glands is directly under the influence of Progesterone.

> 10. Collections of glands at the ends of the ducts are known anatomically as lobules. Well over 95% of breast carcinomas are either ductal or lobular in origin. As 90% of the functioning breast is made up of ducts, then as you would expect 90% of breast carcinomas are ductal carcinomas. Lobular carcinomas make up less than 5% of breast cancers.
>
> 11. Also, as one would expect, a high percentage of ductal carcinomas, if they are reasonable differentiated (though malignant, still retain some of the biological activities of the normal ductal cells), will be still under the influence of Estrogens for growth and thus will have Estrogen receptors and be positive for Estrogen receptors on testing. This percentage of positive receptor status will vary from 73% to 100% depending on the histological type of a cancer.

[5] I note in his letter of May 16, 2007, filed by consent, Dr. Hutton revised this frequency to 73% to 78%. He explained at the first and third paragraphs of page 2 of that letter as follows:

> The percentage of Estrogen positivity will fall as you pass through the various histological stages (grades) from differentiated, moderately differentiated to undifferentiated tumors. When you mix, in situ carcinomas, invasive ductal and lobular carcinomas, you would expect that in testing this mix that you would get in the range of 75% positive Estrogen plus or minus a few percentage points if your IHC assay is reasonably sensitive.

[6] Paragraph 3 on page 2:

> The variations in the positivity or negativity is attributed to mixed patient populations, clinical stage, and treatment status. The mean frequency of Estrogen receptor positivity was 75% (73% to 78%). In other words, the literature seems to support that 75% Estrogen positivity would be the standard for sensitivity.

[7] Dr. Hutton appears to be using a cutoff for staining of nuclei for determination of a positive result at 10 percent based upon his knowledge and the

literature then current from 1996 through 1998. I continue with his affidavit, paragraph 12:

> 12. The formation of glands at the end of ducts is a phenomenon of pregnancy or high levels of or prolonged use of Estrogens (contraception or post-menopausal Hormone Replacement Thearpy (HRT). However the use of Estrogens in these situations has not been shown the increase the incidence of lobular cancer, as dosage is minimal. Lobules of glands make up a small percentage of functioning breast tissue and constitute only 3-5% of breast cancer.

[8] At paragraph 15, he deposes in part:

> 15. We know that the cells of the ducts of the breast are completely dependent for growth and development on Estrogens, and by extension so are the malignant cells of the cancerous growth. ...

[9] At paragraph 17, Dr. Hutton identifies:

> 17. Tamoxifen: This drug competed with estrodiol for Estrogen receptors – effectively blocking Estrogen uptake, resulting in slowing cell growth down or in cell death.
>
> 18. Aromatase Inhibitors: This enzyme converts testosterone to estrone and estrodiol – blocking this enzyme with inhibitors effectively stops the production of Estrogens – no Estrogens, no cell growth.

[10] I understand this enzyme is used after insufficient result with the use of Tomoxifen as the enzyme aromatase inhibitor is more profound in its effect on the female body.

[11] Paragraph 22-24, to conclude with my reference to his affidavit:

22. We start with the formalin fixed paraffin sections as selected by the pathologist with normal tissue (control) and tumor. In order to prepare the tissue for the machine that will detect and stain in ER/PR receptor sites, we have to do two things:
    (a) remove the paraffin (de-wax);

    (b) reverse the formalin fixation which had bound proteins together (cross linkage).

23. This calls for exquisite timing, temperature control and pH values. Two methods are used, water baths and microwave use. The procedure should be done by a dedicated and experienced technologist. The process is called antigen retrieval. The antigen is actually the receptor site on the nucleus of the cell which has been neutralized by the formalin fixation.

24. Studies done on inter-laboratory differences in test results have identified this part of the procedure as the Achilles heel of the ER/PR identification procedure, in that human error is a factor. Once you give the specimen to the machine, the manufacturer can guarantee a reproducibility within a small percentage (allowable limit of error 0-5%).

[12] I will then go to the affidavit of Dr. Allan Gowan filed February 27, 2007, in which he deposes, and I quote paragraphs 22-24:

22. THAT there are several factors which might explain the number of false negative cases tested between 1999 and 2004. Some, all or none of these factors may have contributed to each individual false negative result. Further, some of these factors may have been present in individual tests that were properly determined to be ER-positive. In fact, it is possible that some of these factors may have been present where false negative results were determined but the factor or combination of factors that caused the particular false negative result to occur may vary among individuals. Therefore, an examination of each individual's testing is required to determine what caused each false negative result.

23. THAT the factors referred to in paragraph 20 include, but are not limited to:

    (a) Nature of biopsy – needle core vs. resected tumor;
    (b) Interval between tissue removal and immersion into fixative

(c) Nature of fixative (E.G., composition, PH, ect.);
(d) Duration of fixation;
(e) Tissue processing;
(f) Epitope retrieval – method of heat delivery (e.g., water bath vs. microwave vs. steamer);
(g) Epitope retrieval – buffer employed;
(h) Epitope retrieval – duration;
(i) Epitope retrieval – cooldown time;
(j) Choice of primary antibody;
(k) Length of antibody incubation;
(l) Detection system;
(m) Chromogen;
(n) Nuclear counterstaining intensity (if strong can mask weak immunostaining);
(o) Pathologists assessment of percentage of immunostained nuclei; and,
(p) Cuttoff for positivity.

24. THAT based on my experience with breast cancer ER and PR testing, I would say that, with respect to the ER and PR IHC performed at St. John's Regional Hospital from 1997 to the current time, the quality of the pathologists, the quality of the technical support, and the overall quality of the immunostains employed, are all within the range of what would be found in the vast majority of comparable laboratories in North America today. However, that is not to say that optimal ER and PR IHC is being performed in all these laboratories; indeed, I would not doubt that retesting of any North American laboratory's ER IHC would result in the detection of a significant number of "false negative" tests, especially if different primary antibodies, tissue pretreatments and interpretation rules were to be employed.

[13] The parties confirm their understanding to be that the cutoff for staining of nuclei for determination of a positive ER receptor result to have been 30% from 1997 to 2000 and then 10% from 2000 onwards. I noted from Ms. Predham's affidavit filed February 9, 2007 at paragraph 13, that the Ventana system was installed in April 2004.

