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Assignee: Genentech, Inc.

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DECLARATION OF KAREN GELMON, M.D.

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I. Introduction

1. I have been asked to review and respond to the opinions set forth in the March 22, 2017 Declaration of Mark J. Ratain, M.D.

II. Qualifications

2. I am a Professor of Medicine at the University of British Columbia and a medical oncologist at the BC Cancer Agency. In my current roles, I serve as both a researcher and investigator for clinical trials primarily in breast cancer and as a practicing clinical oncologist. I see over 200 new patients with breast cancer per year and treat approximately 70 breast cancer patients per week.

3. I obtained my M.D. from the University of Saskatchewan in 1979. I then completed my internal medicine residency at the University of British Columbia and became a Fellow of the Royal College of Physicians and Surgeons of Canada in Internal Medicine in 1984. I also completed my American Internal Medicine Boards. I trained in Medical Oncology and obtained my Fellowship in Medical Oncology from the Royal College of Physicians and Surgeons of Canada in 1986. From that time forward, I have held faculty positions at the University of British Columbia. I did further training in clinical trials in the UK with the Medical Research Council.

4. I have over thirty years of experience in breast oncology and have been involved in more than 150 clinical trials. I have served as the Clinical Head of the Investigational Drug Program at the BC Cancer Agency since 1990. I am a past Co-Chair of the NCIC Clinical Trials Group Breast Site Committee and serve on the Breast International Group (BIG) Executive Board. In addition, I am a Komen Scholar and serve on the Scientific Advisory Board (SAB) of the Susan G. Komen Foundation.

5. I am a co-author on more than 200 peer-reviewed articles and more than 200 abstracts in the field of breast oncology. I have co-authored at least 50 publications that studied trastuzumab. In addition to acting as a reviewer for grants and journals, I hold positions on the International Advisory Boards of The Lancet and The Oncologist, and have been on the editorial board of Lancet Oncology and Clinical Breast Cancer. A copy of my curriculum vitae is attached as **Appendix A**.

III. Summary of Opinions

6. It is my opinion that a person of ordinary skill in the art (“POSA”) in August 1999 would not have been motivated to administer trastuzumab on a three-week schedule as claimed in U.S. Patent Nos. 6,627,196 (“the ’196 patent”) and 7,371,379 (“the ’379 patent”). Oncologists finally had a drug that was effective in patients with a devastating type of breast cancer. Not only was trastuzumab effective, it was also exceedingly well-tolerated, and patient compliance was high.

As a monoclonal antibody therapy, the first ever approved for a solid tumor and one of the first approved to treat cancer generally, trastuzumab was a very different type of drug from the chemotherapeutic agents that oncologists regularly prescribed.

7. Oncologists in August 1999 were not seeking to change trastuzumab's dosing regimen. Petitioner asserts that convenience and ease of scheduling with paclitaxel, a chemotherapeutic agent dosed every three weeks, would have motivated such a change. However, without a compliance problem, convenience standing alone rarely motivates an oncologist to risk making a life-saving treatment less effective by altering its dosing schedule. Further, the fact that trastuzumab and paclitaxel were given in combination would not have prompted a clinical oncologist to experiment with trastuzumab's dosing schedule to "match" it to paclitaxel's. Instead, if an oncologist in 1999 cared to synchronize the schedules, he/she would likely have experimented with the dosing of paclitaxel, a familiar chemotherapeutic agent, instead of the dosing of the novel monoclonal antibody therapy. In 1999, oncologists were studying whether more frequent dosing of some chemotherapy agents (including paclitaxel) would be more effective, and in cancer treatment, efficacy reigns supreme.

8. It is also my opinion that a skilled artisan would not have had confidence that administering trastuzumab on a three-week dosing interval would have been as clinically effective as the weekly dosing based on the pharmacokinetic data presented Watanabe (Ex. 1006), the Slamon Abstract (Ex. 1005), the 1998 Herceptin Label (Ex. 1008), Baselga '96 (Ex. 1007), and Pegram '98 (Ex. 1009). I know from my experience working with pharmacokineticists on clinical trials that they make mathematical models or rely on other mathematical equations to describe drug levels in a patient's serum, and can make predictions for drug levels in a patient's serum for an alternative dosing regimen. I also know that if a drug shows certain pharmacokinetic characteristics such as non-linearity, the pharmacokineticist cannot simply ignore the characteristic; otherwise, the pharmacokineticist's predictions may not accurately predict the levels of drug in the patient's body over time. The prior art provided only sparse pharmacokinetic data, and particularly for a drug with documented non-linear kinetics—a characteristic that Petitioner's expert glosses over—it was not possible to accurately predict whether an alternative dosing regimen would maintain high enough levels of the drug in the patient's serum to be effective. Further, Petitioner's expert relied on an admittedly inaccurate calculation to predict trough serum levels that barely slide above the minimum therapeutic target. At least because of the unfamiliarity that comes with a new class of drug, and because

trastuzumab was already a very effective treatment for an aggressive disease, a clinical oncologist would not have taken chances by using the new regimen on a patient with a life-threatening illness.

IV. Person of Ordinary Skill in the Art

9. I understand that the Petitioner and Dr. Ratain defined a person of skill in the art as having either an M.D. with subspecialty training in oncology and/or a Ph.D. with substantial experience in oncology drug development. I also understand that the Petitioner and Dr. Ratain state that a skilled artisan would have had familiarity with the treatment of breast cancer and substantial experience in the design and/or implementation of oncology clinical trials, as well as expertise in clinical pharmacology, including pharmacokinetics. (Paper 1 at 14; Ex. 1003, Ratain Decl. ¶ 44.) The skilled artisan would have had access to and worked on a team with a number of other individuals involved in drug development with expertise in clinical pharmacology, including pharmacokinetics.

10. For the purpose of this declaration, I have applied this definition of a person of skill in the art, and my opinions are offered from the perspective of a skilled artisan as that hypothetical person would have understood matters on August 27, 1999, which I understand is the relevant date for the analysis.

11. In 1999, I specialized in treating breast cancer patients and had designed and/or served as a principal investigator in numerous oncology clinical trials. Also

at the time of invention, I had published around 20 papers specifically on breast cancer treatment, including publications in the New England Journal of Medicine and in the Journal of Clinical Oncology. Further, I had knowledge of pharmacokinetics because of my involvement in Phase I clinical trials. I typically consulted with a pharmacokineticist for these trials, and I have done so here by consulting with Dr. George Grass.

V. Background and State of the Art

A. Treatment Before Trastuzumab

12. By the mid-20th century, doctors had observed that some breast cancers were clearly more aggressive than others, meaning that the cancers grew and spread more rapidly. The reason behind this difference in behavior was unknown.

In the late 1980s, researchers identified a potential explanation for some breast cancers; the gene encoding the HER2 protein was amplified in a fraction of breast cancers, and the amplification was a predictor of poor overall survival and time to relapse. (Ex. 2031, Dennis J. Slamon, *Human Breast Cancer: Correlation of Relapse and Survival with Amplification of the HER-2/neu Oncogene*, 235 SCIENCE 177 (1987) at 177; Ex. 2032, Dennis J. Slamon, *Studies of the HER-2/neu Proto-oncogene in Human Breast and Ovarian Cancer*, 244 SCIENCE 707 (1989) at 707.)

During this period numerous other markers of prognosis were also described but HER2 amplification or overexpression was more robust than many others, which

are now long forgotten. By the mid-1990s, it was increasingly recognized in the field that HER2-positive status was one predictor of aggressive cancer and poor prognosis, with a high rate of tumor recurrence and spreading to other areas of the body. (Ex. 2029, Michael S. Kopreski et al., *Growth Inhibition of Breast Cancer Cell Lines by Combinations of Anti-P185^{HER2} Monoclonal Antibody and Cytokines*, 16 ANTICANCER RES. 433 (1996) at 433; Ex. 2030, Steven Lehrer et al., *Tumour HER2 Protein in Breast Cancer and Family History*, 341 THE LANCET 1420 (1993) at 1420; Ex. 2031 at 179-180.) HER2-positive patients had “a shorter time to relapse as well as a shorter overall survival” even after surgery, chemotherapy, and/or radiation. (Ex. 2032 at 707; Ex. 2031 at 179-180.) Existing treatments were not effective, so the harsh reality for HER2-positive patients in 1996 was a life expectancy of “only 18 months post-diagnosis.” (Ex. 2033, David Holzman, *Gene Therapy for HER-2-Related Cancer*, MOLECULAR MED. TODAY, April 1996 at 138; see also Ex. 2034, Russ Hoyle, *Genentech Is Poised for an Anti-cancer Breakthrough*, 16 NATURE BIOTECHNOLOGY 887 (1998) at 887 (“[B]reast cancer patients who overproduce HER2 can now expect to live some 10 to 12 months after metastasis begins, a horribly rapid progression compared to six or seven years for HER2-normal patients.”).)

13. Many women were affected by the lack of an effective treatment for HER2-positive breast cancer. In 1998, approximately 180,000 new cases of breast cancer

were being diagnosed every year in the United States, and of those 180,000 diagnosed women, 25-30% had the HER2-positive subtype. (*See* Ex. 2043 at 1, 5; *see also* Ex. 1007 at 3.)

14. Researchers looked for ways to target the source of this deadly disease. Because HER2 protein is overexpressed on the cell surface, scientists investigated whether HER2 could serve as a target for a large macromolecule, such as a monoclonal antibody, that might interfere with the ability of HER2 protein to bind to receptors and initiate the cascade of cell signaling associated with aggressive breast cancer. (Ex. 2044, Robert M. Hudziak et al., *p185^{HER2} Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor*, 9 MOLECULAR & CELLULAR BIOLOGY 1165 (1989) at 1165.) The idea of using antibodies as targeted cancer therapies had been floated for decades. (Ex. 2045, Richard P. Junghans et al., *Antibody-Based Immunotherapies for Cancer*, in CANCER CHEMOTHERAPY & BIOTHERAPY: PRINCIPLES AND PRACTICE (1996) at 655.) Although antibodies targeting a specific antigen could be obtained from mice and other animals, the human immune system would identify these nonhuman antibodies as foreign antigens and attack them. (*Id.* at 683.) The resulting “antigenic” or “immunogenic” response inactivated the antibodies and resulted in rapid clearance from the body, curtailing therapeutic usefulness. (*Id.* at 683.) By the early 1990s, numerous antibodies had been tested

in patients with different cancers, including breast cancer, but they showed “no hint of a consistent therapeutic efficacy.” (Ex. 2002, Gert Riethmüller & Judith P. Johnson, *Monoclonal Antibodies in the Detection and Therapy of Micrometastatic Epithelial Cancers*, 4 CURRENT OPINION IN IMMUNOLOGY 647 (1992) at 649; *id.*, Table 2 (identifying failed antibody clinical trials for gastrointestinal tumors; breast, colon, ovarian, and lung cancer; pancreatic adenocarcinoma; neuroblastoma; and melanoma).)

15. Genentech collaborated with researchers at a variety of academic and research institutions including the University of California, Los Angeles and the Memorial Sloan-Kettering Cancer Center to find a solution to the daunting problem. First, researchers at Genentech developed a mouse monoclonal antibody that targeted the HER2 protein. (Ex. 2044 at 1165.) The next and crucial step was the development of a humanized version of this monoclonal antibody, which would be made up of mostly human components and very few mouse components to reduce immunogenic responses in patients. (Ex. 2048, Paul Carter et al., *Humanization of an Anti-p185^{HER2} Antibody for Human Cancer Therapy*, 89 PROC. NAT’L ACAD. SCI. (1992).) That humanized antibody came to be known as Herceptin® (trastuzumab).

B. Trastuzumab Clinical Development

1. Phase I

16. When the first trastuzumab clinical trials began in 1992, antibody therapies were not in favor in the oncology field. Despite theoretical promise in the lab, clinical researchers had experienced many failures when other antibody therapies were tested on patients. Harmful immunogenic responses were often observed in the clinic. In addition, the complexity of cell signaling pathways in the body as well as the difficulty of safely delivering effective doses of these large macromolecules posed a slew of new challenges for researchers in the field.

17. In light of these challenges, Phase I pharmacokinetic trials of trastuzumab were initially conducted with a small number of patients and Genentech's studies were not published, which is surprising considering the subsequent success of the drug. Limited information from these studies was eventually included in the 1998 Herceptin Label (Ex. 1008) and described in a cursory fashion in a small handful of publications. (*See, e.g.*, Ex. 1013 at 4; Ex. 1007 at 3-4.) Results from a Japanese Phase I dose escalation study of only 18 patients were published in an abstract (Watanabe) years after the Genentech Phase I studies were completed, but no detailed pharmacokinetic information was included. (*See* Ex. 1006 at 5.)

2. Phase II

18. Two Phase II studies of trastuzumab were conducted. (*See* Ex. 1007, Ex. 1009.) The results from these trials showed preliminary suggestions of trastuzumab's activity, but needed to be validated in larger trials. Clinicians do not trust results from small trials because they may not predict whether and how the drug will work in the broader patient population. Small trials also do not have the statistical power to demonstrate any benefit of the new therapy over existing therapy. Further, many small studies are single center studies which is also a concern for clinicians as there are concerns about bias, patient selection, and the potential validation of the results. Clinical skepticism was especially high during the clinical development of trastuzumab because of the failure of prior antibody therapies.

19. In one Phase II study (results published as Baselga '96), 46 patients with HER2-overexpressing metastatic breast cancer received trastuzumab at a dose of 250 mg intravenously on week one, then 100 mg intravenously weekly for 10 weeks. (Ex. 1007 at 3.) The results showed 1 complete and 4 partial responses among 43 evaluable patients for an objective tumor response rate of about 12%. (*Id.*) In the other Phase II study (results published as Pegram '98), 37 patients with HER2-overexpressing metastatic breast cancer received trastuzumab at a dose of 250 mg intravenously on week one, then 100 mg intravenously weekly for 9 weeks

plus cisplatin at a dose of 75 mg/m² on days 1, 29, and 57. (Ex. 1009 at 2.) The results showed 9 partial responses and 9 minor responses or stable disease among the 37 evaluable patients. (*Id.*)

20. Neither of the papers that published the results of these studies—Baselga '96 and Pegram '98—included detailed pharmacokinetic data. For example, Baselga '96 provides serum concentration data for only two patients. (Ex. 1007 at 6.) Similarly, Pegram '98 provides isolated mean pharmacokinetic parameters without including any of the underlying data. (Ex. 1009 at 8 (Table 6).)

3. Phase II/III Pivotal Trials

21. Trastuzumab was approved based on two pivotal trials in metastatic breast cancer patients: a Phase II single agent trial conducted in 222 patients and a Phase III combination therapy trial conducted in 469 patients. (*See* Ex. 2046, Melody A. Cobleigh et al., *Multinational Study of the Efficacy and Safety of Humanized Anti-HER2 Monoclonal Antibody in Women Who Have HER2-Overexpressing Metastatic Breast Cancer That Has Progressed After Chemotherapy for Metastatic Disease*, 17 J. CLINICAL ONCOLOGY 2639 (1999) at 2639; Ex. 2047, Dennis J. Slamon et al., *Use of Chemotherapy Plus a Monoclonal Antibody Against HER2 for Metastatic Breast Cancer That Overexpresses HER2*, 344 NEW ENG. J. MED. 783 (2001) at 783.) In these trials, trastuzumab was administered at an initial dose of 4 mg/kg followed by weekly maintenance doses of 2 mg/kg. The first dose of

antibody was infused intravenously over 90 minutes. In the absence of significant infusion-related toxicity, subsequent doses were infused intravenously over 30 minutes. Pharmacokinetic data for the Phase II single agent trial was not published until September 1999. (*See* Ex. 2046.) Data from the Phase III combination therapy trial was not published before August 1999.

22. Slamon announced remarkable preliminary efficacy results to a packed audience at the 1998 American Society of Clinical Oncology (“ASCO”) meeting. (Ex. 1005 at 5.) He also submitted an abstract for that meeting that briefly summarized the Phase III study results (the Slamon Abstract). (Ex. 1005 at 5.) There was excitement as oncologists finally had the level of proof they needed that a targeted treatment was effective in aggressive HER-positive cancers.

23. The FDA approved trastuzumab later that same year. (*See* Ex. 2043.) It was the first antibody approved to target solid tumors and the first approved to treat breast cancer. (Ex. 2003, Janice M. Reichert, *Probabilities of Success for Antibody Therapeutics*, 1 MABS 387 (2009) at 388.) The approved dosing regimen consisted of a 4 mg/kg loading dose followed by 2 mg/kg weekly maintenance doses. (Ex. 1008 at 1; Ex. 1013 at 1-2, 6-7.)

C. Success of Trastuzumab

24. Clinical oncologists, including myself, were excited to finally have an effective targeted therapy to treat a group of patients with a poor prognosis and very high risk advanced breast cancer. When the results of the Phase III trial were announced, many of us in the oncology field shared the opinion that trastuzumab was a major breakthrough. Both patients and oncologists had dreaded a HER2-positive diagnosis. Trastuzumab changed that. After the approval of trastuzumab, it has become a diagnosis that indicates treatable disease.

D. Trastuzumab was a breakthrough in the treatment of HER2-positive breast cancer, but a great deal of efficacy-focused research remained before oncologists could fully realize and utilize the drug's potential.

25. Soon after trastuzumab's approval, researchers everywhere wanted to be involved in the drug's future. This initial wave of research focused 1) on identifying patients who could most benefit, and 2) on improving efficacy by combining trastuzumab with other chemotherapy agents. (See Ex. 2021, José Baselga, *Current and Planned Clinical Trials With Trastuzumab (Herceptin)*, 27 (SUPPL. 9) SEMIN. ONCOLOGY 27 (2000); Ex. 2035, Steven Shak, *Overview of the Trastuzumab (Herceptin) Anti-HER2 Monoclonal Antibody Clinical Program in HER2-Overexpressing Metastatic Breast Cancer*, 26 (Suppl. 12) SEMIN. ONCOLOGY 71 (1999) at 76.)

1. Researchers at the time wanted to identify patients who could most benefit from the drug.

26. First, persons of skill prioritized identifying patients who could most benefit from trastuzumab, including by finding out how early the treatment should start.

27. Neoadjuvant treatment is treatment given before surgery to remove cancerous lumps, intended to reduce the size of the tumor. Adjuvant treatment is treatment given after surgery to remove cancerous lumps, intended to kill remaining cancer cells. These treatments are primarily for patients with early breast cancer that has not metastasized. If trastuzumab showed efficacy in the adjuvant and neoadjuvant treatment settings, it would become available to a much broader and more treatable group of patients. (*See* Ex. 2035 at 76) (“It will be particularly important to perform clinical trials in patients with early breast cancer, in which the more limited tumor burden would suggest even greater opportunities for clinical benefit.”)

28. In 1998, as soon as the Phase III trastuzumab pivotal trial results were announced, Genentech signaled that it intended to study the drug in patients with early breast cancer. Large cooperative research groups had similar intent. Around the time of invention, the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the North Central Cancer Treatment Group (NCCTG) were making proposals for adjuvant therapy trials that would enroll thousands of patients.

2. Trastuzumab was a novel, important tool for clinicians to add to their toolbox of cancer-fighting drugs, but oncologists had much to explore in terms of improving its efficacy and tying it in with existing treatments.

29. Oncologists readily adopted trastuzumab, but therapeutic monoclonal antibodies were a whole new world. Trastuzumab was different from anything that oncologists had been prescribing for breast cancer before, which for the last half of the twentieth century had been largely chemotherapy. During the five years following the approval of trastuzumab, hundreds of papers and abstracts were published in which researchers explored various ways to maximize use of trastuzumab, as well as more traditional chemotherapy treatments.

a) Efficacy, not convenience, was the focus of cancer treatment in the 1990s.

30. Most chemotherapy drugs are cytotoxic to a broad range of normal and malignant cells, usually on the basis of nonspecific DNA damaging activity. (Ex. 2024, Walter M. Stadler & Mark J. Ratain, *Development of Target-based Antineoplastic Agents*, 18 INVESTIGATIONAL NEW DRUGS 7 (2000) at 7.) This means that healthy, rapidly dividing cells, like hair follicles and cells lining the intestine, tend to be damaged the worst, leading to symptoms such as hair loss and gastrointestinal issues. Nausea, vomiting, and fatigue are also common. But perhaps the most alarming possible side effect is myelosuppression, which is suppression of bone marrow activity, resulting in the creation of fewer white blood

cells. When the bone marrow is not able to produce enough white blood cells, the body cannot fight off infection. Neutropenia, a condition in which the patient has an abnormally low number of a particular type of white blood cell, can be life-threatening.

