IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA Plaintiff, v. GENENTECH, INC. Defendant.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, The Trustees of the University of Pennsylvania, by and through its attorneys, for its complaint against Defendants Genentech, Inc., hereby allege as follows:

THE PARTIES

1. The Trustees of the University of Pennsylvania ("Penn") is a Pennsylvania non-profit organization focused on higher education, research and patient care with a principal place of business of 3154 Walnut Street, Philadelphia, Pennsylvania 19104.

2. On information and belief, Defendant Genentech, Inc. ("Genentech") is Delaware corporation with a principal place of business at 1 DNA Way, South San Francisco, California, 94080.

JURISDICTION AND VENUE

3. This is an action for patent infringement under 35 U.S.C. § 271 *et seq.*

4. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338 because all claims in this action arise under the patent laws of the United States.

5. This Court has personal jurisdiction over Genentech as a corporation organized under the laws of the State of Delaware.

6. Venue in this district is proper under 28 U.S.C. §§ 1391 and 1400 at least because Genentech is incorporated in this district, this Court has personal jurisdiction over Genentech, and infringement has occurred in this judicial district.

BACKGROUND

7. Plaintiff Penn is a leader in the research, development, and administration of cancer therapies and treatment of cancer patients. Penn's Abramson Cancer Center was founded in 1973 with the goal of transforming scientific breakthroughs into innovative cancer treatments. At Penn's Cancer Center, scientists, medical oncologists, pathologists, and surgeons work together on the complex steps of turning discoveries into treatments that will benefit cancer patients throughout the world.

8. On December 1, 2009, United States Patent No. 7,625,558 (the "'558 patent") entitled "Compositions and Methods of Treating Tumors" was duly and legally issued by the United States Patent and Trademark Office (the "USPTO"). A copy of the '558 patent is attached as Exhibit A.

9. The '558 patent is a continuation of U.S. patent application No. 09/111,681, which issued as U.S. Patent No. 6,417,168 (the "'168 patent"). Both the '558 and '168 patents claim priority to the same provisional patent application No. 60/076,788.

10. Penn is the owner and assignee of all right, title, and interest in and to the '558 patent.

11. The inventions of the '558 patent were invented by Drs. Mark Greene, Donald O'Rourke, Ramachandran Murali, and Byeong-Woo Park all of whom were working at the Perelman School of Medicine of the University of Pennsylvania. Drs. Greene and O'Rourke are still employed by Penn. Dr. Greene is Professor of Medical Science Emeritus in the Department of Pathology and Laboratory Medicine at Penn's Perelman School of Medicine. Dr. O'Rourke is the John Templeton, Jr. M.D. Professor of Neurosurgery in the Department of Neurosurgery at Penn's Perelman School of Medicine.

12. Drs. Green, O'Rourke, Murali, and Park developed therapies for treating ErbB protein mediated cancer tumors by administering a compound, such as a peptide or antibody, that inhibits the formation of ErbB protein dimers, followed by radiation. In particular, they made the surprising finding that administering a cytostatic antibody that inhibits tumor cell growth actually enhances subsequent administration of radiation in a synergistic manner. Their efforts resulted in the inventions claimed in the '558 patent.

13. The '558 patent discloses and claims methods of treating an individual who has an ErbB protein mediated tumor. For example, claim 15 of the '558 patent depends from claim 1, and claims the following:

> 15. [A method of treating an individual who has an erbB protein mediated tumor which method comprises steps of:
>
> > (a) administering to said individual an antibody which inhibits formation of erbB protein dimers that produce elevated tyrosine kinase activity in a tumor cell, said inhibition having a cytostatic effect on the tumor cell; and
> >
> > (b) thereafter exposing said individual to a therapeutically effective amount of anti-cancer radiation]
> >
> > wherein the antibody inhibits formation of a p185 homodimer.[1]

[1] The elements recited by claim 1 are contained within the brackets.

