

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	32475383
<b>Application Number:</b>	15965638
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6067
<b>Title of Invention:</b>	EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST AND USES THEREOF
<b>First Named Inventor/Applicant Name:</b>	Thomas B. Ottoboni
<b>Customer Number:</b>	108547
<b>Filer:</b>	Wen Li/Julie Costello
<b>Filer Authorized By:</b>	Wen Li
<b>Attorney Docket Number:</b>	092459-0223/8032.US00
<b>Receipt Date:</b>	27-APR-2018
<b>Filing Date:</b>	
<b>Time Stamp:</b>	18:50:34
<b>Application Type:</b>	Utility under 35 USC 111(a)

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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		092459_0223_con_appln.pdf	252452  <small>07cc1831c93668631f19ea14b9da7c649d54d023</small>	yes	46

Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Specification			1	42	
Claims			43	45	
Abstract			46	46	
<b>Warnings:</b>					
<b>Information:</b>					
2	Oath or Declaration filed	092459_0223_oath.pdf	184417	no	2
			d045f8c729f646d55e304462e83298bd997482b1		
<b>Warnings:</b>					
<b>Information:</b>					
3	Drawings-only black and white line drawings	092459_0223_drwgs.pdf	246706	no	4
			01e46bbb4bbf3bde5c7a2433976a7f5e54a9e18d		
<b>Warnings:</b>					
<b>Information:</b>					
4	Application Data Sheet	092459_0223_ads.pdf	1822537	no	8
			a283b965470c859b1b9430b365c65cae9674ff50		
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			2506112		

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**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

**Remarks**

Claims 1-28 are cancelled without prejudice or disclaimer.

Claims 29-45 are newly added. New claims 29-45 are consonant in scope with the original claims subject to the Restriction Requirement mailed in the parent U.S. Application No. 15/012,532 (now U.S. Patent No. 9,974,742, the '742 patent) on November 4, 2016 ("Restriction Requirement). In particular, new claims 29-45 are directed to the subject matter of Group III set forth in the Restriction Requirement. New claims 29-45 further require the elements of claims 1-17 issued in the '742 patent.

Accordingly, this application is a divisional to the parent U.S. Application No. 15/012,532. Applicant further amended the specification to reflect the correct relationship between this application and the parent U.S. Application No. 15/012,532. A corrected Application Data Sheet is also concurrently filed.

No new matter has been introduced by virtue of the amendments provided herein.

Entry of these amendments is respectfully requested.

If there are any additional fees due in connection with the filing of this Preliminary Amendment, please charge the fees to our Deposit Account No. 01-0885.

If the Examiner feels that a telephone conference would in any way expedite prosecution of the application, the Examiner is kindly urged to call the undersigned at telephone number (650) 815-7399.

Respectfully submitted,

Dated: September 24, 2018

Wen Li/

Wen Li, Ph.D.

Registration No. 62,185

Correspondence Address:

Customer No. 108547

**AMENDMENTS TO THE CLAIMS**

This list of claims will replace all prior version and listing of claims in this application.

1.-28. (Cancelled)

29. (New) A method for treating a subject in need thereof, comprising administering to the subject an injectable pharmaceutical emulsion, wherein the emulsion comprises:

- a neurokinase-1 (NK-1) receptor antagonist;
- 11 wt/wt% to 15 wt/wt% of an emulsifier;
- an oil;
- a co-surfactant which comprises an alcohol;
- a tonicity agent;
- a pH modifier; and
- water;

wherein the pH of the emulsion ranges from about 7.5 to 9.0, and the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%).

30. (New) The method according to claim 29, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%).

31. (New) The method according to claim 29, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%).

32. (New) The method according to claim 29, wherein the ratio of emulsifier to oil ranges from about 1:1 to 3:1 (wt/wt%).

33. (New) The method according to claim 29, wherein the emulsifier is a phospholipid.

34. (New) The method according to claim 29, wherein the emulsifier is an egg lecithin.

35. (New) The method according to claim 29, wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase.

36. (New) The method according to claim 29, wherein the NK-1 receptor antagonist is selected from the group consisting of rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant.

