IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

AMENDMENT AFTER FINAL

Commissioner of Patents
United States Patent Office
Alexandria, Virginia

TROUTMAN SANDERS
Customer Number 06980

Dear Sir:

In reply to the Office Action mailed December 6, 2013, please consider the Remarks presented herein.

Amendments to the Claims are reflected in the listing of claims in this paper.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

1-11. (CANCELLED)

12. (PREVIOUSLY PRESENTED) 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;

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.

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

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

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

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

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

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

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

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

24. (PREVIOUSLY PRESENTED) 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.

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

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

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

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

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

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

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

32. (CURRENTLY AMENDED) The method of claim ~~32~~ 31, wherein said solution comprises about 41.5 mg/mL mannitol and about 0.5 mg/mL EDTA.

33. (PREVIOUSLY PRESENTED) 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; and

a tonicifying effective amount of mannitol;

wherein said solution optionally comprises one or a combination of a citrate buffer and a chelating agent,

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.

34. (PREVIOUSLY PRESENTED) The method of claim 33, wherein said intravenous administration to said human occurs over a period of time of 10 to 60 seconds.

35. (PREVIOUSLY PRESENTED) The method of claim 33, wherein said intravenous administration reduces the likelihood of acute nausea and vomiting in said human.

36. (PREVIOUSLY PRESENTED) The method of claim 33, wherein said intravenous administration reduces the likelihood of delayed nausea and vomiting in said human.

37. (PREVIOUSLY PRESENTED) The method of claim 33, wherein said solution comprises a citrate buffer.

38. (PREVIOUSLY PRESENTED) The method of claim 33, wherein said solution comprises a chelating agent.

39. (PREVIOUSLY PRESENTED) The method of claim 38, wherein said chelating agent is EDTA.

40. (PREVIOUSLY PRESENTED) The method of claim 39, wherein said solution comprises from about 0.3 mg/mL to about 0.7 mg/mL EDTA.

41. (PREVIOUSLY PRESENTED) The method of claim 33, wherein said solution comprises from about 10 mg/mL to about 80 mg/mL mannitol.

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