14. On April 9, 2019, Penn requested *ex parte* reexamination of the '558 patent under Reexamination Control No. 90/014,282 ("the '282 reexamination"). The reexamination certificate for the '282 reexamination issued on February 27, 2020 and is attached as Exhibit B. The claims of the '558 patent as referenced herein include the reexamination claims.

15. The February 27, 2020 reexamination certificate amended the claims to, among other things, include claims 42 through 88. For example, after the '282 reexamination, claim 62 of the '558 patent claims the following:

> 62. A method for inhibiting proliferation of a tumor cell in an individual, said tumor cell being from an erbB mediated tumor, which method comprises steps of:
>
> (a) contacting the cell with an anti-erbB antibody that disrupts erbB kinase activity, said disruption resulting in cytostasis of said tumor cell; and
>
> (b) thereafter exposing the tumor cell to an effective amount of anti-cancer radiation delivered from an external source; wherein said erbB mediated tumor cell is not a skin epithelial tumor cell, and wherein said administering of said antibody radiosensitizes said erbB mediated tumor so as to achieve a synergistic increase in apoptosis of the cells of said erbB mediated tumor following exposure to anti-cancer radiation as compared to apoptosis achieved by the antibody or radiation administered alone.

16. As a further example, after the '282 reexamination, claim 72 of the '558 patent claims the following:

> 72. A method for inhibiting proliferation of a tumor cell in an individual, said tumor cell being from an erbB mediated tumor, which method comprises steps of:
>
> (a) contacting the cell with an anti-erbB antibody that disrupts erbB kinase activity, said disruption resulting in cytostasis of said tumor cell; and
>
> (b) thereafter exposing the tumor cell to an effective amount of anti-caner radiation administered from and external source,
>
> wherein said tumor is not growth-inhibited by EGF.

DEFENDANT'S INFRINGING PRODUCTS AND ACTIVITIES

I. Herceptin

17. On information and belief, Genentech markets Herceptin in the United States, and Genentech sells Herceptin and distributes Herceptin to others.

18. Herceptin (trastuzumab) is a HER2/neu receptor antagonist. Specifically, trastuzumab is an anti-ErbB antibody that disrupts ErbB kinase activity and inhibits formation of ErbB protein dimers.

19. On information and belief, Genentech is the owner of Biologics License Application ("BLA") No. 103792, under which the Food and Drug Administration ("FDA") approved the use of Herceptin in combination with chemotherapy to treat patients with metastatic breast cancer who have tumors that overexpress the HER2 protein. Specifically, under BLA 103792, Genentech has engaged in the commercial manufacture, use and/or sale of Herceptin in combination with chemotherapy followed by radiation.

20. Herceptin has been marketed and sold in the United States with a label including instructions for its use (the "Herceptin Prescribing Information") as approved by the FDA. The Herceptin Prescribing Information includes a suggested use that involves administering Herceptin in combination with chemotherapy followed by radiation for treatment of ErbB2 (HER2)-mediated breast cancer, which is not a skin epithelial tumor. The Herceptin Prescribing Information teaches that radiation can commence once chemotherapy is concluded in the adjuvant regime.

21. The Herceptin Prescribing Information provides instructions for administering trastuzumab, which is an antibody.

22. Trastuzumab inhibits the proliferation of tumor cells from ErbB-mediated tumors.

23. Trastuzumab inhibits the formation of ErbB protein dimers that produce elevated tyrosine kinase activity in a tumor cell.

24. Trastuzumab has a cytostatic effect on tumor cells. When trastuzumab contacts tumor cells from an ErbB-mediated tumor, it disrupts ErbB kinase activity resulting in cytostasis of such tumor cells.

25. Trastuzumab inhibits formation of p185 homodimers.

26. The Herceptin Prescribing Information teaches exposing an individual to a therapeutically effective amount of anti-cancer radiation after chemotherapy, including in combination with trastuzumab, has concluded.

27. Trastuzumab radiosensitizes ErbB-mediated tumor cells to achieve a synergistic increase in apoptosis of these cells following exposure to anti-cancer radiation as compared to apoptosis achieved by trastuzumab or radiation administered alone.

