IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
John Zhiqiang Jiang, *et al.*	)	Group Art Unit: 1627
	)	
Application No.: 14/658,058	)	Examiner: Kara R. McMillian
	)	
Filed: March 13, 2015	)	Confirmation No.: 5683

Title: LEVOTHYROXINE FORMULATIONS

AMENDMENT IN REPLY TO ACTION OF MAY 6, 2015

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

Please amend the above-identified application as follows:

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

Remarks/Arguments begin on page 4 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

1. (Original) A lyophilized solid composition, comprising:
between 100 and 500 micrograms of a salt of levothyroxine;
a buffer; and
between 2 and 4 milligrams of mannitol.

2. (Original) The lyophilized solid composition of claim 1, wherein, when the lyophilized solid composition is stored at 25°C for a predetermined time period, less than 0.20% of the salt of levothyroxine is converted to liothyronine.

3. (Original) The lyophilized solid composition of claim 2, wherein the predetermined time period is 12 months.

4. (Original) The lyophilized solid composition of claim 1, wherein, when the lyophilized solid composition is stored at 40°C for a predetermined time period, less than 0.20% of the salt of levothyroxine is converted to liothyronine.

5. (Original) The lyophilized solid composition of claim 4, wherein the predetermined time period is 6 months.

6. (Original) The lyophilized solid composition of claim 1, wherein about 3 milligrams of mannitol is in the lyophilized solid composition.

7. (Currently Amended) The lyophilized solid composition of claim 1, wherein the buffer is a phosphate buffer.

8. (Currently Amended) The lyophilized solid composition of claim 7, wherein the phosphate buffer is dibasic sodium phosphate in an amount between 400 and 600 micrograms.

9. (Currently Amended) The lyophilized solid composition of claim 1, wherein the salt of levothyroxine is levothyroxine sodium.

10. (Original) A pharmaceutical solution, comprising:
the lyophilized solid composition of claim 1; and
a pharmaceutically acceptable liquid carrier.

11. (Original) The pharmaceutical solution of claim 10, wherein a concentration of the salt of levothyroxine in the pharmaceutical solution is between 5 and 500 μg/mL.

12. (Original) The pharmaceutical solution of claim 10, wherein the pH of the pharmaceutical solution is between 9.5 and 11.5.

13. (Currently Amended) A method of providing levothyroxine to a patient in need thereof, the method comprising:
administering the pharmaceutical solution of claim [[7]] 10 to the patient in need thereof.

14. (Currently Amended) The method of claim 13, wherein the pharmaceutical solution is administered to the patient in need thereof such that between about 50 to 500 micrograms of salt of levothyroxine is administered to the patient in need thereof.

15. (Currently Amended) The method of claim 14, wherein the pharmaceutical solution is administered to the patient in need thereof such that between about 50 to 100 micrograms or about 300 to 500 micrograms of salt of levothyroxine is administered to the patient in need thereof.

REMARKS

In reply to the non-final Office Action of May 6, 2015, Applicants respectfully request that all claims be allowed in view of the amendments to the claims and the following remarks. Claims 1-15 are pending, with claim 1 being independent. Claims 7-9 and 13-15 have been amended. Applicants submit that no new matter has been introduced.

Interview Summary

Applicants thank Examiner McMillian for the courtesies extended to the Applicants' representative, Hussein Akhavannik, during the telephonic interviews conducted on April 22, 2015. As reflected by the Examiner-Initiated Interview Summary mailed May 6, 2015, Applicants' representative and Examiner McMillian discussed filing a terminal disclaimer, filing the 37 C.F.R. 1.132 declaration filed in this application's parent patent, U.S. Patent No. 9,006,289, on December 23, 2014, and amending the claims to recite a "patient in need thereof," to place this application in condition for allowance. Only to expedite prosecution, Applicants are filing the terminal disclaimer and the 37 C.F.R. 1.132 declaration with this amendment, as well as amending the claims to recite a "patient in need thereof." Accordingly, for at least these reasons, Applicants respectfully submit that this application is in condition for allowance.

Information Disclosure Statement

Applicants note that an Information Disclosure Statement (Form PTO/SB/08a) was submitted on May 4, 2015, which was before the May 6, 2015 mailing date of the non-final Office Action. Accordingly, applicants respectfully request that the Examiner return a copy of the Form PTO/SB/08a submitted on May 4, 2015 with the Examiner's initials indicating that the cited references were considered.

Claim Rejections - Double Patenting

Claims 1-15 have been provisionally rejected for non-statutory obviousness-type double patenting as being unpatentable over claims 1-21 of this application's parent patent, U.S. Patent No. 9,006,289, and further over claims 1-30 of co-pending U.S. Patent App. No. 14/641,426. A terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) with respect to U.S. Patent No. 9,006,289 and U.S. Patent App. No. 14/641,426 is being filed concurrently with this amendment.

Accordingly, in view of the terminal disclaimer, Applicants respectfully request reconsideration and withdrawal of this non-statutory double patenting rejection.

Claim Rejections - 35 U.S.C. § 103

Claims 1-15 have been rejected as being unpatentable over Bedford Laboratories, "Levothyroxine Sodium For Injection," 2003 ("Bedford") in view of Collier (*AAPS PharmSciTech., 11(2):* 818-825 (2010)), Baheti (*J. Excip. Food Chem., 1(1):* 41-54 (2010)) and Kim (*J. Pharm. Sci., 87(8):* 931-935 (1998)).

Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness with respect to claims 1-15. In particular, Applicants respectfully submit the 37 C.F.R. 1.132 declaration of Dr. Usayapant, originally filed in this application's parent patent, U.S. Patent No. 9,006,289, on December 23, 2014, establishes that the superior stability and extended shelf-life of the compositions according the claims of this application are unexpected to one of ordinary skill in the art.

Moreover, as noted above in the interview summary, the Examiner agreed that the filing of this declaration would place this application in condition for allowance. Accordingly, for at least these reasons, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection of independent claims 1 and its dependent claims.

Conclusion

Applicants submit that all claims are in condition for allowance.

It is believed that all of the pending issues have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this reply should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this reply, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The fee of $160 in payment of the Terminal Disclaimer fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

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