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. § 1.111

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

Dear Sir:

This communication responds to the Office Action mailed on March 6, 2014. 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 of Leonard J. Chyall 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), (Previously Presented), 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.-10. (Canceled)

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

12. (Currently Amended) The composition of claim 11, where the amount of levothyroxine sodium is about 100 micrograms and the mass ratio of mannitol to levothyroxine sodium is about 30:1.

13. (Currently Amended) The composition of ~~claim 12~~ claim 11, where the amount of levothyroxine sodium is about 200 micrograms and the mass ratio of mannitol to levothyroxine sodium is ~~at most 30:1~~ about 15:1.

14. (Currently Amended) The composition of ~~claim 13, further comprising a~~ claim 12, where the phosphate buffer is dibasic sodium phosphate in an amount from 400 to 600 micrograms.

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

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

18. (Currently Amended) The composition of ~~claim 17, where the mass ratio of mannitol to levothyroxine sodium is at most 15:1~~ claim 14, 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.

19. (Currently Amended) The composition of ~~claim 18, further comprising a~~ claim 13, where the phosphate buffer is dibasic sodium phosphate in an amount from 400 to 600 micrograms.

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. (Currently Amended) The composition of ~~claim 20, where the amount of dibasic sodium phosphate in the liquid mixture is from 400 to 600 micrograms~~ claim 14, 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.

22. (Currently Amended) The composition of ~~claim 11~~ claim 19, 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. (Currently Amended) The composition of ~~claim 11~~ claim 19, 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,
a phosphate buffer, and
mannitol;
where the mass ratio of mannitol to levothyroxine sodium is ~~at most 10:1~~ from 2:1 to 10:1, and the composition is a lyophilized solid.

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

26. (Currently Amended) The composition of claim 25, ~~further comprising a~~ where the phosphate buffer is dibasic sodium phosphate in an amount from 400 to 600 micrograms.

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. (Currently Amended) 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~~ claim 24, where when the composition is stored at 25 °C, at most 0.15% of the levothyroxine sodium is converted to liothyronine over a period of 12 months.

29. (Currently Amended) The composition of ~~claim 24~~ claim 26, where when the composition is stored at 25 °C, at most 0.15% of the levothyroxine sodium is converted to liothyronine over a period of 12 months.

30. (Currently Amended) The composition of ~~claim 24~~ claim 26, where when the composition is stored at 40 °C, at most 0.15% of the levothyroxine sodium is converted to liothyronine over a period of 3 months.

31. (New) The composition of claim 24, where when the composition is stored at 40 °C, at most 0.15% of the levothyroxine sodium is converted to liothyronine over a period of 3 months.

32. (New) The composition of claim 11, where the mass ratio of mannitol to levothyroxine sodium is from 5:1 to 35:1.

33. (New) The composition of claim 32, 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.

34. (New) The composition of claim 32, where the phosphate buffer is dibasic sodium phosphate in an amount from 400 to 600 micrograms.

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