28. Health care professionals directly infringe the ‘558 patent when they administer Herceptin for the treatment of an ErbB protein mediated tumor followed by radiation.

29. The offer for sale and sale of Genentech’s Herceptin will induce infringement of, and contribute to the infringement of, the ’558 patent.

II. Perjeta

30. On information and belief, Genentech markets Perjeta in the United States, and Genentech sells Perjeta and distributes Perjeta to others.

31. Perjeta (pertuzumab) is a HER2/neu receptor antagonist. Specifically, pertuzumab is an anti-ErbB antibody that disrupts ErbB kinase activity and blocks heterodimerization of ErbB thereby inhibiting the formation of ErbB protein dimers.

32. On information and belief, Genentech is the owner of BLA No. 125409, under which the FDA approved the use of Perjeta in combination with trastuzumab and chemotherapy to treat patients with metastatic breast cancer who have tumors that overexpress the HER2 protein. Specifically, under BLA No. 125409, Genentech has engaged in the commercial manufacture, use and/or sale of Perjeta in combination with trastuzumab followed by radiation.

33. Perjeta has been marketed and sold in the United States with a label including instructions for its use (the "Perjeta Prescribing Information") as approved by the FDA.

34. On information and belief, in seeking FDA approval for Perjeta, Genentech conducted a trial in the adjuvant regimen in which 70% of the patients were administered Perjeta in combination with trastuzumab and chemotherapy followed by radiation for treatment of ErbB2 (HER2)-mediated breast cancer, which is not a skin epithelial tumor.

35. The Perjeta Prescribing Information provides instructions for administering pertuzumab, which is an antibody.

36. Pertuzumab inhibits the proliferation of tumor cells from ErbB-mediated tumors.

37. Pertuzumab inhibits the formation of ErbB protein dimers that produce elevated tyrosine kinase activity in a tumor cell.

38. Pertuzumab has a cytostatic effect on tumor cells. When pertuzumab contacts tumor cells from an ErbB-mediated tumor, it disrupts ErbB kinase activity resulting in cytostasis of such tumor cells.

39. Pertuzumab inhibits formation of p185 homodimers.

40. During clinical trials for Perjeta, individuals were exposed to a therapeutically effective amount of anti-cancer radiation after administration of Perjeta in combination with trastuzumab and chemotherapy.

41. Pertuzumab radiosensitizes ErbB-mediated tumor cells to achieve a synergistic increase in apoptosis of these cells following exposure to anti-cancer radiation as compared to apoptosis achieved by pertuzumab or radiation administered alone.

42. Health care professionals directly infringe the ’558 patent when they administer Perjeta in combination with trastuzumab and chemotherapy followed by radiation.

43. The offer for sale and sale of Genentech’s Perjeta will induce infringement of, and contribute to the infringement of, the ’558 patent.

III. Herceptin Hylecta

44. On information and belief, Genentech markets Herceptin Hylecta in the United States, and Genentech sells Herceptin Hylecta and distributes Herceptin Hylecta to others.

45. Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) is a combination of trastuzumab and hyaluronidase. Trastuzumab is a HER2/neu receptor antagonist. Specifically, trastuzumab is an anti-ErbB antibody that disrupts ErbB kinase activity, and inhibits formation of ErbB protein dimers.

46. On information and belief, Genentech is the owner of BLA No. 761106, under which the FDA approved the use of Herceptin Hylecta in combination with chemotherapy to treat patients with metastatic breast cancer who have tumors that overexpress the HER2 protein. Specifically, under BLA 761106, Genentech has engaged in the commercial manufacture, use and/or sale of Herceptin in combination with chemotherapy followed by radiation.