37. (New) The method according to claim 29, wherein the pH modifier is oleic acid or a salt thereof.

38. (New) The method according to claim 29, wherein the pH modifier is a buffer.

39. (New) The method according to claim 38, wherein the buffer is Tris buffer.

40. (New) The method according to claim 29, wherein the oil is soybean oil.

41. (New) The method according to claim 29, wherein the alcohol is ethanol.

42. (New) The method according to claim 41, wherein the ethanol is present in the emulsion at less than 10 wt/wt%.

43. (New) The method according to claim 29, wherein the NK-1 receptor antagonist is not aprepitant.

44. (New) The method according to claim 29, wherein the subject is at risk of or is suffering from nausea and/or vomiting.

45. (New) The method according to claim 29, wherein the nausea and/or vomiting is induced by chemotherapy, surgery, or radiotherapy.



UNITED STATES PATENT AND TRADEMARK OFFICE

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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for 15/965,638 and 108547, 7590, 01/11/2019, listing inventor Thomas B. Ottoboni and attorney McDermott Will & Emery LLP. Also includes examiner HEYER, DENNIS, art unit 1628, and notification date 01/11/2019.

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com



Art Unit: 1628

*The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.*

## DETAILED ACTION

### ***Species Elections***

This application contains claims directed to the following patentably distinct species:

**Applicant is required to elect:**

a) A single injectable emulsion specie, said emulsion containing a single combination of each of a single claimed or otherwise disclosed neurokinase-1 (NK-1) receptor antagonist; emulsifier oil; a co-surfactant, alcohol, tonicity agent and pH modifier.

b) A single, condition from those recited in Claim 27 (i.e. 'at risk of' OR 'suffering from') or otherwise disclosed.

If Applicant elects the condition of Claim 27, Applicant is FURTHER required to elect:

c) A form of inducing nausea/vomiting from those recited in Claim 28.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species, for example, species elections drawn to specific chemical compounds are defined by a unique set of physical and chemical properties and are prepared by a different method. Further, the 'condition'

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species are distinct because they are drawn to different patient populations. In addition, these species are not obvious variants of each other based on the current record.

**Applicant is required under 35 U.S.C. 121 to elect from specie (a) – (c), as defined above, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added.**

There is an examination and search burden (e.g., searching different classes/subclasses or electronic resources, or employing different search queries) for these patentably distinct compound species due to their mutually exclusive characteristics (structure, physical and chemical properties, etc.) which require different fields of search. Further, the patentably distinct ‘condition’ species are drawn to different patient populations and thus search queries for one ‘condition’ will not encompass the subject matter for all ‘condition’ species recited.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at

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the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### ***Multiple Inventors***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on 7-7 EST Monday-Friday.

Art Unit: 1628

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WINSTON SHEN can be reached at (571)272-3157. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DENNIS HEYER/  
Primary Examiner, Art Unit 1628

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:

Ottoboni et al.

APPLICATION No.: 15/965,638

FILED: APRIL 27, 2018

FOR: **EMULSION FORMULATIONS OF AN NK-1  
RECEPTOR ANTAGONIST AND USES  
THEREOF**

EXAMINER: DENNIS HEYER

ART UNIT: 1628

CONF. No.: 6067

Mail Stop AMENDMENT  
Commissioner for Patents  
U.S. Patent & Trademark Office  
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**RESPONSE TO REQUIREMENT OF SPECIES ELECTION**

Dear Commissioner:

This paper is in response to the Election of Species Requirement mailed January 11, 2019. Consideration of this response is respectfully requested.

**Remarks** begin at page 2 of this paper.

**Remarks**

**I. Election of Species**

The Office requires election of species a)-c):

a) A single injectable emulsion specie, said emulsion containing a single combination of each of a single claimed or otherwise disclosed neurokinase-1 (NK-1) receptor antagonist; emulsifier, oil; a co-surfactant, alcohol, tonicity agent and pH modifier,

b) A single, condition from those recited in Claim 27<sup>1</sup> (i.e. 'at risk of' OR 'suffering from') or otherwise disclosed. If a condition of Claim 27 is elected, Applicant is further required to elect:

c) A form of inducing nausea/vomiting from those recited in Claim 28<sup>2</sup>.