31. The goal of most chemotherapy dosing was to deliver the largest tolerable dose that would kill the greatest number of tumor cells without causing life-threatening toxicity, such as severe myelosuppression and neutropenia. Thus, from the time chemotherapeutic agents were first prescribed up until the end of the 1980s, chemotherapy agents were typically dosed in a way that allowed the patient's bone marrow to recover and produce white blood cells between doses.

32. Despite inconvenience and toxicity, oncologists in the 1990s were pushing the bounds of chemotherapy because there was a desperate need for more effective treatment. Many of the newer chemotherapy treatment regimens carried higher risks, caused more serious side effects, and were more inconvenient than even standard chemotherapy. For example, many oncologists were studying high-dose chemotherapy plus autologous bone marrow transplant (ABMT), a treatment that involved administration of extremely high doses of chemotherapy, so high that it killed patients' bone marrow. (See Ex. 2050, Gabriel N. Hortobagyi, Mien-Chie Hung, & Aman U. Buzdar, *Recent Developments in Breast Cancer Therapy*, 26

(SUPPL. 12) SEMIN. ONCOLOGY 11 (1999) at 13; Ex. 2049 at 1180; Ex. 2051, *High-Dose Chemotherapy and Autologous Bone Marrow or Stem Cell Reconstitution for Solid Tumors*, CURRENT PROBS. IN CANCER, May/June 1998 at 142.) ABMT allowed a patient to receive much higher dosages of chemotherapy than was ordinarily possible because it restored the bone marrow by reinfusing stem cells (the bone marrow cells that mature into blood cells) taken from the patient before chemotherapy. (See Ex. 2050 at 13.) The procedure carried high risks, side effects were severe, and it typically required hospitalization. (See Ex. 2052, William P. Peters et al., *High-Dose Chemotherapy and Autologous Bone Marrow Support as Consolidation After Standard-Dose Adjuvant Therapy for High-Risk Primary Breast Cancer*, 11 J. CLINICAL ONCOLOGY 1132 (1993) at 1134 (“Patients were then admitted to the next available bed in the transplant unit and were cared for in private rooms with positive-pressure, high-efficiency particle filtration (HEPA) air systems. During the high-dose consolidation phase of treatment, access to patient rooms required masks, gloves, gowns, and shoe covers; a low-bacterial, low-fungal content diet was prescribed.”).) “The stakes are high, but the potential payoff is well worth it if more women with breast cancer can be saved from death.” (Ex. 2051 at 156.)

33. Oncologists at the time were also interested in dose-dense chemotherapy. The dose-dense hypothesis, popularized by Dr. Larry Norton and tested at many

institutions in the 1990s, was that if oncologists could administer more drug per unit of time by reducing the interval between treatment cycles, they could reduce the time for tumor re-growth. (See Ex. 2053, Larry Norton, *Evolving Concepts in the Systemic Drug Therapy of Breast Cancer*, 24 (SUPPL. 10) SEMIN. ONCOLOGY S10-3 (1997) at S10-3, -5; Ex. 2051 at 154 (“Norton popularized the concept of dose density, which shortens the interval between treatment cycles and uses doses of single agents requiring only cytokine support rather than stem cell support, in an attempt to achieve high total dose and dose intensity simultaneously. . . . This concept of dose density is currently being evaluated.”).) Skilled artisans also theorized that shorter intertreatment intervals would allow less opportunity for the emergence of drug-resistant cancer cells and that the more sustained exposure may permanently impair growth-promoting intracellular signaling. (Ex. 2065, Andrew D. Seidman, *One-Hour Paclitaxel Via Weekly Infusion: Dose-Density with Enhanced Therapeutic Index*, 12 (SUPPL. 1) ONCOLOGY 19 (1998) at 22; Ex. 2053 at S10-5.) I was personally involved in several dose-dense studies in the 1990s. Dose-dense therapy showed great promise for efficacy and some of the myelotoxicity and neutropenia could be managed by administering granulocyte colony-stimulating factor (G-CSF). (See Ex. 2049 at 1179.) G-CSF facilitates bone marrow recovery and stimulates the production of white bloods cells, which in turn allows for more frequent dosing. (See Ex. 2053 at S10-5; Ex. 2054, John

Crown et al., *High-Intensity Chemotherapy with Hematopoietic Support In Breast Cancer*, 698 ANNALS N.Y. ACAD. SCI. 378 (1993) at 383.) For example, chemotherapy in a dose-dense regimen could be administered once every week or every two weeks instead of every three weeks. (See Ex. 2050 at 13; Ex. 2053 at S10-3, -6-7.)

34. None of these treatments could be described as convenient, showing that efficacy was a higher priority than convenience for oncologists treating cancer in August 1999.

b) Skilled artisans recognized that the principles that applied for dosing chemotherapeutic agents did not apply for dosing trastuzumab.

35. Compared to other intravenous cancer treatments available in August 1999, trastuzumab was exceptionally well tolerated. Trastuzumab had few and relatively mild side effects, including infusion reactions such as chills and fever after the first infusion that did not typically recur after subsequent administrations. (Ex. 2055, Charles L. Vogel & Jean-Marc Nabholz, *Monotherapy of Metastatic Breast Cancer: A Review of Newer Agents*, 4 THE ONCOLOGIST 17 (1999) at 26) (“Aside from fever and chills, which generally occur only with the first dose of drug, toxicities have been rare. Patient tolerability and acceptance have been excellent, because the antibody is not associated with alopecia, significant gastrointestinal problems, or myelosuppression.”). Trastuzumab could lead to cardiotoxicity in

some patients and this caused concern as the cardiac toxicity was a surprise and did not appear to be related to dose. Although it appeared to be related to combining it with cardiotoxic drugs such as anthracyclines, it also occurred sporadically which was not well understood. (*Id.*) Other symptoms included mild to moderate pain at the tumor site, diarrhea, and nausea. (Ex. 1008 at 2). Trastuzumab did not cause myelosuppression or neutropenia, and these severe, dose-related side effects were key drivers of three-weekly dosing for a number of chemotherapeutic agents.

36. Another key difference between trastuzumab and chemotherapeutic agents is that trastuzumab is a targeted antibody therapy. Targeted cancer therapies interact with specific molecular targets involved in the growth, progression, and spread of cancer. The goal of antibody dosing is to ***maintain*** therapeutic trough serum levels over the course of the dose interval. If the serum levels dip too low, the antibody will no longer be effective to treat cancer. The thinking around the time of invention was that, for targeted therapies, it was better to hit the target more often and keep the serum levels higher by dosing more frequently.

c) Even if clinical oncologists wanted to match the schedules of trastuzumab and a chemotherapeutic agent, they would have changed the dosing schedule of the chemotherapeutic agent rather than the schedule of the novel therapeutic antibody.

37. Around the time of invention, skilled artisans were planning numerous trials to evaluate agents other than paclitaxel to combine with trastuzumab, and with so

many different options, there was no intention to alter trastuzumab's dosing schedule to match any or all of these other agents. Some researchers were planning studies of trastuzumab in combination with cyclophosphamide/methotrexate/5-fluorouracil (CMF), one of the most widely used regimens in breast cancer. (*See* Ex. 2021 at 28.) Others planned to combine trastuzumab with docetaxel, gemcitabine, vinorelbine, interleukin-2, and tamoxifen, among others. (*See id.*; Ex. 2056, H.A. Burris et al., *Phase II Trial of Docetaxel and Herceptin (R) as First- or Second-Line Chemotherapy for Women with Metastatic Breast Cancer Whose Tumours Overexpress HER2*, 35 (SUPPL. 4) EUR. J. CANCER S322 (Abstract 1293) (1999).)

38. As for paclitaxel, the FDA-approved partner drug for trastuzumab, persons of skill were still determining the safest and most effective dosing schedule. Around the time of invention, the dose and schedule of paclitaxel for breast cancer patients was the subject of a number of clinical trials. (Ex. 2016, Andrew D. Seidman et al., *Dose-Dense Therapy with Weekly 1-Hour Paclitaxel Infusions in the Treatment of Metastatic Breast Cancer*, 16 J. CLINICAL ONCOLOGY 3353 (1998) at 3353.) Weekly paclitaxel studies in breast cancer were encouraged by a substantial pool of positive data generated from weekly paclitaxel studies in non-small-cell lung cancer. (*See* Ex. 2057, Wallace Akerley et al., *Weekly Paclitaxel in Patients with Advanced Lung Cancer: Preliminary Data from a Phase II Trial*, 24

(SUPPL. 12) SEMIN. ONCOLOGY S12-10 (1997) at S12-10 - S12-12; Ex. 2058, Hak Choy et al., *Multiinstitutional Phase II Trial of Paclitaxel, Carboplatin, and Concurrent Radiation Therapy for Locally Advanced Non-Small-Cell Lung Cancer*, 16 J. CLINICAL ONCOLOGY 3316 (1998) at 3316; Ex. 2059, Hak Choy et al., *Phase II Trial of Weekly Paclitaxel and Concurrent Radiation Therapy for Locally Advanced Non-Small Cell Lung Cancer*, 4 CLINICAL CANCER RES. 1931 (1998) at 1931-32.) Further, paclitaxel was a well-studied drug. (Ex. 2016 at 3360) (“Perhaps more information on the use of single-agent paclitaxel in metastatic breast cancer is or will be available than for any other chemotherapeutic agent.”) Breast oncologists were beginning to shift from the prior standard three-weekly schedule toward a new standard—weekly. (See Ex. 2036, Edith A. Perez, *Paclitaxel in Breast Cancer*, 3 THE ONCOLOGIST 373 (1998) at 370, 375-76) (“Weekly moderate-dose paclitaxel administration is also generating much interest, given the high relative dose intensity and dose density delivered, yet very modest myelosuppression and manageable neurotoxicity observed.”); see also Ex. 2038, Giuseppe Frasci et al., *Weekly Paclitaxel-Cisplatin Administration with G-CSF Support in Advanced Breast Cancer: A Phase II Study*, 49 BREAST CANCER RES. & TREATMENT 13 (1998) at 15) (“The weekly administration of paclitaxel has raised much interest in the last few years in view of the quite astonishing doses delivered with this schedule.”) Weekly administration of paclitaxel showed efficacy and a

remarkably favorable toxicity profile for the high amount of drug delivered in numerous clinical trials. (See Ex. 2016 at 3353, 3357-58; Ex. 2038 at 15, 24; Ex. 2036 at 373, 375-76; Ex. 2040, AM Alvarez et al., *Reinduction of Response with Weekly Taxol(T) in Advanced Breast Cancer (ABC)*, 18 PROC. AM. SOC'Y CLINICAL ONCOLOGY 165a (Abstract 636) (1999); Ex. 2017, S. Breier et al., *Long-Term Weekly Paclitaxel (P) in Metastatic Breast Cancer (MBC): A Phase II Trial in Pretreated Patients (PTS)*, 17 PROC. AM. SOC'Y CLINICAL ONCOLOGY 192a (Abstract 740) (1998); Ex. 2020, E. Mickiewicz et al., *A Promising Second Line Treatment with Weekly Taxol (T) in Anthracycline Recurrent, Advanced Breast Cancer (ABC) Patients (PTS)*, 18 PROC. AM. SOC'Y CLINICAL ONCOLOGY 135a (Abstract 515) (1999); Ex. 2022, E.A. Perez et al., *A Large Phase II Trial of Paclitaxel Administered as a Weekly One Hour Infusion in Patients with Metastatic Breast Cancer*, 18 PROC. AM. SOC'Y CLINICAL ONCOLOGY 126a (Abstract 480) (1999); Ex. 2065 at 20-21; Ex. 2018, W. Sikov et al., *Weekly High-Dose Paclitaxel Demonstrates Significant Activity in Advanced Breast Cancer (BC)*, 17 PROC. AM. SOC'Y CLINICAL ONCOLOGY 112a (Abstract 432) (1998); Ex. 2019, C Sola et al., *Phase II Study of Weekly Paclitaxel (P) Treatment in Recurrent Breast Cancer After High-Dose Chemotherapy (HDC)*, 18 PROC. AM. SOC'Y CLINICAL ONCOLOGY 65a (Abstract 245) (1999).) There were even plans to explore the weekly co-administration of paclitaxel and trastuzumab. (See Ex. 2016

at 3360 (“The recent observation of meaningful translation of preclinical synergy into clinical benefit for the combination of paclitaxel (3-hour infusion every 3 weeks) and Herceptin (trastuzumab; Genentech, Inc., San Francisco, CA) has motivated us to explore the weekly co-administration of these two agents (paclitaxel via weekly 1-hour infusion) in a phase II trial that is well underway (MSKCC IRB protocol 98-28.”); Ex. 2021 at 29 (“The results of preclinical studies and the pivotal phase III study have led to the design of a series of follow-up studies with taxanes plus trastuzumab both in the advanced and adjuvant setting . . . Investigators at Memorial Sloan-Kettering Cancer Center (New York, NY), building on their experience with dose-dense weekly paclitaxel, have initiated a phase II study of weekly paclitaxel plus trastuzumab in patients with metastatic breast cancer.”)). In fact, by the time of invention, one group had shown that weekly trastuzumab combined with weekly paclitaxel (Taxol®) was both safe and efficacious in a Phase II study in metastatic breast cancer patients. (See Ex. 2037, M Fornier, *Weekly (W) Herceptin (H) + 1 Hour Taxol (T): Phase II Study in HER2 Overexpressing (H2+) and Non-Overexpressing (H2-) Metastatic Breast Cancer (MBC)*, 18 PROC. AM. SOC’Y CLINICAL ONCOLOGY 126a (Abstract 482) (1999).)

VI. Dr. Ratain's Opinions Contradict Key Teachings in the Prior Art as Well as the Motivations and Reasonable Expectations of Success of Persons Skilled in the Art in August 1999.

A. A clinical oncologist's primary motivating factors are efficacy and safety; convenience is a lesser priority.

39. Clinical oncologists in 1999 focused on efficacy and would not have been motivated to change the proven trastuzumab regimen for convenience. Clinical experience with trastuzumab in August 1999, less than a year after FDA approval, was still very limited. Oncologists focused on getting the drug to patients who could benefit and on improving its efficacy. A clinical oncologist would not have been evaluating an alternative dosing regimen so soon after approval and for a drug that was so unlike the chemotherapy agents they were familiar with.

40. But if a clinician were to evaluate an alternative dosing regimen for trastuzumab, efficacy was the paramount consideration. HER2-positive breast cancer was, and still is, a life-threatening disease. If trastuzumab was dosed in such a way that it did not have its intended effect on cancer, other considerations—such as toxicity and convenience—simply would not matter.

41. Although cancer patients' quality of life is important, convenience is not at the top of a clinical oncologist's list of considerations and would not have been a motivating force to a skilled artisan in 1999 if he/she were designing an alternative dosing regimen for trastuzumab. Convenience may command greater weight if it

leads to better patient compliance, but compliance was not an issue for patients taking trastuzumab in 1999. Convenience, which is simply making the drug easier to take, is infrequently a standalone motivating factor. And when it is, it is typically for drugs that treat conditions where the stakes are lower, not for drugs like trastuzumab that treat an aggressive form of cancer.

1. Convenience divorced from compliance is rarely a motivating factor, and compliance was not a problem for patients taking trastuzumab in 1999.

42. Convenience is typically a concern only when there are issues with patient compliance, i.e., patients failing to administer or receive a drug as scheduled.

Compliance was not an issue for patients taking trastuzumab in 1999, largely because cancer is an acute disease that will quickly take the patient's life if left untreated. From the moment they are diagnosed, patients know that cancer will impact their mortality. Most patients need little additional convincing in the form of convenience to take trastuzumab. Around the time of invention, I personally observed that patient compliance was high, likely due to both the life-threatening nature of the disease and the limited number of effective treatment options for patients with HER2- positive cancer.

43. Even for patients who do need additional convincing, compliance, or the lack thereof, is more often a result of the tolerability of a drug, not the convenience of administration. (See Ex. 2061, Cynthia Campbell-Baird et al., *Incidence of*

Acute Phase Adverse Events Following Denosumab or Intravenous Bisphosphonates: Results from a Randomized, Controlled Phase II Study in Patients with Breast Cancer and Bone Metastases, 7 COMMUNITY ONCOLOGY 85 (2010) at 85) (“Effective therapies with fewer side effects would improve treatment compliance and substantially benefit these [metastatic breast cancer] patients.”).)

44. For example, compliance with bisphosphonates is poor in part due to the high incidence of GI adverse events. “Oral medications that elicit GI or other side effects that significantly affect quality of life are less likely to be taken than treatment regimens without major side effects. . . . Oral bisphosphonate therapy has been associated with a fairly high rate of noncompliance and early study withdrawal because of its complicated treatment regimen and high rate of GI adverse events. The global rate of noncompliance with long-term oral bisphosphonate therapy for osteoporosis has been reported as >50%.” (Ex. 2062, PierFranco Conte & Valentina Guarneri, *Safety of Intravenous and Oral Bisphosphonates and Compliance with Dosing Regimens*, 9 (SUPPL. 4) THE ONCOLOGIST 28 (2004) at 33.)

45. Additionally, convenience may motivate changing a dosing regimen for drugs for conditions that may not have instant, noticeable effects, so doctors must

oftentimes coax patients into taking these medications by making efforts to increase convenience. Patients with osteoporosis (the disease that bisphosphonates like ibandronate are prescribed to treat) may not feel ill or frail at all; the adverse outcome is the possibility of a broken hip many years later.

46. The factors that frequently contribute to noncompliance do not apply to trastuzumab. First, trastuzumab is exceedingly well tolerated, so patients need not quit the drug due to unbearable side effects. Second, Her2-positive patients typically feel the ill effects of their disease and have regular check-ups that tell the patient whether the drug is working. HER2-positive patients are aware of the drug's effect and in my experience are more likely to comply. This is especially true when the check-ups reveal that the drug is working. "New and efficacious treatments clearly can enhance patients' sense of efficacy and therefore their willingness and ability to adhere to those and other treatments." (Ex. 2066, David Spiegel, *Psychosocial Aspects of Breast Cancer Treatment*, 24 (SUPPL. 1) SEMIN. ONCOLOGY (1997) at S1-40.)

47. I have reviewed the literature related to trastuzumab prior to the priority date and have not found any suggestion of a problem with compliance or any other motivation that would lead a skilled artisan to pursue a less frequent dosing regimen. Dr. Ratain provides no relevant documentary evidence to support his

conclusion that there was such a motivation at the time of the claimed invention. (*See, e.g.*, Ex. 1003, Ratain Decl. ¶¶ 89-91.) He also lacks the personal experience treating breast cancer that I have; he does not focus on treating breast cancer and cannot recall the extent to which he was treating breast cancer patients in the late 1990s. (Ex. 2026, Ratain Tr. at 13:2-14:21; 50:9-18.) Indeed, Dr. Ratain could not remember if he even saw patients with breast cancer in the late 1990s, nor could he recall whether any patient complained about the inconvenience of weekly trastuzumab. (*Id.*)

2. Weekly trastuzumab does not reduce patient quality of life.

48. Weekly trastuzumab therapy did not reduce patient quality of life. In fact, in 1999, researchers who published the results of a study of trastuzumab's impact on patient quality of life came to the conclusion that "in the doses and schedules used in the[] studies, trastuzumab is not associated with worsening HRQL [health-related quality of life]" and even suggested that "trastuzumab may be associated with an amelioration of the deleterious effects of chemotherapy alone." (*See* Ex. 2039, David Osoba & Michael Burchmore, *Health-Related Quality of Life in Women with Metastatic Breast Cancer Treated with Trastuzumab (Herceptin)*, 26 SEMIN. ONCOLOGY 84 (1999) at 84.) Researchers used a questionnaire called the QLQ-C30. (*See id.*) They applied the questionnaire in Phase II and Phase III trials

of trastuzumab, the same studies in Petitioner's prior art references the Slamon

Abstract and the 1998 Herceptin Label. The authors concluded:

In previous studies of chemotherapy in breast cancer, it has been shown that HRQL scores deteriorate while patients are receiving treatment. In the phase II trial reported here, no significant deterioration in HRQL scores was observed in patients treated with trastuzumab. In the phase III study, deterioration in HRQL scores appeared to be shorter in duration in patients treated with trastuzumab alone compared with those treated with trastuzumab and chemotherapy. These results suggest that not only is there no additional deterioration of HRQL associated with trastuzumab therapy, but trastuzumab therapy also may be associated with an ameliorative effect on HRQL. (*Id.* at 87.)

