



Le-Exam

Patent Attorney's Docket No. 22338-10230

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Control Nos.:

90/007,542 90/007,859 Group Art Unit:

3991

Confirmation Nos.:

7585 ('542) 6447 ('859) Examiner:

B.M. Celsa

Filed:

13 May 2005

('542)

23 December 2005

('859)

Patent Owner:

Genentech, Inc. and

City of Hope

For:

Merged Reexaminations of U.S. Patent No. 6,331,415 (Cabilly et al.)

## RESPONSE UNDER 37 C.F.R. § 1.550(b)

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Sir:

This communication responds to the non-final Office action mailed on August 16, 2006, setting an original due date of October 16, 2006. Owners timely requested an extension of time to respond. In a Decision mailed on October 17, 2006, the Office granted an extension of two weeks, to Monday, October 30, 2006, for Owners to file a response. As this reply is filed within the extended period for response, it is timely filed.

Patent Owners (Owners) respectfully request reconsideration of the claims in view of the following remarks.

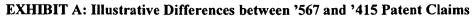


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## I. Preliminary Matters

### A. Information Disclosure Statement

Owners thank the Examiner for his indication that materials previously submitted to the Office have been fully considered. Owners request consideration of the additional materials provided in the accompanying information disclosure statement (PTO Form 1449).

### B. Interview Summary

Owners thank Examiners Celsa, Jones and Padmashri for the courtesy of an interview held on September 27, 2006. At the interview, as summarized in the interview summary form, the representatives of Owners and the Examiners discussed a number of issues.

<u>First</u>, the Owners explained that the prosecution history of U.S. Patent No. 4,816,567 (the '567 patent) demonstrates that the term "or" as used in the claims has its conventional meaning (i.e., as referring to one of the enumerated alternatives). Owners explained that the actions of the PTO and of the Owners (then applicants) before and after the amendment which introduced claims 53, 57 and 63 plainly shows that neither the Owners nor the Office viewed "or" as meaning the "logical or" (i.e., meaning "and/or"). Owners indicated that they would provide the Office a summary of the relevant prosecution history of the '567 patent in this response.

Owners also sought a confirmation that "Claim Interpretation 1" and rejections premised on it were contingent on the Examiner's determination that the term "or" was being read as the "logical or" (i.e., as if the claims had been amended by replacing "or" with the words "and/or"). The Examiners concurred that this was the premise of the rejections under Claim Interpretation 1; namely, that the rejection is premised on the belief that the word "or" actually was intended to mean "and/or". The Examiners indicated that if the prosecution history and the specification showed that the term "or" was used with its ordinary meaning (i.e., as referring to alternatives), the rejections premised on Claim Interpretation 1 would be withdrawn.

Owners also discussed the relationship between the claims of the '415 and '567 patents. In particular, Owners referred to the explanation in their Response of November 25, 2005, which explained why the claims of the '415 patent cannot be interpreted as defining a "genus" of methods that includes "species" methods defined in the '567 patent. The Examiners confirmed



that rejections in the First Office Action based on such a finding were withdrawn in favor of the new rejections under the two claim interpretation theories set forth in the Office action mailed August 16, 2006 ("Second Office Action.")

Second, Owners discussed the obviousness-type double patenting rejections based on "Claim Interpretation 2." Owners emphasized the importance of using the proper perspective when considering the teachings of the various references cited in the Office Action; namely, what the references would have taught or suggested to a person of ordinary skill in the art in early April of 1983. Owners explained that each of the experts who had previously submitted declarations under 37 C.F.R. § 1.132 was qualified to explain this perspective based on their respective experiences in the relevant time frame. Owners further addressed the teachings of the various cited prior art references, and explained why the '567 patent claims, considered in view of any or all of these references, would not have rendered the claims of the '415 patent obvious.

The Examiners agreed that the obviousness-type double patenting questions are to be evaluated by considering the question of non-obviousness of the '415 claims in view of the '567 patent claims, taken in view of other prior art. The Examiners also agreed that the question of "obviousness" must be considered from the perspective of a person of ordinary skill in the art in early April of 1983, including what the references would have taught such a person at that time.

Owners requested that the Examiners review the prosecution histories of the '415 and '567 patents. Owners noted, for example, that the Office had previously considered most of the references now being employed in the obviousness-type double patenting rejections. The Examiners indicated they would consider the prosecution histories of the '415 and '567 patents incidental to the consideration of Owners' response.

Third, Owners discussed the complex physical structure of immunoglobulins and the limited understanding that persons of ordinary skill in the art had in early April of 1983 regarding the processes of immunoglobulin gene expression and subsequent production and assembly of immunoglobulin proteins. The Owners also discussed the experiences of those working in the art in the relevant time frame concerning production of monomeric eukaryotic proteins having molecular weights much lower than those of tetrameric immunoglobulins. The



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