47. Herceptin Hylecta has been marketed and sold in the United States with a label including instructions for its use (the “Hylecta Prescribing Information”) as approved by the FDA. The Hylecta Prescribing Information includes a suggested use that involves administering Herceptin Hylecta in combination with chemotherapy followed by radiation for treatment of

ErbB2 (HER2)-mediated breast cancer, which is not a skin epithelial tumor. The Hylecta Prescribing Information teaches that radiation can commence once chemotherapy is concluded in the adjuvant regime.

48. The Hylecta Prescribing Information provides instructions for administering trastuzumab, which is an antibody.

49. Trastuzumab inhibits the proliferation of tumor cells from ErbB-mediated tumors.

50. Trastuzumab inhibits the formation of ErbB protein dimers that produce elevated tyrosine kinase activity in a tumor cell.

51. Trastuzumab has a cytostatic effect on tumor cells. When trastuzumab contacts tumor cells from an ErbB-mediated tumor, it disrupts ErbB kinase activity resulting in cytostasis of such tumor cells.

52. Trastuzumab inhibits formation of p185 homodimers.

53. The Hylecta Prescribing Information teaches exposing an individual to a therapeutically effective amount of anti-cancer radiation after chemotherapy has concluded, including in combination with trastuzumab.

54. Trastuzumab radiosensitizes ErbB-mediated tumor cells to achieve a synergistic increase in apoptosis of these cells following exposure to anti-cancer radiation as compared to apoptosis achieved by trastuzumab or radiation administered alone.

55. Health care professionals directly infringe the ‘558 patent when they administer Herceptin Hylecta followed by radiation.

56. The offer for sale and sale of Genentech’s Herceptin Hylecta will induce infringement of, and contribute to the infringement of, the ’558 patent.

IV. Phesgo

57. On information and belief, Genentech markets Phesgo in the United States, and Genentech sells Phesgo and distributes Phesgo to others.

58. Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) is a combination of ErbB (HER2/neu) receptor antagonists and hyaluronidase. Pertuzumab and trastuzumab are anti-ErbB antibodies that disrupts ErbB kinase activity. Phesgo inhibits formation of ErbB protein dimers.

59. On information and belief, Genentech is the owner of BLA No. 761170, under which the FDA approved the use of Phesgo in combination with chemotherapy to treat adult patients with metastatic breast cancer who have tumors that overexpress the HER2 protein. Specifically, under BLA No. 761170, Genentech has engaged in the commercial manufacture, use and/or sale of Phesgo in combination with chemotherapy followed by radiation.

60. Phesgo has been marketed and sold in the United States with a label including instructions for its use (the "Phesgo Prescribing Information") as approved by the FDA.

61. On information and belief, in seeking FDA approval for Phesgo, Genentech conducted a trial in which some patients were administered Phesgo in combination with chemotherapy followed by radiation for treatment of ErbB2 (HER2)-mediated breast cancer, which is not a skin epithelial tumor.

62. The Phesgo Prescribing Information provides instructions for administering trastuzumab and pertuzumab, both of which are antibodies.

63. Pertuzumab and trastuzumab inhibit the proliferation of tumor cells from ErbB-mediated tumors.

64. Pertuzumab and trastuzumab inhibit the formation of ErbB protein dimers that produce elevated tyrosine kinase activity in a tumor cell.

65. Pertuzumab and trastuzumab have a cytostatic effect on tumor cells When pertuzumab and trastuzumab contact tumor cells from an ErbB-mediated tumor, they disrupt ErbB kinase activity resulting in cytostasis of such tumor cells.

66. Pertuzumab and trastuzumab inhibit formation of p185 homodimers.

67. During clinical trials for Phesgo, individuals were exposed to a therapeutically effective amount of anti-cancer radiation after administration of Phesgo in combination with chemotherapy.

68. Pertuzumab and trastuzumab radiosensitize ErbB-mediated tumor cells to achieve a synergistic increase in apoptosis of these cells following exposure to anti-cancer radiation as compared to apoptosis achieved by trastuzumab, pertuzumab, or radiation administered alone.

69. Health care professionals directly infringe the ‘558 patent when they administer Phesgo followed by radiation.

70. The offer for sale and sale of Genentech’s Phesgo will induce infringement of, and contribute to the infringement of, the ’558 patent.

