Reexam

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 23 December 2005	('542) ('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 timely responds to the final Office action mailed on February 25, 2008. By petition granted on March 19, 2008, the original response date of April 25, 2008 was extended until June 6, 2008.

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

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REMARKS

I. Preliminary Matters

A. Information Disclosure Statement

Owners thank the Office for the indication that all materials previously submitted to the Office have been fully considered. Owners respectfully request consideration of materials provided in the accompanying supplemental information disclosure statement.

B. Interview Summary

Owners thank Examiners Celsa, Jones and Padmashri for the courtesy of an interview held on April 2, 2008. Owners' summary of the interview is provided in Attachment A to this response, in compliance with 37 C.F.R. § 1.560(b).

C. Status of Litigation Involving the '415 Patent

Owners have previously indicated that U.S. Patent No. 6,331,415 ("the '415 patent") has been the subject of litigation in the Central District of California. Owners now report that the parties to that litigation have jointly requested dismissal of the action with prejudice pursuant to a settlement agreement between the parties, and that the dismissal was ordered on June 4, 2008. Owners also report that on May 30, 2008, an action was filed in the Central District of California by Centocor seeking, inter alia, a declaratory judgment that the '415 patent is invalid and not enforceable. A copy of the complaint is provided in the accompanying information disclosure statement.

D. Additional Evidence Provided with this Response

Owners submit and request favorable consideration of this response and the accompanying declarations under 37 C.F.R. § 1.132 of Dr. Steven McKnight and Dr. Finton Walton. Owners submit the declaration of Dr. McKnight in response to new scientific findings of the Office in the final Office action ("Final Action"). Owners submit the declaration of Dr. Walton in response to the Office's observations about the legal significance of licensing of Axel (U.S. Patent No. 4,399,216), and in support of the non-obviousness of the '415 patent claims.

Owners submit that "good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented" exist pursuant to 37 C.F.R. § 1.116. Specifically, the

Office makes new factual determinations, and advances new or changed theories to support rejections in the Final Action, particularly at pages 21-46. Examples include: use of Moore (U.S. Patent No. 5,840,545) to support findings of obviousness of co-expression despite a significantly changed interpretation of the Moore prior art disclosure (Final Action at 5, 15-16); reliance on Axel as teaching production of "functional proteins" (Final Action at 30); reliance on Ochi (Ochi et al., Nature 302: 340-42 (1983)) and Oi (Oi et al., Proc. Nat'l. Acad. Sci. (USA) 80: 825-29 (1983)) as providing additional motivation to co-transform host cells (Final Action at 38); use of Dallas (PCT Publication No. WO 82/03088) to modify the teachings in Moore (Final Action at 40); and references to licensing of Axel (Final Action at 46). Owners could not have reasonably predicted that the Office would make these new or changed findings, or use them to support the rejections set forth in the Final Action. The declarations of Drs. McKnight and Walton respond to these new issues. Owners submit that presentation of the present declaration evidence is thus appropriate under 37 C.F.R. § 1.116.

II. Response to Rejections

A. Withdrawn Rejections

Owners appreciate withdrawal of rejections under 35 U.S.C. §§ 102 and 103, and for double patenting, based on Moore, alone or in combination with the '567 patent (U.S. Patent No. 4,816,567), Axel and Accolla (Accolla et al., Proc. Nat'l. Acad. Sci. (USA) 77(1): 563-66 (1980)). The Office indicates that Moore is entitled to a § 102(e) effective date for "*single host expression* of variable light and heavy chain for producing single-chain antibody" only as of "the June 5, 1995 date since the original 06/358,414 specification and claims 1-25 only disclose the separate expression of the heavy and light chain antibody fragment in different host cells . . . ." Final Action at 5 (emphasis original). The Office also indicates that Moore does not have support for "single host expression of variable light and heavy chains . . ." prior to June 5, 1995.[1] Id. at 6.

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[1] At page 16 of the Final Action, the Office states that Moore "discloses a method of making 'an immunologically functional fragment' comprising independently expressing in a host cell variable and heavy light chain domains . . . ." This appears to be an inadvertent error in view of the Office's conclusions noted above.

B. Summary of the Rejections

The Office rejects claims 1-36 for obviousness-type double patenting based on the '567 patent, in view of Axel, Rice (Rice et al., Proc. Nat'l. Acad. Sci. (USA) 79: 7862 (1982)) and Kaplan (European Patent No. 0044722), further in view of Dallas, and further in view of Deacon (Deacon et al., Biochem. Soc. Trans. 4: 818-20 (1976)), Valle 1981 (Valle et al., Nature 291: 338-40 (1981)), or Ochi, alone or further in view of Moore. Dependent claims 10 and 27-32 are rejected when these references are further considered with Builder (U.S. Patent No. 4,511,502), and dependent claim 22 is further rejected in view of Accolla. The Office sets forth the basis of its rejections at pages 10 to 20 of the Final Action. At pages 21 to 46, the Office addresses issues raised by Owners in their previous responses.

The Office bases the final rejection on two conclusions, namely: (i) "One of ordinary skill in the art would have been motivated to express, in a single host, light and heavy immunoglobulin chains (using one or two vectors) when viewing the reference Cabilly 1 ['567] patented invention in light of the prior art" (Final Action at 12); and (ii) "The prior art provides further motivation to make active antibody with a reasonable expectation of success" (Final Action at 14). Owners respectfully request withdrawal of the rejections because the Office's conclusions are inconsistent with the collective teachings and suggestions of the cited references, and with the beliefs and expectations of the person of ordinary skill in the art in early April 1983.

Owners respectfully traverse the rejections set forth in the Final Action, and request withdrawal of rejections of claims 1-36.

C. Brief Summary of Why the '415 Claims Are Not Obvious From the '567 Claims and in View of the Prior Art

Owners provide with this response a second declaration by Dr. Steven McKnight responding to issues raised in the Final Action. Dr. McKnight accurately presents the views of a person of ordinary skill in the art in April 1983, based on his relevant experience and training from that time. He explains that, unlike the '567 claims, the '415 patent claims require three separate steps: (i) a host cell must be transformed with immunoglobulin heavy chain and light chain DNA sequences; (ii) the DNA sequences must be independently expressed (transcribed and translated) by the host cell to produce polypeptides; and (iii) the polypeptides must be

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