IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Desai Application No.: 10/616,709 Filed: 10 Jul 2003 Title: Propofol Formulations With Non-Reactive Container Closures Attorney Docket No.: APP01_005_US	Art Unit: 1654 Examiner: Roy R. Teller Confirmation No.: 2620

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR 1.111

Dear Sir:

This communication responds to the Office Action mailed on January 28, 2011. Applicants respectfully request that the Examiner reconsider the rejections in view of the following amendments and remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2.

Remarks begin on page 16.

IN THE CLAIMS:

In accord with Rule § 1.121, a complete claim listing is presented below, including appropriate status identifiers. The changes in amended claims are shown by strikethrough or double brackets for deleted material, and by underlining for added material.

1. (Currently Amended) A sterile pharmaceutical composition of propofol in a container, comprising:

a container which includes a closure and a composition in the container, and

the composition in the container comprising from 0.5% to 10% by weight propofol and less than 10% by weight solvent for propofol, ~~and~~

where 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 (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol.

2. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, the composition further comprising an aqueous phase and protein.

3. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the protein is albumin.

4. (Previously presented) The sterile pharmaceutical composition in a container according to claim 3, wherein the albumin is present in an amount of from about 0.01% to about 5% by weight of the composition.

5. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the aqueous phase comprises water for injection and a pH modifier.

6. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition comprises a tonicity agent.

7. (Previously presented) The sterile pharmaceutical composition in a container according to claim 3, wherein the pH modifier is sodium hydroxide.

8. (Previously presented) The sterile pharmaceutical composition in a container according to claim 6, wherein the tonicity agent is glycerin.

9. (Previously presented) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition further comprises a surfactant.

10. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition further comprises a solvent for propofol.

11. (Previously presented) The sterile pharmaceutical composition in a container according to claim 10 wherein the solvent is a water-immiscible solvent.

12. (Previously presented) The sterile pharmaceutical composition in a container according to claim 11, wherein the water-immiscible solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glyceral ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof.

13. (Previously presented) The sterile pharmaceutical composition in a container according to claim 12, wherein the water-immiscible solvent is soybean oil.

14. (Previously presented) The sterile pharmaceutical composition in a container according to claim 10, wherein the solvent is selected from the group consisting of chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic

hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

15. (Previously presented) The sterile pharmaceutical composition in a container according to claim 9, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids, natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block co-polymers, polyvinyl pyrrolidone, and polyvinylalcohol and combinations thereof.

16. (Previously presented) The sterile pharmaceutical composition in a container according to claim 15, wherein the surfactant is selected from the group consisting of egg phosphatides, soya phosphatides, egg lecithins, soya lecithins, and combinations thereof.

17. (Previously presented) The sterile pharmaceutical composition in a container according to claim 16, wherein the surfactant is egg lecithin.

18. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure is coated with a material inert to propofol.

19. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure consists essentially of a material that is itself inert to propofol.

20. (Previously presented) The sterile pharmaceutical composition in a container according to claim 19, wherein the closure material is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

21. (Previously presented) The sterile pharmaceutical composition in a container according to claim 19, wherein the closure material is a non-rubber selected from the group consisting of metal, plastics, and mixtures thereof.

22. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises a material selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

23. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

24. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized bromobutyl rubber.

25. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises a non-rubber selected from the group consisting of metal, plastics, and mixtures thereof.

26. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

27. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized chlorobutyl rubber.

28. (Previously presented) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition comprises soybean oil in an amount of from about 0.5% to about 6% by weight of the composition, egg lecithin in an amount of from about 0.1% to about 5% by weight of the composition and human serum albumin in an amount of from about 0.1% to about 5% of the composition.

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.