[14] To assist is explaining this aspect of the testing process which is completed after antigen retrieval by the laboratory technologists who apparently are employees of the defendant, in his affidavit filed with the interlocutory application, Dr. Hutton deposes at paragraphs 26-28 as follows:

> 26. The next step is the interpretation of the amount (number of nuclei staining) and the intensity of staining by the pathologist. This has a subjective element. The amount of staining is based on the number of nuclei staining per 100 cells (1/100-1%, 10/100-10% etc.), a form of proportion scoring.
>
> 27. The intensity of staining varies from negative through weak to strong. There is no problem with a high nuclear staining with strong intensity and completely negative results, but in between there is only 60% agreement by pathologists. This of course is based on the assumption that the antigen retrieval procedure has been correctly performed and the automatic processor is working. The pathologist can only read what he sees under the microscope.
>
> 28. In 2000, the National Institute of Health (NIH) consensus statement on adjuvant therapy for breast cancer recommended that any staining be considered positive and that anti-Estrogen therapy be instituted (Tamoxifen or Aromatase Inhibitors).

[15] That ends my second reference to his affidavit. This part of the test then to which Dr. Hutton has referred is apparently completed by the pathologist. The plaintiff is not, in this action, pursing any pathologist but only the alleged corporate liability of the defendant for alleged failures it proposes to have probably occurred in the antigen retrieval segment of the testing process.

[16] Based upon the results of testing confirmed by Heather Predham in her answer to interrogatories, paragraph 3, sworn May 10, 2007, Dr. Hutton at page 2 of his letter of May 16, 2007, filed by consent, states in the last paragraph, that is the 4th paragraph on page 2.

The performance of the Eastern Health Board laboratory as supplied by Ms. Predham show the following:

Dako system	Total Tests	Pos.%	Neg.%
May 1997 to December 31	137	58	42
January 1, 1998 to December 31	147	48	52
January 1, 1999 to December 31	360	68	32
January 1, 2000 to December 31	370	54	46
January 1, 2001 to December 31	374	60	40
January 1, 2002 to December 31	344	58	42
January 1, 2003 to December 31	373	76	24
January 1, 2004 to April	109	85	15
Total	**2214**	**62.8%**	**37.2%**
Ventana system			
April 2004 to December 31	381	90	10
January 1, 2005 to July 31	114	84	16
Totals	**495**	**87%**	**13%**

[17] The plaintiff's position is that the evidence is that the antigen retrieval process for comparative purposes with Mount Sinai is fixed in that the same patient tissue is retrieved for both the defendant's testing and the Mount Sinai testing. Consequently, the process leading up to the antigen retrieval, for purposes of proof, are not relevant to the proof the plaintiff needs for the common issue which I will have to consider shortly.

[18] The plaintiff has advanced evidence on a preliminary basis which it alleges will confirm that, on the balance of probabilities, the original testing has, in common, scientifically identified deficiencies in the laboratory antigen retrieval which serve to damage the tissue making the testing incapable of proper accuracy.

[19] The plaintiff proposes that this was all within the control of the defendant's technicians. It proposes that the results in the second half of 1997 disclosed only 58% ER/PR receptor positivity; 48% in 1998; 68% in 1999; 54% in 2000; 60% in 2001 and 58% in 2002, and that at the relevant time this should have alerted the

defendant to the plaintiff's suggested conclusion that these results were falling far below the expected stand and median of 75% as proposed in Dr. Hutton's evidence.

Class Defined

[20] The plaintiff has revised the class definition and it may be found as set out in the plaintiff's reply brief, page 4, paragraph 9:

> (a) Patients including their estates who underwent ER (estrogen) and PR (progesterone) receptor tests in which their breast tissue samples were tested at the defendant's hospital during the Class period; and
>
> (b) Persons who have a claim for loss of consortium and loss of guidance, care and companionship on account of a relationship with a person in paragraph (a).
>
> The Class is restricted to residents of Newfoundland and Labrador.
>
> The "Class Period" is defined as: May 1, 1997 to August 8, 2005, or such other dates as may be approved by the court.

[21] In her letter of answer to interrogatories sworn May 10, 2007, Heather Predham deposes at paragraphs 4 and 5 as follows:

> 4. *As to paragraph 21, of the 330 (763 less 433) false negatives found on retesting by Mount Sinai, how many occurred while the Dako system was in use?*

Answer: My affidavit dated the 9th day of February 2007 reviewed test results from the perspective of treatment change rather than a change in test results. Of the 330 remaining patients calculated by question #4, a further 13 patients of the 330 patients calculated did not see a change in their test results but a change in treatment was recommended as the standard interpretation of what constituted an ER-positive result had changed between the time of the original testing and the Tumour Board's review. Of the remaining 317 patients, whose test results were different on retesting at Mount Sinai, a further 4 had a change in their diagnosis and another 4 saw their test results change from positive to negative. Therefore, there were 309 patients whose test results were different on retesting at Mount Sinai and 306 of those patients' original test results were obtained using the Dako system.

5. *As to paragraph 25, what criteria were used in the selection of the 101 patient samples for restesting?*

Answer: The 101 patients referred to in paragraph 25 of my Affidavit were not "selected" for retesting. A decision was made by an Ethics Committee during the retesting process that no further tissue samples for deceased patients would be sent for retesting unless a request was made by the deceased patient's family. At the time, 101 of the 176 deceased patients' tissue samples had been retested a further 2 were retested upon request.

[22] In his letter of May 16, 2007, filed by consent, Dr. Hutton states at page 3:

From May 1997 to December 31, 2002, a period of 5 years 8 months, the average percentage of positivity was **58.5%** (range 48 to 68%). Including the year 2003 and three months of 2004, the overall average of positivity for the period in which the Dako system was in use, was 62.8% (range 48% to 85%). See the tables compiled from the recent Answers to Interrogatories at Schedule A.

Further information provided by Ms. Predham states that of the 309 cases which were retested at Ms. Sinai and found to be false negative, 306 of these cases were originally tested under the Dako system. Further, an additional 105 of the 176 deceased patients were retested at Mt. Sinai and 36 or 34% were false negative.
If we take 34% of the remaining 71 that were not retested, then we get an additional 24 false negatives.