Applicant hereby elects a) an emulsion comprising rolapitant, egg lecithin, soybean oil, ethanol, sucrose, and sodium oleate, b) at risk of nausea and/or vomiting as recited in claim 44, and c) the nausea and/or vomiting is induced by chemotherapy.

Claims 29-37 and 40-45 read on the elected species.

The above-elected species are elected without traverse. It is Applicant's understanding upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR §1.141

**II. Conclusion**

The Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-5907.

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<sup>1</sup> This should claim 44 not claim 27.

<sup>2</sup> This should be claim 45 not claim 28.

If the Examiner feels that a telephone conference would in any way expedite prosecution of the application, the Examiner is kindly urged to call the undersigned at telephone number (650) 815-7399.

Respectfully submitted,

Dated: March 11, 2019

/Wen Li/

Wen Li, Ph.D.  
Registration No. 62,185

Correspondence Address:

Customer No. 108547



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EXAMINER
HEYER, DENNIS

ART UNIT PAPER NUMBER
1628

NOTIFICATION DATE DELIVERY MODE
03/19/2019 ELECTRONIC

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mweipdocket@mwe.com



Art Unit: 1628

*The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.*

### **Status of Claims**

Claims 29 – 45 are currently pending.

### **Election/Restrictions**

Acknowledgement is made of Applicant's election, without traverse, in the response filed on March 11, 2019, of a single injectable emulsion specie, said emulsion comprising:

- a) 'rolapitant' as the neurokinase-1 (NK-1) receptor antagonist
- b) 'egg lecithin' as the emulsifier
- c) 'soybean oil' as the oil
- d) 'ethanol' as the alcohol co-surfactant
- e) 'sucrose' as the tonicity agent, and
- f) 'sodium oleate' as the pH modifier

Claims 38 and 39 (requiring a buffer) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected injectable emulsion specie, there being no allowable generic or linking claim. It is noted that, as disclosed on p [0019] of the specification, the pH modifier sodium oleate is distinct from a 'buffer'.

Claims 38 and 39 are withdrawn. Claims 29 – 37 and 40 – 45 are under examination in the instant office action.

***Priority***

This application, 15/965,638, filed 04/27/2018 is a division of 15/012,532, filed 02/01/2016, now U.S. Patent 9,974,742.

***Claim rejections – 35 USC § 112***

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 – 43 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

The claim is indefinite because the language “a subject in need thereof” renders the claim incomplete as it fails to identify the scope of those subjects (i.e. the patient population) that is “in need” of being administered the injectable pharmaceutical emulsion recited in Claim 29. As such because the scope of said subject is not defined the metes and bounds of those subjects in need thereof cannot be determined.

Applicant may overcome this ground of rejection by amending Claim 29 by incorporating the limitations of Claim 44.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all

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requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to

<http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 29 – 37 and 40 – 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 12 – 21 of US patent 9,561,229 and Claims 1 – 15 of US patent 9,808,465.

The instant claims and the claims of the US patents each recite a method for treating nausea and vomiting in a subject in need thereof comprising administering to the subject an injectable pharmaceutical emulsion comprising egg yolk lecithin, soybean oil, sodium oleate, ethanol and a tonicity agent (sucrose) in a pH that ranges from 7.5 to 9.0, and in amounts and/or ratios that at least overlap with one another, and thus render said amounts and/or ratios *prima facie* obvious.

The difference between the instant and US patent claims is that the active pharmaceutical ingredient in the instant claims is a neurokinase-1 (NK-1) receptor antagonist (e.g. the elected NK-1 antagonist rolapitant), while the active pharmaceutical ingredient in the US patent claims is aprepitant.

As evidenced by instant Claims 43, aprepitant is a neurokinase-1 antagonist. Further, as disclosed by Curran *et al.* in *Drugs* 69(13):1853 – 1878 (2009), aprepitant (Emend®) is a known neurokinin-1 (NK-1) antagonist compound which is used therapeutically to prevent chemotherapy-induced nausea and vomiting (CINV, Abstract). Moreover, as disclosed and claimed by Wan *et al.* in US 2011/0038925, intravenous formulations of neurokinin-1 antagonist of Formula I (rolapitant) are known to treat CINV.

