Patent Docket P1256R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Susan D. Hellman et al. (as amended) Serial No.: 09/208,649 Filed: December 10, 1998 For: TREATMENT WITH ANTI-ErbB2 ANTIBODIES	Group Art Unit: 1642 Examiner: J. Nichols (Hunt)

DECLARATION UNDER 37 CFR §1.131

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Susan D. Hellmann, M.D., M.P.H., do hereby declare and say as follows:

1. I am an inventor of the subject matter of the above-identified patent application. I am the sole inventor of method claims 1-13 and 24-27 of the above application. All work described hereinafter was performed by me or on my behalf in the United States of America.

2. Prior to December 12, 1996, I conceived of and first began to reduce to practice a method of treating a human patient with a disorder characterized by overexpression of ErbB2 receptor comprising administering a combination of an anti-ErbB2 antibody and a taxoid (in the absence of an anthracycline derivative) in an amount effective to extend the time to disease progression (TTP) in the patient.

3. Evidence of the conception and reduction to practice of the claimed invention is set forth in the exhibits attached to this declaration (with dates and irrelevant information obscured).

4. Exhibit A attached represents copies of selected slides from a presentation I gave to Genentech's Product Development Committee (PDC). The presentation was prior to December 12, 1996. At the presentation, I discussed revisions to the rhuMAb HER2 clinical plan. (rhuMAb HER2 is the recombinant humanized anti-HER2/ErbB2 antibody (HERCEPTIN®) disclosed in the Example of the above application.) One revision to the H0648 clinical trial I had conceived of, and presented at that

EXHIBIT
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time, was to treat metastatic breast cancer in human patients with a combination of an anti-ErbB2 antibody (rhuMAb HER2) and a taxoid (paclitaxel), in the absence of an anthracycline derivative. The patients to be treated in the H0648 pivotal trial were "HER2 positive", *i.e.* had a disorder characterized by overexpression of ErbB2 receptor. Copies of the minutes of this PDC presentation are attached as Exhibit B.

5. Exhibit C is a copy of the minutes from a further PDC presentation at which I co-presented prior to December 12, 1996. As noted in the Q & A section of those minutes, by that time I had conceived that the combination of the anti-ErbB2 antibody and the taxoid (paclitaxel) would extend the TTP in patients treated with this combination.

6. Thus, before December 12, 1996, I had conceived of the invention of treating a human patient with a disorder characterized by overexpression of ErbB2 receptor, comprising administering a combination of an anti-ErbB2 antibody and a taxoid (in the absence of an anthracycline derivative) in an amount effective to extend the TTP in the human patient. Further, on a date preceding December 12, 1996, reduction to practice of the invention was initiated under my direction via the enrollment of human patients in the H0648 clinical trial, with the enrolled patients being treated with the combination of rhuMAb HER2 and paclitaxel, in the absence of an anthracycline derivative. The work to establish that the therapy extended TTP was conducted continuously thereafter, up until filing on December 12, 1997 the provisional application on which the present application is based.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 8/23/00

Susan D. Hellmann, M.D., M.P.H.

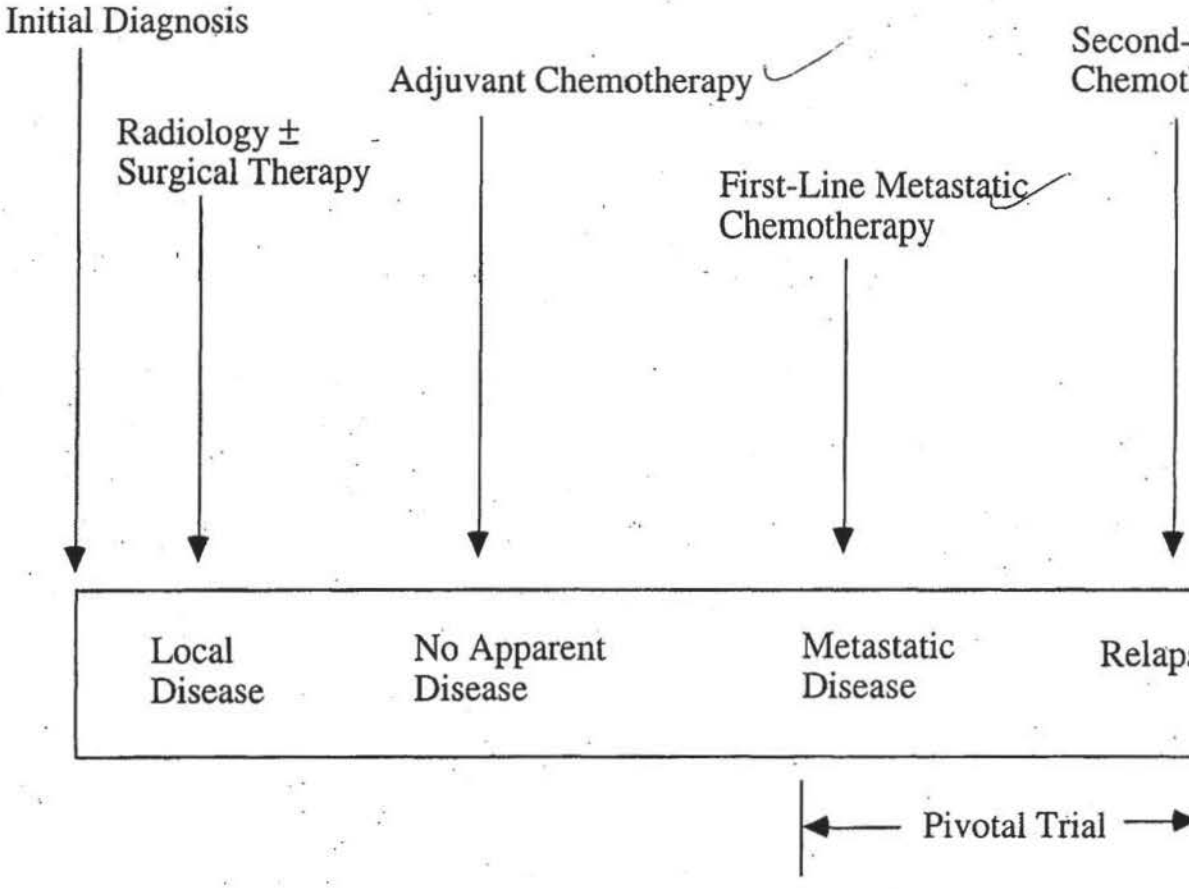
PDC

SUE HELLMANN

rhuMAb HER2 CLINICA
PLAN REVISION

EXHIBI

Therapy in Breast Cancer



HOS

rhuMAb HER2
REGISTRATIONAL PROGRA

H0648: 450 patient pivotal trial: first line metastatic (mets) therapy randomized, blin + chemotherapy

HOSI

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