306 false negative confirmed by Mt. Sinai

36	false negative of 105 deceased patients confirmed by Mt. Sinai
24	false negatives of 71 deceased patients (not retested but calculated at 34%
366	**total false negatives**

As it is admitted that these false negatives occurred while the Dako system was in use then the following summary can be made:

2214	tests on Dako system
1390	tests were positive (62.8%)
824	were negative (37.2%)
458	confirmed negative by Mt. Sinai
366	were false negative (44.7% false negatives of 824 cases)
16.6%	overall percentage total false negatives/total tests

Improper preservation and fixation of the breast specimen has been identified as a cause of false negatives and undoubtedly, contained within the 458 negatives confirmed by Mt. Sinai, is an unknown number or percentage of false negatives which can be added to the 366 confirmed false negatives.

[23] The plaintiff then notes that there are three categories of patients as potential class members:

1) Those allegedly suffering mental distress or nervous shock upon learning that there was a retesting ongoing and who fell within the testing period;
2) Those who allegedly did not receive anti-hormone therapy and had some delay;
3) Those who allegedly had received chemotherapy unnecessarily.

[24] The plaintiff alleges that her circumstances are representative of each of these three categories.

Purpose of the Class Action

[25] **Western Canadian Shopping Centre Inc. v. Dutton**, [2001] 2 S.C.R. 534, dealt with the purpose of class actions in which Chief Justice MaLachlin stated at paragraphs 26-29:

> 26. The class action plays an important role in today's world. The rise of mass production, the diversification of corporate ownership, the advent of the mega-corporation, and the recognition of environmental wrongs have all contributed to its [page549] growth. A faulty product may be sold to numerous consumers. Corporate mismanagement may bring loss to a large number of shareholders. Discriminatory policies may affect entire categories of employees. Environmental pollution may have consequences for citizens all over the country. Conflicts like these pit a large group of complainants against the alleged wrongdoer. Sometimes, the complainants are identically situated vis-à-vis the defendants. In other cases, an important aspect of their claim is common to all complainants. The class action offers a means of efficiently resolving such disputes in a manner that is fair to all parties.
>
> 27. Class actions offer three important advantages over a multiplicity of individual suits. First, by aggregating similar individual actions, class actions serve judicial economy by avoiding unnecessary duplication in fact-finding and legal analysis. The efficiencies thus generated free judicial resources that can be directed at resolving other conflicts, and can also reduce the costs of litigation both for plaintiffs (who can share litigation costs) and for defendants (who need litigate the disputed issue only once, rather than numerous times): see W. K. Branch, Class Actions in Canada (1998), at para. 3.30; M. A. Eizenga, M. J. Peerless and C. M. Wright, Class Actions Law and Practice (1999), at para. 1.6; Bankier, supra, at pp. 230-31; Ontario Law Reform Commission, Report on Class Actions (1982), at pp. 118-19.
>
> 28. Second, by allowing fixed litigation costs to be divided over a large number of plaintiffs, class actions improve access to justice by making economical the prosecution of claims that would otherwise be too costly to prosecute individually. Without class actions, the doors of justice remain closed to some plaintiffs, however strong their legal claims. Sharing costs ensures that injuries are not left unremedied: see Branch, supra, at para. 3.40; Eizenga, Peerless and Wright, supra, at para. 1.7; [page550] Bankier, supra, at pp. 231-32; Ontario Law Reform Commission, supra, at pp. 119-22.
>
> 29. Third, class actions serve efficiency and justice by ensuring that actual and potential wrongdoers do not ignore their obligations to the public. Without class actions, those who cause widespread but individually minimal harm might not take into account the full costs of their conduct, because for any one plaintiff the

> expense of bringing suit would far exceed the likely recovery. Cost-sharing decreases the expense of pursuing legal recourse and accordingly deters potential defendants who might otherwise assume that minor wrongs would not result in litigation: see "Developments in the Law -- The Paths of Civil Litigation: IV. Class Action Reform: An Assessment of Recent Judicial Decisions and Legislative Initiatives" (2000), 113 Harv. L. Rev. 1806, at pp. 1809-10; see Branch, supra, at para. 3.50; Eizenga, Peerless and Wright, supra, at para. 1.8; Bankier, supra, at p. 232; Ontario Law Reform Commission, supra, at pp. 11 and 140-46.

[26] I would also note under the heading of "Purpose of Class Actions" *Rule 7A.01, subs. 4*, which supplements the purpose of the *Class Actions Act*. It states:

> (4) The rules of court, including Rule 7A, and the procedures to be followed with respect to class proceedings shall be interpreted and applied to achieve the objects of the Act, and in particular
>
> (a) to promote the effective and economical use of the judicial system;
>
> (b) to make the court system more accessible to the public; and
>
> (c) to ensure that parties responding to a class proceeding are able to present their case fairly to the court.

[27] With respect to the applicable provisions of the *Class Actions Act*, I reference the following:

> 5. (1) On an application made under section 3 or 4 , the court shall certify an action as a class action where
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> (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 a common issue, whether or not the common issue is the dominant issue;

(d) a class action is the preferable procedure to resolve the common issues of the class; and

(e) there is a person who

(i) is able to fairly and adequately represent the interests of the class,

(ii) has produced a plan for the action that sets out a workable method of advancing the action on behalf of the class and of notifying class members of the action, and

(iii) does not have, on the common issues, an interest that is in conflict with the interests of the other class members.

(2) In determining whether a class action would be the preferable procedure for the fair and efficient resolution of the common issues, the court may consider all relevant matters including whether

(a) questions of fact or law common to the members of the class predominate over questions affecting only individual members;

(b) a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;

(c) the class action would involve claims that are or have been the subject of another action;

(d) other means of resolving the claims are less practical or less efficient; and

(e) the administration of the class action would create greater difficulties than those likely to be experienced if relief were sought by other means.

6(2) An order certifying an action as a class action is not a determination of the merits of the action.

8. The court shall not refuse to certify an action as a class action solely for one or more of the following grounds:

(a) the relief claimed includes a claim for damages that would require individual assessment after determination of the common issues;

(b) the relief claimed relates to separate contracts involving different class members;

(c) different remedies are sought for different class members;

(d) the number of class members or the identity of each class member is not determined or may not be determined; or

(e) the class includes a subclass whose members have claims that raise common issues not shared by all class members.

