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B.M. Celsa

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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.

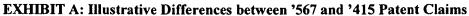


## **REMARKS**

I.	PRELIMINARY MATTERS4					
	A.	Information Disclosure Statement	4			
	В.	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.	I. RESPONSE TO REJECTIONS					
	A.	SUMMARY OF THE REJECTIONS	8			
	В.	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				
		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				
		(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	-			
		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			



b. The Correct Perspective for Evaluating Prior Art is a Person of Ordinary Skill in the Art as of Early April of 1983		;	a. Differences Between The Claims of the '567 Patent and the Claims of the '415 Patent	29
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		1		30
Erroneous Interpretations of the Teachings of the Prior Art		•	Would Have Been Shaped by Experiences in Producing Polypeptides Using Recombinant DNA Technology, the Nature of the Protein Being Produced, and	31
View of the Various Cited References Rests on a Flawed and Incorrect Analysis of the Claims and the Teachings of the Cited References		•		36
in a Single Transformed Host Cell		•	View of the Various Cited References Rests on a Flawed and Incorrect Analysis	38
Cell, It Would Not Have Motivated a Person of Ordinary Skill in the Art to Modify the '567 Claims				41
Multiple Immunoglobulin Chains in One Transformed Host Cell			Cell, It Would Not Have Motivated a Person of Ordinary Skill in the Art to	46
Ordinary Skill in the Art in April of 1983 to Modify the '567 Claims in View of Axel, Rice or Kaplan				53
Rejection Based on the '567 Patent, Taken in View of Axel, Rice or Kaplan, Taken Further in View of Dallas		i	Ordinary Skill in the Art in April of 1983 to Modify the '567 Claims in View of	54
'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. The Rationale for the Rejections of the Dependent Claims is Fundamentally Improper       64         2. The Cited Subsidiary References Provide No Evidence or Guidance That Makes the Dependent Claims Obvious       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		:	Rejection Based on the '567 Patent, Taken in View of Axel, Rice or Kaplan,	56
D. THE DEPENDENT CLAIMS OF THE '415 PATENT ARE NOT OBVIOUS       64         1. The Rationale for the Rejections of the Dependent Claims is Fundamentally Improper       64         2. The Cited Subsidiary References Provide No Evidence or Guidance That Makes the Dependent Claims Obvious       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		1	'567 Patent, Taken in View of Axel, Rice or Kaplan, Taken Further in View of	62
1. The Rationale for the Rejections of the Dependent Claims is Fundamentally Improper       64         2. The Cited Subsidiary References Provide No Evidence or Guidance That Makes the Dependent Claims Obvious       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	D.	Тне		
2. The Cited Subsidiary References Provide No Evidence or Guidance That Makes the Dependent Claims Obvious       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				
Dependent Claims Obvious       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				
b. Claims 6-8, 19, 20, and 26				
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		;	a. Claim 5	65
d. Claims 10 and 27-32       68         e. Claim 12       68         f. Claim 14       69         g. Claim 22       69         h. Claims 34-36       69		1	b. Claims 6-8, 19, 20, and 26	66
e. Claim 12		(	c. Claims 9 and 29	67
f. Claim 14		•	d. Claims 10 and 27-32	68
g. Claim 22		(	e. Claim 12	68
h. Claims 34-3669		1	f. Claim 14	69
		;		
III. CONCLUSION70		1	h. Claims 34-36	69
	III. CO	NCI	LUSION	70





## 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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