DEFENDANT’S KNOWLEDGE OF THE ’558 PATENT

71. On information and belief, Genentech had pre-suit knowledge of the ’558 patent.

72. On information and belief, Genentech’s actions have been with the specific intent to cause infringement and/or Genentech has been willfully blind to the fact that its acts were infringing, contributing to, or inducing infringement of the ’558 patent since before the filing of this action. In particular, Genentech’s knowledge of the ’558 patent is demonstrated by the efforts

of its parent company, Hoffman-La Roche ("Roche"), to revoke foreign counterparts of the '558 patent in the European Patent Office ("EPO").

73. In 2007, Roche, along with several third parties filed in the European Patent Office ("EPO") an opposition (the "2007 EPO Opposition") opposing the issuance of Penn's European patent application (the "99908641.6 Application"). The 99908641.6 Application is a foreign counterpart to Penn's '168 and '558 U.S. patents. The 2007 EPO Opposition identifies priority applications for the 99908641.6 Application, including the '558 patent's parent application (U.S. Application No. 09/111,681, which issued as the '168 patent).

74. Then, in 2016, Roche and Genentech filed in the EPO an opposition (the "2016 EPO Opposition") opposing the issuance of Penn's European patent application (the "0607149.1 Application"). The 0607149.1 Application is a foreign counterpart to Penn's '168 and '558 U.S. patents. The 2016 EPO Opposition identifies priority applications for the 0607149.1 Application, including the '558 patent's parent application (U.S. Application No. 09/111,681, which issued as the '168 patent).

75. Finally, in 2019, Roche filed in the EPO an opposition (the "2019 EPO Opposition") opposing the issuance of Penn's European patent application (the "15183218.5 Application"). The 15183218.5 Application is a foreign counterpart to Penn's '168 and '558 U.S. patents. The 2019 EPO Opposition identifies priority applications for the 15183218.5 Application, including the '558 patent's parent application (U.S. Application No. 09/111,681, which issued as the '168 patent).

76. On information and belief, Genentech and its parent company, Roche, have participated in, monitored, and continue to monitor the status of patent disputes involving patents related to Herceptin, Herceptin Hylecta, Perjeta, and Phesgo, including the '558 patent. On

information and belief, Genentech and Roche have known of the '558 patent since its issuance or shortly thereafter, and have known of the EPO Opposition and the '558 patent parent and family since 2007.

FIRST CAUSE OF ACTION

(Infringement of the '558 Patent - Herceptin)

77. Penn incorporates by reference paragraphs 1 – 76.

78. On information and belief, Genentech has marketed and sold Herceptin in the United States with the Herceptin Prescribing Information, which provides instructions for administering Herceptin, and teaches administering Herceptin in combination with chemotherapy followed by radiation for treatment of ErbB-mediated tumors. On information and belief, Genentech had knowledge of the '558 patent and, based on the clinical trials and literature available, Genentech knew or should have known that the sale and offer for sale of Herceptin would induce actual infringement of the '558 patent claims.

79. Health care professionals directly infringe the '558 patent when they administer Herceptin followed by radiation in accordance with the instructions and teachings of the Herceptin Prescribing Information and in a manner consistent with the available clinical trials and literature.

80. On information and belief, Genentech indirectly infringes at least claims 8, 13, 15, 18, and 32-88 of the '558 patent by, without authorization from Penn, actively encouraging, instructing, and inducing others to use or practice in the United States infringing combination therapies, including administration of Herceptin in combination with chemotherapy, followed by radiation for the treatment of ErbB-mediated breast cancer tumors. On information and belief, physicians have infringed and will continue to infringe at least these claims of the '558 patent by treating such patients in this manner.