49. A patient's HRQL scores can deteriorate in two main ways: 1) the patient's symptoms directly caused by the tumor worsen; and/or 2) the patient's symptoms caused by the treatments worsen. The author notes that it was somewhat difficult to interpret HRQL scores from the study because it was difficult to calculate scores for patients with missing data later in the study as the patients were further along in their disease; the study approach of carrying the last available observation forward could tend to overestimate the results because the results from earlier time points were likely to be better. (Ex. 2039 at 87.) Even if the results are skewed towards the early assessments, the results still provide valuable information about whether the *treatment* causes the patient's symptoms to worsen, though less information about the patient's symptoms caused by progressive disease. The results show that there was little to no deterioration in patient quality of life due to trastuzumab treatment toxicity at least during the times which were assessed. (*Id.*) Although

these were more representative of the time points before progression they are relevant in terms of assessing toxicity for trastuzumab. The study is not perfect, but it certainly indicates that trastuzumab was well tolerated and that receiving the drug weekly did not negatively impact patients' quality of life. (*See id.* at 84.) Thus, while oncologists may generally look to improve patient well-being, there was no specific motivation in 1999 to improve trastuzumab patients' well-being by experimenting with novel dosing regimens, since the then state-of-the-art weekly dosing regimen for trastuzumab was shown to have an ameliorative effect on health-related quality of life in patients when compared to less frequent chemotherapy dosing alone.

3. Convenience must be balanced against other potential benefits of weekly visits.

50. The first FDA-approved dosing regimen for trastuzumab indeed required patients to come to the clinic every week and to spend time doing so, but not all the time spent at the clinic was fruitless. Weekly visits allowed patients who were facing a frightening, major illness more opportunities to ask doctors and nurses questions, which some patients found comforting. Some patients formed bonds with other patients in the infusion room. Some patients wanted to feel that they were actively taking steps to combat their disease. I did not receive any complaints about inconvenience from patients taking trastuzumab in 1999, and I am not aware that any of my colleagues received such complaints. Patients, however, are

individuals with individual preferences and there may be some who would find it inconvenient. But this would not be the primary consideration of a woman with an aggressive incurable cancer with the opportunity to get a potentially effective treatment. Most saw it as a small price to pay for a life-saving treatment.

4. Clinical oncologists would not have been motivated to dose trastuzumab on a three-weekly schedule like a chemotherapeutic agent because they are dosed according to different principles.

51. A clinical oncologist would not have been motivated in 1999 to administer an antibody like trastuzumab at the same three-weekly dosing interval as chemotherapeutic agents because the two types of drugs are dosed according to different principles.¹

52. Trastuzumab did not typically cause myelosuppression and neutropenia, so the primary consideration driving chemotherapy dosing did not factor into designs for trastuzumab dosing. Petitioner's expert Dr. Ratain agrees that trastuzumab

¹ More fundamentally, the fact that certain chemotherapeutic agents were co-administered with trastuzumab would not have necessarily motivated a clinical oncologist to dose trastuzumab on the same schedule as one of those chemotherapeutic agents. Like all doctors, clinical oncologists regularly prescribe a host of medications to patients without any expectation that administration schedules will necessarily be aligned.

does not cause bone marrow suppression or neutropenia, and agrees that the rationale that would lead a person of skill to dose chemotherapy every three weeks would not apply to dosing trastuzumab. (Ex. 2026, Ratain Tr. at 57:18-59:18.)

53. Even assuming a skilled artisan would have been motivated to dose a chemotherapeutic agent and a targeted antibody on the same schedule, it was much more likely that a skilled artisan would have *modified the dose of the chemotherapeutic agent to shorten the dosing interval* rather than disrupt trastuzumab's established schedule. First, since trastuzumab was the first antibody drug approved for treatment of breast cancer, clinical oncologists in August 1999 had little to no experience adjusting antibody dosing schedules. And some oncologists were wary of changing the dose because of the surprising cardiotoxicity. In contrast, skilled artisans had plenty of experience altering the schedules of chemotherapy drugs, particularly paclitaxel, and would have done so much more readily. Second, in 1999, a skilled artisan's main focus was efficacy, which typically involved delivering the maximum amount of treatment. Oncologists were prescribing higher doses of chemotherapy and shortening intervals between treatments. Electing to administer chemotherapy weekly with trastuzumab would have been a natural choice.

54. For example, oncologists in 1999 had been actively experimenting with paclitaxel doses, infusion times, and schedules for several years. Results from numerous clinical studies were emerging and showing the benefits of biweekly or weekly paclitaxel. (*See, e.g.*, Ex. 2016 at 3353.) Weekly administration of paclitaxel showed efficacy and a remarkably favorable toxicity profile for the high amount of drug delivered. (*See* Ex. 2016 at 3353, 3357-58; Ex. 2038 at 24.) Petitioner's expert admits that "if one wants to develop weekly paclitaxel, one would not be motivated to modify the trastuzumab schedule to give it every three weeks." (Ex. 2026 at 37:10-13.)

55. The most powerful evidence that a skilled artisan would have modified the schedule of paclitaxel rather than the schedule of trastuzumab is that this in fact occurred. At the time of invention, there were plans to explore the weekly co-administration of paclitaxel and trastuzumab, and one group had already obtained favorable results in a trial of weekly trastuzumab combined with weekly taxoid. (*See* Ex. 2016 at 3360; Ex. 2021 at 29; Ex. 2037.)

5. I disagree with Dr. Ratain's opinion that a skilled person would be motivated to change trastuzumab's dosing regimen less than a year after approval for the sake of convenience.

56. Dr. Ratain's statements regarding a skilled artisan's motivation to extend trastuzumab's dosing interval are cursory. (*See* Ex. 1003 at ¶ 89 ("[T]he weekly

trastuzumab regimen disclosed by Slamon would have required three times as many infusion visits as chemotherapy alone.”); *see id.* at ¶ 90 (“For the convenience of both patient and clinician, a POSA therefore would have been motivated to administer trastuzumab for the treatment of metastatic breast cancer characterized by overexpression of ErbB2, as disclosed by Slamon, but on the same schedule—once every three weeks—as chemotherapy.”); *see id.* at ¶ 91 (“[I]n order to improve patient and clinician convenience, a POSA would have been motivated to administer trastuzumab as an 8 mg/kg loading dose, followed by 6 mg/kg maintenance doses, with a three week interval between doses, given that the chemotherapy was given every three weeks.”).)

57. Dr. Ratain never states and cites no evidence to indicate that convenience or compliance was a problem for patients taking trastuzumab. As I explained above, compliance was not a problem for patients taking trastuzumab, patients did not complain about trastuzumab’s schedule, and it did not reduce patient quality of life. And in any case, patients in 1999 saw trastuzumab as a wonder drug. They were grateful for the treatment and were willing to tolerate some inconvenience to receive it.

58. Dr. Ratain provides no basis for his assertion that maintaining the same dose intensity—a strategy designed for chemotherapeutic drugs—would apply in the

same way to therapeutic monoclonal antibodies. (See Ex. 1003, Ratain Decl. ¶ 91.)

First, chemotherapeutic agents and antibodies work against cancer cells in different ways. Chemotherapeutic agents cause nonspecific DNA damage, therefore also damaging healthy cells. Therapeutic monoclonal antibodies are targeted, only attaching to a certain molecular receptor. In 1999, oncologists did not know enough about trastuzumab's mechanism of action to feel comfortable automatically applying principles from chemotherapy dosing to trastuzumab dosing. As Dr. Ratain stated in a publication only about a year after the invention:

The discovery of a plethora of target-based anti-neoplastic compounds has opened up an era of new opportunities and extraordinary challenges in drug development. The vast majority of anticancer drugs used in the clinic are cytotoxic to a broad range of normal and malignant cells, usually on the basis of rather nonspecific DNA damaging activity. . . . The elucidation of a large number of molecular alterations in cancer has greatly expanded the number of potential targets (presumably rational targets) for treatment of malignant disorders. These drugs of the future have the potential to be relatively specific and hopefully nontoxic at clinically effective doses. . . . ***Most clinical investigators and sponsors are well aware of the distinction between the newer agents and classical cytotoxics.***

(Ex. 2024 at 7-8 (emphasis added).)

59. Second, increasing the dose amount and extending the dosing interval was known to cause higher peak and lower trough concentrations as compared to smaller dose amounts administered more frequently. (Ex. 2005, Sarfaraz Niazi, *Chapter 7: Pharmacokinetic Principles, in* TEXTBOOK OF BIOPHARMACEUTICS AND

CLINICAL PHARMACOKINETICS 141 (1979) at 171 (greater dosing interval corresponds to greater percent fluctuation in plasma concentration).)

60. Dr. Ratain fills many pages of his declaration attempting to justify that a skilled artisan would have expected a three-weekly trastuzumab regimen to be safe and effective. (*See, e.g.*, Ex. 1003 ¶¶ 92-109.) Dr. Ratain thus acknowledges that safety and efficacy are of greater concern than convenience.

B. A clinical oncologist would not reasonably expect the claimed dosing regimen to be effective without sufficient evidence and assurances from a pharmacokineticist that the regimen would achieve therapeutic trough serum levels, and the prior art did not provide adequate information to support such assurances.

61. Even in the unlikely event that a clinical oncologist would have been motivated to consult with a pharmacokineticist to predict alternative trastuzumab dosing regimens, the clinical oncologist would have been concerned that extending the dosing interval to three weeks would cause the trough serum concentration to dip below the minimum therapeutic level, such that the regimen would not be effective to treat cancer. While clinical oncologists do not require one hundred percent certainty that a dosing regimen will be effective before testing it, we do require strong evidence that it would be as safe and effective as those dosing regimens already shown to work. We require this evidence because the stakes are high. Failure to achieve a therapeutic response from trastuzumab treatment can be fatal because, without trastuzumab treatment, patients with HER2-positive breast

cancer have a short life expectancy. And at the end of the day, we already had an effective, well-tolerated regimen that patients complied with, which meant that I would not change that regimen if supplied with a back-of-the-envelope calculation claiming that a new regimen worked. Dr. Ratain's analysis strikes me as just this type of calculation for three main reasons: 1) he glosses over trastuzumab's documented non-linearity; 2) his analysis is propped up on a scarce amount of pharmacokinetic data; and 3) a skilled artisan designing a new dosing regimen who already has an effective regimen in hand does not aim to cut it close with therapeutic drug levels, as Dr. Ratain does.

1. A clinical oncologist would not trust a pharmacokinetic analysis that ignored a key teaching in the prior art that impacts how a skilled artisan predicts the concentration of trastuzumab in a patient's serum over time.

62. In August 1999, I would have been concerned that Dr. Ratain's analysis ignores a key teaching—that trastuzumab exhibits dose-dependent kinetics—in the very publications he uses to form the basis of his opinions. The 1998 Herceptin Label states that trastuzumab has “demonstrated dose-dependent pharmacokinetics.” (Ex. 1008 at 1.) Baselga '96 also states that trastuzumab has “documented dose-dependent pharmacokinetics”. (Ex. 1007 at 4.) Watanabe demonstrates that the trough concentrations do not rise proportionally with the

trastuzumab dose, a phenomenon associated with dose-dependent kinetics. (Ex. 1006 at 5; Ex. 2027, Grass Decl. ¶ 35.)

63. I understand from Dr. Grass and other pharmacokineticists I have worked with over the years that, for drugs with non-linear kinetics, pharmacokinetic parameters such as half-life and clearance *change* as a function of the concentration of the drug in the plasma. (Ex. 2008 at 123; Ex. 2027, Grass Decl. ¶ 57.) This means that when the dose amount *or* the dosing interval is changed, the corresponding half-life derived from that dosing schedule no longer applies. (Ex. 2027, Grass Decl. ¶ 57.) So for a drug with dose-dependent kinetics, if a pharmacokineticist plugs into a formula the half-life that was derived from the weekly administration of one dose, it would be of little value in predicting the concentration of a different dose amount at a different dosing interval. (*Id.* at ¶¶ 57, 64.) I understand from Dr. Grass that to accurately predict an alternative dosing regimen for a drug with non-linear kinetics, more data is needed. (*Id.* at ¶¶ 56-76.)

64. A skilled artisan would not simply assume that a drug exhibiting dose-dependent kinetics would be eliminated more slowly at higher doses. (Ex. 2027, Grass Decl. ¶¶ 48-55, 76.) Non-linear pharmacokinetics can result from a number of potential factors. (*Id.* at ¶ 65.) Without the appropriate data, it is difficult to

predict how changes to a dosing regimen for a drug with non-linear pharmacokinetics will affect the drug's serum concentration over time. (*Id.* at ¶ 76.) Thus, a skilled artisan would not have used such an assumption as an excuse to avoid taking nonlinear kinetics into account in a pharmacokinetic analysis.

2. The prior art did not contain sufficient data to accurately predict the results of an alternative trastuzumab dosing regimen.

65. According to Dr. Grass's declaration (which I have reviewed), the prior art references do not provide sufficient pharmacokinetic data to accurately predict trough serum concentrations of an every-three week dosing regimen as claimed in the '196 and '379 patents. (Ex. 2027, Grass Decl. ¶¶ 56-76.) Dr. Grass also explains that the prior art provides enough information to show that trastuzumab exhibits dose-dependent kinetics for the dosing schedules tested, but not enough information for a skilled person to understand the bounds of that non-linearity. (*Id.* at ¶¶ 33-38, 66.) A pharmacokineticist needs to understand those bounds to make accurate predictions for alternative dosing regimens. (*Id.* at ¶ 66.) I have interacted with pharmacokineticists over many years of conducting clinical studies. When I asked a pharmacokineticist to make predictions regarding an alternative dosing regimen, I knew that there had to be data to work with. Dr. Ratain agrees. (Ex. 2026, Ratain Tr. at 169:19-22) ("Q: Now, the validity of pharmacokinetic modeling depends, to a large extent, on the quality of the data that you have to

work with; correct? A: Yes.”.) Dr. Ratain also admits that there was insufficient data in the prior art to model an extended interval dosing regimen for a drug with non-linear kinetics. (*Id.* at 159:19-160:2.)

66. As Dr. Grass explains, for trastuzumab in 1999, the prior art only included a minimal amount of pharmacokinetic data. (Ex. 2027, Grass Decl. ¶¶ 66-71.)

Baselga '96 provides serum concentration data for only two patients, and not in a manner a skilled artisan could use to construct a pharmacokinetic model, much less a non-linear model. (Ex. 1007 at 6.) The 1998 Herceptin Label and Pegram '98 only provide a handful of pharmacokinetic parameters such as half-life, not individual patient data. (Ex. 1008 at 1; Ex. 1009 at 8 (Table 6).) Watanabe reports some pharmacokinetic data for 18 patients—trough serum levels—but does not report when the trough levels were measured or whether the reported values are individual or mean levels. (Ex. 1006 at 5.) The Slamon Abstract does not provide pharmacokinetic data at all. (Ex. 1005 at 5.)

67. Dr. Ratain expressly acknowledges the deficiencies in four of the five prior art references used in his analysis. Dr. Ratain acknowledges the lack of any pharmacokinetic information in Slamon. (Ex. 2026, Ratain Tr. at 85:17-86:11.) Dr. Ratain further acknowledges that, looking at the information in Watanabe, one could not say, “I know what’s going on based on Watanabe.” (*Id.* at 185:6-8.) He

admitted that one would not know, looking at Watanabe, what the reported trough concentrations represented (e.g., minimum, maximum, or average trough). (*Id.* at 184:20-185:8.) Regarding Baselga '96, Dr. Ratain stated that there was “insufficient [data] for a POSA to calculate any pharmacokinetic parameters with any reasonable clarity.” (*Id.* at 106:16-107:7.) Further, when asked why he did not rely on the 1998 Herceptin Label, Dr. Ratain stated that drug labels do not have much information and that “[t]hey’re kind of like abstracts.” (*Id.* at 132:15-133:8.) He also alleged that the 1998 Herceptin Label “has less information” than Pegram '98 or Baselga '96 and that “by looking only at this label, one wouldn’t know terribly much.” (*Id.* at 142:17-143:11.)

68. If a pharmacokineticist presented to me an analysis like Dr. Ratain’s, I would have been skeptical because I would have known that the foundation of the analysis was shaky. I do not treat patients based on clinical studies with limited numbers of patients, and likewise, I would not take the advice of a pharmacokineticist who made predictions based on studies with limited data.

3. A skilled artisan designing a new dosing regimen who already has an effective regimen in hand does not aim to cut it close with therapeutic drug levels.

69. A person of skill would aim for serum concentration levels that would assuredly treat most of the skilled artisan’s patients with a comfortable margin. A skilled artisan would not administer an alternative dosing regimen to treat a life-

threatening disease such as metastatic breast cancer unless she was reasonably certain that the claimed protocol reached serum levels that were previously shown to have been effective. Dr. Ratain's predicted trough serum concentrations of 10.9 to 21.1 µg/mL are barely above the targets of 10-20 µg/mL established by the preclinical studies, and far below the levels reached in clinical studies. (Ex. 1003, Ratain Decl. ¶¶ 104, 109; Ex. 1007 at 8, Table 6; Ex. 1008 at 1.) Based on the lack of a tumor response at a trough serum concentration of 9 µg/mL reported in Watanabe (Ex. 1006 at 5), a skilled artisan would have appreciated that the margin of error surrounding the lower bound of therapeutic trough serum concentrations was very slim and would not have proceeded.

70. Dr. Ratain even admits that his calculations were not intended to be accurate. (Ex. 2026, Ratain Tr. at 177:3-9.) He also states that he does not need a detailed pharmacokinetic model of a dosing regimen before using it to treat patients with cancer. (*Id.* at 169:19-22.) "I need – you know – need to be comfortable, so to speak, with the back-of-the-envelope calculation, 'Does this make sense? Does it' – you know, no prediction is ever perfect." (*Id.* at 169:10-13.)

71. For the reasons explained above, Dr. Ratain's analysis would not have provided me with adequate assurances that the levels of trastuzumab in patients'

serum would remain high enough to treat cancer over the course of the entire dosing interval. Therefore, I would not have put my patients' lives at risk.

72. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made knowing that willful false statements and the like so made are punishable by fine, imprisonment, or both, under Section 1001 of title 18 of the United States Code.



