

EXHIBIT 14



APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,016	07/06/2005	Amar Lulla	PAC/20632 US (4137-04700)	4912
30652	7590	02/16/2011	EXAMINER	
CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024			NIELSEN, THOR B	
			ART UNIT	PAPER NUMBER
			1616	
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			02/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

10/518,016

LULLA ET AL.

Examiner**Art Unit**

THOR B. NIELSEN

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 September 2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,6-22,26,27,30,35-38,44,45 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,6-22,26,27,30,35-38,44,45 and 53-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/24/2010; 10/19/2010.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Status of Examination

In brief, the claims were initially reviewed and a non-Final rejection mailed on January 23, 2009. In that action, the claim set was restricted and claims 23, 24, and 46-52 were withdrawn from consideration. Then-pending claims 1-4, 7, 9-10, 12-21, 30-32, and 44-45 were rejected as anticipated by EP 0780127 (Cramer). In that same action, then-pending claims 5 and 35-38 were rejected as obvious over Cramer; claims 22 and 26-27 were rejected as obvious over Cramer in view of US 6,294,153 (Modi); claims 1-3 and 6 were rejected as obvious over US 6,391,340 (Malmqvist-Granlund); and claims 28-29 were rejected as obvious over Cramer in view of US 6,017,963 (Alfonso). No claims were allowed.

In response, Applicant amended the claims, submitted a Declaration under 37 CFR 1.132, and argued for patentability. Of note, the Applicant incorporated the limitations of claim 5, which had not been rejected as anticipated, into claim 1.

A Final Office Action was mailed on April 28, 2010, rejecting then-pending claims 1-2, 4, 7-21, 30, 35-38, 44-45, and 53-56 as obvious over Cramer. In addition, claims 22 and 26-27 were rejected as obvious over Cramer in view of Modi; claims 1-2 and 6 were rejected as obvious over Cramer in view of US 6416743 (Fassberg); and claims 1, 25, 28-29 were rejected as obvious over Cramer in view of Alfonso. No claims were allowed.

The current Action is responsive to the Amendment and Response to Final Rejection filed on September 24, 2010, and the revised Declaration under 37 CFR 1.132 by Geena Malhotra, with Exhibits A-D, dated September 23, 2010.

A Request for Continuing Examination was filed on September 27, 2010.

The examiner in this application has changed. Please address future correspondence accordingly.

Status of Claims

Claims 1-2, 4, 6-22, 26-27, 30, 35-38, 44-45, and 53-56 are pending. Of these claims, claims 26, 27, and 30 were amended in the most recent response. The Amendments are entered of right.

Anticipation rejection, reinstated in part and new in part

In the Office Action that was mailed on January 23, 2009, claim 5, directed to a steroid range, was not rejected as *anticipated* by Cramer. That was an error, because, as discussed further below, Cramer discloses the claimed amounts of steroid. This examiner recognizes that the correction of the error places an additional burden on the Applicant.

The rejection of claims 1-2, 9-10, 12-21, 30, 45, and 55-56 as obvious over Cramer is **withdrawn** in favor of the following anticipation rejection.

Claim Rejections - 35 USC § 102

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