81. On information and belief, despite Genentech's knowledge of the '558 patent and its parent company's attempts to revoke foreign counterparts of the '558 patent in the EPO, Genentech proceeded with its infringing activity, and with specific intent to cause (or willful blindness to causing) infringement of the '558 patent by others who, in accord with the Herceptin Prescribing Information, administer Herceptin in combination with chemotherapy followed by radiation for the treatment of ErbB mediated tumors.

82. On information and belief, Genentech has no reasonable basis for believing that the '558 patent was invalid or otherwise unenforceable.

83. Genentech's infringement of the '558 patent is willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

84. Penn has suffered damages as a result of Genentech's infringement of the '558 patent, and will suffer additional damages as a result of Genentech's continuing infringement.

SECOND CAUSE OF ACTION

(Infringement of the '558 Patent - Perjeta)

85. Penn incorporates by reference paragraphs 1 – 84.

86. On information and belief, Genentech has marketed and sold Perjeta in the United States with the Perjeta Prescribing Information, which provides instructions for administering Perjeta.

87. On information and belief, Genentech submitted its BLA No. 125409 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Perjeta in combination with Herceptin followed by radiation for the treatment of erbB-mediated tumors. On information and belief, Genentech had knowledge of the '558 patent and, based on

the clinical trials and literature available, Genentech knew or should have known that the sale and offer for sale of Perjeta would induce actual infringement of the '558 patent claims.

88. Health care professionals directly infringe the '558 patent when they administer Perjeta followed by radiation in accordance with the instructions and teachings of the Perjeta Prescribing Information and in a manner consistent with the available clinical trials and literature.

89. On information and belief, Genentech indirectly infringes at least claims 8, 13, 15, 18, and 32-88 of the '558 patent by, without authorization from Penn, actively encouraging, instructing, and inducing others to use or practice in the United States infringing combination therapies, including administration of Perjeta in combination with Herceptin, followed by radiation for the treatment of ErbB-mediated breast cancer tumors. On information and belief, physicians have infringed and will continue to infringe at least these claims of the '558 patent by treating such patients in this manner.

90. On information and belief, despite Genentech's knowledge of the '558 patent and its parent company's attempts to revoke foreign counterparts of the '558 patent in the EPO, Genentech proceeded with its infringing activity after it knew of the '558 patent, and with specific intent to cause (or willful blindness to causing) infringement of the '558 patent by others who, in accord with the Perjeta Prescribing Information, administer Perjeta in combination with Herceptin followed by radiation for the treatment of ErbB mediated tumors.

91. On information and belief, Genentech has no reasonable basis for believing that the '558 patent was invalid or otherwise unenforceable.

92. Genentech's infringement of the '558 patent is willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

93. Penn has suffered damages as a result of Genentech's infringement of the '558 patent, and will suffer additional damages as a result of Genentech's continuing infringement.

THIRD CAUSE OF ACTION

(Infringement of the '558 Patent – Herceptin Hylecta)

94. Penn incorporates by reference paragraphs 1 – 93.

95. On information and belief, Genentech has marketed and sold Herceptin Hylecta in the United States with the Hylecta Prescribing Information, which provides instructions for administering Herceptin, and teaches administering Herceptin Hylecta in combination with chemotherapy followed by radiation for treatment of ErbB-mediated tumors. On information and belief, Genentech had knowledge of the '558 patent and, based on the clinical trials and literature available, Genentech knew or should have known that the sale and offer for sale of Herceptin Hylecta would induce actual infringement of the '558 patent claims.

96. Health care professionals directly infringe the '558 patent when they administer Herceptin Hylecta followed by radiation in accordance with the instructions and teachings of the Hylecta Prescribing Information and in a manner consistent with the available clinical trials and literature.

97. On information and belief, Genentech indirectly infringes at least claims 8, 13, 15, 18, and 32-88 of the '558 patent by, without authorization from Penn, actively encouraging, instructing, and inducing others to use or practice in the United States infringing combination therapies, including administration of Herceptin Hylecta in combination with chemotherapy, followed by radiation for the treatment of ErbB-mediated breast cancer tumors. On information and belief, physicians have infringed and will continue to infringe at least these claims of the '558 patent by treating such patients in this manner.

