Reexam

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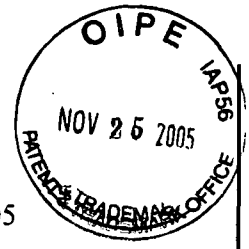

Control No.:	**90/007,542**	Group Art Unit:	3991
Confirmation No.:	7585	Examiner:	B. Celsa
Filed:	13 May 2005		
Patent Owner:	Genentech, Inc. and City of Hope		
For:	Reexamination of U.S. Patent No. 6,331,415		

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RESPONSE UNDER 37 C.F.R. § 1.550(b)

Sir:

This communication is responsive to the Patent Office's communication mailed September 13, 2005. Owners note that on October 26, 2005, they filed a petition for extension of time to respond to the Patent Office's September 13, 2005 communication. That petition was granted by James Dwyer, the Director for the Central Reexamination Unit, on November 7, 2005, extending Owner's time to respond to the Patent Office's communication through November 27, 2005. The owners of U.S. Patent No. 6,331,415 respectfully request reconsideration of the rejection of the claims in view of the following remarks.

Remarks begin on Page 4.

Table of Contents

I. Overview of the Response

In the September 13, 2005 Office Action, the Office rejected the independent claims and certain dependent claims of U.S. Patent No. 6,331,415 (the '415 patent) for obviousness-type double patenting solely in view of certain claims of U.S. Patent No. 4,816,567 (the '567 patent). The Office also has rejected the remaining dependent claims of the '415 patent for obviousness-type double patenting based on certain claims of the '567 patent taken in view of several printed publications and patents.

The '415 patent claims are directed to production of immunoglobulin molecules or immunologically functional fragments comprising at least the variable domains of the heavy and light immunoglobulin chains. These claims require the production of both heavy and light immunoglobulin chains in a single host cell. The '567 patent claims, by contrast, do not require production of an immunoglobulin molecule or an immunologically functional fragment. They also do not require that both the heavy and the light chains be produced in one host cell. Instead, they recite, and thus require only that a single chimeric immunoglobulin light or heavy chain be produced, and that the end result of the process be a heavy or light chimeric immunoglobulin chain polypeptide.

Each of the rejections is premised on an incorrect characterization of the claims of the two patents, and on numerous factual and legal errors. In summary:

- The Examiner improperly construes the claims of the '415 and '567 patents. Specifically, the Examiner incorrectly portrays claims of the '567 patent as defining "species" included within the scope of what he believes are "genus" claims in the '415 patent, which, under his logic, would cause the '567 patent claims to anticipate the '415 patent claims. The Examiner's errs by comparing only one feature shared by the claims of the two patents (i.e., whether the immunoglobulin chains are "chimeric" or not), instead of comparing what each claim, considered as a whole, defines. When the claims are construed properly, it is apparent that the inventions claimed in the '567 patent and the inventions claimed in the '415 patent are not related as species and genus.

- The Examiner improperly focuses on the fact that claims of the '567 patent "read on" and thus "dominate" subject matter also claimed by the '415 patent. This is legally irrelevant to the question of obviousness-type double patenting. Instead, an obviousness-type double patenting analysis must compare what the claims of the second patent require relative to what claims of the first patent require. The claims of the '567 patent and the claims of the '415 patent recite, and therefore require, different elements or features.

- Each of the rejections of the remaining dependent claims of the '415 patent is grounded on the Office's incorrect finding that the underlying independent claim is anticipated by the '567 patent. The Examiner engages in an overly simplistic exercise of locating in the prior art references the elements required by the '415 dependent claims that are missing from the '567 patent claims. The Examiner's approach mischaracterizes the teachings and suggestions of the cited references, and what those references would have suggested to a person of skill in the art in early April of 1983. Read properly, none of the cited references would have rendered the dependent claims of the '415 patent obvious to a person of skill in the art in early April of 1983.

- The rejections of all of the '415 patent claims for obviousness-type double patenting contradict numerous past findings by the Board of Patent Appeals and Interferences (the "Board") and different Examiners that claims to production of immunoglobulin molecules or immunologically functional fragments requiring production of heavy and light chains in a single host cell are separately patentable from claims that do not require production of both heavy and light chains in a single host cell.

The rejections of the claims of the '415 patent thus are plainly improper and should be withdrawn.

During the interview on October 25, 2005, the Examiners invited Owners to provide their views on two prior art references, namely, U.S. Patent No. 4,399, 216 to Axel et al ("Axel") and Rice et al., Proc. Natl. Acad. Sci. USA 79:7862-7865, December 1982 ("Rice").

Owners note that the Office has not rejected the independent claims of the '415 patent based on the '567 patent claims, taken in view of Axel, Rice, or any other prior art. Similarly, neither the Third Party Requestor nor the Office in its Order for Reexamination has suggested that the claims of the '567 patent, taken in view of Axel, Rice, or any other prior art, would have rendered the independent claims of the '415 patent obvious. Rejecting the independent claims of the '415 patent as being obvious from the '567 patent claims taken in view of Axel or Rice would contradict repeated findings by the Office that the independent claims of the '415 patent are not obvious over the '567 claims. Doing so would present an entirely new ground of rejection not suggested in the Office Action of September 13, 2005, the Order establishing this reexamination, or even the Third Party Request.

Nonetheless, Owners provide comments on Axel and Rice in response to the Examiner's invitation at the interview to do so. As explained below, neither Axel nor Rice would have suggested to a person of skill in the art, in early April of 1983, that the inventions defined by the '415 patent claims are obvious variants of the '567 claims. Simply put, neither

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