[28] With respect to the evidentiary threshold in these cases, I would note the decision in this Court in **Wheadon et al v. Bayer Inc**., [2004] N.J. No. 147 SCTD, a decision of Barry, J., as he then was, where he stated at paragraph 91:

> I agree with the Plaintiffs that this test establishes a "low threshold" for class certification. This was confirmed in Hollick where the Chief Justice noted the evidentiary threshold is not an onerous one Canadian courts have tended to give class proceedings legislation a large and liberal interpretation to insure that its policy goals are realized. Courts must be mindful not to impose undue technical requirements on plaintiffs.

[29] At paragraph 92 in part:

> Class certification is not a trial. It is not a summary judgment motion. Class certification is a procedural motion which concerns the form of an action, not its merits. Contentious factual and legal issues between the parties cannot be resolved on a class certification motion. …

[30] I will then refer to the case referenced by Justice Barry, in **Wheadon**, namely **Hollick v. City of Toronto**, 2001 3 S.C.R. 158, in which Madam Justice

McLachlin again dealt with the evidentiary threshold and stated at paragraph 25 in part:

> … In my view, the class representative must show some basis in fact for each of the certification requirements set out in s. 5 of the Act, other than the requirement that the pleadings disclose a cause of action. That latter requirement is of course governed by the rule that a pleading should not be struck for failure to disclose a cause of action unless it is "plain and obvious" that no claim exists: see Branch, supra, at para. 4.60.

Disclosure of Cause of Action

(1) Negligence, breach of contract and loss of consortium

[31] The defendant acknowledges that the statement of claim adequately pleads a cause of action in negligence and for breach of contract (for those whose tests were false negatives, converted). It also acknowledges that family members may have a claim for loss of consortium, but that such is an individual claim.

[32] At this stage of the proceedings, s. 5(1)(a) is limited to a determination of only of whether the pleadings disclose a cause of action. On the pleadings on this stage, I cannot conclude that it is plain and obvious that the representative plaintiff’s claim for loss of consortium will fail. The plaintiff has established a basis in fact for this cause of action.

(2) Breach of Fiduciary Duty

[33] The defendant argues that the relationship between a hospital and a patient is not fiduciary in that the hospital board is not in a position of power as regards the patient. I note the case of **McInerney v. MacDonald** 1992 Carswell NB 63 (S.C.C.) at paragraph 20 and 21, La Forest, J. stated:

> 20 In characterizing the physician-patient relationship as "fiduciary", I would not wish it to be thought that a fixed set of rules and principles apply in all circumstances or to all obligations arising out of the doctor-patient relationship. As I noted in Canson Enterprises Ltd. v. Boughton & Co., [1991] 3 S.C.R. 534, not all fiduciary relationships and not all fiduciary obligations are the same; these are shaped by the demands of the situation. A relationship may properly be described as "fiduciary" for some purposes, but not for others. That being said, certain duties do arise from the special relationship of trust and confidence between doctor and patient. Among these are the duty of the doctor to act with utmost good faith and loyalty, and to hold information received from or about a patient in confidence. (Picard, supra, at pp. 3 and 8; Ellis, supra, at pp. 10-1 and 10-12, and Hopper, supra, at pp. 73-74.) When a patient releases personal information in the context of the doctor-patient relationship, he or she does so with the legitimate expectation that these duties will be respected.
>
> 21. The physician-patient relationship also gives rise to the physician's duty to make proper disclosure of information to the patient; see Reibl v. Hughes, [1980] 2 S.C.R. 880 …

[34] Given these comments of Justice La Forest, fiduciary relationships are shaped by the demands of the situation and the presence of potential for trust and confidence in which a dominant status of the hospital might reasonably be argued as being fiduciary and, given there is no definitive statement of law specific to the non-existence of such a relationship, this issue, I feel, is best deferred for adjudication on the facts as they might give rise to this claim. I cannot safely conclude, at this time, that it is plain and obvious that the claim for breach of fiduciary duty will fail. As well, the plaintiff has established a basis in fact for this cause of action.

[35] The statement of claim pleads at 19(f) an alleged failure of the defendant to inform patients of the change in their testing in a timely manner. I note that

Russell, J. of this court in **Rideout v. Health Labrador Corp.**, 2005 NLTD 116, at paragraphs 66-67 was unable to conclude at that early stage that it was plain and obvious that the claim for breach of fiduciary duty had failed.

(3) Loss of Guidance, Care and Companionship

[36] I adopt the statements of Russell, J. of this Court in **Rideout, supra** at paragraphs 88-96 and in his consideration of **Ordon Estate v. Grail** (1998) 166 D.L.R. (4th) 193 (S.C.C.), I conclude that it is not plain and obvious that this claim would fail. I am satisfied that the plaintiff has established a basis in fact for this cause of action. I conclude the proposed cause of action meets the requirement of s. 5(1)(a) of the *Class Actions Act*. However, as the defence properly notes, these actions are derivative of the family members whose causes of action are being submitted for certification. The defendant acknowledges in argument that it accepts the approach taken in **Rideout** at this stage.

(4) Mental Distress/Nervous Shock

[37] The defendant argues that there is no cause of action for mental distress available in this jurisdiction. The defendant also argues that any claim for nervous shock will require evidence of psychiatric harm that is foreseeable in a person of normal fortitude and sensibility with reference to **Hodder et al v. Waddletom and Waddleton's Store Ltd.**, 1993 Carswell Nfld. 373 (SCNL). The defendant notes in this latter regard that individual proof will be required.

[38] The defendant notes that the basis for the decision to advance the claim for mental distress/nervous shock in **Rideout, supra** no longer is present in that the Ontario Court of Appeal had now concluded that the test continues to require the element of identifiable psychiatric harm with reference to **Mustapha v. Culligan of Canada Ltd.**, 2006 Carswell Ont. 7937 at paragraph 30, (Ont. CA).

[39] Given the changes in the development in psychiatry as to what constitutes an illness, patients and or their family members might successfully allege that these alleged circumstances so contributed to result in psychiatric illness. The state of the law in this province and in others, at present requires, as a threshold issue, that persons so alleging be taken to have reasonable fortitude and robustness.

