2006 01 T 2966 CP

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

AFFIDAVIT

I, Heather Predham, of the City of St. John's, in the Province of Newfoundland and Labrador, make oath and say as follows:

1. **THAT** I am a Risk Management Consultant/Assistant Director of Quality and Risk Management with the Defendant, Eastern Regional Integrated Health Authority ("Eastern Health") and was the Quality Initiatives representative in attendance at all meetings of the Tumor Board referred to in paragraph 19 of the within affidavit. As such I have been informed by pathologists and laboratory staff with Eastern Health of all activities of the Tumor Board including the retesting of breast cancer tumors and tissue samples more fully detailed in the within Affidavit. I am a registered nurse and completed a Bachelor of Nursing degree at Memorial University of Newfoundland. I make this affidavit as a representative of Eastern Health. The facts deposed in this Affidavit are true to the best of my knowledge, information and belief based on my review of medical literature and

my experiences and interactions with oncologists, pathologists and other medical professionals on the topic of breast cancer and breast cancer testing.

2. THAT breast cancers have many different characteristics and once a breast cancer tumor or sample is removed from the body, it is tested and analyzed to diagnose a patient to determine whether the type of breast cancer is invasive and whether lymph nodes are involved and, if so, how many.

3. THAT other features of the cancer including the size of the tumor, the hormone receptor status of the tumor, the tumor grade, the HER 2 expression, and tumor histology are also tested to assist oncologists in their determination of treatment options and the long-term health of the patient.

4. THAT the hormone receptor status of a breast tumor involves testing a tumor to determine whether the cancer cells have estrogen and/or progesterone receptors ("ER/PR"). Breast cancers that are either ER-positive or PR-positive or both may respond to hormone therapy, such as the drug Tamoxifen.

5. THAT literature which I have read suggests that approximately 75% of breast cancers are either ER-positive or PR-positive or both.

6. THAT hormonal therapy, chemotherapy and radiation are adjuvant therapies. The aim of adjuvant therapy is to decrease breast cancer recurrence rates and improve overall survival rates. Adjuvant therapies are generally additional treatments given after potentially curative surgery.

7. THAT immunohistochemistry is used to determine whether a tumor is ER-positive or PR-positive. To make the determination, laboratory technicians use antibodies to visualize cellular proteins. Antibodies are molecules that are able to combine specifically with cellular antigens of interest. Using a good antigen at the right level is critical to the success of the test.

8. THAT testing to determine whether a tumor is ER-positive or PR-positive ("ER/PR testing") is a complicated procedure that involves more than 40 steps.

9. THAT there are no standardized laboratory procedures in Canada for immunohistochemistry testing. Likewise there is currently no national laboratory accreditation process for immunohistochemistry laboratories.

10. THAT hospitals throughout the province of Newfoundland and Labrador sent tissue samples to the testing laboratory of Eastern Health for ER/PR testing once the fixation process was completed. Therefore, Eastern Health had no control over the pre-analytical or fixation phase of ER/PR testing for these tissue samples.

11. THAT there is a degree of subjectivity involved in ER/PR testing and, at Eastern Health, a number of different pathologists have been involved in interpreting the tests to determine the level of estrogen or progesterone positivity in a tumor.

12. THAT prior to April 2004, the Dako testing technique was used in Eastern Health's laboratories which required the manual boiling of tissue samples and also the measuring of minute mixtures of immunioperoxidase staining.

13. **THAT** in April 2004, Eastern Health installed the Ventana system for conducting ER/PR testing. This new system automated the process, thereby removing much of the human manipulation of samples.

14. **THAT** in May 2005 a patient, who had 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 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 13 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 4 of these patients originally had a degree of ER positivity but were negative on retesting.

24. **THAT** the remaining 213 patients whose ER/PR tests results were different on retesting did not require a change in the treatment that had been originally recommended for them because:

(a) 60 of these patients had a very low risk or recurrence;

(b) 148 of these patients had previously been treated with Tamoxifen or another aromatase inhibitor either at their request or their oncologist's recommendation following a review of the test results and their particular medical and family histories;

(c) 13 of these patients were not placed on Tamoxifen for their original disease but for subsequent metatstatic disease; and

(d) 5 of these patients received no treatment as they required assessment prior to any recommendation being made.

25. **THAT** 176 of the patients whose ER/PR tests were originally reported as negative are deceased. Of these 176 patients:

(a) 101 patient's samples were retested and results have been received;

(b) 2 patient's samples have been retested on request; and

(c) 73 patient's samples will not be retested unless requested by the families.

26. **THAT** based upon my involvement as a member of the Tumor Board, there was no one reason to explain why the respective test results converted on retesting and in many instances the cause of the conversions is unknown. Any number of the following factors may have contributed to the conversions:

(a) Where the samples were collected,

(b) How the samples were fixated;

(c) When the sample was tested initially;

(d) Who interpreted the initial results;

(e) What constituted a positive ER/PR test at the time of the original testing; and

(f) The technology used to perform the ER/PR testing for each patient, in particular, the antibodies used and antigen retrieval techniques utilized.

27. **THAT** in at least two cases, two different tissues samples were sent to Mount Sinai hospital for each of the two patients. Mount Sinai Hospital advised that the slightly different results obtained for each patient, when the two different tissue sample test results were compared, may be explained by the fact that conducting testing of different portions of a single patient's tissue sample may render different results.

28. **THAT** in at least two further cases, Mount Sinai retested the same tissue samples for two patients. I am not certain whether the duplication of effort was inadvertent or intentional. In these two cases Mount Sinai tested the same tissue sample from the same patient twice and each time obtained different test results.

29. **THAT** for false negative ER test results and confirmed ER negative test results, I have been informed that controls were run in all instances and that documentation exists in some instances confirming that controls were run as part of quality assurance in place at the time.

30. **THAT** the focus of the Tumor Board and all persons involved with the retesting of breast tumor samples has been on patient care and the communication and implementation of treatment recommendations. The compilation of statistical information has only recently been addressed.

31. **THAT** I provide this Affidavit to the Court for the purpose of responding to the Application for Certification filed on behalf of the Plaintiff.

SWORN TO at St. John's, in the province of Newfoundland and Labrador, this 9th day of February, 2007, before me:

Heather Predham