Karen A Gelmon, M.D., FRCPC

Date: December 20, 2017

Appendix A

University of British Columbia
Curriculum Vitae for Faculty Members

Date: 20 December 2017

Initial: _____

FIRST NAME: Karen

MIDDLE NAME(S): A

1. SURNAME: Gelmon

2. DEPARTMENT/SCHOOL: Medicine (Medical Oncology)

3. FACULTY: Medicine

JOINT APPOINTMENTS:

4. PRESENT RANK: Professor

SINCE: Jul 1, 2011

5. POST-SECONDARY EDUCATION

(a)

University or Institution	Degree	Subject Area	Dates
University of Saskatchewan	BA (Hons)	Philosophy	1974
University of Saskatchewan	MD	Medicine	1979
University of British Columbia	FRCPC	Internal Medicine	1983
University of British Columbia	ABIM	Medical Oncology	1985
University of British Columbia	FRCPC	Oncology	1986

(b) Title of Dissertation and Name of Supervisor

(c) Continuing Education or Training

(d) Continuing Medical Education

(e) Professional Qualifications

6. EMPLOYMENT RECORD

Prior

University, Company or Organization	Rank or title	Dates
Roswell Park Memorial Institute, Buffalo, NY	Fellow	1983
BC Cancer Agency	Fellow	1984
UBC	Clinical Instructor	July 1984 to 1985
National Cancer Institute	Investigator	1984-1988
UBC	Clinical Assist. Professor	July 1985 to July 1994
National Health Research and Development	Researcher	1987-1988

Program		
University of London (UK) Epidemiology	Research Fellow	1988-1989
University College & Middlesex Hospitals, U of London (UK)	Sr. Lecturer & Consultant	1988-1989
UBC	Clinical Assoc. Professor	July 1994 to July 1999

UBC	Clinical Professor	July 1999 to July 2011
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Present

University, Company or Organization	Rank or title	Dates
BC Cancer /UBC	Chair UBC/BCCA Ethics Board	2018 - to present
BC Cancer Agency	Clinical Head - Investigational Drug Program	1990 to present
UBC	Professor	July 2011 to present
BC Cancer Agency	Medical Oncologist	1990 to present
UBC	Active Staff Interim Head Division of Medical Oncology	October 2013 to January 2017
Vancouver General Hospital	Active Staff	1990 to present
University Hospital of Northern BC	Consulting Staff	Dec 2012 to present

c) Date of granting tenure at UBC:

7. LEAVES OF ABSENCE

University, Company Or Organization at which Leave was taken	Type of Leave	Dates
Middlesex Hospital, London UK	Senior lecturer/consultant	Jan/1988 - Nov/1989
Brompton Hospital, UK	Fellow, Epidemiology,& UK HIV Clinical Trials physician	May/1988 - Nov/1989
Shaare Tzedek Hospital, Jerusalem, Israel	Sabbatical	1/Mar/1998 - 1/Jun/1998

8. TEACHING

(a) Areas of special interest and accomplishments

- 1 Investigational new drugs in cancer, Clinical trials particularly new treatment options and Phase I/II clinical trials including theory of new drug development in oncology, clinical research in breast cancer, translational research in breast cancer.
- 2 Percentage of overall time devoted to:
 - 1) Non-clinical instruction 5%
 - 2) Clinical instruction 35% (overlaps with clinical practice)
 - 3) Research/publication 15% (overlaps with clinical practice)
 - 4) Administration 10%
 - 5) Clinical practice 35% (overlaps with clinical instruction)
 - 6) Other (specify) 5% overlaps with clinical practice and administration - tertiary care responsibilities of advising, educating physicians, health care professionals, public

(b) Courses Taught at UBC:

Year	Session	Course Number	Scheduled Hours	Class Size	Hours Taught	Lecture	Tutorials	Labs	Other
	Ambulatory Care Teaching		16 hrs/wk						
	Bedside Teaching - Residents	Int Med - in clinics and wards	3-5 hrs/wk						
	Bedside Teaching - Residents	Oncology - on wards	1-4 hrs/wk						
	Med 1	Examination Skills in breast examination	4-6 hr /yr						
	Med 3 - Rotating Students	Medicine, elective in Oncology	4-8 wks/yr						
	Med 4 - Elective in Oncology	1-4 wks of supervision	20 hrs/yr	2-5/yr					
1990,92, 94,96	Med 3 - Subspecialty	Clin Teaching, Breast Cancer	varies						
1990,92, 94,96	Med 3 - Subspecialty	Clin, Oncol emergencies	2 hrs/yr						
1990,92, 94,96	Med 3 - Subspecialty	Clin, Oncol Problems	varies						
1990 - 1997	Med 3 - Bedside Teaching In Internal Medicine	Clinical Skills	30 hrs/year + exam x 2						
1990 - present	Med Oncol & Int Res		12 hrs/yr	4-6/ sess					

				ion		
1990 - present	Med Oncol Seminar Series	Investigational New Drugs	2 hrs/yr	8-10		
1990 - present	Med Oncol Seminar Series	Metastatic Breast Cancer	2 hrs/yr	8-10		
1992 - 1993	Radiation Residents, HIV-related	Malignancies, Investigational New Drugs	3 hrs/yr			
1993 - 1994	Med 1	Elective Student	120 hrs/yr			
1997	Med 1	History Taking	8 hrs/yr			
1997		Pharmacol 403, U of A	3 hrs/session			
1997 - 1998	Med 1	History & Physical	8 hrs/yr			
1998	98/11/05	Anat 548-S	2 hrs	6		2 hrs
1998-present	Med 2	History Taking	8 hrs/yr			
1999-present	Med 1, Surgery	PE of Breast INDE 420	4 hrs/yr	6		
1999-present	Med 2	INDE 420	4 hrs/yr	12		
1999-present	Medical Oncology residents series	Seminar Series New Drugs Development	1 hrs/yr	1		
1999-present	Medical Oncology residents series	Serminar Series Metastatic Breast Cancer	1 hrs/yr	1		
2009	Medical Oncology residents series	Serminar Series Taxanes, Anthracyclines etc	1 hrs/yr	1		
2009, 2010, 2011, 2012	Undergraduate Medicine UBC	Internal Medicine 3 rd year exams	6 -9 hrs / year	12-18		
2010-2011	INDE 420 Clinical Skills		12 hrs/year	4		
2010-2011	MEDI 430		8 hrs/year	3		
2011-2012	INDE 420		12 hrs/year	4		
2011-2012	MEDI 430 – Oral Exam		5 hrs/year	3		
2012-	INDE 420 Clinical		6 hrs/year	2		

2013	Skill		
2013	INDE 420	12 hrs / year	2
2013	INDE 410	8 hrs / year	10
2013	Medical Oncology-residents series	3 hrs / year	8
2013/14	Academic Half Day: Oncology	6 hrs / year	100
2014-2015	MEDI 430 – Oral Exam Teaching Session	2 hrs/year	1
2015-2016	MEDI 430 – Oral Exam Teaching Session	6 hrs/year	3

(c) Graduate Students supervised at UBC:

Student Name	Program Type	Year Start	Finish	Principal Supervisor	Co-Supervisors
A. Diab	Oncology - Liposomal Vincristine Studies (Post Doc)	1993	1994		
Gwyn Bebb	PhD Residency	1994	1997	G. Dougherty	K. Skov, K. Gelmon
Anna Forbes	Resident research project Cancer (Post Doc)	1995	1996		
Susan Gudelis	Medical Student Exchange from McMaster	June 1996	July 1996		
Jeff Matthews	PhD	1996	1997	B. Palcic	K. Skov, K. Gelmon
Vanessa Bernstein	Medicine Resident Research Project (Post Doc)	1996	1997		
Kim Chi	Fellowship (Post Doc)	1997	1999	K. Gelmon	L. Mayer, A. Tolcher
Stephen Chia	Fellowship (Post Doc)	1998	2000	K. Gelmon/M. Bally	
Nancy Dos Santos	PhD	1999	2003	M Bally	K Gelmon
Sheela Abraham	PhD	2000	2004	M Bally	K Gelmon
					H Burt
Bernie Eigl	Resident in Oncology (Post Doc)	2002	2003	K. Gelmon	A. Karsan

Kirsten Lane	PhD	2002	2005	D McKenzie	K Gelmon D Worsley
Andrew Robinson	Resident in Oncology - research project (Post Doc)	2004	2005	K Gelmon	D Huntsman
Jessica Kalra	PhD	2005		M Bally	S Dedhar, S Dunn, K. Gelmon
Kirsten Lane	Post Doc fellowship	2006	2010	K Gelmon	D McKenzie
Simon Crabb	Fellowship year in breast oncology (Post Doc)	2006	2007	K Gelmon	Sam Aparicio Stephen Chia
Rinat Yerushalmi	Fellowship in breast oncology (Post Doc)	2007	2010	K Gelmon	Hagen Kennecke
Nilesh Patankar	PhD	2006		M Bally	M Ensom, K Gelmon, H Burt, P Cullis
Jose Monzon	Medical Oncology (Post Doc)	2009	2010	K Gelmon	M Haydn
Lianne Dolan	PhD	2008	2010	D McKenzie	K Gelmon
Svetlana Bortnik	PhD	2010	2014	S Gorski	K Gelmon
Rachel Cossetti	Medical Oncology Fellow (Post Doc)	2013/04	2014/07	K Gelmon	
Momir Bosiljcic	Masters	2012	2014	H Pritchard	K Gelmon, A Minchinton, M Bally, W Lam, K Bennewith
Margot Davis	Cardiology Fellow – Medical Oncology (Post Doc)	2012/09	2014/09	S Virani, J Cairns	K Gelmon
WenYee Chay	Medical Oncology Fellow (Post Doc)	2014/04	2015/07	K Gelmon	
Amy Kirkham	Medical Oncology Fellow (Post Doc)	2014/03	2015/07	K Gelmon	K Campbell, D McKenzie
Wee Yee Chay	Oncology Fellow (Post Doc)	2014/04	2015/07	K Gelmon	
Amy Kirkham	PhD Kinesiology (Post Doc)	2013/04	2016/07	K Gelmon	

(d) Continuing Education Activities

- 1 Nurses - in-service teaching (6 - 10 hrs/yr)
- 2 Laboratory staff in Investigational Drug Unit (~1-2 hrs/mth)
- 3 Video - use of Taxol for patients and health care professionals (4 hours)
- 4 Pharmacy at BCCA - inservice (2 hrs/yr)
- 5 1984, 1985, 1986, 1987 Grand Rounds, St. Paul's Hospital

6 Jun/1992 CME Common Cancers, Powell River
 7 1994 University of Saskatchewan, Saskatoon
 8 1994 St. Paul's Hospital "Kaposi's Sarcoma" (1 hour)
 9 1994 Vancouver Hospital "Kaposi's Sarcoma" (1 hour)
 10 Oct/1994 Communities Oncology course (8 hours)
 11 1994, 1995, 1997 Canadian Oncology Symposium (1 hr/yr)
 12 1995 Dalhousie University, Halifax
 13 1995 Vancouver Hospital - Hematology/Oncology Case Presentations (1 hour)
 14 Jun/1995 Oncology Nurses course on Taxol - Charles, S. Carolina (8 hours)
 15 1996 University of Mississippi, Jackson. Breast Cancer Course
 16 1996 Vancouver Hospital - Hematology/Oncology Case Presentations (1 hour)
 17 Mar/1996 HIV Malignancy, North Thames CME Course, London UK
 18 1997 Vancouver Hospital - Hematology/Oncology Case Presentations (1 hour)
 19 Mar/1997 UBC Interdisciplinary Conference CME, Breast Cancer Myths and Realities, Chair of Plenary Committee
 20 Nov/1997 CME Course in Breast Cancer Therapy, San Antonio, Texas
 21 Apr/1997, Apr/2000 National Oncology Pharmacists Symposium (NOPS)
 22 1998 Vancouver Hospital "Towards treating cancer as a chronic disease" (1 hour)
 23 1998 Haifa University, Haifa
 24 1998 Vancouver Hospital - Hematology/Oncology Case Presentations (1 hour)
 25 1998-1999 Chair of UBC Interdisciplinary Conference CME, Breast Cancer Myths & Realities, Feb 1999
 26 1999 St. Paul's Hospital - Hematology/Oncology Case Presentations (1 hour)
 27 1999-2001 Chair, UBC Interdisciplinary Conference CME Women and Cancer, Myths and Realities, March 2001
 28 2000 St. Paul's Hospital - Hematology/Oncology Case Presentations (1 hour)
 29 2000 Planning Committee BCCA Annual Group Meeting Nov 2000
 30 2000-2001 Planning Committee of Breast, CME, Jan 2001
 31 2000-2001 Planning Committee of Women and Cancer CME, March 2001
 32 2001-2002 Planning Committee, B.C. Women's Institute January 2002
 33 2002 Planning Committee, Head of Breast Session, COPE, Canadian Oncology Peer Exchange, Bermuda, 2002
 34 2002 Chair B.C. Breast Education Day, November 2002
 35 2002-2003 Chair, Breast Section, Western Canada Oncology Meeting 2003
 36 2002-2003 Planning Committee Joint Forum of B.C. Women's and the Screening Mammography Program of B.C., October, 2003
 37 2002 - 2003 Planning Committee Head of Breast Section, COPE, Canadian Oncology Peer Exchange, Banff October 2003
 38 2003 Chair B.C. Breast Education Day, November, Vancouver
 39 2004 - Education Committee Breast Cancer, American Society of Clinical Oncology
 40 2004 - Education Committee Breast Cancer, American Society of Clinical Oncology
 41 2004 - UBC Annual Internal Medicine Conference - Hormones and Breast Cancer
 42 2003 Planning Committee and Speaker Western Canada Oncology Meeting, February 2004
 43 2004 - Systemic Therapy Nurses' Update, February 2004, Vancouver

- 44 2004 - Round Table Discussion on Adjuvant Treatment of Breast Cancer, Feb 2004, Vancouver
- 45 2004 - New Oral Agents in Breast Cancer Treatment, Chair, Toronto, April 2004
- 46 2004 - New Targeted Treatments in Breast Cancer - Chicago, May 2004
- 47 2004 - St Paul's Annual Conference - Update on Breast Cancer, Nov 2004, Vancouver
- 48 2004-2005 - Track Chair for the Breast Site for the American Society of Clinical Oncology
- 49 2005 - Co Chair of Breast Session at Canadian Winter Oncology Meeting, Sun Peaks
- 50 2005 - UBC Annual Internal Medicine Conference - Breast Conference Vancouver
- 51 2005 - Breast Cancer Symposium - Mt Tremblant, Quebec
- 52 2005 - Organizing Committee and Speaker for Western Canadian Consensus Conference, Banff
- 53 2005 - Breast Cancer - Issues in Treatment of Post Menopausal Women with Breast Cancer, Whistler
- 54 2005 - Chair and Coordinators of ASCO Education Session - Young women with Breast Cancer
- 55 2005 - Annual Cancer Conference BCCA - Session on HER2 in breast Cancer - Vancouver, Nov 2005
- 56 2006 - Chair of Canadian Winter Oncology Meeting
- 57 2006 - ASCO Education Session - Chair of Education Session on Phase II Clinical Trials- Targeted Agents
- 58 2006 - UBC - Family Practice Telehealth - Breast Cancer - April 2006
- 59 2006-2007- Chair, Canadian Winter Oncology Meeting
- 60 2007 Organizing Committee Fall Breast Cancer Symposium, Vancouver BC, Oct 2007
- 61 2007 – 2008 Chair, Breast Cancer Updates, Roche Brazil, Vancouver Oct 2007/ Jan 2008
- 62 2008 - NCIC CTG, IND and Breast Cancer Retreat, Toronto, January 2008
- 63 2008 - ASCO Educational Session, Anthracyclines – should they still be used, Chicago, June 2008
- 64 2008 – Annual Cancer Conference BCCA, Amgen Sponsored Symposium, Chair and Speaker, Nov 2008
- 65 2008 – San Antonio Breast Meeting, Symposium, Extended Adjuvant Treatment, Speaker, Dec 2008
- 66 2009- ASCO, invited discussant, oral presentation session. June 2009
- 67 2009- San Antonio Breast Meeting, Chair Symposium, New Targeted therapies,
- 68 2010 – Breast Cancer Symposium, Toronto, Session Chair, New Therapies
- 69 2010, 2011– ASCO, member Education Committee
70. 2012 – 2013, Chair ASCO Education Committee Breast Site
- 71 October 2014, Invited Speaker, Fraser Valley Breast Rounds, Hormonal Therapy of Metastatic Breast Cancer

(e) Visiting Lecturer (indicate university/organization and dates)

- 1 Jun/1989 Grand Rounds, Southampton General Hospital.
- 2 Jun/1989 IV International Conference on AIDS, Montreal.
- 3 Sept/1989 The European Conference on Venererology and Dermatology, Clinical Trials on HIV, Florence.
- 4 Sept/1989 Grand Rounds, St. Georges Medical School.
- 5 Jun/1990 Advances in Internal Medicine, Vancouver.
- 6 Jul/1990 International Conference on Aids, San Francisco.
- 7 Jul/1990 Medical Grand Rounds, University of British Columbia.
- 8 Nov/1990 David Boyes Society Annual Meeting.
- 9 May/1991 Northwest Society for Rehabilitation Medicine Annual Conference.
- 10 June/1992 CME Common Cancers, Powell River.
- 11 Oct/1992 36th Annual Cancer Symposium, Regina.

- 12 Nov/1992 First International Conference on the Treatment of HIV, Glasgow.
- 13 Mar/1993 Medical Grand Rounds, Vancouver General Hospital, Vancouver.
- 14 Mar/1993 Medical Grand Rounds, St. Paul's Hospital, Vancouver.
- 15 Apr/1993 BCCA Research Centre Day.
- 16 Apr/1993 Pediatric HIV/AIDS Conference, Vancouver.
- 17 May/1993 Canadian Association for HIV Research, Montreal.
- 18 May/1993 University of B.C. HIV Rounds, St. Paul's Hospital, Vancouver.
- 19 Aug/1993 Canadian Federation of University Women, Vancouver.
- 20 Sept/1993 Powell River General Hospital Grand Rounds.
- 21 Oct/1993 BC Communities Oncology Oncologists Update, Vancouver.
- 22 Oct/1993 BC Pharmacy Symposium, Vancouver.
- 23 Oct/1993 National Cancer Institute of Canada Fall Meeting, Ottawa.
- 24 Nov/1993 European Conference on Clinical Oncology (ECCO), Jerusalem.
- 25 Nov/1993 Bristol Myers Round Table on Taxol, New York.
- 26 Dec/1993 UBC Gynecology Grand Rounds.
- 27 Jan/1994 Bristol Myers Squibb Canadian Update.
- 28 Feb/1994 Grand Rounds, Royal University Hospital, Saskatoon.
- 29 Feb/1994 Oncology Rounds, Regina General Hospital, Regina.
- 30 Mar/1994 Taxol Update, Madrid.
- 31 Mar/1994 Taxol Update, Rome.
- 32 Apr/1994 BCCA Research Centre Day.
- 33 May/1994 Burnaby General Grand Rounds.
- 34 Jun/1994 Highlights in Medicine, University of Saskatchewan.
- 35 Sept/1994 Royal College Meeting, Toronto, ON.
- 36 Nov/1994 Speaker and Organizer of Malignancy Session, Second International Congress on Drug Therapy in HIV infection
- 37 Nov/1994 Chemotherapy Foundation Symposium XII Innovative Cancer Chemotherapy for Tomorrow, New York.
- 38 Nov/1994 Bristol Myers Oncology Seminar, Chicago, Illinois.
- 39 Mar/1995 Fox Chase Annual Investigators Meeting, St. John's, Virgin Islands.
- 40 Apr/1995 Biweekly Taxol in the Treatment of Metastatic Breast Cancer, Montreal
- 41 Apr/1995 BC Communities Oncology, Oncologists Update
- 42 May/1995 Chair, organizer and speaker. Taxol in Breast Cancer. Symposium sponsored by Bristol- Myers Squibb in Toronto.
- 43 May/1995 Halifax Grand Rounds
- 44 Jun/1995 Taxol for Metastatic Breast Cancer, Oncology Nurses Conference, Charleston, NC
- 45 Jul/1995 Chair, organizer and speaker. Vinorelbine in the Treatment of Breast Cancer. Symposium sponsored by Burroughs Wellcome - ICC Meeting, Montreal.
- 46 Sept/1995 Recent Advances in Breast Cancer Treatment: the Taxoids. Royal College of Physicians and Surgeons, Montreal.
- 47 Dec/1995 A Symposium on Selected Topics in Lung Cancer. Lung Tumor Group BCCA and the BC Thoracic Society, Vancouver, B.C.