[40] I note, in particular, **Mustapha** and paragraphs 30-35 as follows:

> 30 In Vanek, supra, at para. 25, MacPherson J.A. accepted this proposition and summarized the general law respecting liability in cases of psychiatric harm in the following fashion:
>
> > In Canadian law, a plaintiff can recover for the negligent infliction of psychiatric damage if he or she establishes two propositions - first, that the psychiatric damage suffered was a foreseeable consequence of the negligent conduct; second, that the psychiatric damage was so serious that it resulted in a recognizable psychiatric illness: see Linden, Canadian Tort Law, supra, at pp. 389-92.
>
> 31 Foreseeable consequences, however, as noted in Vanek at para. 45, are consequences that the "event and its aftermath might engender in the reasonable person." [Emphasis in original.] At para. 58, MacPherson J.A. adopted the following passage from the speech of Lord Griffiths in White, supra, at pp. 462-463, as "a particularly succinct and useful statement on the foreseeability issue in this type of case":
>
> > There is a further requirement in the bystander case and that is that psychiatric injury was reasonably foreseeable as a likely consequence of exposure to the trauma of the accident or its immediate aftermath. The law expects reasonable fortitude and robustness of its citizens and will not impose liability for the exceptional frailty of certain individuals. This is not to be confused with the "eggshell skull" situation, where as a result of a breach of duty the damage inflicted proves to be more serious than expected. It is a threshold test of breach of duty; before a defendant will be held in breach of duty to a bystander he must have exposed them to a situation in which it is reasonably foreseeable that a person of reasonable robustness and fortitude would be likely to suffer psychiatric injury. [Emphasis added.]

32 Vanek is close to the case at bar in a factual sense, although it is clearly a "bystander" case. Mr. and Mrs. Vanek's eleven-year old child drank a small amount from a juice bottle containing toxic fluids at school. She noticed the drink had a foul taste and regurgitated some of it, although she did not vomit or lose consciousness. The parents were called to the school, and took the child to the hospital. At the hospital, the child was examined and the parents were assured that she had not been poisoned and would suffer no long-term effects. The parents subsequently received the same assurances from different government and health authorities. The child showed no further symptoms from the incident and returned to her normal life. The parents, however, became obsessed with the possibility that the child might suffer harm in the future. They sued the distributor of the drink and its manufacturer. At trial, they recovered moderate damages for anxiety and distress.

33 The judgment was reversed on appeal. Writing for the Court, MacPherson J.A. concluded that the parents' reaction to what was, in effect, a minor mishap of the type that frequently occurs in schools and in family life, was not that of an average concerned parent. He further found that the defendants could not have reasonably foreseen the parents' highly unusual reaction and the psychiatric damages engendered by it. After noting the passage from the speech of Lord Griffiths in White, cited above, and observing that the actual event witnessed by the Vaneks was neither "distressing in the extreme" (McLoughlin, supra) nor "horrifying or gruesome" (Haliburton Estate, supra) - the same may be said in the case at bar - MacPherson J.A. determined as follows at para. 60:

> In conclusion, the juice incident on June 16, 1993 was the type of incident that happens, in schools and in family life, every day. A minor mishap occurs ... Life goes on. Unfortunately, for the Vaneks normal life did not go on. They became obsessed with the incident. In doing so, they were not acting like the average concerned parent. They were displaying a "particular hypersensitivity" (Duwyn v. Kaprielian); they lacked the "reasonable fortitude and robustness" (White v. Chief Constable of South Yorkshire [Police]) that the law expects of all its citizens, including concerned parents.

34 Why should the same principles not apply to the claim of Mr. Mustapha? Mr. Pape says: because Mr. Mustapha was not a bystander but a primary participant and this rendered reasonable foreseeability of psychiatric harm unnecessary. He submits that it was reasonably foreseeable that a

> purchaser or consumer of Culligan water would be injured in some fashion if Culligan distributed contaminated bottled water, and that this foreseeability is sufficient for the purpose of Mr. Mustapha's claim.

35 I do not accept that argument.

[41] Given the continued challenges to judicial development of expected responses to changing social and community mores, I would not at this stage be satisfied that it is clear and obvious that a court could not respond to a review of this threshold requirement for persons and their families who, by their facing exceptional crises in health and longevity would be taken by the health care provider as foreseeable persons who might so suffer and, as such, exempt from the robust threshold generally acceptable in everyday life. Should that threshold be considered for judicial review, the plaintiff has by her affidavit and exhibits presented sufficient evidence of fact to support such a claim, given that the evidentiary threshold is low at this stage. I will comment on this evidentiary base again briefly when I deal with the identifiable class issue shortly.

[42] The plaintiff has claimed for mental stress arising from breach of contract on the basis of peace of mind being an implied term. Neither of the parties advances any authority in respect to this claim. On its face this is not of the kind of claim for mental distress for breach of contract that promises pleasure, relaxation or peace of mind as recently considered by the Supreme Court of Canada in **Fidler v. Sun Life Assurance Company of Canada**, 2006 SCC 30.

[43] However, for the same reasons I have noted, I cannot conclude that it is plain and obvious that a court would not give consideration to a claim of implied contractual peace of mind in reliance upon a standard of care for provision of medical services in these circumstances as allegedly presented.

[44] I am of the view that these prospective class members should not be precluded from advancing a new factual and or novel argument that may find justification for consideration at law.

[45] At this stage I cannot conclude that it is plain and obvious that this cause of action for mental distress on these two bases will fail.

Identifiable Class of Two or More Persons

[46] The defendant agues that, as to the second class, the determination of membership in the claims for loss of consortium and loss of guidance, care and companionship offends against the requirement that class membership be capable of objective determination prior to a finding on the merits. While the defendant may have modified its position in oral argument under this identifiability requirement, the identification of these persons flows logically for families whose members have been identified under the first part of the description of the class. This objection I would view as premature to the determination of the identifiable members in the first class. I note as well that, by virtue of s. 8(d) of the *Class Actions Act*, refusal for certification is not permitted solely for the reasons that the identity of each class member is not determined or may not be determinable. As noted in **Heward v. Eli Lilly & Co.**, [2007] O.J. 404 (S.C.J.) paragraph 76, this objection may in fact beg the question of the merits issue, assuming certification is granted.