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It would have been *prima facie* obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the neurokinin-1 (NK-1) antagonist compound aprepitant in the claimed method of the US patents with an alternative instantly claimed neurokinin-1 antagonist such as the NK-1 antagonist of Formula I (rolapitant) in Wan. One would have been motivated to do so, with a reasonable and predictable expectation of success because both compounds are art-recognized (Curran and Wan) to prevent chemotherapy-induced nausea and vomiting (CINV). See MPEP 2143, KSR Exemplary Rationale B) Simple substitution of one known element for another to obtain predictable results.

### **Conclusion**

Claims 29 – 37 and 40 – 45 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on 7-7 EST Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WINSTON SHEN can be reached at (571)272-3157. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1628

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/DENNIS HEYER/  
Primary Examiner, Art Unit 1628

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:

Ottoboni et al.

APPLICATION No.: 15/965,638

FILED: APRIL 27, 2018

FOR: **EMULSION FORMULATIONS OF AN NK-1  
RECEPTOR ANTAGONIST AND USES  
THEREOF**

EXAMINER: DENNIS HEYER

ART UNIT: 1628

CONF. No.: 6067

Mail Stop AMENDMENT  
Commissioner for Patents  
U.S. Patent & Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. §1.111**

Dear Commissioner:

This paper responds to the Non-final Office Action mailed March 19, 2019, please amend the application as follows:

**Amendments to the Claims** begin at page 2 of this paper.

**Remarks** begin after the amendment section of this paper.

**AMENDMENTS TO THE CLAIMS**

This list of claims will replace all prior version and listing of claims in this application.

1.-28. (Cancelled)

29. (Currently Amended) A method for treating a subject ~~in need thereof~~, comprising administering to the subject an injectable pharmaceutical emulsion, wherein the emulsion comprises:

- a neurokinase-1 (NK-1) receptor antagonist;
- 11 wt/wt% to 15 wt/wt% of an emulsifier;
- an oil;
- a co-surfactant which comprises an alcohol;
- a tonicity agent;
- a pH modifier; and
- water;

wherein the pH of the emulsion ranges from about 7.5 to 9.0, and the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%), and wherein the subject is at risk of or is suffering from nausea and/or vomiting.

30. (Previously Presented) The method according to claim 29, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%).

31. (Previously Presented) The method according to claim 29, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%).

32. (Previously Presented) The method according to claim 29, wherein the ratio of emulsifier to oil ranges from about 1:1 to 3:1 (wt/wt%).

33. (Previously Presented) The method according to claim 29, wherein the emulsifier is a phospholipid.

34. (Previously Presented) The method according to claim 29, wherein the emulsifier is an egg lecithin.

35. (Previously Presented) The method according to claim 29, wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase.

36. (Previously Presented) The method according to claim 29, wherein the NK-1 receptor antagonist is selected from the group consisting of rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant.

37. (Previously Presented) The method according to claim 29, wherein the pH modifier is oleic acid or a salt thereof.

38. (Withdrawn) The method according to claim 29, wherein the pH modifier is a buffer.

39. (Withdrawn) The method according to claim 38, wherein the buffer is Tris buffer.

40. (Previously Presented) The method according to claim 29, wherein the oil is soybean oil.

41. (Previously Presented) The method according to claim 29, wherein the alcohol is ethanol.

42. (Previously Presented) The method according to claim 41, wherein the ethanol is present in the emulsion at less than 10 wt/wt%.

43. (Previously Presented) The method according to claim 29, wherein the NK-1 receptor antagonist is not aprepitant.

44. (Cancelled)

45. (Previously Presented) The method according to claim 29, wherein the nausea and/or vomiting is induced by chemotherapy, surgery, or radiotherapy.

**Remarks**

**I. Claim Amendments**

Without prejudice or disclaimer, claims 1-28 were previously cancelled.

Claim 44 is cancelled herein without prejudice or disclaimer.

Claim 29 is amended to incorporate the element of claim 44.