48 Feb/1996 Taxol in the Treatment of Metastatic Breast Cancer, Oncology Nurses Conference, West Palm Beach, Florida
 49 Feb/1996 New Drugs in the Treatment of Breast Cancer, Portland Oregon
 50 Mar/1996 HIV Malignancy, North Thames CME Course, London UK.
 51 Apr/1996 Medical Oncology Grand Rounds, Sudbury, Ont.
 52 Apr/1996 City Wide HIV Rounds
 53 May/1996 Medical Oncology Grand Rounds, Hamilton Cancer Centre
 54 May/1996 Oncology Grand Rounds, University of Mississippi, Jackson, Mississippi.
 55 May/1996 Medical Grand Rounds, University of Mississippi, Jackson, Mississippi
 56 Sept/1996 Plenary lecture, Assoc. of Canadian Medical Oncologists, Royal College of Physicians, Halifax
 57 Oct/1996 Medical Oncology Rounds - Ottawa Regional Cancer Centre
 58 Oct/1996 Medical Oncology Grand Rounds, London Regional Cancer Centre.
 59 Mar/1997 Pharmacy 403 U of Alberta, visiting lecture, Taxanes in Cancer Therapy
 60 Apr/1997 National Oncology Pharmacy Symposium, Montreal
 61 Jun/1997 Korean Medical Oncology Annual Meeting
 62 Jun/1997 Taiwanese Medical Oncology Symposium on Breast Cancer.
 63 Jun/1997 American Association of Gynecology annual meeting, Halifax.
 64 Sept/1997 Taxol and other advances in cancer treatment, update lecture, Pharmacy World Congress, Vancouver
 65 Nov/1997 Changing Approaches to the Systemic Management of Breast Cancer, Vancouver
 66 Nov/1997 Changing approaches to the systemic management of breast cancer. Vancouver.
 67 Apr/1998 Speaker - Breast cancer - New Issues, Israeli Oncology Association
 68 Apr/1998 New directions in adjuvant therapy. Tel Aviv, Israel.
 69 Apr/1998 New issues in breast cancer. Tel Aviv, Israel.
 70 May/1998 Guidelines in the treatment of breast cancer. Dept. of Oncology, Rambam Hospital, Haifa.
 71 May/1998 Canadian guidelines in breast cancer. Dept. of Oncology, Rabin Hospital, Tel Aviv.
 72 May/1998 Canadian guidelines in breast cancer. Hadassah Hospital, Jerusalem.
 73 Jun/1998 New issues in breast cancer. Ben Gurion University of Israel.
 74 Nov/1998 Medical Grand Rounds, VGH
 75 Sept/1999 Breast Cancer - From Lab to the Clinic - Testing, Pitfalls & Issues, Crossing the Strait at Georgia
 76 Oct/1999 HER 2 in Breast Cancer, Vancouver, BC
 77 Mar/2000 HER 2 in Breast Cancer, Vancouver, BC
 78 Apr/2000 New Issues in Breast Cancer, National Oncology Pharmacy Symposium (NOPS), Toronto
 79 Jun/2000 Treatment of Metastatic Breast Cancer, Hong Kong Oncology Society, Hong Kong
 80 Oct/2000 Treatment of HER 2 negative Breast Cancer, Pheonix
 81 Nov/2000 Chemotherapy Foundation Symposium XVIII, .. Cancer Therapy for Tomorrow, New York
 82 Jan 2001 Oncologist's View of Sentinel Node Dissection, CME course, Vancouver, BC
 83 March 2001 Postgraduate Update Course CME, Vancouver, BC
 84 May 2002 UBC Update on Gynecology, Screening for Breast Cancer, Vancouver B.C.
 85 May 2002 Guelph-Ontario Her-2 Update
 86 June 2002 UBC Medicine in the 21st Century, Advances in Internal Medicine, Hormones and Breast Cancer
 87 Sept 2002 Genentech investigators meeting Herceptin after progression Scottsdale Arizona

- 88 Oct 2002 Memorial University HER-2 and Breast Cancer St. John Newfoundland
- 89 Oct 2002 HER-2 and Breast Cancer Halifax Nova Scotia
- 90 Oct 2002 Toronto Sunnybrook Regional Cancer Centre- How to use Herceptin in 2002, Toronto Ontario
- 91 Oct 2002 Screening Mammography Program of BC- Annual Meeting, DCIS-Current Treatment
- 92 May 2003 Medical Oncology Rounds, Tom Baker Cancer Centre, Calgary Alberta
- 93 June 2003 Highlights in Medicine, 50Th Anniversary of the University of Saskatchewan Medical School, Saskatoon, Saskatchewan
- 94 June 2003 Ontario Oncology Update, Ottawa Ontario, Update on the treatment of Metastatic Breast Cancer
- 95 February 2004 Medical Oncology Rounds, VA Hospital, San Antonio, Texas
- 96 February 2004 Medical Oncology Rounds, Tom Baker Cancer Centre, Calgary Alberta
- 97 June 2004 Plenary Alumni Speaker, Highlights in Medicine, 50Th Anniversary of the University of Saskatchewan Medical School, Saskatoon, Saskatchewan
- 98 October 2004 COPE Conference, Utility of Guidelines in Cancer Treatment
- 99 November 2004, Annual St Paul's Meeting, Invited Lecturer, Breast Cancer Current Treatments, Vancouver BC
- 100 May 2005, Invited Speaker, American Association of Breast Radiology Annual Meeting, Vancouver BC
- 101 June 2005 BC Cancer Research Centre Rounds, A Snapshot View of Phase I Clinical Trials.
- 102 June 2005 South American Oncology Conference, Treatment of HER2 Positive Disease
- 103 June 2005, Invited Speaker, Annual Internal Medicine Review, Vancouver BC
- 104 November 2005, Invited Speaker, St Paul's Meeting, Update on Breast Cancer Treatments, Vancouver BC
- 105 December 2005 Invited speaker, COPE meeting, San Antonio Breast Cancer Conference
- 106 January 2006, Invited Speaker, Israeli Society of Oncology Annual Meeting, Eilat, Israel
- 107 February 2006, Invited Speaker, Roche International Meeting, Vienna
- 108 March 2006, Invited Speaker, Nice Breast Meeting, Understanding Breast Cancer, Media Event, Nice France

- 109 April 2006 Plenary Speaker Canadian Medical Oncology Association, Annual Meeting (Royal College equivalent), Montreal
- 110 May 2006 Speaker - Canadian Breast Cancer Research Alliance (CBCRA) Meeting, Montreal
- 111 May 2006 Plenary Speaker - Vancouver Island Medical Oncology Annual Meeting, Victoria
- 112 May 2006 Invited Speaker - COMET, Community Oncologists, Pharmacists and Oncology Nurses of Greater Toronto meeting, Toronto
- 113 June 2006 Poster Discussant - American Society of Clinical Oncology
- 114 June 2006, Invited Speaker - Targeted therapies for Breast Cancer– Annual Breast Cancer Meeting University of Toronto, Toronto
- 115 June 2006 Invited Speaker - Weekend To End Breast Cancer Research Meeting, Vancouver BC
- 116 June 2006 Invited Speaker, Western Canada Community Oncology Meeting
- 117 October 2006, Invited Speaker, Atlantic Canada Oncology Meeting, Halifax, NS
- 118 October 2006, Invited Speaker, Society of Gynecologic Oncology, Santa Monica, Ca
- 119 January 2007, Invited Speaker, Israeli Society of Oncology Annual Meeting, Eilat, Israel
- 120 May 2007, Invited Speaker, Novartis Symposium, Barcelona
- 121 May 2007, Invited Speaker, HOTT meeting, Sydney Australia
- 122 May 2007, Invited Speaker, Peter McCallum Cancer Centre, Melbourne, Australia
- 123 July 2007, Invited Speaker, Dana Farber Breast Cancer Course, Harvard Medical School, Boston, Mass

124 July 2007, Invited Speaker, Weekend To End Breast Cancer Research Meeting, Toronto, Ontario
 125 October 2007, Invited Speaker, Seattle Breast Conference,
 126 October 2007, Invited Speaker, Hotel Dieu Breast Rounds, Montreal
 127 October 2007, Invited Speaker, McGill Breast Rounds, Montreal
 128 November 2007, Invited Speaker, Breast Cancer Update Conference, Vancouver
 129 November 2007, Invited Speaker, BCCA Annual Cancer Conference, Vancouver
 130 December 2007, Invited Speaker, CORE program, San Antonio Breast Cancer Conference
 131 December 2007, Invited Speaker, Roche Symposium, San Antonio Breast Cancer Conference
 132 March 2008, Invited Speaker, Canadian Oncology Winter Conference, Sun Peaks, BC
 133 June, 2008, Invited Speaker, ASCO Educational Session, Chicago
 134 September 2008, Invited Speaker, 26th Congress of the International Association for Breast Cancer Reserch, Japan
 135 September 2008, Invited Speaker, Japanese Breast Cancer Society Annual Meeting, Japan
 136 October 2008, Invited Speaker, Lynn Sage Breast Meeting, Chicago, Ill
 137 October 2008, Invited Speaker, Seattle Breast Cancer Meeting, Seattle, Wash
 138 January 2009, Invited Speaker, Israeli Cancer Society Conference, Eilat, Israel
 139 April 2009, Invited Speaker, Crossing the Straights of Georgia, BC Research Meeting, Squamish, BC
 140 April 2009, Invited Speaker, New Drugs in Breast Cancer, Rome, Italy
 141 May 2009, Invited Speaker, Chinese Breast Cancer Association, Hong Kong
 142 June 2009, Invited Speaker, Discussant at Poster Session, ASCO 2009, Orlando Florida
 143 July 2009, Invited Speaker, Dana Farber /Harvard Breast Cancer Course, Boston Mass
 144 Sept 2009, Invited Speaker, HER2 treatment, grand rounds, Tel Hashomer, Hadassah, Rambam Cancer Centres
 145 October 2009 – Invited Speaker, Translational Medicine Rounds, London Regional Cancer Centre, London, Ont
 146 October 2009, Invited Speaker, BC Surgical Conference, Vancouver, BC
 147 November 2009, Invited Speaker, GSK symposium, Toronto, Ontario
 148 December 2009, Invited Speaker, Roche Symposium, San Antonio, Texas
 149 January 2010, Invited Speaker, Israel Cancer Society, Annual Meeting, Eilat Israel
 150 February 2010, Invited Speaker, Regina Cancer Clinic, Regina, Saskatchewan
 151 March 2010, Invited Speaker, HOTT Cancer Conference, Melbourne, Australia
 152 March 2010, Invited Speaker, BC Laboratory Technologists Rounds, Vancouver BC
 153 May 2010, Invited Speaker, GSK Symposium, Vancouver, BC
 154 July 2010, Invited Speaker, Australia/New Zealand Clinical Trials Group, Sydney, Australia
 155 September 2010, Invited Speaker, Texas Internists Medicine Conference, Vancouver BC
 156 October 2010, Invited Speaker, New Brunswick Breast Forum, Saint John, New Brunswick
 157 October 2010, Invited Speaker, Inova 19th Annual Breast Cancer Symposium, Washington DC
 155 October 2010, Invited Speaker, Quebec Annual Conference on Resistance in Cancer, Montreal
 156 October 2010, Invited Speaker, Ovarian Cancer Research Symposium, Seattle Washington
 157 November 2010, Invited Speaker, BC Cancer Agency Annual Cancer Conference, Vancouver, BC
 158 November 2010, Invited Speaker, Roche Symposium, BCCA Annual Cancer Conference, Vancouver, BC
 159 January 2011, Review of Bone markers in Breast Cancer, Vancouver
 160 March 2011, Lecturer – Postgraduate course in molecular oncology, UBC, Vancouver

161 March 2011, Invited Speaker, Cross Cancer Agency, HER2 agents in breast cancer, Edmonoton Alberta
 162 May 2011, Invited Speaker, Brazilian Update on Breast Cancer, Sao Paolo, Brazil
 163 May 2011, Invited Speaker, International Conference on Molecular Oncology, Torino Italy
 164 June 2011, Invited Speaker, GSK Symposium on HER2 targeted agents, Chicago, Illinois
 165 June 2011, Invited Speaker, Update on Breast Cancer Conference, Vancouver, BC
 166 October 2011, Invited Speaker, 2nd International Conference on New Drugs in Breast Cancer. Rome, Italy
 167 November 2011, Invited Speaker, 1st International Consensus Conference on Advanced Breast Cancer, Lisbon, Portugal
 168 January 2012, Invited Speaker, Tel Aviv University, Tel Aviv Israel
 169 January 2012, Invited Speaker, Translational Research Rounds, Hebrew University, Jerusalem Israel
 170 March 2012, Invited Speaker, 6th Brazilian Breast Cancer Conference, Sao Paolo, Brazil
 171 March 2012, Invited Speaker, EBCC Genomic Health Symposium, Vienna Austria
 172 April 2012, Invited Speaker, 4th International Symposium on Hereditary breast and ovarian Cancer, Montreal, PQ
 173 June 2012, Invited Speaker, ASCO educational Session, Chicago, Illinois
 174 June 2012, Invited Speaker, ASCO update, Beirut Lebanon
 172 June 2012, Invited Speaker, International Symposium on Breast Cancer, Sao Paolo Brazil
 173 August 2012, Invited Speaker, 22nd Annual Mayo Clinic Hematology/Oncology Reviews 2012, Jacksonville, Florida
 166 October 2011, Invited Speaker, 2nd International Conference on New Drugs in Breast Cancer. Rome, Italy
 167 November 2011, Invited Speaker, 1st International Consensus Conference on Advanced Breast Cancer, Lisbon, Portugal
 168 January 2012, Invited Speaker, Tel Aviv University, Tel Aviv Israel
 169 January 2012, Invited Speaker, Translational Research Rounds, Hebrew University, Jerusalem Israel
 170 March 2012, Invited Speaker, 6th Brazilian Breast Cancer Conference, Sao Paolo, Brazil
 171 March 2012, Invited Speaker, EBCC Genomic Health Symposium, Vienna Austria
 172 April 2012, Invited Speaker, 4th International Symposium on Hereditary breast and ovarian Cancer, Montreal, PQ
 173 June 2012, Invited Speaker, ASCO educational Session, Chicago, Illinois
 174 June 2012, Invited Speaker, ASCO update, Beirut Lebanon
 172 June 2012, Invited Speaker, International Symposium on Breast Cancer, Sao Paolo Brazil
 173 August 2012, Invited Speaker, 22nd Annual Mayo Clinic Hematology/Oncology Reviews 2012, Jacksonville, Florida
 174 October 2012, Invited Speaker, Amgen Meeting, Vancouver
 175 November 2012, Invited Speaker, Danish Breast Cancer Society, Copenhagen
 176 November 2012, Invited Speaker, Annual Cancer Conference, BC Cancer Agency, Vancouver, BC
 177 December 2012, Invited Speaker, San Antonio Breast Cancer Symposium, HER2 education session, San Antonio
 178 February 4, 2013, Invited Speaker, "Access to Clinical trials and research internationally", Komen Global Cancer Initiative, Washington, DC
 179 June 12th 2013, Invited Speaker, "Challenges in Taking Personalized medicine into the clinic", Canadian Pharmacy Conference, Vancouver, BC
 180 June 13th 2013, Invited Speaker, "When is anticancer therapy appropriate for the palliative patient", Annual Palliative Care Conference, Vancouver, BC
 181 June 20th 2013, Invited Speaker, "Personalizing treatment in Triple Negative Breast Cancer", Annual Toronto Breast Cancer Symposium, Toronto, Ontario

- 182 June 26th 2013, Invited Speaker, “Challenging Clinical Aspects of the Treatment of Triple Negative Breast Cancer”, Breakthrough Cancer Meeting, Triple Negative Breast Cancer, London UK
- 183 October 2013, Invited Speaker, Terry Fox Annual Conference on Cancer Research, Vancouver, BC
- 184 November 08th 2013, Invited Speaker, “Treatment of Special Populations of Advanced Breast Cancer”, Advanced Breast Cancer International Meeting 2, Lisbon, Portugal
- 185 November 14th. 2013, Invited Speaker, “Endocrine therapy of Breast Cancer”, International meeting on Investigational New Drug in Breast Cancer, Rome Italy
- 186 November 15th, 2013, Invited Speaker, “New Advances in HER2 therapy of Metastatic breast cancer”, International meeting on Investigational New Drug in Breast Cancer, Rome Italy
- 187 January 15th, 2014, Invited Speaker, “Do we need another chemotherapy agent for metastatic Breast Cancer”, Israel Society of Cancer Treatment, Israel
- 188 September 2014, Invited Speaker, Breast Cancer Symposium, Dublin, Ireland, Ireland Treatment of young women with hormone sensitive breast cancer HER2 therapies in 2014
- 189 October 2014, Invited Speaker, 6th Annual International Breast Cancer Conference, Jedda, Saudi Arabia, Treatment of small HER2 tumours Are bisphosphanates standard therapy Treatment of Endocrine Sensitive breast cancers
- 190 November 2014, Invited Speaker, 2nd International Consensus Conference on Young Women with Breast Cancer, Dublin, Ireland, Ireland Biology and Young Women with Breast Cancer
- 191 March 2015, Invited Speaker, St Gallen’s Breast Cancer Meeting, Symposium on ER positive cancers
- 192 June 2015, Invited Speaker, Susan G Komen Annual Meeting, New Therapies – how to introduce? Dallas Tx
- 193 July 2015, Invited Speaker, Australian and New Zealand Breast Cancer Clinical Trials Group Annual Meeting, CDK 4/6 Inhibitors in Breast Cancer, Neoadjuvant Therapy in Breast Cancer, Treatment of HER 2 positive advanced breast cancer, Perth Australia
- 194 October 2015, Invited Speaker, HER2 Positive treatment in 2015, Centre of the North, Prince George, BC,
- 195 October 2015, Invited Speaker, Annual Breast Cancer Symposium, Jeddah Saudi Arabia. CDK4/6 Inhibitors in Breast Cancer, Treatment of Brain Metastases, Small tumours – how to treat, Endocrine Resistance in Breast Cancer.
- 196 November 2015, Invited Speaker, 3rd International Consensus Conference on Advanced Breast Cancer, ABC3, Lisbon Portugal, Dealing with Long survival in metastatic disease
- 197 November 2015, Invited Speaker, 4th International Conference on New Drugs in Breast Cancer, Rome Italy, Hormone Resistance in Breast Cancer, New HER 2 couplets
- 198 2016, Invited Speaker, Canadian Breast Cancer Symposium, Whistler BC, Treatment of Triple Negative Breast Cancer
- 199 March 2016, Invited Speaker, German Breast Cancer Clinical Trials Group, Frankfurt Germany, Canadian Clinical Trials Group Breast Cancer Site
- 200 March 2016, Invited Speaker, European Breast Cancer Conference, Amsterdam, Netherlands, New Targets, Summary of the Proceedings of the Conference at the Wrapup
- 201 April 2016, Invited Speaker, AACR meeting, New Orleans, Louisiana, Women in Cancer Research Forum
- 202 April 2016, Invited Speaker, First Annual Women’s Health Research Symposium, Vancouver, BC, Targeted Therapy for Breast Cancer
- 203 May 2016, Invited Speaker: 25th JK Friesen Conference, Simon Fraser University, Gerontology
- 204 June 2016, Invited Speaker. Atlantic Canada Oncology Conference, Halifax, Nova Scotia
- 205 June 2016, Invited Speaker Susan G Komen Annual Lunch, Omaha Nebraska
- 206 June 2016, Invited Speaker Canadian Communities Oncology Conference, Whistler BC

(f) Other

- 1 Sept/1993 Chair, Royal College Meeting, Oncology Session

2 Sept/1994 Royal College Meeting, Toronto, Ontario.

3 Nov/1994 Planning Committee Drug Therapy in HIV Infection, Chair Malignancy Session

4 Oct/1995 Discussion Group for Needs Assessment Working Group of the Professional Education Strategy, Health Canada, Vancouver.

5 Jul/1996 Chair, Malignancy session, XI International Conference on Drug Therapy of HIV Infection, Vancouver. Also helped organize this session.

