IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Giorgio CALDERARI et al.	Group Art Unit: 1628
Application No.: 13/902,132	
Filed: May 24, 2013	Examiner: Shirley V. GEMBEH
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	Confirmation No.: 2532

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

Commissioner:

AMENDMENT AND RESPONSE TO OFFICE ACTION

In reply to the Office Action mailed August 8, 2013, please amend the above-identified application as follows:

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

Remarks/Arguments follow the amendment sections of this paper and begin on page 8.

Dr. Reddy's Laboratories, Ltd., et al.
v.
Helsinn Healthcare S.A., et al.
U.S. Patent No. 8,729,094

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AMENDMENTS TO THE CLAIMS:

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

1-11. (Canceled)

12. (Currently Amended) A method for reducing the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising intravenously administering to a human in need thereof ~~the~~ a pharmaceutical single-use, unit-dose formulation comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of about 5.0 ± 0.5, said solution ~~of claim 10,~~ comprising:

about 0.05 mg/mL palonosetron hydrochloride based on the weight of its free base;

about 41.5 mg/mL mannitol;

about 0.5 mg/mL EDTA; and

a citrate buffer,

wherein said formulation is stable at 24 months when stored at room temperature, and

wherein said intravenous administration to said human occurs before the start of the cancer chemotherapy.

13. (Previously Presented) The method of claim 12, wherein said intravenous administration to said human occurs over a period of time of 10 to 60 seconds.

14. (Previously Presented) The method of claim 12, wherein said intravenous administration reduces the likelihood of acute nausea and vomiting in said human.

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15. (Previously Presented) The method of claim 12, wherein said intravenous administration reduces the likelihood of delayed nausea and vomiting in said human.

16. (New) A method for reducing the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising intravenously administering to a human in need thereof a pharmaceutical single-use, unit-dose formulation comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of about 5.0 ± 0.5, said solution comprising:

about 0.05 mg/mL palonosetron hydrochloride based on the weight of its free base;

from about 10 mg/mL to about 80 mg/mL mannitol; and

from about 0.3 mg/mL to about 0.7 mg/mL EDTA;

wherein said solution optionally comprises a citrate buffer,

wherein said formulation is stable at 24 months when stored at room temperature, and

wherein said intravenous administration to said human occurs before the start of the cancer chemotherapy.

17. (New) The method of claim 16, wherein said intravenous administration to said human occurs over a period of time of 10 to 60 seconds.

18. (New) The method of claim 16, wherein said intravenous administration reduces the likelihood of acute nausea and vomiting in said human.

19. (New) The method of claim 16, wherein said intravenous administration reduces the likelihood of delayed nausea and vomiting in said human.

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20. (New) The method of claim 16, wherein said solution comprises from about 20 mg/mL to about 60 mg/mL mannitol.

21. (New) The method of claim 20, wherein said solution comprises from about 40 mg/mL to about 45 mg/mL mannitol.

22. (New) The method of claim 21, wherein said solution comprises about 41.5 mg/mL mannitol and about 0.5 mg/mL EDTA.

23. (New) The method of claim 16, wherein said solution comprises a citrate buffer.

24. (New) A method for reducing the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising intravenously administering to a human in need thereof a pharmaceutical single-use, unit-dose formulation comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

about 0.05 mg/mL palonosetron hydrochloride based on the weight of its free base;

a tonicifying effective amount of mannitol; and

from about 0.3 mg/mL to about 0.7 mg/mL EDTA;

wherein said solution optionally comprises a citrate buffer and optionally has a pH of from about 5.0 ± 0.5,

wherein said formulation is stable at 24 months when stored at room temperature, and

wherein said intravenous administration to said human occurs before the start of the cancer chemotherapy.

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25. (New) The method of claim 24, wherein said intravenous administration to said human occurs over a period of time of 10 to 60 seconds.

26. (New) The method of claim 24, wherein said intravenous administration reduces the likelihood of acute nausea and vomiting in said human.

27. (New) The method of claim 24, wherein said intravenous administration reduces the likelihood of delayed nausea and vomiting in said human.

28. (New) The method of claim 24, wherein said solution comprises a citrate buffer.

29. (New) The method of claim 24, wherein said solution is buffered at a pH of about 5.0 ± 0.5.

30. (New) The method of claim 24, wherein said solution comprises from about 10 mg/mL to about 80 mg/mL mannitol.

31. (New) The method of claim 30, wherein said solution comprises from about 20 mg/mL to about 60 mg/mL mannitol.

32. (New) The method of claim 32, wherein said solution comprises about 41.5 mg/mL mannitol and about 0.5 mg/mL EDTA.

33. (New) A method for reducing the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising intravenously administering to a human in need thereof a pharmaceutical single-use, unit-dose formulation comprising a 5 mL sterile aqueous isotonic solution buffered at a pH of about 5.0 ± 0.5, said solution comprising:

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