[47] As to the first class, the defendant argues it is too broad in that there is no single common issue which the members share. It argues there are persons whose ER/PR values changed on retesting and whose treatments were changed, those

whose values changed and yet had received the hormone therapy in any event, and those whose values had not changed.

[48] The defendant argues that, for those prospective plaintiffs whose test results did not convert to ER/PR positivity after retesting, they have no claim. This is an alternative argument to the defendant's position that they have no cause of action for mental stress/nervous shock in that if they have such a claim, they are not identified by the plaintiff. In this regard the defendant argues that there must be factual support to identify the existence of these persons. In this regard the defendant refers to **Hollock, supra**, paragraph 25. The defendant also refers to **Wheadon, supra**, paragraph 10, in which affidavits confirming ingestion of the medication were filed by two persons.

[49] In my view, common sense has to notice that the presence of test results equates with the existence of a persons. The absence of a named person at this stage does not preclude the persons' existences in the proposed class of persons who may have suffered mental stress/nervous shock. In any event, I note that Ms. Doucette, in her affidavit has made reference to other persons of the class having concern for not knowing their status and, as an officer of the court, plaintiff's counsel had noted the recent Hansard public record by which such concerned persons have identified themselves to legislative members.

[50] I note again that s. 8(d) of the *Class Actions Act* precludes refusal of certification on the grounds that, at this stage, the identity of the class member has not been determined or may not be determined.

[51] If then it was concluded that there was a common issue, on its face there is identified a significant number whose issue could be significantly advanced if certified after all criteria for certification are assessed. At this stage to disallow for lack of mere precise identification would, in my view, be a disservice to the policy of the legislation. As well I note that in **Ragoonan v. Imperial Tobacco Inc.**, 2005, 78 O.R. (3d) 98 (S.C.J.); **Heward v. Eli Lilly & Co., supra**, paragraph 27-

70; and **Hollick, supra** at paragraph 21, there is a tolerance for over-inclusion of persons.

[52] In my view, in this case, the disadvantage of the potential inclusion of persons who may subsequently be determined not to be members is outweighed by the reality of the presence of a significant number of persons who could be included in the class. As well, their exclusion at this stage would preclude the availability of the claim for mental distress. For those subsequently determined as non-inclusive, upon that occurrence, the defendant may well have a resolution of that issue for them. For the others the defendant has the benefit of a consolidated identified group.

[53] In my view, the defendant's argument that, for those whose tests did not convert, they have no claim, begs the question as to who in the class allegedly received wrong tests. In my view, the *Class Actions Act* by its policy and provisions tolerates this deficiency. I conclude the proposed action meets the requirements of s. 5(1)(b) of the *Class Actions Act*. The plaintiff has established a basis in fact for the identity and identification of class members.

Common Issue

[54] The plaintiff's allegation, incorporating a proposed common issue, is that the defendant had sufficient information in the test results on an annual basis to recognize that the results were falling below a normal range of ER/PR positive testing and that the statistics should have required an earlier response.

[55] Within that allegation is contained the alleged probability that the antigen retrieval component performed by the laboratory technician was improperly completed.

[56] The defendant admits to the issue of whether or not it owed a duty. The defendant argues that the issue of whether it breached that duty and if so when and how it was breached, cannot be resolved or materially advanced due to the diversity of the claims to be advanced by each potential member. It argues that proceeding on one common issue will not avoid the requirement to enter into duplication of findings of fact and legal analysis.

[57] In **Wheadon, supra**, Barry, J., as he then was, noted that the determination of common issue is not a determination of liability. Rather the court looks to determine if there is present a common issue which, if decided at trial in a class action, would advance the litigation for the members in some meaningful way.

[58] I would note that the alleged errors are pleaded to have been detected upon retesting of the same tissue samples at Mount Sinai Hospital as were previously tested by the defendant. The plaintiff argues that any prior testing deficiencies impacting on the outcome by other health care parties other than the defendant prior to delivery to the defendant would not have been the source of the alleged difference noted in the Mount Sinai testing results, both testing having been done on the same tissue samples. The comparative testing of both the defendant and Mount Sinai are apparently within the control of each respectively from the outset of the antigen retrieval process.

[59] The defendant's position is that an assessment of whether the defendant has breached the duty of care cannot be completed without examining each patient's testing procedure to determine if the false negative result, which if it has now been concluded as converting to positive, fell below the standard of care of similarly situation hospitals. It is the defendant's position that there is no generic causal link between those individual tests and the breach of duty.

[60] That position effectively states the common issue in this case. It is a determination of whether the defendant has had in place a standard of testing that fell below the acceptable standard resulting in a breach of duty.

[61] As noted in **Hollick, supra**, at paragraph 19, the question is whether the putative class member has some aspect of the issue of liability in common and whether, in that context, there is a rational connection between the class as defined and the asserted common issue.

[62] Here the plaintiff points to a specific period of time when testing specific to all members of the first group of the proposed class took place. As well it points to a decision by the defendant to retest. The plaintiff then alleges that the retesting discloses variances evidencing differences in result which themselves combines to support a rational or logical basis to conclude, on the balance of probabilities, the defendant, for that original testing, did not meet an acceptable standard.

[63] The defendant challenges the sufficiency of the evidentiary base upon which the plaintiff alleges the existence of a common issue for resolution.

[64] The defendant points to the cases of **Rumley v. British Columbia**, [2001] 3 S.C.R. 184 at paragraph 29 and **Cloud v. Canada (Attorney General)**, 2004 Carswell Ont. 5026, Ont. C.A., at paragraph 69 in which systemic child abuse was alleged in residential schools. It was concluded that the individual characteristics of proof of abuse were not suitable to a common issue resolution as individual proof in each plaintiff's claim was necessary.

[65] The defendant also points to the case of **Chada v. Bayer Inc.**, 2003 Carswell 49, Ont. C.A., at paragraphs 30 and 52. In that case expert evidence was to be proffered to prove a common effect on the proposed plaintiffs in the price fixing allegation against the defendant. The court concluded that the proposed expert evidence made an assumption of necessary fact and did not provide the methodology for proof.