6 Jul/1996 Chair, Meet the Experts session on cytopenias in HIV, XI International AIDS Conference, Vancouver.

7 Nov/1996 Planning Committee, Drug Therapy in HIV Infection

8 Sept/1997 Chair, New Directions in Lung Cancer Therapy, Vancouver

9 Nov/1998 Planning Committee, Drug Therapy in HIV Infection, Glasgow

10 Nov/2000 Planning Committee, BC Tumour Group Meeting

11 Nov/2000 Rethinking Cancer Research, Blue Skying the Future, Cambridge, UK

12 May 2002 Chair Breast Section, Canadian Oncologist: Patient Continued Education.

13 June/2002 Co-Chair Western Canada Conference Oncology Conference

14 June/2002 Chair, New direction in Breast Cancer Treatment

15 Nov/2002 Chair How should we be treating locally advanced breast cancer.

16 January 2003, Chair, Western Canadian Oncology Conference, New Advances in Targeted therapy

17 October 2003, Chair Breast Section, Canadian Oncologist Patient Continued Education

18 March 2004 - Advances in Breast Cancer, House Call Series, Vancouver Public Library

19 2005 - Case Study Based CME Learning in Hormonal Therapy of Breast Cancer, Toronto

20 2005 - Approaches to Postmenopausal Hormone Treatment of Breast Cancer, Montreal

21 2005 - Postmenopausal Hormone Treatment of Breast Cancer, St Agathe, Quebec

22 2006 - Chair, New Advances in Hormonal Therapy, Vancouver

23 2007 – Speaker and organizing Committee, Breast Cancer Advances, Vancouver

24 2008 – Symposium on Treatment of Bone related Events, Annual Cancer conference BCCA, Amgen symposium

25 2008 – Chair, Working meeting on Bone Related Events in Breast Cancer, Amgen sponsored, Vancouver

26 2009 Speaker, Hormonal Therapy in Breast Cancer, Novartis Symposium, St Gallen, Switzerland

27 2009 -10– Chair, New targeted therapeis, GSK Advisory Board

28 2010 – Chair, Pfizer Advisory Board, Toronto, New therapies in breast cancer

27 2010 – Chair, Roche Advisory Board, New Anti HER2 therapies

28 2011– Chair, Amgen Advisory Board, May 2011, Vancouver

29 2011 – Chair, Roche Advisory Board, Toronto,

30 2011 – Chair and Planner for Scientific Excellence and Award Section at Canadian Breast Cancer Symposium, Toronto, Ont

31 2012 – C0 Chair and Planner for NCI symposium on ER resistance in Breast Cancer, Washington DC

32 2012 – Chair of ASCO education session on Personalized medicine, Chicago, Ill

33 2012 – Organizer for Young women with Breast Cancer Symposium

2014 – Organizing Committee, International Consensus Conference on Young Women with Breast Cancer

9. SCHOLARLY AND PROFESSIONAL ACTIVITIES

(a) Areas of special interest and accomplishments

- 1 I am interested in the investigation of new drugs. At the BCCA I am the Clinical Head of Advanced Therapeutics and work in the Phase I clinical trials program. I previously was Head of the NCIC Investigational New Drug Site which coordinates early phase trials of anticancer agents in Canada. I am interested in novel therapeutics, new developments in anticancer treatment, the theory and evolution of how new agents are being developed, issues in the regulatory assessment of new drugs and how they can be introduced into clinical medicine with evidence based clinical guidelines. I am interested in Phase I studies in malignancy in general and also Phase II studies in specific malignancies such as breast cancer. My affiliation with the BC Cancer Research Foundation and Experimental Therapeutics gives me an opportunity to develop new therapies with a translational approach and work directly with research scientists. This link and collaboration provides me as a clinician with a greater understanding of drug development and the research questions that need to be answered as well as the technologies available.
- 2 I am interested and very involved in breast cancer specifically including treatment, new directions in diagnosis and therapy, the genetic aspects of breast cancer, epidemiological issues, patient education and the interactions of patients and physicians. I was Chair of the BC Provincial Breast Tumor Group from 1998 -2008. This provided me with a role that combines clinical care, research, and administration, as well as the opportunity to have an impact on the care of breast cancer in British Columbia. Developing guidelines in all aspects of the care of patients with breast cancer in BC has been rewarding and challenging. My focus has been on increasing clinical and translational research, providing timely access to evidence based treatments and standards, improving patient /oncologist/ family physician communication, and creating an interest in survivorship issues. In my role as tumour group chair I have been particularly interested in improving communication and have established the Breast Tumour Group secretariat. One of the roles has been hiring a communications liaison to work with a wide variety of communities to improve cancer education and awareness. This has included a network for young women with breast cancer and a First Nations Breast Cancer Network. As well, I have been pleased to have increased the workings of both the Breast Outcomes Unit and the GPEC committees to increase the research capabilities of the group. As well, the arrival of a Chair of Breast Cancer Research has increased our ability to do translational research within the Breast Tumour Group.
- 3 I am the CoChair role of the NCIC Breast Site Committee after sitting on the executive for a number of years and sit on the The Breast Cancer Intergroup of North America Committee. As well I sit on the Breast International (BIG) Executive Board.. I have initiated studies with a number of colleagues as well as residents and fellows. These include: studies in HER 2 over-expression and breast cancer, time of metastatic disease development in breast cancer, a laboratory study of resistance in breast cancer and a study involving family physicians and screening mammography. I am also involved in two studies of exercise and breast cancer one which has been funded from the NCIC. I headed a translational research grant bringing together basic scientists and clinical researchers that has been funded by the Canadian Breast Cancer Research Alliance that is attempting to accelerate the discovery of novel targets that can be used to develop new therapeutics.
4. I am on the Scientific Advisory Board (SAB) of the Komen Foundation and help support and direct research through this large foundation. I also co Chair the Ontario Institute of Cancer Research (OICR) SAB which reviews the research portfolio of that institution. Through these activities as well as acting as a reviewer for grants and for journals I am exposed to a wide variety of research activities. I both learn from this and it is an opportunity to provide support.

(b)+(c) Research or equivalent grants/contracts (indicate under COMP whether grants were obtained competitively (C) or non-competitively (NC))

Grant

Granting Agency	Subject	COMP	\$ Per Year	Year	Principal Investigator	Co-Investigator(s)
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BC Health Care Award	Co-Factors in the Development of AIDS.	C	45,000	1986-1988	M. Schechter	S. Sheps K. Gelmon
BC Government, Science and Technology	Investigational Drug Program	C	100,000	1989-1990	J. Goldie	K. Gelmon
BC Health Research Foundation	Investigational Drug Program	C	140,000	1990-1991	J. Goldie	K. Gelmon
BC Government Science Council	Investigational Drug Program	C	100,000	1991-1992	J. Goldie	K. Gelmon
BC Science Fund	Anticancer Drug Development	C	360,000	1992-1994	J. Goldie	K. Gelmon
BC Government	Investigational Drug Program	C	360,000	1992-1995	K. Gelmon	J. Goldie
Canadian Breast Cancer Foundation (B.C. Chapter)	Apoptosis in Breast Cancer	C	15,000	1994-1995	K. Skov	K. Gelmon J. Matthews M. Hayes A. Coldman
Lohn Foundation	Apoptosis in Breast Cancer	C	19,000	1995-1996	K. Gelmon	K. Skov J. Matthews G. Bebb
BC Government	Investigational Drug Program	C	160,000	1995-1996	J. Goldie	K. Gelmon
Medical Research Council & Micrologix	Antitumor Activity for Channel Forming Peptides	C	24,000 / 24,000	1996-1997	M. Bally	K. Gelmon
BC Government	Investigational Drug Program	C	160,000	1996-1997	K. Gelmon	J. Goldie
BC Government	Clean Room Initiation	C	90,000	1996-1997	K. Gelmon	L. Mayer
BC Government	Investigational Drug Program	C	90,000	1997-98	K. Gelmon	L. Mayer
Lohn	EF5 and Hypoxia	C	75,000	1998-1999	K. Skov	K. Gelmon
NCIC Breast Initiative	Combining Molecular Targets & Chemotherapy in the Treatment of Breast Cancer	C	109,000	1998-2000	M. Bally	K. Gelmon
NCIC	Treatment of Soybean and Menopause	C	120,000	1998-2000	C. Kutynec	I. Olivotto, J. Prior, K. Gelmon
CBCRI	Discovery and use of clinically relevant molecular	C	20,000	1999-2000	T Whelan	P. Kirkbride, V. Benk, P.

changes in breast cancer

						Craighead, I. Olivotto, M. Levine, K. Gelmon, W.Muller, F. O'Malley
CBCRI	A randomized trial of soyamilk in the treatment of menopausal symptoms in postmenopausal women with a history of breast cancer	C	40,967	1999-2000	C. Kutynec	I. Olivotto, E. Templeton, K. Chambers, J. Prior, K. Gelmon
BC Lung	Hypoxia and Lung Cancer	C	25,000	2000-2001	K. Gelmon	K. Skov
CBCRI	Discovery and use of clinically relevant molecular changes in breast cancer	C	3,500,000	2000-2003	T. Whelan	K. Gelmon, V. Giguier, J. Hassell, J. Latreille, M. Levine, W. Miller, I. Olivotto, F. O'Malley, M Park, K Pritchard, C Sawka, J Woodget
NCI	Multicentre study to assess the positive predictive value of positron emission tomography (PET) in the preoperative evaluation of internal mammary nodes in breast cancer patients	C	\$ 24,000	2003 - 2008	D Mankoff/ V Bernstein	K Gelmon, C Lohrisch, S Chia, L Weir, C Bryce,
CBCRA	Assessment and validation of new and novel prognostic and predictive factors in breast cancer with tissue microarrays.	C	225,620	2002-2004	S. Chia	D. Huntsman, B. Gilks, K. Gelmon
CBCRA	Comparison of aerobic versus resistance exercise training in enhancing quality of life in early stage breast cancer patients receiving chemotherapy.	C	516,693	2002-2005	K. Courneya	R. Segal, J. Mackey, K. Gelmon, D. McKenzie, J. Friedenreich
NCIC	Combining conventional therapeutics with molecular targeting strategies for the treatment of breast cancer.	C	108,740	2002-2005	M. Bally	K. Gelmon, S. Chia, P. Gill
US Department of Defense Congressional Directed Medical Research Program	Phase I/II Study of Combination neoadjuvant hormone therapy and weekly OGX-011 (Clusterin Antisense Oligonucleotide) prior to radical prostatectomy in pts with localized prostate cancer	C	283,000 (US)	2002-2005	K. Chi	M. Gleave, L. Goldenberg, K. Gelmon
CBCRA	Translating Target	C	\$2,000 000	2003-	K. Gelmon	M. Bally, J. Lee, S.

	Discovery into Better Health Outcomes for Women with Breast Cancer			2007	D Huntsman	Dedhar, S. Chia, B. Norris, B. Gilks, I. Olivotto, C. Badjik
CBCF	Identification of Cancer Care and protocol characteristics associated with low enrollment rate in breast cancer clinical trials	C	\$ 41,800	2005-2007	J Lemieux	K Pritchard, P Goodwin, M Levine, K Gelmon
CBCRA	Combining conventional therapeutics with molecular targeting strategies for the treatment of HER2 positive relapsed and metastatic breast cancer	C	\$488,800	2006-2009	M Bally	S Dunn, K Gelmon
Hoffman La Roche	The outcome and analysis of T1a, T1b, and T1c HER2 overexpressing tumours	C	\$90,000	2006-2008	K Gelmon	D Huntsman, B Norris, S Chia
Rethink Breast Cancer	The use of non-invasive imaging and molecular techniques to determine the relationship between cellular tumour markers and the tumours microenvironment to identify new anticancer therapies	C	\$140,000	2006-2010	D Yapp	M Bally, K Gelmon
CBCRA	Randomized Controlled Trial of Combined Aerobic and Resistance Exercise in Breast Cancer Survivors Receiving Chemotherapy: CARE Trial	C	\$946,646	2006-2009	K Courneya	D MacKenzie, R Reid, R Segal, J Mackey, K Gelmon, C F
Hoffman La Roche	Detection of hypoxia and blood flow using PET and CT scans in patients with advanced non small cell lung cancer receiving chemotherapy with bevacizumab	C	\$325,000	2007 - 2009	J Laskin	N Murray, B Melosky, C Ho, K Skov, M Bally, T Ruth, M Adam, D Wilson, D Yapp, K Gelmon
Rethink Breast Cancer	The use of non-invasive imaging and molecular techniques to determine the relationship between cellular tumour markers and the tumours microenvironment to identify new anticancer therapies	C	\$140,000	2006-2010	D Yapp	M Bally, K Gelmon
CBCRA	Randomized Controlled Trial of Combined Aerobic and Resistance Exercise in Breast Cancer Survivors	C	\$946,646	2006-2009	K Courneya	D MacKenzie, R Reid, R Segal, J Mackey, K Gelmon, C F

	Receiving Chemotherapy: CARE Trial					
CBCF	Therapeutic Target Expression in Circulating Breast Cancer Cells	C	\$ \$86,000	2008 - 2009	K Gelmon	D Huntsman, Mishaeli M, Yerushalmi R
CBCF	Molecular and genomic characterization of breast cancer according to metastatic site	C	\$45,000/ pt	2008- 2009	H Kennecke	K Gelmon, S Aparicio, Nielsen, Voduc,
CIHR	Reductase enzyme variants as biomarkers of prostate cancer and anthracycline based cardiotoxicity	C	\$ 147,000	2009 - 2011	W Riggs	K Gelmon, M Gleave, D Hogge
AstraZeneca	Randomized Anastrozole Exercise Study (RAE) trial	C	\$100,000	2008 - 2010	H Kennecke C Lohrisch	S Chia, K Gelmon, T Shenkier, S Sun, H Lim
CIHR Catalyst Grant	A feasibility pilot to develop a community based weight loss and physical activity lifestyle intervention in women living with breast cancer	C	\$91,965	2009 - 2010	K Campbell	C Van Patten, D McKenzie, K Gelmon, C Gotay
CBCRA	Translating Target Discovery into Better Health Outcomes for Women with Breast Cancer	C	\$122,500	2008 - 2009	K Gelmon	S Chia, M Bally, S Dedhar, D Huntman
CBCRA	Mammographic Density and Columnar Cell Lesions	C	\$150,000	2009 - 2012	S Aparicio	K Gelmon, C Wilson, P Watson, N Boyd
CIHR	Team grant investigating autophagy proteins as molecular targets for cancer treatment	C	\$500,000	07/2010 - 06/2015	S Gorski	K Gelmon, M Bally, J Lum, R Young, H Cote, K Humphries, X Jiang, S Jones
Komen Foundation	Markers of resistance for taxanes and PARPi in breast cancer	C	\$250,000	2010- 2012	K Gelmon	
CIHR	Identifying cytoprotective responses triggered following initial exposure to targeted therapy: defining improved treatment strategies for patients with HER2 positive breast cancer	C	\$154, 831	2010- 2015		K Gelmon, S Jones
CCSRI	Improving Cancer Related Outcomes in Shiftworkers	C	\$521, 143	2011- 2014	C Gotay	M Borugian, J Fleming, K Gelmon, M Pollak, J Spinelli
CCSRI	A prospective randomized	C	\$172, 824	2012-	S Virani	K Gelmon, T Tsang

	placebo controlled study of the effect of eplerenone on left ventricular diastolic function in women receiving anthracycline therapy for breast cancer			2014		
CIHR	Future NCIC Clinical Trials Group Activities in Oncologic Translational Research addressing strategies in personalized medicine	C	\$24, 525	2012-2013	Ralph Meyer	K Gelmon, etc
CCSRI	Operating Grant for the NCIC Clinical Trials	C	\$33,689,109.00	July 1, 2010 – Jan 31, 2017	Ralph Meyer	K Gelmon, etc
Susan G Komen	Support breast cancer studies of spatial heterogeneity, novel therapies and TNBC	C	\$200,000	07/2012 - 07/2019	K Gelmon	
NCI	CA13-006 – NCI Experimental Therapeutics-Clinical Trials Network with Phase I Emphasis (ET-CTN) (UM1) Princess Margaret Phase I Consortium (PMP1C) Funding reference: 1UM1-CA-186644-01	C	\$1,756,985 (total)	April 7, 2014 – Feb 28, 2019	Lillian Siu	K Gelmon etc
Stand Up to Cancer	Translational development of novel drugs targeting tumor vulnerabilities	C	\$8,999,852	2015-2019	TW Mak, S Aparicio	M Park, K Pritchard, K Gelmon
CBCF	Immune Response Biomarkers as Predictive Factors for Different anti-HER2 Targeted Therapies in Metastatic Breast Cancer	C	\$96,099	2015-2017	T Nielsen	K Gelmon, B Chen, Z Kos
CIHR Project Grant	A Randomized Trial of Regional Radiotherapy in Luminal A Breast Cancer	C	\$957,325 (total)	07/2016 – 06/2025	T Whelan	K Gelmon, A Bane, M Basik, JR Bellon, T Berrang, BE Chen, BH Chua, AW Fyles, A Ho, JS, Hoch, I Kong, MN Levine, TO Nielsen, IA Olivotto, WR Parulekar, E Rakovitch, V Theberge
CIHR Foundation Grant	Lipid nanomedicines for health and disease	C	\$ 576,045 (total)	07/2016 – 06/2023	P Cullis	K Gelmon, Bally MB, MA Ciufolini, CJ Eaves, ME Gleave, CL

						Hansen, KW Harder, WN Hardy, KR Humphries, E Jan, TJ Kieffer, M MacLachlan, BA Macvicar, PS Rennie, M Roberge, F Rossi, TP Snutch, BC Verchere, L Whitehead, RN Young
CIHR Foundation	Targeted radiopharmaceuticals to improve cancer diagnosis and treatment	C	\$1,432,266 (total)	07/2016 – 06/2023	F Benard	K Gelmon, S Aparicio, Bally MB, A Celler, ME Gleave, S Jones, Hagen K, K Lin, JJ Lum, DM P, TJ Ruth, KJ Savage, P Schaffer
CIHR Foundation Grant	Targeting the dynamics and genomics of clonal evolution in cancer patients	C	\$2,833,460 (total)	07/2016 – 06/2023	S Aparicio	K Gelmon, CL Hansen, PA Hieter, M Hirst, DG Huntsman, MA Marra, SP Shah, PC Stirling
CCSRI	LA LEAST. Luminal A, Limited Endocrine Adjuvant Systemic Therapy, a phase II trial of abbreviated hormone therapy for low risk hormone receptor positive, HER2 negative early breast cancer	C	\$150,000	07/2017 – 06/2020	C Lohrisch	K Gelmon, T Nielsen, Lemieux J, Parulekar W, Balneaves L, Levasseau, Shepherd L, Whelan T, Basik M, Chia S, Chen B

Contract

Granting Agency	Subject	COMP	\$ Per Year	Year	Principal Investigator	Co-Investigator(s)
BM Squibb	Taxol 175 mg vs 135 mg in Breast Cancer	NC	26,000	1992	K. Gelmon	S. O'Reilly
BM Squibb	Taxol 3 hr vs 24 hr in Breast Cancer	NC	26,000	1992- 1993	K. Gelmon	S. O'Reilly
BM Squibb	Cisplatin and Taxol in Breast Cancer	NC	20,000	1994- 1995	K. Gelmon	A. Tolcher S. O'Reilly
INEX Pharmaceuti cals	Phase I Liposome Vincristine Study	NC	25,000	1994- 1996	K. Gelmon	A. Tolcher
BM Squibb	Cisplatin and Taxol in Lung	NC	30,000	1994-	K. Gelmon	N. Murray

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	Cancer			1997		
BM Squibb	Biweekly Taxol in Breast Cancer	NC	38,000	1995-1996	K. Gelmon	A. Tolcher S. O'Reilly
INEX Pharmaceuticals	Colon Cancer Liposome Vincristine Phase II Study	NC	25,000	1996-1997	A. Tolcher	K. Gelmon
INEX Pharmaceuticals	Pancreatic Cancer Liposome Vincristine Phase II Study	NC	25,000	1996-1997	A. Tolcher	K. Gelmon
BM Squibb	BR96 in Breast Cancer	NC	20,000	1996-1997	A. Tolcher	K. Gelmon
NCIC CTG	Phase I Study of R019881A administered as a weekly 1 hour intravenous infusion to patients with advanced solid tumours	NC	40,000	1996-1998	K. Gelmon	A. Tolcher
	IND 101					
NCIC-CTG	Phase II--High Dose Taxol with or without Amifostine in Metastatic Breast Cancer	NC	40,000	1996-1998	K. Gelmon	G. Batist E. Tomiak M. Blackstein
Rhone-Poulenc Rorer	Phase II Study of FAC vs TAC in Node Positive Breast Cancer	NC	30,000	1997-1998	K. Gelmon	S. O'Reilly
NCIC - CTG	Phase III Study of Marmistat in Small Cell Lung Cancer BR12	NC	10,000	1997-1999	K. Gelmon	N. Murray A. Shah
Eli Lilly and Company	Pharmacokinetics of Taxol plus Amifostine	NC	10,000	1998	K. Gelmon	L. Mayer, A. Tolcher
NCIC CTG MA 19	Phase II Study of DPPE/Doxorubicin vs Doxorubicin in Breast Cancer	NC	30,000	1998-1999	K. Gelmon	S. O'Reilly K. Khoo
NCIC CTG MA16	Phase III Study of High Dose Chemotherapy in Metastatic Disease	NC	20,000	1998-2000	S. O'Reilly	A. Tolcher K. Gelmon T. Shenkier J. Ragaz
NCIC CTG IND 124	Phase I of MG 98-001 given as a 21 day continuous IV infusion in advanced malignancies	NC	40,000	1999-2000	K. Gelmon	M. Moore, L. Sui
	IND 124					
NCIC – CTG IND 123	Phase I of NX 211 given as an IV infusion days 1, 2 and 3 every three weeks in advanced malignancies	NC	100,000	1999-2000	K. Gelmon	L. Reyno, H. Hirte
	IND 123					
Roche Pharmaceuticals	Phase I Study of Taxol and Herceptin given every 3 weeks in metastatic breast cancer	NC	66,000	1999-2000	K. Gelmon	K. Chiu, S. O'Reilly, C. Bryce, T. Shenkier
NCIC CTG IND 129	Phase II Study of ZD0473 in Breast Cancer	NC	30,000	2000	K. Gelmon	S. O'Reilly, C. Bryce, T. Shenkier

