

2006 01T 2966CP

IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
TRIAL DIVISION

BETWEEN

VERNA DOUCETTE

PLAINTIFF

AND:

**EASTERN REGIONAL INTEGRATED
HEALTH AUTHORITY**

DEFENDANT

Brought under the *Class Actions Act*, SNL 2001. c. C-18.1

STATEMENT OF DEFENCE

1. With respect to paragraph 1 of the Statement of Claim, the Defendant admits that the Plaintiff was born and resides as stated therein. As to the balance of paragraph 1, the Defendant states that, by an Order dated the 28th day of May, 2007, Mr. Justice Thompson, *inter alia*, certified the within action as a class action and appointed Verna Doucette as the representative plaintiff of the class.
2. With respect to the remainder of the Statement of Claim, the Defendant denies all the facts and allegations asserted therein except where expressly admitted.
3. As to paragraph 2 of the Statement of Claim, the Defendant admits that it was constituted as stated therein, to manage and control the operation of several facilities including the General Hospital, Health Sciences Centre, St. John's. With respect to the balance of paragraph 2 of the Statement of Claim, the Defendant admits that it was responsible for the management and control of its employees including some members of the laboratory staff. The Defendant denies that it is liable, vicariously or otherwise, for the acts of independent contractors, including salaried physicians who practice at the Defendant's facilities on a fee for service basis.

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4. With respect to paragraph 3 of the Statement of Claim, the Defendant admits that patients diagnosed with certain types of breast cancers often receive what are referred to as hormone receptor tests. The Defendant further states that patients diagnosed with ductal carcinoma in situ (“DCIS”) are not usually administered hormone receptor tests.
5. As to the balance of paragraph 3, the Defendant states that a hormone receptor test is a lab test used to determine whether a particular patient’s cancer cells have estrogen (“ER”) or progesterone (“PR”) receptors. Cancers that are either ER or PR positive may need ER or PR to grow and the result of this test, along with other factors, may affect how the patient’s cancer is treated.
6. The Defendant admits paragraph 4 of the Statement of Claim.
7. With respect to paragraph 5 of the Statement of Claim, the Defendant admits that Tamoxifen is taken orally. As to the balance of paragraph 5, the Defendant denies that Tamoxifen is solely adjuvant therapy following primary treatment after diagnosis of breast cancer.
8. The Defendant admits paragraphs 6 and 7 of the Statement of Claim.
9. The Defendant denies the allegations outlined in paragraph 8 of the Statement of Claim and holds the Plaintiff to the proof of those allegations.
10. With respect to paragraph 9 of the Statement of Claim, the Defendant states that a change in test results occurred for an individual patient originally tested using the Dako system whose tissue sample was retested on the Ventana system. The patient’s tissue sample was retested following a request by her treating oncologist at the suggestion of physicians in the United States with whom the treating physician had consulted. The physicians had questioned the patient’s hormone receptor test results given the type of breast cancer with which she had been diagnosed. As a result of the change in the test result for this particular patient, oncologists were asked to identify patients whose tissue samples would be retested on the Ventana system. The Defendant admits that some of the retested patients’ hormone receptor tests changed from clinically negative to clinically positive.

11. With respect to paragraph 10 of the Statement of Claim, the Defendant admits that it retested all of the “clinically negative” hormone receptor tests conducted at its facility using immunohistochemical techniques during the period 1997 to August 2005. During the retesting process a test was considered to be “clinically negative” without reference to the patient’s complete medical file and solely on the basis of the staining of ER receptors as recorded in each patient’s original pathology report. If an original test conducted from 1997-2001 stained positive for ER receptors at approximately 30% or less, then it was considered clinically negative. If an original test conducted from 2001-2005 stained positive for ER receptors at approximately 10% or less, then it was considered clinically negative. For the purpose of identifying patients whose tissue samples would be retested, no reference was made to the staining of PR receptors in determining whether a patient’s original hormone receptor test was “clinically negative”.

The rationale behind choosing these stringent standards in determining whether an original test was “clinically negative” was to identify as many patients as possible who might have been deemed by their original treating physicians as having had a negative hormone receptor test and who might receive some benefit from receipt of the drug Tamoxifen. A “Tumour Panel” was formed, which consisted of a group of pathologists and oncologists who were to review the re-test results and determine whether a change in treatment was warranted without regard to why a change in test results occurred. The Defendant states that it was not obligated to re-test the patient tissue samples and that the decision to retest all “clinically negative” samples went beyond the standard of care expected of the organization.

The Defendant admits that it halted testing at its facility in August 2005 and sent specimens for retesting/testing to Mount Sinai in Toronto. The Defendant denies that the retesting showed an “error rate” of at least 10-20% and holds the Plaintiff to the proof of those allegations.

