

**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<sup>-1</sup> 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<sup>-1</sup> 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<sup>-1</sup>.
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<sup>-1</sup> 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<sup>-1</sup>.
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<sup>-1</sup> 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<sup>-1</sup> 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<sup>-1</sup>.
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<sup>-1</sup> 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<sup>-1</sup>.
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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.