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Re: 2005 01 T. 9400
In the Supreme Court of Newfoundland and Labrador, Trial Division
Michelle B. Hanlon v. Eastern Regional Integrated Health Authority

Message: We attach herewith a copy of the Statement of Defence filed on your behalf with the Supreme Court of Newfoundland and Labrador on May 12, 2006

Janie L. Bussey

2005 01T 9400

IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR
TRIAL DIVISION

BETWEEN

MICHELLE B. HANLON

PLAINTIFF

AND:

**EASTERN REGIONAL INTEGRATED
HEALTH AUTHORITY**

DEFENDANT

STATEMENT OF DEFENCE

1. The Defendant admits paragraphs 1, 2, and 4 of the within Statement of Claim.
2. As to the remainder of the Statement of Claim, the Defendant denies all the facts and allegations asserted therein except where expressly admitted.
3. With respect to paragraph 3 of the within Statement of Claim, the Defendant admits that, at all material times, the Defendant's laboratory was solely and exclusively responsible for the immunohistochemical testing of the Plaintiff's malignant breast tumour, for, *inter alia*, the presence (or absence) of estrogen (ER) and progesterone (PR) receptors. The Defendant denies the balance of paragraph 3.
4. The Defendant states that on or about February 18, 2000, the Plaintiff reported to the Hospital (as defined in paragraph 2 of the within Statement of Claim) with pain and swelling of the left arm pit with no known injury. Breast examination at that time revealed three potential breast lumps. Anaprox was prescribed and a follow-up appointment with Dr. Kwan was booked.
5. The Plaintiff was assessed by Dr. Kwan in the Surgery Clinic on March 3, 2000. In a clinic note dated March 17, 2000, Dr. Kwan noted that the referral was the result of a lump in the axilla measuring about 3 x 3 cm in size, very dense in the inferior quadrant of

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the left breast with a smaller mass in the upper quadrant of the left breast. A biopsy was arranged.

6. In a clinic note dated March 31, 2000, Dr. Kwan notes having seen the Plaintiff in surgery clinic on March 24, 2000 for follow up of three breast lumps found in February 2000. The lump in her axilla, which had been painful, subsequently decreased in size although it was still palpable. A second lump in the upper left quadrant of her left breast was again identified. A third lump on the inferior margin of her left breast was considered to be of concern to the Radiologist on mammogram and it was recommended that a biopsy be performed.
7. The Defendant admits paragraph 5 of the within Statement of Claim and adds that the carcinoma was identified as positive for EMA and negative for leukocyte common antigen which stains strongly for the inflammatory component raising the question of whether the Plaintiff suffered from an inflammatory carcinoma. It was also noted that there was infiltration by malignancy in the adipose tissue.
8. The Defendant admits paragraph 6 of the within Statement of Claim.
9. The Defendant admits paragraph 7 of the within Statement of Claim and adds that the lymph node measured 3x2 cm in diameter.
10. The Defendant admits paragraph 8 of the within Statement of Claim and adds that the Plaintiff's Discharge Summary Pathology Report confirmed carcinoma of the breast with extensive axillary metastases. The final surgical report noted extensive metastatic infiltrating ductal carcinoma in the group of matted axillary lymph nodes.
11. The Defendant has no direct knowledge of the statements contained in paragraphs 9, 10, 11, 12 and 13.
12. The Defendant admits paragraph 14 of the within Statement of Claim and states that the CT scan of May 1, 2001, confirmed the presence of a 1.8 cm soft tissue mass on the Plaintiff's left lung. A biopsy revealed a lobulated slightly irregular soft tissue mass to the anterior aspect of the 1st rib. A fine needle biopsy aspiration was performed on or

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about June 7, 2001 which identified poorly differentiated metastatic carcinoma of the left lung from the Plaintiff's prior breast carcinoma.

13. The Defendant has no direct knowledge of the statements contained in paragraph 15 of the within Statement of Claim.
14. With respect to paragraphs 16 and 17 of the within Statement of Claim, the Defendant has no direct knowledge of the statements contained therein.
15. With respect to paragraph 18 of the within Statement of Claim, the Defendant states that on March 31, 2003, during a follow-up investigation, it was determined that cancerous lesions had reappeared on the Plaintiff's lungs.
16. The Defendant has no direct knowledge of the statements contained in paragraphs 19 and 20 of the within Statement of Claim.
17. The Defendant admits paragraph 21 of the within Statement of Claim.
18. The Defendant has no direct knowledge of the statements contained in paragraphs 22 and 23 of the within Statement of Claim.
19. The Defendant admits paragraph 24 of the within Statement of Claim but notes that antibody PGR1294 was the cocktail used in the LSAB procedure rather than TBA 250/CB11.
20. The Defendant has no direct knowledge of the statements contained in paragraph 25 of the within Statement of Claim.
21. The Defendant admits paragraph 26 of the within Statement of Claim.
22. With respect to paragraph 27 of the within Statement of Claim, the Defendant admits that it was solely responsible for overseeing and managing the operation of the Hospital's laboratory but states that the Plaintiff will be required to prove the particular responsibilities and standards listed in paragraphs (a) through (g).
23. With respect to paragraph 28 of the within Statement of Claim, the Defendant admits that it is vicariously liable for the actions or omissions of laboratory staff who are either

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employees, agents, servants or personnel of the Hospital and who are carrying out work at the Hospital's laboratory. However, the Defendant denies that it is vicariously liable for the acts or omissions of salaried pathologists as the Defendant was not responsible for either the standard or conduct of their respective practices.