Upon entry of this paper, claims 29-37, 40-43, and 45 are under examination; claims 38 and 39 are withdrawn for being directed to non-elected subject matter.

**II. Claim Rejections – 35 U.S.C. §112**

Claims 29-43 are rejected under 35 U.S.C. §112(b) for allegedly being indefinite. Specifically, the Office contends that the term “a subject in need thereof” renders the scope of the claim unclear. Applicant respectfully disagrees.

However, solely to advance prosecution, Applicant has amended claim 29 to incorporate the elements of claim 44 as suggested by the Office. This rejection therefore should be withdrawn.

**III. Double Patenting**

Claims 29-37 and 40-45 are rejected on the ground of non-statutory obviousness-type double patenting over claims 12-21 of U.S. Patent No. 9,561,229 and claims 1-15 of U.S. Patent No. 9,808,465.

Applicant hereby submits a terminal disclaimer to render moot these double patenting rejections.

**IV. Conclusion**

The Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-0417.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 815-7399.

Respectfully submitted,

Dated: September 18, 2019

/Wen Li/  
Wen Li, Ph.D.  
Registration No. 62,185

Correspondence Address:  
Customer No. 108547

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:

Ottoboni et al.

APPLICATION No.: 15/965,638

FILED: APRIL 27, 2018

FOR: **EMULSION FORMULATIONS OF AN NK-1  
RECEPTOR ANTAGONIST AND USES  
THEREOF**

EXAMINER: DENNIS HEYER

ART UNIT: 1628

CONF. No.: 6067

Mail Stop AMENDMENT  
Commissioner for Patents  
U.S. Patent & Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. §1.111**

Dear Commissioner:

This paper responds to the Non-final Office Action mailed March 19, 2019, please amend the application as follows:

**Amendments to the Claims** begin at page 2 of this paper.

**Remarks** begin after the amendment section of this paper.

**AMENDMENTS TO THE CLAIMS**

This list of claims will replace all prior version and listing of claims in this application.

1.-28. (Cancelled)

29. (Currently Amended) A method for treating a subject ~~in need thereof~~, comprising administering to the subject an injectable pharmaceutical emulsion, wherein the emulsion comprises:

- a neurokinase-1 (NK-1) receptor antagonist;
- 11 wt/wt% to 15 wt/wt% of an emulsifier;
- an oil;
- a co-surfactant which comprises an alcohol;
- a tonicity agent;
- a pH modifier; and
- water;

wherein the pH of the emulsion ranges from about 7.5 to 9.0, and the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%), and wherein the subject is at risk of or is suffering from nausea and/or vomiting.

30. (Previously Presented) The method according to claim 29, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%).

31. (Previously Presented) The method according to claim 29, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%).

32. (Previously Presented) The method according to claim 29, wherein the ratio of emulsifier to oil ranges from about 1:1 to 3:1 (wt/wt%).

33. (Previously Presented) The method according to claim 29, wherein the emulsifier is a phospholipid.

34. (Previously Presented) The method according to claim 29, wherein the emulsifier is an egg lecithin.

35. (Previously Presented) The method according to claim 29, wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase.

36. (Previously Presented) The method according to claim 29, wherein the NK-1 receptor antagonist is selected from the group consisting of rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant.

37. (Previously Presented) The method according to claim 29, wherein the pH modifier is oleic acid or a salt thereof.

38. (Withdrawn) The method according to claim 29, wherein the pH modifier is a buffer.

39. (Withdrawn) The method according to claim 38, wherein the buffer is Tris buffer.

40. (Previously Presented) The method according to claim 29, wherein the oil is soybean oil.

41. (Previously Presented) The method according to claim 29, wherein the alcohol is ethanol.

42. (Previously Presented) The method according to claim 41, wherein the ethanol is present in the emulsion at less than 10 wt/wt%.

43. (Previously Presented) The method according to claim 29, wherein the NK-1 receptor antagonist is not aprepitant.

44. (Cancelled)

45. (Previously Presented) The method according to claim 29, wherein the nausea and/or vomiting is induced by chemotherapy, surgery, or radiotherapy.

