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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Cases IPR2016-01693
Patent 6,407,213

DECLARATION OF JOHN RIDGWAY BRADY

Mylan v. Genentech

I, John Ridgway Brady, declare as follows:

I. Background

1. I am a research technician employed by Genentech, Inc. for the past 29 years. During that time, I have performed research in a number of areas including cell culture and cell line development, protein engineering, and bio-oncology.

2. In 1984, I obtained my Bachelors of Science degree in cell biology from the University of California, Santa Barbara. In 1987, I began working for Genentech, and I am currently a senior research associate.

3. In the late 1980s to early 1990s, I worked in the Cell Genetics Department in the laboratory of Cornelia Gorman, Ph.D., conducting experiments on plasmid construction and expression of proteins in mammalian cell lines.

4. During my tenure with Dr. Gorman, I conducted numerous experiments at the direction of Drs. Gorman and Paul Carter to express various humanized 4D5 antibodies in the adenovirus-transformed human embryonic kidney cell line 293.

5. In particular, Dr. Carter provided me with vectors containing the DNA encoding for different versions of the humanized 4D5 heavy and light chains, and directed me to produce an assortment of humanized 4D5 antibodies by using combinations of the various heavy and light chains. Per these directions, I

expressed and purified different humanized variants of the 4D5 antibody, and then provided them for assay analyses to determine binding affinity to HER2 and an ability to prevent proliferation in the SK-BR-3 cell line. I also developed stable cell lines that expressed certain humanized 4D5 antibodies. This work is included in the research paper, "Humanization of the anti-p185 antibody for human cancer therapy," published in Proc. Nat'l. Acad. Sci., Vol. 89, pp. 4285-4289, May 1992, which I co-authored.

6. The purpose of this work was to develop a humanized 4D5 antibody for use as a human therapeutic to treat cancers overexpressing p185^{HER2}. Our work led to Herceptin[®], which is used to treat certain breast and gastric cancers.

7. As described below, [REDACTED], I had expressed six humanized 4D5 antibodies with different combinations of humanized heavy and light chains and provided them for assay analysis, which showed that each of these variants had binding affinity to HER2.

II. My Laboratory Notebooks

8. My work on humanized 4D5 antibodies is documented in laboratory notebooks that I maintained. Genentech's library issued laboratory notebooks to researchers to document their experiments, and each notebook had a unique number.

9. Attached to this declaration as Exhibit 2005 is my Notebook 10840,¹ which Genentech's library issued to me on [REDACTED]. I used Notebook 10840 to detail experiments that I conducted from [REDACTED] to [REDACTED], relating to the construction of plasmids, and in particular, creating plasmids to express humanized 4D5 antibodies.

10. Attached to this declaration as Exhibit 2006 is my Notebook 11162, which was issued to me on [REDACTED]. Notebook 11162 details experiments that I conducted from [REDACTED], relating to the transfection of cell lines and assay testing.

11. As a Genentech researcher, I am expected to maintain a record of my experiments in my laboratory notebooks. Consistent with this expectation, I recorded the experiments I was doing in real time, providing the date of the experiment at the top left-hand corner of the page, followed by a brief description of the protocol and results. After an experiment was completed, I further dated and signed the page in the lower right-hand corner, and obtained the signature of a

¹ Notebooks 10840 and 11162 were issued under the name John Ridgway, which was my legal name at the time. In 1996, I changed my legal name from John Ridgway to John Ridgway Brady.

witness. As a result, the date in the upper left-hand corner of each page is the date that I performed the experiment recorded on the page.

12. I kept my laboratory notebooks in the ordinary course of my work as a research technician with Genentech. I have retained my laboratory notebooks in my possession in connection with my work at Genentech, except to allow for filming and/or scanning by Genentech's records department. Genentech regularly creates copies of completed notebooks as an additional record of each researcher's work. For example, as shown on the covers of my Notebooks 10840 and 11162, they were both originally filmed on December 23, 1991.

III. My Work on Humanized 4D5 Antibodies

13. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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