[66] The defendant argues that even if the antigen retrieval is found to be the cause, there are, within the antigen retrieval processes, occurrences of false

negative results as an unavoidable feature of the test. It points to this being acknowledged by Dr. Hutton and in particular in his cross-examination on his affidavit. In my view, in that cross-examination, Dr. Hutton does acknowledge false negatives but it would appear that he does so with reference to the pre-analytical stage and there as being small in number and that, in the post-analytical stage, these false negatives could be identified as either pathologists' errors and obvious as such or as a result of the specimen being associated with the wrong patient (i.e. a "mix-up").

[67] In the context of Dr. Hutton's admitted post-analytical pathology error, I note that the plaintiff does not claim for liability in this proceeding against the pathologist and it appears such errors are, on Dr. Hutton's evidence, apparent for identification as I have just noted. I reference his deposition of cross-examination, pages 138, 140 and 157 given April 23, 2007.

[68] The defendant further argues that, based on the evidence of Dr. Gowan, the reason for the discrepancy can be due to any number of factors and that each test would have to be reviewed individually in order to determine a cause. The defendant understands Dr. Gowan's evidence to be that it is possible in all events to determine the reasons for the variance in comparative results within the components of the testing process.

[69] The plaintiff's allegation is directed to a failure in the antigen retrieval part of the test. The defendant agrees that it is possible to determine the reason for the discrepancy in all aspects of the testing process.

[70] If the reason is determinable, then it is reasonable to conclude that if antigen retrieval is the reason, it is scientifically identifiable and confirmable.

[71] It may be the defendant is correct in that other causes other than antigen retrieval may be determined. That, of course, would be a merit argued issue.

[72] It would appear that if the source of the alleged error is antigen retrieval, the plaintiff, with that determined, would have proven that common issue. Conversely, if not proven the common issue is resolved for the benefit of the defendant.

[73] The defendant also suggests that in the antigen retrieval process itself there may be variations of what occurred. The plaintiff has proposed expert evidence which supports there being a commonality of fact. The Plaintiff alleges antigen retrieval is a probable cause of the original test error. The plaintiff has proposed evidence of error common to the class. The plaintiff has proposed evidence that, if such was the error, it was within the defendant's control. Even if, within antigen retrieval, variations may be determined, on the evidence before me, I cannot be satisfied at this stage that such a variation would outweigh the plaintiff's burden of proof.

[74] The plaintiff has shown it has evidence to confirm that testing errors occurred for a significant number in the class that a standard of positive ER/PR percentage exists and that, in the years of the class period, the defendant's tests fell below that standard. The plaintiff chose to name only the corporate defendant as responsible. The plaintiff chose to propose the probable cause of the error to be the antigen retrieval part of the test. The plaintiff advanced expert evidence to confirm that such conclusion can be supported.

[75] In my view, the plaintiff has presented evidence, which on the balance of probabilities, discloses evidence which demonstrates an ability to lead evidence which supports the plaintiff's theory that for the class period the standard of care was deficient and that the antigen retrieval was a reason. As well, if the plaintiff chose to advance it in its assessment of its obligation to meet the required standard of proof on the common issue, then, on the balance of probabilities on the information made available in this application, scientific proof of the cause of the defect in the testing process in any one or more cases is also available.

[76] Consequently, the plaintiff has succeeded in establishing on balance of probabilities that it has a basis in fact for proof of the common issue and there exists a methodology by which the plaintiff can pursue that proof.

[77] I recognize as well that the issue of causation and damages will remain to be resolved. This again, as noted by Barry, J. in **Wheadon**, paragraphs 134 and 135, is an acceptable outcome.

[78] The resolution of whether there was a duty of care and, if so, whether it was breached, as directed specifically to the antigen retrieval of the potential plaintiffs' tests will not have to involve their participation in the evidentiary process to resolve that common issue. In saying this, I recognize that the plaintiff may choose to pursue testing analysis in some specific cases. Even then the plaintiff's participation would appear limited as the issue appears limited to the testing process.

[79] I note as well that variation over time in the standard of care is also an acceptable deficiency.

[80] I conclude that the common issue is suitable for certification.

Preferable Procedure

[81] The *Class Actions Act*, s. 5(1)(d) requires that the plaintiff demonstrate that a class action is the preferable method to resolve the common issue of the class. This involves a consideration of the extent to which the proposed proceeding will achieve the goals of the *Class Actions Act*, namely, judicial economy, access to justice and behaviour modification.

[82] Section 5(2) of the *Act* confirms that, in determining whether a class action would be the preferable procedure for the fair and efficient resolution of the common issues, the court may consider all relevant matters including those enumerated in subs. 5(2)(a) through (e).

(1) Judicial Economy

[83] The defendant argues that, while it has yet to consider its position on third party joinder, in view of having to entertain the defence of one plaintiff only at this stage, the possibility exists, that, because the testing has components entirely within the control and expertise of the pathologists, notably in the cutoff for staining of nuclei for positive results and for assessment of apparent error in the review of the antigen retrieval process on viewing a slide presented, pathologists may have to be joined. The defendant says this will depend on the assessment of each stage of each individual test.

[84] I cannot accept at this stage that potential for third party joinder should impair access to the class procedure. The narrowly proposed focus on liability on the common issue is the alleged corporate liability arising from the antigen retrieval process. Should the plaintiff make out the common issue on that basis, it appears, on the face of the present application, that the pathologists may have limited involvement. The defendant has intimated it may have supervision issues to address in respect of pathologists and the defendant's technicians, but again the narrow point of the plaintiff's allegation on the common issue may well result in a concurrent common supervisory issue for the defendant in that third party claim, if made.

[85] The defendant's position is that, even where the cause of the false result is determined, the liability inquiry will not be complete even if it is concluded that the defendant's failure caused the wrong result and the defendant had not met the applicable standard of care. In that event, however, in my view, the litigation has been significantly advanced. I have already considered the significant potential for

advancement of the litigation in the common issue discussion going to liability. On balance, it appears that the resolution of the common issue would advance the litigation one way or another and the judicial economy is at present a reasonable expectation of that process. Again, it is within the policy of the *Class Actions Act* that final liability may not be achieved in the resolution of the common issue. It would appear that the resolution of the common issue, however, significantly advances the liability for the class and for the defendant. Duplication of multiple claims and hearings on a significant issue are potentially avoided.