24. The Defendant denies paragraph 29 of the within Statement of Claim.
25. As to paragraph 30 of the within Statement of Claim, the Plaintiff denies that it was negligent as alleged therein or at all and states that:
 - (a) As for the particulars of negligence set forward in paragraph 30(a), the Defendant denies that it erroneously and negligently concluded that the Plaintiff's breast cancer tumour cells were negative for ER/PR receptors.
 - (b) As for the particulars of negligence set forward in paragraph 30(b), the Defendant denies that it failed to monitor, supervise and enforce Hospital procedure and scientific protocol with respect to the pathological examination of breast cancer tumours and, in particular, with respect to the immunohistochemical testing for the presence of ER/PR receptors in tumour cells.
 - (c) As for the particulars of negligence set forward in paragraph 30(c), the Defendant denies that it disseminated erroneous or inaccurate ER/PR testing results.
 - (d) As for the particulars of negligence set forward in paragraph 30(d), the Defendant denies that it failed to properly administer ER/PR testing procedures conducted on the Plaintiff's breast cancer tumour cells.
 - (e) As for the particulars of negligence set forward in paragraph 30(e), the Defendant denies that it failed to exercise due care in the employment or retaining of staff so as to prevent negligent and/or substandard practices and/or procedures.
 - (f) As for the particulars of negligence set forward in paragraph 30(f), the Defendant denies that it failed to provide adequate instruction, direction and supervision to the Defendant's agents, servants, and/or employees. The Defendant denies that it

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was responsible for providing instruction, direction, or supervision to any laboratory physician.

- (g) As for the particulars of negligence set forward in paragraph 30(g), the Defendant denies that it failed to provide adequate staff, equipment and/or facilities in the laboratory for conducting ER/PR testing.
- (h) As for the particulars of negligence set forward in paragraph 30(h), the Defendant denies that it failed to employ adequate quality control procedures respecting all ER/PR testing procedures carried out by the laboratory to ensure that consistent and accurate ER/PR test results were being obtained at the laboratory.
- (i) As for the particulars of negligence set forward in paragraph 30(i), the Defendant denies that it failed to periodically inspect or audit ER/PR testing procedures to ensure that all testing and analytical procedures were being properly carried out and consistent and accurate results were being obtained.
- (j) As for the particulars of negligence set forward in paragraph 30(j), the Defendant denies that it failed to implement or follow a schedule of inspection and maintenance for all laboratory equipment and testing protocols or procedures utilized in ER/PR testing.
- (k) As for the particulars of negligence set forward in paragraph 30(k), the Defendant denies that it failed to ensure that all laboratory equipment used to conduct ER/PR testing was in proper working order and was functioning properly at all times.
- (l) As for the particulars of negligence set forward in paragraph 30(l), the Defendant denies that it utilized laboratory equipment or products for ER/PR testing that were faulty, defective or otherwise functioning improperly when the Defendant knew, or ought to have known, of the fault, defect or improper function.
- (m) As for the particulars of negligence set forward in paragraph 30(m), the Defendant denies that it failed to ensure that all products and equipment used by the laboratory were properly used by laboratory personnel in accordance with appropriate scientific and medical standards.

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- (n) As for the particulars of negligence set forward in paragraph 30(n), the Defendant denies that it was required to and/or failed to repeat ER/PR testing of the Plaintiff's tumour cells with a further excision.
 - (o) As for the particulars of negligence set forward in paragraphs 30(o) and (p), the Defendant denies that the applicable standard of care required it to monitor for, apprehend or notice any trend in the ER/PR test results.
 - (p) As for the particulars of negligence set forward in paragraph 30(q), the Defendant denies any negligence for not having the Plaintiff's ER/PR testing repeated at another facility given her medical history and other pathology.
26. The Defendant denies paragraphs 31 and 32 of the within Statement of Claim and 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.
27. The Defendant denies paragraphs 33, 34, 35, 36, 37, 38, 39, 40 and 41 of the within Statement of Claim and states that treatment of the Plaintiff with hormone-based therapies, such as Tamoxifen and Femera would not have prevented the Plaintiff from undergoing a prophylactic mastectomy of her right breast, developing metastatic tumors on her lung, liver and brain, or undergoing radiation, chemotherapy or the symptoms associated therewith.

AND THE DEFENDANT REQUESTS:

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

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DATED AT St. John's, in the Province of Newfoundland and Labrador, this 10th day of May, 2006.



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AND TO: **LOIS J. SKANES, Q.C.**
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