IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Jiang Application No.: 13/597,884 Filed: August 29, 2012 Title: Levothyroxine Formulations	Art Unit: 1627 Examiner: Kara R. McMillian Docket No.: FKA01_007_US

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116

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

Dear Sir:

This communication responds to the Office Action mailed on April 3, 2013. Applicants respectfully request that Examiner McMillian reconsider the rejections in view of the following amendments and remarks. This paper is believed to be timely filed.

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

Remarks begin on page 7.

Declaration pursuant to 37 CFR § 1.132 is included with the response.

IN THE CLAIMS:

In accord with Rule § 1.121, a complete claim listing is presented below. A status identifier (Original) or (Currently Amended) precedes each claim. 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 composition, comprising:
from 100 to 500 micrograms of levothyroxine sodium, and
from 1 to 5 milligrams mannitol;
where the composition is a lyophilized solid.

2. (Original) The composition of claim 1, where the amount of mannitol is from 2 to 4 milligrams.

3. (Original) The composition of claim 1, where the amount of mannitol is from 2.9 to 3.1 milligrams.

4. (Original) The composition of claim 1, further comprising a phosphate buffer.

5. (Original) The composition of claim 4, further comprising a base;
where, when the composition is reconstituted in 5 milliliters of 0.9% aqueous sodium chloride, the pH of the reconstituted liquid is from 9.5 to 11.5.

6. (Original) The composition of claim 5, where the amount of mannitol is from 2.9 to 3.1 milligrams.

7. (Original) The composition of claim 5, where the composition is formed by
forming a liquid mixture by combining
the levothyroxine sodium,

the mannitol,
dibasic sodium phosphate,
a solvent comprising water, and
a base; and
lyophilizing the liquid mixture.

8. (Original) The composition of claim 7, where the amount of dibasic sodium phosphate in the liquid mixture is from 400 to 600 micrograms.

9. (Original) The composition of claim 1, where when the composition is stored at 25 °C, at most 0.20% of the levothyroxine sodium is converted to liothyronine over a period of 12 months.

10. (Original) The composition of claim 1, where when the composition is stored at 40 °C, at most 0.20% of the levothyroxine sodium is converted to liothyronine over a period of 3 months.

11. (Currently Amended) A composition, comprising:
from 100 to 200 micrograms of levothyroxine sodium, and
mannitol;
where the mass ratio of mannitol to levothyroxine sodium is at most 40:1, and
the composition is a lyophilized solid.

12. (Original) The composition of claim 11, where the amount of levothyroxine sodium is about 100 micrograms.

13. (Original) The composition of claim 12, where the mass ratio of mannitol to levothyroxine sodium is at most 30:1.

14. (Original) The composition of claim 13, further comprising a phosphate buffer.

15. (Original) The composition of claim 14, where the composition is formed by forming a liquid mixture by combining

the levothyroxine sodium,
the mannitol,
dibasic sodium phosphate, and
a solvent comprising water; and

lyophilizing the liquid mixture.

16. (Original) The composition of claim 15, where the amount of dibasic sodium phosphate in the liquid mixture is from 400 to 600 micrograms.

17. (Original) The composition of claim 11, where the amount of levothyroxine sodium is about 200 micrograms.

18. (Original) The composition of claim 17, where the mass ratio of mannitol to levothyroxine sodium is at most 15:1.

19. (Original) The composition of claim 18, further comprising a phosphate buffer.

20. (Original) The composition of claim 19, where the composition is formed by forming a liquid mixture by combining

the levothyroxine sodium,
the mannitol,
dibasic sodium phosphate, and
a solvent comprising water; and

lyophilizing the liquid mixture.

21. (Original) The composition of claim 20, where the amount of dibasic sodium phosphate in the liquid mixture is from 400 to 600 micrograms.

22. (Original) The composition of claim 11, where when the composition is stored at 25 °C, at most 0.20% of the levothyroxine sodium is converted to liothyronine over a period of 12 months.

23. (Original) The composition of claim 11, where when the composition is stored at 40 °C, at most 0.20% of the levothyroxine sodium is converted to liothyronine over a period of 3 months.

24. (Currently Amended) A composition, comprising:
about 500 micrograms of levothyroxine sodium, and
mannitol;
where the mass ratio of mannitol to levothyroxine sodium is at most 10:1, and
the composition is a lyophilized solid.

25. (Original) The composition of claim 24, where the mass ratio of mannitol to levothyroxine sodium is at most 6:1.

26. (Currently Amended) The composition of claim 25, further comprising a phosphate buffer~~;~~.

27. (Original) The composition of claim 26, where the composition is formed by
forming a liquid mixture by combining
the levothyroxine sodium,
the mannitol,
dibasic sodium phosphate, and
a solvent comprising water; and
lyophilizing the liquid mixture.

28. (Original) The composition of claim 27, where the amount of dibasic sodium phosphate in the liquid mixture is from 400 to 600 micrograms dibasic sodium phosphate.

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.