UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,709	07/10/2003	Neil P. Desai	APP01_005_US	2620

66140 7590 11/29/2011

BLANCHARD & ASSOCIATES
566 WEST ADAMS STREET
SUITE 600
CHICAGO, IL 60661

EXAMINER	
TELLER, ROY R	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
11/29/2011	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	Application No.	Applicant(s)	
	10/616,709	DESAI ET AL.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- 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 *28 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ 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

5)☒ Claim(s) *1-64,68,69 and 71-88* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-64,68,69 and 71-88* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ 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).

12)☐ 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

13)☐ 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 *11/10/11*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

This office action is in response to the amendment filed and entered 7/28/11.

Claims 1-64, 68-69 and 71-88 are under examination.

Information Disclosure Statement

The information disclosure statement filed 11/10/11 is acknowledged. A signed copy is enclosed hereto.

Response to Amendments/Arguments

Applicant's arguments and amendments filed 7/28/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-64, 68-69 and 71-88 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (USPN 6,399,087) in view of Lundgren et al. (USPN 6,576,245) and Sautou-Miranda et al. (International Journal of Pharmaceutics, 1996, 130, pp-251-255).

The instant invention is drawn to a sterile pharmaceutical composition for parenteral administration of propofol, wherein said composition is stored in a container having a closure wherein said closure is inert to propofol, wherein the composition comprises:

a) about 0.5% to 10% by weight propofol,

b) 3-6% by weight of soybean oil,

c) 0.2-1.0% by weight of egg lecithin,

d) about 2.25% by weight of glycerin,

e) sodium hydroxide,

f) water to 100%,

g) pH between 5.0-8.5,

and when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration measured by HPLC that is at least 93% of the starting concentration of the propofol.

Zhang et al. discloses a sterile pharmaceutical composition for parenteral administration of propofol, wherein the composition comprises :

a) about 1% to 2% by weight propofol,

b) 3-6% by weight of soybean oil,

c) 0.2-1.0% by weight of egg lecithin,

d) about 2.25% by weight of glycerin,

e) sodium hydroxide,

f) water to 100%, and

g) pH between 5.0-7.5.

See, i.e., for example, abstract, column 3, lines 21-22, claims 1-14.

Zhang does not disclose a container having a closure wherein said closure is inert to propofol.

Lundgren et al. discloses a primary package containing low molecular weight peptide-based thrombin inhibitors which package is sealed with a rubber stopper or plunger containing bromobutyl rubber. Lundgren discloses the preferred low molecular weight peptide based thrombin inhibitor be kept in glass vials or syringes. See, i.e., for example, abstract, column 2, lines 1-2, claims 1-5.

Sautou-Miranda et al. discloses propofol stored in glass and polypropylene containers for 30 days with little lose of potency. See, for example, abstract, and page 255.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the composition of Zhang with the beneficial teachings of Lundgren because Lundgren discloses the a low molecular weight package sealed with bromobutyl rubber. The brombutyl rubber would inherently work for a low molecular weight (below 1,000 M.W.) composition such as propofol (M.W. -178.27). Further, Sautou-Miranda disclosure of propofol stored in glass and polypropylene containers for 30 days with little lose of potency beneficially teaches a composition of propofol comprising a container which is inert to propofol. It would be obvious to put any known pharmaceutical composition within that type of sealed container-for well known sterility, stability and transport purposes. Sautou-Miranda disclosure of propofol stored in glass and polypropylene containers for 30 days with little lose of

DOCKET ALARM

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.