[86] The defence notes that the majority of the class as presented involves claims for mental distress which will likely not exceed $5,000 and that their presence will impair access to justice for the remainder of the proposed class. At this stage, I cannot accept that a reasonable program for their assessment post-common-issue-resolution, if then required, cannot be developed so as not to impair the ability of the class and the defendant to pursue a conclusion of all issues.

(2) Access to Justice

[87] It is reasonable to take into consideration that a proportion of the potential class members have been ill, others continue to be ill and others face the real prospect of shorter life expectancy. Expediency of resolution and the common support of the members of the class make the prospect of litigation on a combined basis a more favourable prospect and, reasonably, would provide for a more acceptable vehicle by which to access justice.

[88] The cost of the medical expertise necessary for resolution of the common issue has to be very significantly reduced. Its repetition for each case might weigh against the access to the courts for some as it may be for many of the class members.

(3) Behaviour Modification

[89] The defence argues that behaviour modification is not an appropriate consideration for this defendant. It notes that it took the initiative to review these tests, stopped testing completely in August 2005; completed external and internal reviews; established a separate IHC laboratory with dedicated pathologists handling breast tissue; implemented an external quality assurance program in the IHC laboratory; purchased a newer version of the Ventana system and has taken initiative to revise a national IHC program offering its laboratory as the lead laboratory.

[90] I recognize as quite acceptable that this defendant would have as its goal and policy the best heath delivery for its patients. Professional and ethical standards themselves provide confidence that the best standards available will be advanced by the defendant.

[91] At the same time in a publicly funded system of delivery of health care, the availability of funds to secure those standards and provisions for care must always be measured. It is reasonable to consider that, if the measure of standards are to be impacted by the measure of resources then, by these patients having combined capacity to advance their claim, if legitimate, that combined advancement may result in financial consequences for the defendant. Consequently, measurement for the defendant and similar prospective defendants of the resources to support the standard may take into consideration the measurement of the loss consequent upon a failure to have in place a comparative acceptable standard or a failure to meet it.

[92] I hasten to add that, at this stage, no conclusion of merits are made by me and no judgment or criticism of the defendant is being proposed. Behaviour medication, as an element of preferable procedure consideration, simply requires that I assess this issue.

S. 5(2)

[93] While I realize that the preferable procedure test has a somewhat low threshold as it is presented in the context of the preferable procedure for resolution of the "common issue" and not the "whole controversy", I recognize that the question of preferability must take into account the importance of the common issue in relation to the claim as a whole. I note in this regard the direction in **Hollock** at paragraph 30. In doing so I will follow the guideline provided by s. 5(2) of the *Act.*

S. 5(2)(a)

[94] The resolution of the common issue in an assessment of the existence of a duty of care, its breach, when and how, through a determination of the existence of a standard of care and a determination of the allegation of a deficiency in the antigen retrieval process, has the reasonable prospect of being determinative of whether or not this cause of action will fail or succeed. While it is not necessarily to be resolved simply, due to its technical features, it is focused, it is common and, upon disposition, will have significantly advanced the litigation in one direction or another. Other issues may follow from it if it is successful; litigation may well immediately end for some or all; or litigation may leave the parties well advanced in that a major aspect of liability has been concluded. At this stage the issue can reasonably be taken to predominate all others, given the significance of the outcome for the cause of action and the other issues. I note in this regard that it need not have to predominate. In **Wheadon**, paragraph 143, Barry, J. as he then was, was satisfied that the common issues were not negligible in relation to the individual ones.

S. 5(2)(b) and (c)

[95] In respect of the stipulated considerations of s. 5(2)(b) and (c), I cannot conclude that significant class members have an interest in individual control; nor have persons come forward in this regard. There is no evidence that this action includes claims subject of other actions; the only indication to date is that one or

maybe two claims would be present and these would, at this stage, be subsumed by agreement.

S. 5(2)(d) and (e)

[96] As to subsection 5(2)(d) and (e), again the burden of proof for individual actions with the presently known identity requirements and the number of persons involved, makes it reasonable to conclude at this stage that existing means for resolution of private rights and remedies are less practical and efficient. Equally, the class administration should facilitate the claims process.

Litigation Plan, s. 5(1)(e)

[97] A Litigation plan has been produced. The defence argues that claims of many individuals cannot be resolved by panels of experts as section 27(1)(b) of the *Act* only permits such as an inquiry and these persons cannot adjudicate the parties rights and remedies. As well it notes that a quick review of medical charts for mental distress is not likely as individual inquiry will be necessary. The defence argues that case management in individual actions is more appropriate.

[98] I accept this criticism. At this stage the litigation plan is a preliminary projection and will be adjusted. It is not defective at this stage. I cannot accept that a reasoned, logical and efficient plan cannot be developed in preparation for, and after determination of issues, rights and remedies, if then necessary

[99] With respect to section 5(1)(e) of the *Act* it is not in issue that Ms. Doucette is representative of the class. Her interest in not in conflict with the interest of any other class members.

Order

[100] Accordingly, for the reasons that I have just outlined, an order will issue under section 9(1) of the *Class Actions Act*:

1) certifying this action as a class action;

2) describing as a class those persons described in the amendment of the plaintiff in its reply brief as follows:

(a) Patients, including their estates, who underwent ER (estrogen and PR (progesterone) receptor tests in which their breast tissue samples were tested at the Defendant's hospital during the Class Period; and

(b) Persons who have a claim for loss of consortium and loss of guidance, care and companionship on account of a relationship with a person in paragraph (a).

The Class is restricted to residents of Newfoundland and Labrador

The "Class Period" is defined as: May 1, 1997 to August 8, 2005, or such other dates as may be approved by the court.

3) appointing Verna Doucette as the representative plaintiff of the class;

4) stating the nature of the claims represented of the class to be negligence, breach of contract, breach of fiduciary duty, loss of guidance, care and companionship, loss of consortium, mental distress and nervous shock; and mental distress following from breach of contract;

5) stating the relief to be:

a) all issues of the plaintiff's claims in liability against the defendant, and,

b) all issues of damages as a consequence thereof.

6) stating the common issues to be:

a) did the defendant owe a duty and if so,

b) did the defendant breach that duty and if so when and how?;

7) staying all actions related to this class action until further order of this court;

8) leave is given to the parties to conclude the form and content of the notice of certification and the opting out procedures upon application.

Carl R. Thompson
Justice