PATENT
Attorney Docket No. 11285.0056-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
John R. Evans et al.	) Group Art Unit: 1628
Application No.: 12/285,887	) Examiner: HUI, San Ming R.
Filed: October 15, 2008	) Confirmation No.: 1199
For: FORMULATION	) **VIA EFS-WEB**

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

Sir:

RESPONSE AND AMENDMENT UNDER 37 C.F.R. § 1.111 AND PETITION FOR EXTENSION OF TIME

In reply to the non-final Office Action mailed December 21, 2010 ("Office Action"), and pursuant to 37 C.F.R. § 1.111, Applicants hereby respectfully request reconsideration of this application in view of the following amendments and remarks. Applicants hereby petition for a three-month extension of time to respond to the Office Action. The requisite fee is being paid concurrently with this Response.

Amendments to the Claims are reflected in the listing of claims, which starts on page 2 of this paper. **Remarks** follow the amendment sections of this paper and start on page 9.

AMENDMENTS TO THE CLAIMS

Please add new claims 24-53. Please also cancel claims 1-23 without prejudice or disclaimer. This listing of claims will replace all prior versions and listings of claims in the application.

Claims 1-23 (Cancelled)

24. (New) A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation comprising:

at least 45 $mgml^{-1}$ of fulvestrant;

a mixture of from 17 – 23% w/v of ethanol and benzyl alcohol;

12 - 18% w/v of benzyl benzoate; and

a sufficient amount of castor oil vehicle;

wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks.

25. (New) The method of claim 24, wherein the ethanol and benzyl alcohol are present in the same weight/volume amounts.

26. (New) The method of claim 24, wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$.

27. (New) The method of claim 24, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

28. (New) The method of claim 24, wherein the therapeutically significant blood plasma fulvestrant concentration is attained for at least 4 weeks.

29. (New) The method of claim 24, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

30. (New) The method of claim 24, wherein the method further comprises once monthly administration of the formulation.

31. (New) The method of claim 24, wherein the formulation comprises:

about 50 $mgml^{-1}$ of fulvestrant;

about 10% w/v of ethanol;

about 10% w/v of benzyl alcohol; and

about 15% w/v of benzyl benzoate;

wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$.

32. (New) The method of claim 31, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

33. (New) The method of claim 32, wherein the therapeutically significant blood plasma fulvestrant concentration is attained for at least 4 weeks.

34. (New) The method of claim 33, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

35. (New) The method of claim 34, wherein the method further comprises once monthly administration of the formulation.

36. (New) A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation consisting essentially of:

at least 45 $mgml^{-1}$ of fulvestrant;

a mixture of from 17 – 23% w/v of ethanol and benzyl alcohol;

12 - 18% w/v of benzyl benzoate; and

a sufficient amount of castor oil vehicle;

wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks.

37. (New) The method of claim 36, wherein the ethanol and benzyl alcohol are present in the same weight/volume amounts.

38. (New) The method of claim 36, wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$.

39. (New) The method of claim 36, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

40. (New) The method of claim 36, wherein the therapeutically significant blood plasma fulvestrant concentration is attained for at least 4 weeks.

41. (New) The method of claim 36, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

42. (New) The method of claim 36, wherein the method further comprises once monthly administration of the formulation.

43. (New) The method of claim 36, wherein the formulation consists essentially of:

about 50 $mgml^{-1}$ of fulvestrant;

about 10% w/v of ethanol;

about 10% w/v of benzyl alcohol; and

about 15% w/v of benzyl benzoate;

wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$.

44. (New) The method of claim 43, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

45. (New) The method of claim 44, wherein the therapeutically significant blood plasma fulvestrant concentration is attained for at least 4 weeks.

46. (New) The method of claim 45, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

47. (New) The method of claim 46, wherein the method further comprises once monthly administration of the formulation.

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