98. On information and belief, despite Genentech's knowledge of the '558 patent and its parent company's attempts to revoke foreign counterparts of the '558 patent in the EPO, Genentech proceeded with its infringing activity, and with specific intent to cause (or willful blindness to causing) infringement of the '558 patent by others who, in accord with the Herceptin Hylecta Prescribing Information, administer Herceptin Hylecta in combination with chemotherapy followed by radiation for the treatment of ErbB mediated tumors.

99. On information and belief, Genentech has no reasonable basis for believing that the '558 patent was invalid or otherwise unenforceable.

100. Genentech's infringement of the '558 patent is willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

101. Penn has suffered damages as a result of Genentech's infringement of the '558 patent, and will suffer additional damages as a result of Genentech's continuing infringement.

FOURTH CAUSE OF ACTION

(Infringement of the '558 Patent - Phesgo)

102. Penn incorporates by reference paragraphs 1 – 101.

103. On information and belief, Genentech has marketed and sold Phesgo in the United States with the Phesgo Prescribing Information, which provides instructions for administering Phesgo.

104. On information and belief, Genentech submitted its NDA No. 761170 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Phesgo in combination with chemotherapy followed by radiation for the treatment of ErbB-mediated tumors. On information and belief, Genentech had knowledge of the '558 patent and,

based on the clinical trials and literature available, Genentech knew or should have known that the sale and offer for sale of Phesgo would induce actual infringement of the '558 patent claims.

105. Health care professionals directly infringe the '558 patent when they administer Herceptin followed by radiation in accordance with the instructions and teachings of the Herceptin Prescribing Information and in a manner consistent with the available clinical trials and literature.

106. On information and belief, Genentech indirectly infringes at least claims 8, 13, 15, 18, and 32-88 of the '558 patent by, without authorization from Penn, actively encouraging, instructing, and inducing others to use or practice in the United States infringing combination therapies, including administration of Phesgo in combination with chemotherapy followed by radiation for the treatment of ErbB-mediated breast cancer tumors. On information and belief, physicians have infringed and will continue to infringe at least these claims of the '558 patent by treating such patients in this manner.

107. On information and belief, despite Genentech's knowledge of the '558 patent and its parent company's attempts to revoke foreign counterparts of the '558 patent in the EPO, Genentech proceeded with its infringing activity after it knew of the '558 patent, and with specific intent to cause (or willful blindness to causing) infringement of the '558 patent by others who, in accord with the Phesgo Prescribing Information, administer Phesgo in combination with chemotherapy followed by radiation for the treatment of ErbB mediated tumors.

108. On information and belief, Genentech has no reasonable basis for believing that the '558 patent was invalid or otherwise unenforceable.

109. Genentech's infringement of the '558 patent is willful, justifying the assessment of treble damages pursuant to 35 U.S.C. § 284.

110. Penn has suffered damages as a result of Genentech's infringement of the '558 patent, and will suffer additional damages as a result of Genentech's continuing infringement.

DEMAND FOR RELIEF

WHEREFORE, PENN respectfully requests the following relief:

a) That this Court adjudge and decree that Genentech has been and is currently infringing the '558 patent;

b) That this Court order Genentech to pay damages to Penn to compensate it for each of the unlawful actions set forth in Penn's Complaint;

c) That this Court determine that Genentech's infringement is willful and award Penn enhanced damages for such infringement;

d) That this Court award pre-judgment and post-judgment interest on each of such damages awarded to Penn and order an accounting of damages that accrue between the close of fact discovery and the date a final judgment is entered in this litigation;

e) Enter an order for a post-judgment equitable accounting of damage which, at a minimum, includes a compulsory on-going licensing fee;

f) That this Court determine that this patent infringement case is exceptional and award Penn its costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

g) That this Court award such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Penn respectfully requests a trial by jury on all issues triable thereby.

Dated: January 31, 2022

Respectfully submitted,

FARNAN LLP

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