

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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.

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