INEX	Phase I Study of C Myc Antisense in advanced malignancies	NC	40,000	2000-2001	K. Gelmon	G. Batist
NCIC- CTG IND 130	Phase I Study of T900607 given once every 3 weeks in patients with advanced cancer.	NC	40,000	2000-2001	C. Britten	K. Gelmon
NCIC- CTG IND 131	Phase I Study of Docetaxel and ZD0473 given every 3 weeks in patients with advanced cancer.	NC	40,000	2000-2001	K. Gelmon	C. Britten
NCIC- CTG IND 133	Phase I Study of NX211 and Cisplatin in Solid Tumours.	NC	20,000	2000-2001	K. Gelmon	K Chi
Ontogen Pharmaceuticals	Phase I and pharmacokinetic study of OC1144-093 and paclitaxel in advanced cancer	NC	3000/pt	2001	K Chi	K. Gelmon, S Chia
Pfizer Pharmaceuticals	A Phase II randomized trial of CI 1033 in advanced breast cancer	NC	\$7000/pt	2002-2004	K Gelmon	S Chia, T Shenkier, C Lohrisch, C Bryce
NCIC – CTG MA17	A Randomized trial of letrozole vs placebo in women with early breast cancer who have completed 5 years of tamoxifen MA17	NC	\$1500/pt	2003 - 2005	T Shenkier	K Gelmon, S Chia, C Bryce, J Ragaz, M Knowling, S O'Reilly
NSABP	A randomized trial of placebo vs clodronate in patients with early breast cancer	NC	\$1500/pt	2002-2005	L Weir	K Gelmon, S Chia, T Shenkier, C Bryce, M Knowling, C Parsons, S O'Reilly, M Keyes
NCIC – CTG MA21	A randomized trial of CEF vs EC-paclitaxel vs AC-paclitaxel as adjuvant therapy in high risk node negative or node positive breast cancer	NC	20,000	2001-2005	K. Gelmon	S. O'Reilly, T. Shenkier, J. Ragaz, S. Chia, M. Knowling
NCIC – CTG MA 24	Phase III trial of three weekly herceptin given after standard adjuvant therapy in HER2 overexpressing breast cancer randomizing to no therapy, one year or two years of herceptin	NC	\$70,000	2002-2005	C. Lohrisch	K. Gelmon S O'Reilly S, Chia T. Shenkier
NCIC - CTG	BRMAC3 - A Phase III randomized trial of paclitaxel alone vs paclitaxel plus bevacizumab in women with metastatic breast women	NC	\$10,000	2003-2005	T. Shenkier	K. Gelmon S O'Reilly S Chia C. Lohrisch
NCIC – CTG IND 153	IND 153 A Phase I trial of neoadjuvant clustrin antisense oligonucleotide (OGZ- 011) in prostate cancer	NC	\$ 4500 /pt	2003-2005	K . Chi	S. Chia M Gleave K Gelmon
NCIC –CTG IND 154	IND 154, A Phase I study of clustrin antisense oligonucleotide (OGX - 011) in combination with	NC	60,00/yr	2003-2005	K Chi	K. Gelmon S Chia

	docetaxel					
NCIC CTG MA 27	A Randomized Trial of Exemestane vs Anastrozole in Post Menopausal Women with Breast Cancer	NC	\$ 200, 000	2005 - 2007	H Kennecke	C. Bryce, S Chia K Gelmon, M Knowling, C Lohrisch, S O'Reilly, T Shenkier
NCIC – CTG MAC 4	A Randomized Trial of Tamoxifen Vs Ovarian Ablation Plus Tamoxifen, vs Ovarian Ablation Plus Exemestane in Premenopausal Women with Breast Cancer	NC	\$1500/ pt	2005-	H Kennecke	C. Bryce, S Chia K Gelmon, M Knowling, C Lohrisch, S O'Reilly, T Shenkier
NCIC – CTG MAP3	A Randomized Trial of Exemestane vs Placebo for Prevention of Breast Cancer In Postmenopausal Women	NC	\$4000/pt	2005 -	K Gelmon	C. Bryce, S Chia H Kennecke, L Weir, C Lohrisch, U Kuusk
NCIC – CTG IND 166	IND 166 A Phase I Study of AEG35156 in combination with docetaxel in patients with solid tumours	NC	\$4500/pt	2005 2007	K Chi	S ChiaK Gelmon, C Kollmannsberger,
Celator Pharmaceuti cals	A Phase I study of CPX – 1 (irinotecan HCL Floxuridine) liposome injection in patients with advanced solid tumours	NC	\$11,000/pt	2005-2007	K Gelmon	S Chia, K Chi, C Kollmannsberger
Array Pharmaceuti cals	A Phase I Open Label Multiple Dose study to assess the safety, tolerability and pharmacokinetics of ARRY-334543 given on a daily oral regimen in patients with advanced cancer.	NC	\$15,000/pt	2005 - 2007	K Gelmon	S Chia, K Chi, C Kollmannsberger
Human Genome Sciences	A Phase I multicentre open label dose escalation study to evaluate the safety, tolerability and pharmacokinetics of HGS-TR2J (fully human monoclonal antibody to the TRAIL –R2) in subjects with advanced solid malignancies.	NC	\$ 15,000 /pt	2005-2007	K Gelmon	S Chia, K Chi, C Kollmannsberger
Roche Pharmaceuti cals	A Phase II Study of Omnitarg Plus Herceptin in Metastatic HER2 Positive Breast Cancer	NC	\$6000 per patient	2006 - 2007	K Gelmon	C. Bryce, S Chia H Kennecke, M Knowling, C Lohrisch, S O'Reilly, T Shenkier,
NCIC – CTG IND 163	IND 163 - A randomized Phase II study of RAD 001 in metastatic breast cancer	NC	\$ 4000/pt	2006 - 2007	K Gelmon	C. Bryce, S Chia H Kennecke, M Knowling, C Lohrisch, S O'Reilly, T Shenkier
NCIC – CTG	IND 164 - A Phase II study of	NC	\$ 4000/ pt	2006-	S Chia	C. Bryce, K

IND 164	Taxotere and OGX in patients with metastatic breast cancer			2007		Gelmon, H Kennecke, M Knowling, C Lohrisch, S O'Reilly, T Shenkier
Roche Pharmaceuticals	A Phase III trial of Docetaxel and Bevacicimab in metastatic breast cancer	NC	\$ 6000/ pt	2006-2007	C Lohrisch	C. Bryce, S Chia, K Gelmon, H Kennecke, M Knowling, S O'Reilly, T Shenkier
NCIC – CTG IND 181	IND 181 – A Phase I Study of AT9283 given as a 24 hour infusion on days 1 and 8 every three weeks in patients with advanced incurable malignancy	NC	\$ 4500/pt	2007 - 2008	K Gelmon	K Chi, S Chia, C Kollmannsberger
NCIC – CTG IND 179	A phase I study of CCI -779 in combination with carboplatin and paclitaxel in patients with advanced solid tumours	NC	\$ 4500/ pt	2006-2007	C Kollmannsberger	K Chi, S Chia, K Gelmon
Eli Lilly and Company	A double blind randomized phase 2 trial of capecitabine plus enzastaurin versus capecitabine plus placebo in patients with metastatic or recurrent breast cancer previously treated with an anthracycline and taxane.	NC	\$ 6000/ pt	2007-2009	K Gelmon	C. Bryce, S Chia C Lohrisch, H Kennecke, M Knowling, S O'Reilly, T Shenkier
Novartis Pharmaceuticals	A Phase I open label multicentre dose escalation study to determine the maximum tolerated dose (MTD) and dose limiting toxicity of gimatecan (LBQ707) administered in two different schedules in adult patients with advanced solid tumours.	NC	\$ 6500/pt	2007 - 2008	S Chia	K Chi, K Gelmon, C Kollmannsberger
Twinstand Therapeutics Inc	A phase I study of TST10088 in patients with advanced incurable solid tumours	NC	\$ 7500/ pt	2008-2009	C Kollmannsberger	K Chi, S Chia, K Gelmon
Adherex Technologies	An open label phase II A study in subjects with recurrent, n-cadherin positive advanced solid tumours to investigate the safety and efficacy of ADH-1 administered intravenously as a single agent once every three weeks	NC	\$8,000/ pt	2006 - 2008	K Chi	K Gelmon, S Chia, C Kollmannsberger
Amgen	A randomized double blind multicentre study of denosumab compared with zoledronic acid (Zometa) in the treatment of bone metastases in subjects with advanced breast cancer	NC	\$ 10,000/ pt	2007 - 2008	H Kennecke	C Bryce, S Chia, K Gelmon, C Lohrisch, M Knowling, T Shenkier, S Sun
NCIC – CTG	TAILORX trial – randomizing	NC	\$4000	2007 -	S Chia	C. Bryce, K Gelmon

MAC12	women with hormone sensitive breast cancer to an assessment of a cancer test			2010		C Lohrisch, H Kennecke, M Knowling, T Shenkier
NCIC- CTG MA 31	A randomized trial of lapatinib plus taxane vs herceptin plus taxane in recurrent or metastatic HER2 overexpressing breast cancer MA31.	NC	\$500,000	2008-2010	K Gelmon	C. Bryce, S Chia C Lohrisch, H Kennecke, M Knowling, T Shenkier, D Huntsman, S Aparicio
Astra Zeneca	A correlative Phase II study of AZD 2881 in patients with advanced high grade ovarian cancer or basal like breast cancer or in patients with known BRCA mutations	NC	\$ 260,000	2008-2010	K Gelmon	S Aparicio, D Huntsman, K Swenerton, S Chia, D Miller
GSK	A randomized phase 2 trial of lapatinib plus capecitabine vs lapatinb plus topotecan in recurrent or metastatic HER2 overexpressing breast cancer patients with brain metastases	NC	\$10,000/pt	2008-2010	K Gelmon	C. Bryce, S Chia, C Lohrisch, H Kennecke, M Knowling, T Shenkier
Methylgene	Open label dose escalation trial to evaluate the safety, pharmacokinetics and pharmacodynamics of daily oral MGCD265 administered without interruption to patients with advanced malignancies	NC	\$9500/pt	2009-10	C Kollmannsberger	K Gelmon, K Chi, S Chia
Cornerstone	A Phase I open label dose escalation study to evaluate the safety, tolerability, maximum tolerated dose (MTD), efficacy and pharmacokinetics (PKs) of CPI-613 given twice weekly for three consecutive weeks in cancer patients	NC	\$10,000/pt	2009-2010	K Gelmon	K Chi, C Kollmannsberger, S Chia
Oncogenix Technologie	Phase I study evaluating a second generation antisense oligonucleotide (OGX-427) that inhibits heat shock protein 27 (Hsp27)	NC	\$9000	2008-2010	K Chi	S Chia, C Kollmannsberger, K Gelmon
NCIC MA29	A feasibility study of preoperative sunitinib with multiple pharmacodynamic endpoints in patients with T1c-T3 operable carcinoma of the breast	NC	\$6500	2009 - 2010	S Chia	K Gelmon
Roche	A Phase Ib/II open label study of the safety, tolerability, and efficacy of trastuzumab MCC-DML in combination with	NC	\$10000	2009 - 2010	K Gelmon	S Chia, C Lohrisch, T Shenkier, S Sun, H Lim,

	pertuzumab administered intravenously to patients with HER2 positive, locally advanced or metastatic breast cancer who have previously received trastuzumab					
Roche	BEATRICE – An international multicentre open label 2 arm phase III trial of adjuvant bevacizumab in triple negative breast cancer	NC	\$8000	2008 - 2009	C Lohrisch	K Gelmon, S Chia, H Lim, T Shenkier, S Sun
Amgen	An international randomized double blind placebo controlled phase 2 study of AMG 479 with exemestane or fulvestrant in postmenopausal women with hormone receptor positive locally advanced or metastatic breast cancer	NC	\$7000	2008 - 2010	H Kennecke	K Gelmon, C Lohrisch, T Shenkier, S Sun, H Lim, S Chia
PMH Consortium and GSK	A Phase 2 study of GW786034 (Panzopanib) in patients with recurrent and /or metastatic invasive breast carcinoma	NC	\$2000	2008 - 2009	S Chia	C Lohrisch, K Gelmon, H Lim, T Shenkier, S Sun, H Kennecke
NCIC-MAC13	ALTTO – adjuvant lapatinib and/or trastuzumab treatment optimization study – a randomized multicentre open label phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer	NC	\$6000	2009 - 2011	S Chia	K Gelmon, C Lohrisch, T Shenkier, S Sun, H Lim,
CIRG Imclone	A multicenter multinational randomized double blind phase III study of IMC-1121B plus docetaxel, versus placebo plus docetaxel in previously untreated patients with HER2 negative, unresectable, locally recurrent or metastatic breast cancer	NC	\$8000	2009 - 2011	K Gelmon	C Lohrisch, S Chia, H Lim, T Shenkier, S Sun
ARRAY	A Phase I open label multiple dose study to assess the safety, tolerability and pharmacokinetics of ARRAY 380 given on a daily oral regimen in subjects with advanced cancer	NC	\$6000	2008 - 2010	S Chia	K Gelmon, K Chi, C Kollmannsberger
Omnitura	A phase I open label multiple dose study to assess the safety, tolerability and pharmacokinetics of Aneustat in subjects with advanced cancer	NC	\$125,000 / year	2012 – 2014	K Gelmon	S Chia, K Chi, D Renouf, C Kollmannsberger,
Canadian	A prospective randomized	C	\$86,	2012-	S Virani	K Gelmon, M Davis,

Cancer Society Research Institute	placebo controlled study of the effect of eplerenone on left ventricular diastolic function in women receiving anthracycline therapy for breast cancer		412/year	2014		T Tsang
BCCF Anita Cohrane Memorial Endowment Fund	The Effects of Exercise Before Doxorubicin infusion on cardiac function in breast cancer patients	C	\$6840	2014-2015	K Gelmon	,
Susan G Komen Foundation	Identifying Markers of response and resistance to Olaparib and taxanes	C	\$250,000	2011-2012	K Gelmon	S Aparicio, T Nielsen, S Shah
NCIC CTG	MA32 The effect of Metformin to prevent recurrences in early breast cancer	NC	\$2500/pt	2009 – 2015	K Gelmon	S Chia, C Lohrisch, S Sun, D Villa, T Shenkier, C Simmons
Canadian Cancer Society Research Institute	Improving Cancer Related Outcomes in Shift workers	C	\$173,714/year	2011 - 2014	C Gotay	K Gelmon, M Pollak, M Bourigan, J Spinelli, J Fleming
Canadian Institute of Health Research	Personalized siRNA based nanomedicines	C	\$611,899/yr	2011-2015	P Cullis	K Gelmon,
Canadian Institute of Health Research	Identifying cytoprotective responses triggered following initial exposure to targeted therapy; defining improved treatment strategies for patients with HER2 positive breast cancer	C	\$154, 831/year	2010-2015	M Bally	K Gelmon, S Jones
Canadian Institute of Health Research	CIHR Team in investigating Autophagy proteins as molecular targets for cancer treatment	C	\$500,000/year	2010-2015	S Gorsky	K Gelmon, M Bally, R Young, L Lum, Cote H, Humphries K, Jiang X, Jones S,
Canadian Cancer Society Research Institute	CCS Clinical Trials Group	C	\$25, 586, 666	2010-2017	R Meyer/ J Dancey	K Gelmon, T Whelan, D Jonker, G Goss, M Crump, K Chi
NIH/NCI	Canadian Collaborating Clinical Trials Network (NCTN)	C	\$15,115, 295	2014-2019	R Meyer/ J Dancey	K Gelmon, T Whelan, D Jonker, G Goss, M Crump, K Chi
Stand Up To Cancer	Translational development of novel drugs targeting tumour vulnerabilities	C	\$8,999,852	2015 - 2019	T Mak S Aparicio	K Gelmon, K Pritchard, D Cescon, P Bedard, M Park, L Seymour

National Cancer Institute (US)	Clinical Trials Network with Phase I Emphasis Princess Margaret Phase I consortium	C	\$1,756,985	2014-2019	L Siu	K Gelmon, D Renouf, K Chi, C Kollmannsberger, S Chia,
Canadian Breast Cancer Foundation (CBCF)	Immune response biomarkers as predictive factors for different anti HER2 targeted therapies in metastatic breast cancer	C	\$192,198	2015-2017	T Nielsen	K Gelmon, L Shepherd, Chen B, Kos Z
Susan G Komen Foundation	Spatial Heterogeneity in Breast Cancer	C	\$200,000	2014-2015	K Gelmon	S Aparicio, S Shah, C Mar
Susan G Komen Foundation	Triple Negative breast cancer – identifying markers through ctDNA analysis	C	\$200,000	2016-2017	K Gelmon S Aparicio	

Submitted Grant

Granting Agency	Subject	COMP	\$ Per Year	Year	Principal Investigator	Co-Investigator(s)
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Salary Support Award

Granting Agency	Subject	COMP	\$ Per Year	Year	Principal Investigator	Co-Investigator(s)
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(d) Invited Presentations

1 Please see Section 8 (e)

(e) Other Presentations

1 Please see Section 8 (F)

As well, presentations to the Canadian Cancer Society, public forums, nursing in-services, pharmacy in-services

(f) Other

- 1 Community/Lay Lectures
- 2 Forums for Breast Cancer with VGH/Alliance for Breast Cancer 3-4 x 1 year
- 3 Presentations/Interviews on radio, TV etc on various cancer related subjects

(g) Conference Participation (Organizer, Keynote Speaker, etc.)

