3991

B.M. Celsa

Group Art Unit:

Examiner:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Control Nos.: 90/007,542

90/007,859

Confirmation Nos.: 7585 ('542)

6447 ('859)

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 final Office action mailed February 16, 2007, setting a two-month period for response. Owners timely requested an extension of time to respond under 37 C.F.R. § 1.550(c), and in a Decision dated March 21, 2007, the Office granted an extension to May 21, 2007. As this reply is filed within the extended period for response, it is timely.

We believe that no fee is required for this response. Should any fee be required for entry or consideration of this paper, the Director is requested to charge the appropriate amount to our Deposit Account No. 18-1260.

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



REMARKS

l.	PRELIMINARY MATTERS								
	A.	NTERVIEW SUMMARY							
	B.	Decision on Petition							
	C.	NFORMATION DISCLOSURE STATEMENTS							
	D.	WITHDRAWN REJECTIONS							
	E.	STATUS OF LITIGATION INVOLVING THE '415 PATENT							
II.	RVIEW OF OWNERS' RESPONSE TO NEW REJECTIONS IN FEBRUARY 2007 OFFICE								
111.	. THE REJECTION OF CLAIMS 1-7, 9-10, 14-18, 21, AND 23-36 AS ANTICIPATED BY THE MOORE '545 PATENT IS IMPROPER AND SHOULD BE WITHDRAWN7								
	A. LEGAL STANDARDS GOVERNING THE EFFECTIVE DATE FOR § 102(E) PRIOR ART OF THE MO-								
	B.	THE WRITTEN DESCRIPTION OF THE '414 APPLICATION – THE ONLY APPLICATION FILED PRIOR TO THE EFFECTIVE DATE OF THE '415 PATENT TO WHICH THE MOORE '545 PATENT CLAIMS BENEFIT UNDER 35 J.S.C. § 120 – DOES NOT DESCRIBE CO-EXPRESSION OF HEAVY AND LIGHT CHAIN POLYPEPTIDES IN DNE HOST CELL							
	C.	THE OFFICE IS INCORRECTLY INTERPRETING THE CLAIMS OF THE '545 PATENT AS REQUIRING CO- EXPRESSION OF HEAVY AND LIGHT CHAINS IN ONE HOST CELL							
	D.	ANOTHER EXPERT INDEPENDENTLY CONCLUDED IN 1996 THAT THE SPECIFICATION OF THE '545 PATENT DOES NOT DESCRIBE CO-EXPRESSION							
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IV.		REJECTION OF CLAIMS BASED ON OBVIOUSNESS PURSUANT TO 35 U.S.C. § 103(A) IS ROPER2							
v.	THE REJECTIONS BASED ON OBVIOUSNESS-TYPE DOUBLE PATENTING ARE IMPROPER 2:								
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	B.	GENERAL ISSUES REGARDING THE OFFICE'S MULTIPLE BASES FOR OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS							
		. Overview of Legal Standards of Obviousness-Type Double Patenting2							
		2. The Correct Perspective for Evaluating Prior Art is a Person of Ordinary Skill In the Art as of Early April of 1983, and the Declarations Submitted by Owners Provide This Perspective							
		3. The Office Ignores Distinctions Between the '567 and '415 Patent Claims Due to an Improper and Incorrect Reading of the '567 Claims and Specification2							
		1. The Office Improperly Relies on the Disclosures of the '567 Patent and the Utility of Its Claims to Find a Suggestion or Motivation for Co-Expression Required by the '415 Patent Claims							
		a. The Disclosure and Teachings of the '567 Patent May Not Be Used to Hold the '415 Claims Unpatentable for Obviousness-Type Double Patenting							
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C.	THE REJECTION OF CLAIMS 1-7, 9-11, AND 13-36 FOR OBVIOUSNESS-TYPE DOUBLE PATENTING (AT SECTIONS 4-6 OF THE OFFICE ACTION) MUST BE WITHDRAWN BECAUSE IT IS BASED PRIMARILY ON THE OFFICE'S MISUSE AND INCORRECT ANALYSIS OF THE MOORE '545 PATENT							
	1.	The Rejection of Claims 1-7, 9-11, 13-18, 21, and 23-36 Is Improper, As It Can Not Be Supported by the '545 Patent						
	2.	••						
D.	D. THE REJECTION OF CLAIMS 1-36 BASED ON THE '567 CLAIMS, IN VIEW OF AXEL, RICE, OR KAPLAN, VIEW OF DALLAS, FURTHER IN VIEW OF DEACON, 1981 VALLE, OR OCHI, AND OPTIONALLY IN VIEW THE '545 PATENT IS IMPROPER							
	1.	Axel, Rice, and Kaplan, Considered Alone, Together, or In Combination with Dallas, Would Not Provide a Motivation or Suggestion to Modify the '567 Claims to Transform a Host Cell With, and to Express In That Cell, Exogenous DNA Sequences Encoding Both Light and Heavy Immunoglobulin Chains						
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	<i>3</i> .	Claims 9 and 29						



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Exhibit List to Response Filed Under 37 C.F.R. § 1.550(b)

- -Exhibit A: MedImmune, Inc. v. Genentech, Inc., No. 04-1300/04-1384 (Fed. Cir. Mar. 7, 2007) Order Remanding Case; MedImmune, Inc. v. Genentech, Inc., CV 03-2567 (C.D. Cal. Apr. 12, 2007) Order Setting the Status Conference
- -Exhibit B: U.S. Application No. 06/358,414
- -Exhibit C: Second Supplemental Examiner's Answer mailed January 11, 1996 for U.S. Application No. 08/165,530
- -Exhibit D: Declaration of Geoffrey T. Yarranton filed during prosecution of U.S. Application No. 08/165,530
- -Exhibit E: Office Action mailed May 30, 1997 for U.S. Application No. 08/165,530



I. Preliminary Matters

A. Interview Summary

Representatives of Owners participated in an interview with Examiners Celsa, Jones, and Ponnaluri on March 15, 2007. The interview summary form accurately reflects the subject of the discussions between Owners' representative and the representatives of the Office.

B. Decision on Petition

Owners filed a petition under 37 C.F.R. §§ 1.181 and 1.182 on March 6, 2007, requesting that the Office declare a new reexamination or, in the alternative, withdraw the finality of the outstanding Office Action. In a decision mailed on March 21, 2007, the Office dismissed the petition on procedural grounds. The decision indicated the Owners could file a renewed petition under § 1.182 for a "Request for Continued Reexamination," in accord with the interim policies set forth in the notice regarding changes to reexamination practice published at 1292 Off. Gaz. Pat. & Trademark Office 20 (March 1, 2005). Concurrently with this response, Owners are filing a timely renewed petition under § 1.182, as suggested in the March 21, 2007 decision.

C. Information Disclosure Statements

Owners acknowledge the indication that the materials provided in the information disclosure statements filed on December 14, 2007 and January 16, 2007 have been fully considered. A further information disclosure statement accompanies this response.

Owners also note that the Office has determined that the disclosure in U.S. Patent No. 4,642,334 ("the '334 patent") is cumulative to that of U.S. Patent No. 5,840,545 ("the '545 patent"). See February Office Action, pp. 3-4. The '334 patent was considered during the examination of the application that matured into the patent under reexamination. Thus, the Office fully considered the substance of the '334 and '545 patent disclosures in connection with the original examination of the claims of the '415 patent.

D. Withdrawn Rejections

Owners acknowledge and appreciate the decision of the Office to withdraw all previous grounds of rejection imposed on claims 1 to 36. In particular, the Office no longer is maintaining any rejection based on a determination that the term "or" as it appears in one or



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