

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.
Petitioner

v.

GENENTECH, INC.
Patent Owner

U.S. Patent No. 9,249,218
Issue Date: February 2, 2016
Title: PROTEIN PURIFICATION

Inter Partes Review No. Unassigned

U.S. Patent No. 6,339,142
Issue Date: January 15, 2002
Title: PROTEIN PURIFICATION

Inter Partes Review No. Unassigned

DECLARATION OF KEITH L. CARSON

I, Keith L. Carson, declare as follows:

1. My name is Keith L. Carson. I was the founder and Managing Director of the Williamsburg BioProcessing Foundation (“WilBio”), a corporation that existed from 1994 to 2008 in Norfolk Virginia. The mission of WilBio was stated on our website:

The Williamsburg BioProcessing Foundation sponsors conferences and events related to the bioprocessing industry. Using a highly focused technical content and format developed at our previous conferences, we explore the problems faced while developing bioprocessing related products, and then turning them into viable commercial products. To do this, the Williamsburg BioProcessing Foundation brings together the most talented and experienced people in the field and facilitates the exchange of information with a stimulating but relaxed environment.

(Ex. 1040, <https://web.archive.org/web/19971008053500/http://wilbio.com/>.)

2. One of the main functions of WilBio was to host meetings and conferences throughout the year for skilled people in the field of monoclonal and recombinant antibodies to come together and present the most current ideas and findings at the time. From 1996 to 2008, I was personally involved in organizing and hosting these conferences. In that time period, at least one meeting or conference took place every year, with some years having up to twelve. To the best of my recollection, I attended each and every one of the meetings that WilBio organized.

3. One of the first annual meetings WilBio organized was titled “The Waterside Monoclonal Conference” (“Conference”), and was held at the Omni Waterside Hotel in Harborside – Norfolk, Virginia. The Conference lasted four days from April 22-25, 1996. On three of those days (April 23-25), scientists in the field presented their work related to process development and production issues for monoclonal antibodies to the other scientists in attendance. In addition to the conference presentations, exhibitors from commercial suppliers were present at the Conference.

4. The Conference was publicized in several ways. Mail and facsimile announcements were sent to individuals whom I had identified as skilled persons in the field of monoclonal antibodies and recombinant protein processing and purification. To the best of my recollection, we also advertised the Conference in a publication currently known as Genetic Engineering and Biotechnology News.

5. At least two hundred individuals attended the Conference, which included people skilled in the field of monoclonal antibodies, and recombinant protein processing and purification. My role at the Conference was Conference Chairman. As Conference Chairman, I provided an introduction to the Conference, introduced and attended each presentation, and had overall responsibility for the Conference.

6. When attendees signed in at the Conference, they were provided with a binder that contained a cover page with general information about the Conference, an agenda that included the schedule of the presentations and other events, and printed slide presentations from the Conference. These printed slide presentations were provided to WilBio by the speaker prior to the Conference. The printed slide presentations were then copied, assembled into binders with the cover page and agenda, and distributed at the meeting by my staff. In order to make it easier for attendees to follow presentations with their copy of the slides, two or three presentation slides were usually printed on each page.

7. Once attendees received their binders, they were free to do with it as they wished. We did not restrict use of materials distributed at the meeting. However, if speakers wished to redact certain portions of their presentation from their printed slide presentation, we allowed them to do so. It was WilBio's view at the time that the Conference presentations and printed slides were public, therefore we allowed speakers to control what was distributed to the public in printed form.

8. I have reviewed Exhibit 1005. The first page of Exhibit 1005 is the cover page from the exhibit binder for the Conference. (Ex, 1005 at 1.) The cover page includes the name, date, location, and topic of the Conference, which is consistent with the best of my recollection. I also note that the cover page states that this was the first annual Waterside Conference presented by the Williamsburg

BioProcessing Foundation, which is also consistent with the best of my recollection. I recognize and acknowledge that the fonts and images on the cover page are consistent with what we used at the time.

9. The second page of Exhibit 5 is a copy of the agenda that we distributed with the Conference binder. (Ex, 1005 at 2.) The agenda shows the presentations for the first and second day of the Conference. I recognize and acknowledge that the fonts and formatting of this page would have been consistent with what we used at the time.

10. Pages three through seven of Exhibit 1005 is a printed slide presentation in a format that is consistent with the format that WilBio used when distributing printed slides at Foundation conferences. (Ex, 1005 at 3-7.) To the best of my recollection, the formatting of the slides as two to a page is consistent with how the printed slide presentations were prepared and distributed at the Conference. The slide presentation on page 3 of Exhibit 1005 is entitled “Chromatographic Techniques for the Characterization of Human Monoclonal Antibodies: rhuMAb HER2.” The speaker named on page three of Exhibit 1005 is Reed Harris. The speaker and title on page three matches the speaker and title listed on the Conference agenda on page 2 of Exhibit 1005. (Ex. 1005 at 2-3.) The fact that the speaker and title of the printed slide presentation and the agenda match

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