- 1 Planning Committee, CME, Canadian Oncology Patient continued Education
- 2 Planning Committee, Drug Therapy in HIV Infection, Glasgow, 1992, 1994, 1996, 1998
- 3 Head, Planning Committee, CME Breast Cancer Myths and Reality Conference, Mar/1997
- 4 Head, Planning Committee, RCPS, Oncology meeting, Sept/1997
- 5 Keynote Address Int Pharmacy Forum, Sept/1997
- 6 Chairman & Planning Committee, Current Issues in Resectable Non Small Cell Cancer, Sept/1997
- 7 Chairman & Coordinator, Workshop in Clinical Development of New Non Cytotoxic Agents, 10th at NCI/EORTC Conference on Investigational New Drugs, Amsterdam, Jun/1998
- 8 Head, Planning Committee CME Breast Cancer Conference planned for Feb/1999+Mar/2001
- 9 Planning Committee CME Breast Imaging Conference, Jan/2001
- 10 Chairman Western Canada Oncology Conference New Advances in Breast Cancer, Vernon, Feb/2001
- 11 Chairman Impact Breast Cancer, Whistler, Apr/2001
- 12 Planning Committee CME Breast Imaging Conference, Jan/2003
- 13 Planning Committee, CME, Canadian Oncology Patient continued Education, 2004
- 14 Chair, Western Canadian Oncology Conference, Sun Peak, BC Feb 2006
- 15 Track Leader for the Breast Section of the annual ASCO meeting, Orlando 2005
- 16 Program committee for the Breast Section of the annual ASCO meeting, Atlanta 2006
- 17 Chair Educational Session, Randomized Phase II clinical Trials, ASCO, Atlanta 2006
- 18 Chair, Western Canadian Oncology Conference, Sun Peaks, BC March 2007
- 19 Invited Chair of GPO session at Western Canadian Oncology Conference, Sun Peaks, March 2008
- 20 Faculty and speaker Educational Session, ASCO, Chicago 2008
- 21 ASCO Education Committee, Breast Site Group, Chicago 2010 - 2012
- 22 Chair, NCI – Workshop on Endocrine resistance in breast cancer

10.1 SERVICE TO THE UNIVERSITY

(a) Memberships on committees, including offices held and dates

Local

- 1 AARPT Committee, July 2002-2005
- 2 SPARK, Pharmaceutical Subcommittee, 1990-1995
- 3 AARPT Committee, July 1995-1998
- 4 Advisory Board for Clinical Trials Consortium, 1995-present
- 5 Search Committee Chair of Breast Research, 1997-1998

- 6 Search Committee for Medical Oncology Positions, 1997-1998
- 7 Technology Development Advisory Board BCCA/UBC, 1998 - present
- 8 Search Committee for Head of SMPBC, 2001
- 9 Keynote Speaker 36th Annual Postgraduate Review in Family Medicine UBC, March 2001
- 10 Steering Committee of the BCCA Strategy, Leader Institutes Task Force BCCA 2004
- 11 University Clinical Faculty Appointment and Promotion Committee (UCFAPC) 2004 – 2010
- 12 Chair University Clinical Faculty Appointment and Promotion Committee (UCFAPC) 2006 – 2010
- 13 Member of the Phase II planning committee, 2007 – 2009, 2010
Interim Head, Division of Medical Oncology, 2013 - present

(b) Other service, including dates

- 1 Ethics Advisory Council, BC Cancer Agency, 1991-1998
- 2 Ad Hoc Palliative Care Committee, BC Cancer Agency, 1993-1994
- 3 Member, Operational Assessment and Re-Design (OAR), Patient Care Assessment Team, BCCA, September-December 1995
- 4 Chair, Consent Committee, BCCA, 1996
- 5 Member, Operational Assessment and Re-Design (OAR), Patient Care Design Team, BCCA, January-May 1996
- 6 Vancouver/Richmond Health Board Women's Health Planning Project, 1998 - 2000
- 7 Integrated Breast Services , co chair, 2001 – 2008
- 8 PHSA review of breast diagnostic services, 2002 – 2009
- 9 B.C. Cancer Foundation, Director / Board June 2003 - 2010
- 10 Rethink Breast Cancer Foundation, Director, 2002 - present

10.2 SERVICE TO THE HOSPITAL

(a) Memberships on committees, including offices held and dates

(b) Other service, including dates

11. SERVICE TO THE COMMUNITY

(a) Memberships on scholarly societies, including offices held and dates (International)

- 1 American Association of Medical Oncology
- 2 American Association of Cancer Research
- 3 European Society of Medical Oncology
- 4 Member Scientific Advisory Committee, Komen Foundation – 2012 – to present
Member, Breast International Advisory Committee, 2011 – 2014
- 5 Member, Executive of Breast International Board, 2014 – present

(a) Memberships on scholarly societies, including offices held and dates (National)

- 4 Canadian Association of Medical Oncology
- 5 Royal College, Chairman of Oncology Program, September 1997
- 6 Canadian Association of Medical Oncology Annual Meeting Planning Committee, Apr/1998
- 7.. Member and co Chair of Scientific Advisory Board of OICR, 2010 – present

(b) Memberships on other societies, including offices held and dates (National)

- 8 Medical Advisory Committee, Native Women's Health Collective, 1997

(b) Memberships on other societies, including offices held and dates (Provincial)

- 9 Medical Advisory Committee, BC Chapter of Canadian Breast Cancer Foundation, 1992-present
- 10 Chair, Medical Advisory Committee, BC Chapter of Canadian Breast Cancer Foundation, 1995-1998

(c) Memberships on scholarly committees, including offices held and dates (International)

- 11 Member, North American Breast Intergroup Committee, 2002 - present
- 12 Member Breast International Group(BIG) , 2005- present,
- 13 Chair, Komen Grant Committee, Endocrine B, 2007-2009
- 14 Member, North American Breast Steering Committee, 2008 – present
- Member BIG (Breast International Group) Advisory Committee, 2010-present
- 16 Komen Scholar, 2010 - 2012
- Member, Scientific Advisory Board, Komen Foundation, 2012 – present
- 17 Member, and Co Chair Scientific Advisory Board, Ontario Institute of Cancer Research (OICR), 2011 – present
- 18 Member of the Breast International Executive (BIG), 2014 - present

19
(c) Memberships on scholarly committees, including offices held and dates (National)

- 20 Member, Data and Safety Committee, National HIV Clinical Trials Centre, 1990-1996
- 21 Member NCI, Investigational Drug Committee, 1990-2000
- 22 National Cancer Institute of Canada, Grants Committee, Panel G, 1993-1998
- 23 Member, Phase I Working Group Trial Committee, NCIC, 1993-present
- 24 Member, NCIC, Breast Site Committee, 1999-present
- 25 Member NCIC Breast Executive 2000-present
- 26 CIHR Working Group on Oncology Clinical Trials 2002-2004
- 27 Head, Investigational Drug Committee, National Cancer Institute of Canada, Clinical Trials Group - 2006 – 2008
- 28 Canadian Cancer Research Alliance, Strategic Planning Subcommittee, 2008 – 2009
- 29 Canadian Partnership Against Cancer, Strategic Advisory Committee, 2010 – 2011
- 30 Member – Planning Committee, CIHR and CBCF workshop on Young Women with Breast Cancer

(c) Memberships on scholarly committees, including offices held and dates (Provincial)

- 31 Member, Breast Tumor Group, BCCA, 1986-present

- 32 Member, Lung Tumor Group, BC Cancer Agency, 1990-1998
- 33 Member, Chemoprevention Committee BCCA 1998-2003
- 34 Chair, BC Provincial Breast Tumor Group, 1998 - present
- 35 Member, Scientific Advisory Council, Michael Smith Foundation, 2005 – 2007
- 36 Member Phase I group, BCCA, 2006 – present

(d) Memberships on other committees, including offices held and dates (International)

- 37 Member, Planning Committee, International Conference on HIV-Therapy, 1991
- 38 Member Breast Cancer Intergroup of North America 2001-present
- 39 Chair, Breast Track Program Committee for the Annual International Meeting 2004-2005
- 40 Member, ASCO Breast Program Committee, 2005 - 2006
- 41 Member, Physicians for Human Rights - 2006 - present
- 42 Member, ASCO, Breast Education Committee – 2010 – present
- 43 Member, High Impact Cancer Control Committee of Canadian Partnership against Cancer, 2010 – present
- Member, Scientific Advisory Board, Breast International Group, 2010 – present
- 44 Member, Komen Scientific Advisory Board, 2012 - present

45

d) Memberships on other committees, including offices held and dates (Local)

- 46 Member, St. Paul's Hospital AIDS Care Group, 1984-1988
- 47 Joint MRC/Inserm HIV Clinical Trials Committee, 1988-1989
- 48 Pharmaceutical Forum Planning Committee, 1993-1995
- 49 Chair, Interdisciplinary CME Conference on Breast Cancer for Mar/1997
- 50 Member, Dr. Peter Foundation Committee, 1997-2001
- 51 Board Member of Cabinet, a collaborative Arts Council, Vancouver, 2005 – 2009
- 52 Board Member, Centre A Art Gallery, 2010 - present

(d) Memberships on other committees, including offices held and dates (National)

- 53 Member, Canadian Assoc. of Medical Oncology Annual Meeting Planning Committee
- 54 Member, Canadian HIV Therapeutics Committee, Canadian National Advisory Committee on AIDS, 1985-1988
- 55 Head, Medical Oncology, Royal College 1997 Meeting Planning Committee, 1996 - 1997
- 56 Member, Planning Committee for 1998 Royal College Meetings, 1997 - 1998

(f) Reviewer (journal, agency, etc. including dates) (International)

- 57 International Editorial Advisory Board, The Lancet, 1991-present
- 58 Editorial Advisory Board, Clinical Breast Cancer, 2000 - present
- 59 International Editorial Advisory Board, Lancet Oncology, 2005 – 2010
- 60 Reviewer and Chair of Komen Grant Panel, Systemic Therapies B, 2007-08, 2009, 2010
- 61 Editorial Board, The Oncologist, 2009 – present
- 62 Reviewer AACR grants

(f) Reviewer (journal, agency, etc. including dates) (National)

- 63 Reviewer for The Lancet, Journal of Clinical Oncology, Cancer, AIDS, Canadian Journal of Oncology, Breast Cancer Journal, Investigational New Drugs
- 64 Expert Reviewer, Canadian Cancer Society, Cancer Information Services Network
- 65 Royal College reviewer for Medical Oncology, 1993-1994, 1996-1998
- 66 Reviewer for NCIC, MRC Grants, 1993-present
- 67 Editorial Board, The Breast Cancer Journal, 2000 - present
- 68 Cancer Management Manual Editorial Board BCCA 2002-2005
- 69 Grant Reviewer, CHIR Ideas Grants, 2005
- 70 Grant Reviewer, CBCRA Survivorship Grants, 2006, Co Chair of Review Committee 2007 -2010
- 71 Grant Reviewer, Israeli American Cancer Grants, 2006, 2008, 2009, 2010
- 72 Grant Reviewer, Rethink Breast Cancer, 2003 – present

(h) Consultant (indicate organization and dates) (International)

- 73 International Advisory Board for AstraZeneca, Aventis, Roche, Glaxo Wellcome, sanofi aventis at various times since 1999
- 74 International Advisory Board GSK – 2005- 2008, 2009
- 75 Advisory Board Array Pharmaceuticals, 2006- 2009
- 76 Advisory Board Amgen – 2007
- 77 Advisory Board Genentech 2006 – 2008
- 78 Roche Advisory Board, 2008-2010

(h) Consultant (indicate organization and dates) (Local)

- 79 Member, Safety Committee, Cardiovascular Study Group, 1993-1994
- 80 Kinetek Consultant, 2000

(h) Consultant (indicate organization and dates) (National)

- 81 Member, Canadian Taxotere Advisory Board, 1993-2002
- 82 Member, Canadian Advisory Boards for Aventis, Roche, AstraZeneca, Genetech, Lilly, Novartis, Pfizer, Ortho Biotech, Amgen, BioKinetic, at various times since 1993
- 83 Member, Wellcome Advisory Board, 1994
- 84 Member, Advisory Committee, Bristol Myers Squibb, 1995
- 85 Member, Upjohn CPT11 Advisory Board, 1995-1996
- 86 Member, Advisory Committee, Eli Lilly Canada, 1997, 2006
- 87 Member, Advisory Committee Hoffman-LaRoche, 1998, -
- 88 Member, Advisory Committee GlaxoWellcome, 1999
- 89 Canada Advisory Board for AstraZeneca, 1999 – 2008
- 90 Member, Canadian Advisory Committee for Roche, 1999 - present
- 91 Member, Canadian Advisory Board for Novartis, 2004 - present
- 92 Member, Canadian Advisory Board for GSK – 2006 – 2010
- 93 Member, Pfizer Advisory Board, 2006 – 2007
- 94 Member Advisory Board, Roche 2006-2008

(h) Consultant (indicate organization and dates) (Provincial)

95 Medical Consultant, Quadra Logic Technologies, Inc, 1990-1992

(i) Other service to the community

96 Public Forum in breast cancer in Terrace, Victoria, Abbotsford, Surrey, Cranbrook and North Vancouver at various times since 1996

97 Public Forum in breast cancer Whitehorse 2000

98 Public Forum in breast cancer Campbell River 2000

99 Public Forum in breast cancer Vancouver 2001, 2004, 2007, 2008, 2010

100 Public Forum in breast cancer Nelson 2001

101 Public Forum Canadian Cancer Society 2002, 2005, 2010

102 Public Forum, Vancouver Public Library, 2005, 2008, 2009

(i) Other service to the community (Local)

103 Breast Cancer Alliance - Information Project, 1999 - present

104 VGH / Breast Cancer Alliance Public Forum, 1999 – 2004

105 Keynote Speaker, Breast Cancer Awareness Day, White Rock, 2002

106 Keynote Speaker, Breast Cancer Awareness Day Surrey, 2002

107 Keynote Speaker, Canadian Cancer Society Breast Cancer Awareness Day Richmond, 2003

108 Speaker Vancouver Public Library – April 2007 – Hormones and Breast Cancer

109 Speaker at Pharmacy, Nursing and Medical Forums

110 Breast Cancer Foundation Forums, Vancouver, 1993 - 2010

111 Plenary speaker. Breast Cancer Foundation Meeting, Sept/1993

112 Plenary Speaker, Canadian Breast Cancer Foundation Annual Breakfast, October 1993

113 Keynote speaker. Awareness Day Breakfast, Fraser Valley Chapter of the Canadian Breast Cancer Foundation, May/1995, Richmond 2005 and 2010

114 Cancer Society Public Forum on Breast Cancer, Nanaimo, BC, May 1997

115 Canadian Cancer Society - BC Forum on Breast Cancer, Sept/1997

116 YWCA Forum on Breast Cancer, Nov/1997, 2009

117 Public Forums, Vancouver Shaare Tzedek 2010

(i) Other service to the community (Provincial)

118 Lecture, Breast Health Forum, Prince George, Jun/1996

119 Whistler Public Forum on Breast Cancer, Oct/1997

120 Native Women's Health Forum on Breast Cancer, Oct/1997, 2008

121 BC Woman's Breast Conference: Imaging and Intervention, January 26, 2001

122 Jewish Women's Health Fair, 2002, 2006, 2008,

123 Video Linked conference to 11 sites in northern BC. Followup of Breast Cancer Feb, 2004

124 Video Linked Conference to sites in BC. Toxicities of Breast cancer treatment , June 2004, 2009

125 Video Linked Conference to sites in BC, Adjuvant therapy of Breast Cancer, June 2005, 2009

126 Video Linked Conference to 11 sites in BC - Screening Mammography, January 2006

- 127 Video Linked Conference on treatment complications, 2006, 2008
 128 Video Linked conference on Hormone Replacement and Hormone therapy 2009

i) Other service to the community (National)

12. AWARDS AND DISTINCTIONS

(a) Awards for Teaching (indicate name of award, awarding organizations, date)

- 1 PARA BC teaching award 1993
- 2 YWCA Women of Distinction Award 2003, Lessons for Life
- 3 Queens University Maria Ricci Memorial Lectureship in Medical Oncology, 2008

13. OTHER RELEVANT INFORMATION (Maximum One Page)

**University of British Columbia
Publications Record**

Date: 20 December 2017

Initial: _____

1. SURNAME: Gelmon

FIRST NAME: Karen
MIDDLE NAME(S): A

01. Refereed Publications

(a) Journals

- 1 Murray N, Coppin C, Murphy K, Gelmon K. "Mx FAM for the treatment of metastatic cancer primary unknown. A preliminary report" Proc. 14th Congress of Chemotherapy 1985; 1304.
- 2 Price LA, Hill BT, Gelmon KA. "Intermittent high-dose zidovudine" Lancet 1989; 2(8665):734.
- 3 Gelmon K, Montaner JS, Fanning M, Smith JR, Falutz J, Tsoukas C, Gill J, Wells G, O'Shaughnessy M, Wainberg M, et al. "Nature, time course and dose dependency of zidovudine-related side effects: Results from the multicenter Canadian Azidothymidine trial" AIDS 1989; 3(9):555-561.
- 4 Gelmon K, Weller IV. "Randomized placebo controlled trials in HIV infection: To be or not to be?" Genitourin Med. 1989; 65(3):143-145.
- 5 Rooke R, Tremblay M, Soudeyns H, DeStephano L, Yao XJ, Fanning M, Montaner JS, O'Shaughnessy M, Gelmon K, Tsoukas C, Gill J, Ruedy J, Wainberg M. "Isolation of drug-resistant variants of HIV-1 from patients on long-term zidovudine therapy" Canadian zidovudine multi-centre study group. AIDS 1989; 3(7):411-415.
- 6 Wainberg MA, Falutz J, Fanning M, Gill J, Gelmon K, Montaner JS, O'Shaughnessy M, Tsoukas C, Ruedy J.

- "Cessation of zidovudine therapy may lead to increased replication of HIV-1" JAMA 1989; 261(6):865-866.
- 7 Montaner JS, Le T, Fanning M, Gelmon K, Tsoukas C, Falutz J, O'Shaughnessy M, Wainberg MA, Ruedy J. "The effect of zidovudine on platelet counts in HIV-infected individuals" J. Acquir. Immune Defic. Syndr. 1990; 3: (6):565-570.
 - 8 Gelmon KA. "Cancer in HIV infection" Medicine North America 1990; 8: 957-964.
 - 9 Gelmon, K. AIDS, San Francisco. Lancet 1990, 335; (8705): 1581- 2.
 - 10 Osoba D, Band PR, Goldie JH, Connors JM, Gelmon K, Knowling MA, Fetherstonhaugh EM. "Efficacy of weekly cisplatin-based chemotherapy in recurrent and metastatic head and neck cancer" Annals of Oncology 1992; 3(Suppl. 3):57-62.
 - 11 Schechter MT, Craib KJP, Gelmon KA, Montaner JSG, Le TN, O'Shaughnessy MV. "Aetiology of AIDS" Lancet 1993; 341: 658-659.
 - 12 Embree L, Gelmon KA, Lohri A, Mayer LD, Coldman AJ, Cullis PR, Palaitis W, Pilkiewicz F, Hudon NJ, Heggie JR, Goldie JH. "Chromatographic analysis and pharmacokinetics of liposome encapsulated doxorubicin (TLC D-99) in non-small cell lung cancer patients" J. Pharmaceutical Sciences 1993;82:627-634.
 - 13 Schechter M, Craib K, Montaner J, Lee T, O'Shaughnessy M, Gelmon K. "Aetiology of AIDS" (letter). Lancet 1993;341: 1222-1223.
 - 14 Schechter M, Craib KJ, Montaner JS, Lee TN, O'Shaughnessy MV, Gelmon K. Aetiology of AIDS (letter; comment). Lancet 1993, Apr 10:341(8850); 957-8.
 - 15 O'Reilly SE, Gelmon KA, Onetto N, Parenta J, Rubinger M, Page RA, Plenderleith IH. "A phase I trial of recombinant human granulocytes colony stimulating factor derived from yeast in patients with metastatic breast cancer receiving CAF chemotherapy in adjuvant and metastatic disease" J. Clin. Oncol. 1993; 11(12):1-6.
 - 16 Gregg RWC, Kaizer L, Fine S, Gelmon K, Wielgosz G, Eisenhauer E. "A phase II trial of DuP 937 (teloxantrone) in non-small cell lung cancer" Annals of Oncology 1993; 693-694.
 - 17 Shenkier T, Gelmon K. "Paclitaxel and radiation recall dermatitis" (Letter) Journal of Clinical Oncology 1994; 12(2):439.
 - 18 Olivotto I, Bajdik CD, Plenderleith IH, Coppin C, Gelmon K, Jackson SM, Ragaz J, Noble M, Worth A. "Adjuvant systemic therapy and survival after breast cancer" NEJM 1994;330(12):805-810
 - 19 Gelmon K, Member of Concorde Coordinating Committee. "MRC/ANRS randomized double-blind, controlled trial comparing immediate and deferred zidovudine in asymptomatic HIV infection" Lancet 1994;343(901):892-898.
 - 20 Osoba D, Murray N, Gelmon K, Karsai H, Knowling M, Shah A. "Phase II Trial of Megestrol in the supportive care of patients receiving dose intensive chemotherapy" Oncology 1994; 8(3):43-68.
 - 21 Arnold A, Ayoub J, Douglas L, Hoogendoorn P, Skingdery L, Gelmon K, Hirsch V, Eisenhauer E. "A phase II trial of cisretinoic acid and interferon in non small cell lung cancer" JNCI 1994; 86: 306-309.
 - 22 Gelmon, KA. Biweekly paclitaxel (Taxol) and cisplatin in breast and ovarian cancer. Semin Oncol. 1994; 21 (5 suppl 8): 24-8.
 - 23 Gelmon K. Drug Profile. The Taxoids. The Lancet 1994, vol 344:1267-72.
 - 24 Osoba D, Murray N, Gelmon K, Karsai H, Knowling M, Shah A, McLaughlin M, Fetherstonhaugh E, Page R, Bowman CA. Quality of life, appetite, and weight change in patients receiving dose-intensive chemotherapy. Oncology, 8(4), 1994 Apr: 61-5 discussion 65-6.
 - 25 De Jong G, Gelmon K, Bally M, Goldie J, Mayer L. Modulation on Doxorubicin Resistance in P388/ADR Cells by R044 5912, a Tiapamil derivative. Anticancer Research 15:1(1995) 1-6.
 - 26 O'Reilly SE, Gelmon KA. Biweekly paclitaxel and cisplatin: a phase I/II study in the first-line treatment of metastatic breast cancer. Semin Oncol. 1995; 22 (3 suppl 6): 109-110.
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08. Work Submitted

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