



Re-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 <i>et al.</i> )		

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

Mail Stop **Ex Parte Reexam**  
COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450

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.

**REMARKS**

**I. PRELIMINARY MATTERS ..... 4**

A. INFORMATION DISCLOSURE STATEMENT ..... 4

B. INTERVIEW SUMMARY ..... 4

C. OBSERVATION ON THE OFFICE’S DETERMINATION CONCERNING CUMULATIVE PRIOR ART ..... 6

D. PAST PTO ACTIONS SUPPORT FINDING THE ’415 CLAIMS SEPARATELY PATENTABLE OVER THE 567 CLAIMS ..... 6

**II. RESPONSE TO REJECTIONS ..... 8**

A. SUMMARY OF THE REJECTIONS ..... 8

B. THE REJECTION OF CLAIMS 1-4, 11, 13, 15-18, 21, 23-25 AND 33 OF THE ’415 PATENT BASED ON “CLAIM INTERPRETATION 1” HAS NO BASIS IN LAW OR FROM THE FILE WRAPPER OF THE ’567 PATENT ..... 9

1. *The Owners Did Not Expressly Redefine the Meaning of the Claim Term “or” as Used in the ’567 Claims* ..... 10

2. *The Prosecution History of the ’567 Patent Shows that “or” as Used in the ’567 Patent Claims Has Its Ordinary Meaning* ..... 11

3. *The Specification of the ’567 Patent Does Not Expressly or Implicitly “Redefine” the Claim Term “or”* ..... 14

4. *The Office Does Not Accurately Identify the Differences Between the ’415 and ’567 Claims* ..... 15

5. *The ’567 Claims Do Not “Read On” and Thus Render Unpatentable the ’415 Patent Claims for Reasons of Obviousness-Type Double Patenting* ..... 17

6. *The Office May Not Use the Disclosure of the ’415 and ’567 Patents to Supply Missing Elements of the ’415 Claims Relative to the ’567 Claims* ..... 21

(a) *Settled Law Holds that the Office May Not Use Owner’s Own Disclosure in an Obviousness-Type Double Patenting Rejection to the Missing Elements of the Later Claim* ..... 21

(b) *The Antigen Binding Language in the ’567 Patent Claims Refers to the Structure of the Variable Domain of the Claimed Immunoglobulin Heavy or Light Chains, and Does Not Require Assembly of the Chains into a Functional Immunoglobulin Molecule or Fragment* ..... 22

7. *Conclusion: The Rejection of the ’415 Claims Based on Claim Interpretation 1 of the ’567 Claims is Factually and Legally Improper and Should Be Withdrawn* ..... 26

C. THE REJECTION OF CLAIMS 1-4, 11, 13, 15-18, 21, 23-25 AND 33 OF THE ’415 PATENT BASED ON CLAIMS 1-7 OF THE ’567 PATENT, TAKEN IN VIEW OF AXEL, RICE OR KAPLAN, FURTHER IN VIEW OF DALLAS, AND FURTHER IN VIEW OF DEACON, VALLE 1981 OR OCHI IS IMPROPER... 27

1. *Obviousness-Type Double Patenting is to be Assessed in a Manner Analogous to Obviousness Assessments Under 35 U.S.C. §103 Using a Graham v. John Deere Analysis* ..... 27

2. *The ’415 Claims Would Not Have Been Considered Obvious to a Person of Ordinary Skill in the Art in Early April of 1983 Based on the ’567 Claims, Considered Alone or in View of the Various Combinations of References Employed by the Office, When a Proper Graham v. John Deere Analysis is Employed* ..... 29

a.	Differences Between The Claims of the '567 Patent and the Claims of the '415 Patent.....	29
b.	The Correct Perspective for Evaluating Prior Art is a Person of Ordinary Skill in the Art as of Early April of 1983 .....	30
c.	The Expectations of a Person of Ordinary Skill in the Art in Early April of 1983 Would Have Been Shaped by Experiences in Producing Polypeptides Using Recombinant DNA Technology, the Nature of the Protein Being Produced, and Relevant Insights from Natural Processes in B-Cells .....	31
d.	The Office May Not Disregard Pertinent Expert Testimony Correcting Erroneous Interpretations of the Teachings of the Prior Art.....	36
e.	The Office's Rejection of the '415 Claims Based on the '567 Claims Taken in View of the Various Cited References Rests on a Flawed and Incorrect Analysis of the Claims and the Teachings of the Cited References.....	38
(i)	The Axel Patent Does Not Motivate One to Produce Heavy and Light Chains in a Single Transformed Host Cell .....	41
(ii)	Because Rice Describes Expression of One Exogenous Gene in One Host Cell, It Would Not Have Motivated a Person of Ordinary Skill in the Art to Modify the '567 Claims.....	46
(iii)	The Hypothetical Kaplan Disclosure Does Not Suggest Production of Multiple Immunoglobulin Chains in One Transformed Host Cell.....	53
f.	Dallas Would Not Have Provided Any Additional Motivation to a Person of Ordinary Skill in the Art in April of 1983 to Modify the '567 Claims in View of Axel, Rice or Kaplan.....	54
g.	Deacon and Valle 1981 Do Not Remedy the Deficiencies of the Office's Rejection Based on the '567 Patent, Taken in View of Axel, Rice or Kaplan, Taken Further in View of Dallas.....	56
h.	Ochi Does Not Remedy the Deficiencies of the Office's Rejection Based on the '567 Patent, Taken in View of Axel, Rice or Kaplan, Taken Further in View of Dallas .....	62
D.	THE DEPENDENT CLAIMS OF THE '415 PATENT ARE NOT OBVIOUS.....	64
1.	<i>The Rationale for the Rejections of the Dependent Claims is Fundamentally Improper</i> .....	64
2.	<i>The Cited Subsidiary References Provide No Evidence or Guidance That Makes the Dependent Claims Obvious</i> .....	65
a.	Claim 5.....	65
b.	Claims 6-8, 19, 20, and 26 .....	66
c.	Claims 9 and 29.....	67
d.	Claims 10 and 27-32 .....	68
e.	Claim 12.....	68
f.	Claim 14.....	69
g.	Claim 22.....	69
h.	Claims 34-36.....	69

**III. CONCLUSION** ..... 70

**EXHIBIT A: Illustrative Differences between '567 and '415 Patent Claims**

**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.

First, 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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.