12. The Defendant denies that it “decided not to advise patients or the public of the retesting” and holds the Plaintiff to the proof of those allegations. The Defendant states that, in the circumstances of this case, it had no legal obligation to advise anyone, other than patients, of the changes in test results and, in particular, that it had no legal obligation to

advise the public of changes in test results. The Defendant further states that for those patients whose tissue samples were retested in July-September 2005, it immediately advised individual patients of their retest results as soon as the results were received. By September 2005, once enough information was gathered to inform patients of the situation and it appeared that conversions in test results might not be explained solely on the basis of the change in technology from the Dako system to the Ventana system, the Defendant decided that, in addition to the direct patient contact, the organization would make a public disclosure. The media, having learned of the retesting from patients already directly contacted by the Defendant, reported on the retesting despite requests by medical professionals that the Defendant be given an opportunity to contact patients directly. The Defendant holds the Plaintiff to the proof of the balance of paragraph 11 and states that any alleged consternation or distress relating to the timing of the disclosure was beyond its control.

13. With respect to paragraph 12 of the Statement of Claim, the Defendant states that the allegations contained therein relate to the issue of diagnosis of cancer and not hormone receptor testing; therefore, the women and their families described therein are not members of the class. The Defendant therefore requests that paragraph 12 of the within Statement of Claim be struck pursuant to Rule 14.24 of the *Rules of the Supreme Court, 1986*.
14. The Defendant admits paragraphs 13 and 14 of the Statement of Claim.
15. With respect to paragraph 15 of the Statement of Claim, the Defendant states that it has no knowledge of the allegations asserted therein and holds the Plaintiff to the proof of those allegations.
16. The Defendant admits paragraph 16 of the Statement of Claim.
17. With respect to paragraph 17 of the Statement of Claim, the Defendant states that it has no knowledge of the allegations asserted therein and holds the Plaintiff to the proof of those allegations.
18. With respect to paragraph 18 of the Statement of Claim, the Defendant states as follows:

- The Plaintiff would have received chemotherapy even if her original hormone receptor test had been determined to be “clinically positive”. The Defendant states that chemotherapy was not used as an alternative to treatment with Tamoxifen.
- The Defendant further states that the Plaintiff’s original hormone receptor test conducted in 2002 was hormone receptor positive. The original test was interpreted by the pathologist to demonstrate 8% staining for progesterone receptors. The decision whether to treat with Tamoxifen falls within the decision making scope of the treating oncologist or surgeon on the basis of each patient’s clinical profile. A patient’s clinical profile will include many factors including the hormone receptor test result.
- The Defendant holds the Plaintiff to the proof of the balance of paragraph 18.

19. The Defendant denies paragraphs 19 and 20 of the within Statement of Claim and holds the Plaintiff to the proof of those allegations. In particular, the Defendant states that:

- it provided adequate supervision of technical personnel during the over thirty step process involved in the testing of breast tissue hormone receptors;
- technical staff and technicians were properly and adequately trained to perform their jobs;
- appropriate quality assurance was in place to control the quality of the stain by the use of external/technical and internal controls. If either the internal or external/technical control failed, then the interpreting pathologist could request that the test be repeated. Therefore, the Defendant states that appropriate controls were in place for quality assurance during the period of 1997 to 2005;
- pathologists were appropriately qualified to interpret hormone receptor test slides; and
- the Defendant informed patients regarding “any change” in their test results in a timely and appropriate manner.

20. The Defendant denies paragraph 21 of the Statement of Claim. In particular, the Defendant denies that it had a contractual relationship with the Plaintiff. In the alternative, the Defendant denies any alleged breach of such a contract and states that if its relationship with the Plaintiff and other patients is deemed contractual in nature, then the essence of such a contract is the provision of health care. Such a contract is not a peace of mind contract as that term is defined in law. Finally, the Defendant states as follows:

- it employed properly trained and supervised personnel in the testing process;
- it had in place testing controls to ensure the quality of stains; and
- medical staff were properly trained and qualified to perform assigned work.

21. The Defendant denies paragraphs 22 and 23 of the Statement of Claim and, in particular, that an implied term of the alleged contractual relationship required the Defendant to advise patients that their tissue samples were being retested, and holds the Plaintiff to the proof of those allegations. The Defendant further states that once patients' retest results were received, a group of specialists, including oncologists and pathologists, met to determine whether a treatment change was warranted in any particular case.

22. With respect to paragraph 23 of the Statement of Claim, the Defendant states that a claim for mental distress cannot be validly founded in either tort, contract or otherwise.

23. With respect to paragraph 24 of the Statement of Claim, the Defendant denies that it violated any duties of disclosure of a fiduciary nature to the Plaintiff or other patients.

24. The Defendant denies paragraphs 25 and 26 of the Statement of Claim and holds the Plaintiff to the proof of those allegations

25. The Defendant states that, as to the whole of the Statement of Claim, the Support Services, Supplies, Facilities, Systems and care provided by the Hospital's agents or employees to the Plaintiff were at all times in accordance with the appropriate standard of care for hospitals similarly situated within the Province of Newfoundland and Labrador, the Country of Canada and as hospitals similarly situated in other developed countries.

28. The Defendant therefore requests:

- (a) dismissal of the within action; and
- (b) such further and other relief as this Honourable Court deems mete and just.

DATED AT St. John's, in the Province of Newfoundland and Labrador, this 7th day of December, 2007.



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