IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Sharon Erickson, et al.	Docket No.:	GNE-0073R2C2
Serial No.:	11/949,351	Group Art Unit:	1643
Filing Date:	12/03/2007	Examiner:	Natarajan, Meera
Customer No.	35489	Confirmation No.	4598

For: **METHODS OF TREATMENT USING ANTI-ErbB ANTIBODY-MAYTANSINOID CONJUGATES**

FILED VIA EFS – JULY 6, 2010

AMENDMENT AND RESPONSE TO OFFICE ACTION

MS: AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action mailed on June 8th, 2010 (Paper No./Mail Date 20100604) in connection with the above-identified patent application, which vacates the earlier Office Action mailed on April 1st, 2010. The present Amendment and Response is timely filed within the three month shortened statutory period set in the Office Action, and is accompanied by Declarations of Barbara Klencke, M.D. and Mark X. Sliwkowski, Ph.D., respectively, the entry and consideration of which is respectfully requested.

Amendments to the Specification begin on page **2** of this paper.

Claims begin on page **4** of this paper.

Remarks/Arguments begin on page **6** of this paper.

Amendment to the Specification:

The title of the application has been amended as follows:

~~METHODS OF TREATMENT USING ANTI-ErbB~~ huMAb4D5-8 ANTI-ErbB2 ANTIBODY-MAYTANSINOID CONJUGATES

Paragraph [0217] has been amended as follows:

[0217] HERCEPTIN® (huMAb4D5-8, rhuMAb HER2, U.S. Pat. No. 5,821,337) (1 vial containing 440 mg antibody) was dissolved in 50 mL MES buffer (25 mM MES, 50 mM NaCl, pH 5.6). The sample was loaded on a cation exchange column (Sepharose S, 15 cm x 1.7 cm) that had been equilibrated in the same buffer. The column was then washed with the same buffer (5 column volumes). HERCEPTIN® was eluted by raising the NaCl concentration of the buffer to 200 mM. Fractions containing the antibody were pooled, diluted to 10 mg/mL, and dialyzed into a buffer containing 50 ~~mm~~ mM potassium phosphate, 50 mM NaCl, 2 mM EDTA, pH 6.5.

Paragraph [0229] has been amended as follows:

[0229] Despite its effectiveness at shrinking tumors and suppressing tumor growth, HERCEPTIN®-DM1 does not kill normal human cells, indicating a selective activity. The effect of various concentrations of HERCEPTIN®-DM1 on ~~hummman~~ human mammary epithelial cells, human hepatocytes and human small airway epithelial cells was investigated. At antibody concentrations of up to 10 μg/ml, the conjugate had no significant effect on cell number.

Paragraph [0233] has been amended as follows:

[0233] The results of a similar experiment are depicted in Figure 13. The results of three different dosing regimens of HERCEPTIN®-DM1 conjugate on tumor size are shown compared to matching dosing regimens of RITUXAN®-DM1. Tumor size was reduced and tumor growth was suppressed for at least about 50 days by treatment with 5 doses of HERCEPTIN®-DM1 at a concentration of 300 μg DM1/kg. This was true both when the

HERCEPTIN®-DM1 was administered once a week and when it ~~wsa~~ was administered twice a week. By contrast, administration of 5 doses of HERCEPTIN®-DM1 twice a week at a concentration of 100 μg DM1/kg did not shrink tumor size and suppressed tumor growth for somewhat less time. Matched RITUXAN®-DM1 treatment showed little effect on tumor size, indicating that the observed effect is specific to HERCEPTIN®-DM1. Similarly, unconjugated RITUXAN® (control MAb E25) showed no efficacy.

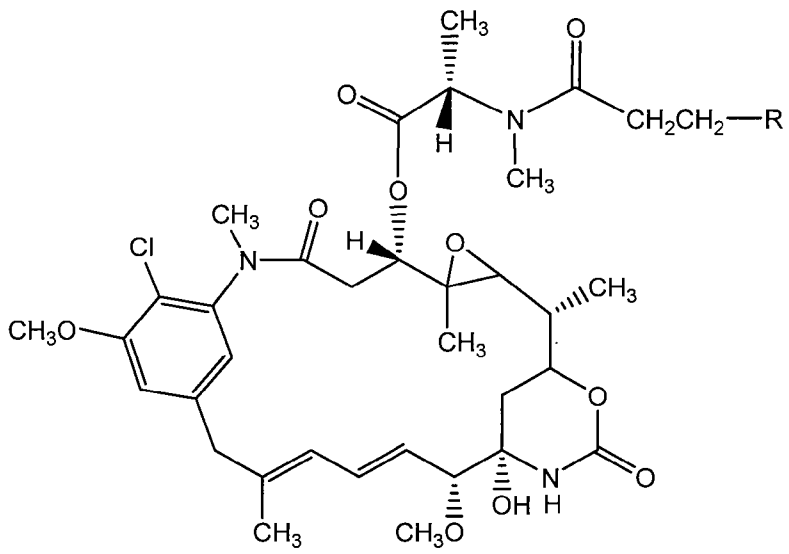
Claims:

This listing of claims will replace all prior listings and versions of claims in this application.

1-39. (canceled)

40. (previously presented) An immunoconjugate comprising an anti-ErbB2 antibody conjugated to a maytansinoid, wherein the antibody is huMAb4D5-8.

41. (previously presented) The immunoconjugate of claim 40, wherein the maytansinoid is DM1 having the structure:



and wherein the antibody is chemically linked to the maytansinoid via a disulfide or thioether group at "R" shown in the structure.

42. (previously presented) The immunoconjugate of claim 40, wherein the immunoconjugate comprises from 3 to 5 maytansinoid molecules per antibody molecule.

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