IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Group Art Unit: Not Yet Assigned
Giorgio CALDERARI et al.	
Application No.: Not Yet Assigned	
Continuation-in-Part of U.S. Application No. 13/087,012	Examiner: Not Yet Assigned
Filed: Herewith	
For: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON	Confirmation No.: Not Yet Assigned

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

Commissioner:

IDENTIFICATION OF CONTINUATION-IN-PART CLAIM SUPPORT REQUIRED UNDER 37 C.F.R. § 1.78(d)(3) AND CHOICE OF LAW

As required by 37 C.F.R. § 1.78(d)(3), as amended effective November 1, 2007, the undersigned representative of the applicant provides the following information.

I. Introduction

Claims 1-8 of the above-identified continuation-in-part application find support under 35 U.S.C. § 112 in the provisional application, 60/444,351 ("the '351 Application") filed January 30, 2003, of copending Application No. 13/087,012 filed April 4, 2011 (*see* Domestic Benefit/National Stage Information in the accompanying Application Data Sheet, which establishes a chain of copendency and specific reference from copending Application No. 13/087,012 back to the '351 Application). Thus, claims 1-8 have an effective filing date (EFD) prior to March 16, 2013.

Claim 9 finds support under 35 U.S.C. § 112 only in newly added Example 8 of the continuation-in-part application filed herewith. Thus, claim 9 has an EFD after March 15, 2013.

II. Choice of Law

Hence, this application falls under both transition provisions 3(n)(1) (because of claim 9) and 3(n)(2) (because of claims 1-8) of the America Invents Act (AIA).[1] For that reason, all of claims 1-9 should, for prior art purposes, be examined solely through the lenses of AIA §§ 102(a)(1), (a)(2), and 103, as well as pre-AIA § 102(g). That point is clearly explained by the USPTO:

> [S]ection 3(n)(2) does indicate that the provisions of 35 U.S.C. 102(g), 135, and 291 as in effect on March 15, 2013, shall apply to "each claim" of an application for patent, and not simply the claim or claims having an effective filing date

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[1] SEC. 3(n)(1): "Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act ***[March 16, 2013]***, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time— (A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph ***[i.e., March 16, 2013]***; or (B) a specific reference under section 120, 121, 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such claim." (Commentary added for emphasis.)

SEC. 3(n)(2): "The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection ***[March 15, 2013]***, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply, if such application or patent contains or contained at any time— (A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection ***[March 16, 2013]***; or (B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim." (Commentary added for emphasis.)

> that occurs before March 16, 2013, if the condition specified in section 3(n)(2) occurs. Therefore, "each claim" of an application presenting a claim to a claimed invention that has an effective filing date before March 16, 2013 ***[here claims 1-8]***, but also presenting claims to a claimed invention that has an effective filing date on or after March 16, 2013 ***[here claim 9]***, is subject to AIA 35 U.S.C. 102 and 103 and is also subject to the provisions of 35 U.S.C. 102(g), 135, and 291 as in effect on March 15, 2013.

See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,069 (February 14, 2013) (commentary added for emphasis).

III. Claims 1-8 Find Support in and Have an EFD of the Pre-AIA '351 Application

A. Claim 1

Claim 1 recites "[a] pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising: palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base; from 0.005 mg/mL to 1.0 mg/mL EDTA; and from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 24 months when stored at room temperature." Support for claim 1 can be found throughout the specification of the '351 Application, for instance, at:

- the abstract at page 21;
- page 2, lines 3-6 and lines 24-29;
- page 3, lines 1-5, lines 11-20;
- page 3, lines 21 to page 4, line 13;

- page 4, lines 19-21;

- page 5, lines 5-15;

- page 5, line 26 to page 6, line 2;

- page 6, lines 16-20;

- page 6, line 21 to page 7, line 1;

- page 7, lines 3-6;

- page 8, lines 2-5, lines 9-11, and lines 13-15;

- page 9, lines 9-23;

- page 10, lines 3-18; and

- original claims 1, 4, 5, 8-10, 12, 33-36, 38, 39, 41, 44, 46, 47, 50-52, 54, and 57.

Claim 1 recites "wherein said formulation is stable at 24 months when stored at room temperature." Support for this phrase can be found throughout the specification of the '351 Application, for instance at page 3, lines 11-12, page 5, lines 5-7, and page 10, lines 9-18. On July 25, 2003, furthermore, US FDA approved Helsinn's Aloxi® (palonosetron hydrochloride injection) product, which is within the scope of the claims, for a 2 year shelf life. *See* Exhibit A, FDA approval letter ("[B]ased on the primary stability data submitted, we are granting a 24-month expiration period for this product."). Hence, the written description and enablement of the new claims is tightly bound to the drug product approved by FDA and within the scope of the claims.

B. Claim 2

Claim 2 depends from claim 1, and recites "[t]he pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL." Support for claim 2 can be found throughout the specification of the '351 Application, such as the support for claim 1 as set forth above. Additional support may be found, for instance, at:

- page 9, lines 9-11; and

- page 12, Example 4.

C. Claim 3

Claim 3 depends from claim 1, and recites "[t]he pharmaceutical formulation of claim 1, wherein said mannitol is in an amount of 41.5 mg/mL." Support for claim 3 can be found throughout the specification of the '351 Application, such as the support for claim 1 as set forth above. Additional support may be found, for instance, at:

- page 9, lines 28 to page 10, line 2;

- page 11, line 25 to page 12, line 2; and

- page 12, Example 4.

D. Claims 4 and 5

Claim 4 depends from claim 1, and recites "[t]he pharmaceutical formulation of claim 1, wherein said solution further comprises a citrate buffer." Claim 5 depends from claim 4, and recites "[t]he pharmaceutical formulation of claim 4, wherein said citrate buffer is at a concentration of 20 millimolar." Support for claims 4 and 5 can be found throughout the specification of the '351 Application, such as the support for claim 1 as set forth above. Additional support may be found, for instance, at:

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