**Remarks**

**I. Claim Amendments**

Without prejudice or disclaimer, claims 1-28 were previously cancelled.

Claim 44 is cancelled herein without prejudice or disclaimer.

Claim 29 is amended to incorporate the element of claim 44.

Upon entry of this paper, claims 29-37, 40-43, and 45 are under examination; claims 38 and 39 are withdrawn for being directed to non-elected subject matter.

**II. Claim Rejections – 35 U.S.C. §112**

Claims 29-43 are rejected under 35 U.S.C. §112(b) for allegedly being indefinite. Specifically, the Office contends that the term “a subject in need thereof” renders the scope of the claim unclear. Applicant respectfully disagrees.

However, solely to advance prosecution, Applicant has amended claim 29 to incorporate the elements of claim 44 as suggested by the Office. This rejection therefore should be withdrawn.

**III. Double Patenting**

Claims 29-37 and 40-45 are rejected on the ground of non-statutory obviousness-type double patenting over claims 12-21 of U.S. Patent No. 9,561,229 and claims 1-15 of U.S. Patent No. 9,808,465.

Applicant hereby submits a terminal disclaimer to render moot these double patenting rejections.

**IV. Conclusion**

The Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-0417.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 815-7399.

Respectfully submitted,

Dated: September 18, 2019

/Wen Li/  
Wen Li, Ph.D.  
Registration No. 62,185

Correspondence Address:  
Customer No. 108547



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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NOTICE OF ALLOWANCE AND FEE(S) DUE

108547 7590 12/16/2019
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001

Table with 2 columns: EXAMINER (HEYER, DENNIS), ART UNIT (1628), PAPER NUMBER

DATE MAILED: 12/16/2019

Table with 5 columns: APPLICATION NO. (15/965,638), FILING DATE (04/27/2018), FIRST NAMED INVENTOR (Thomas B. Ottoboni), ATTORNEY DOCKET NO. (092459-0223/8032.US00), CONFIRMATION NO. (6067)

TITLE OF INVENTION: EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST AND USES THEREOF

Table with 7 columns: APPLN. TYPE (nonprovisional), ENTITY STATUS (SMALL), ISSUE FEE DUE (\$500), PUBLICATION FEE DUE (\$0.00), PREV. PAID ISSUE FEE (\$0.00), TOTAL FEE(S) DUE (\$500), DATE DUE (03/16/2020)

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies. If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above. If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)". For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

**PART B - FEE(S) TRANSMITTAL**

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: **Mail Stop ISSUE FEE**  
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By fax, send to: **(571)-273-2885**

**INSTRUCTIONS:** This form should be used for transmitting the **ISSUE FEE** and **PUBLICATION FEE** (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

108547                      7590                      12/16/2019  
**McDermott Will & Emery LLP**  
**500 North Capitol Street NW**  
**Washington, DC 20001**

**Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/965.638	04/27/2018	Thomas B. Ottoboni	092459-0223/8032.US00	6067

TITLE OF INVENTION: EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST AND USES THEREOF

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0.00	\$0.00	\$500	03/16/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
HEYER, DENNIS	1628	514-125000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE \_\_\_\_\_ (B) RESIDENCE: (CITY and STATE OR COUNTRY) \_\_\_\_\_

Please check the appropriate assignee category or categories (will not be printed on the patent) :  Individual  Corporation or other private group entity  Government

4a. Fees submitted:  Issue Fee  Publication Fee (if required)  Advance Order - # of Copies \_\_\_\_\_

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

- Electronic Payment via EFS-Web  Enclosed check  Non-electronic payment by credit card (Attach form PTO-2038)
- The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. \_\_\_\_\_

5. Change in Entity Status (from status indicated above)

- Applicant certifying micro entity status. See 37 CFR 1.29
- Applicant asserting small entity status. See 37 CFR 1.27
- Applicant changing to regular undiscounted fee status.

**NOTE:** Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

**NOTE:** If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

**NOTE:** Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

**NOTE:** This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 15/965,638 filed 04/27/2018 by Thomas B. Ottoboni, attorney McDermott Will & Emery LLP.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

<b>Notice of Allowability</b>	<b>Application No.</b> 15/965,638	<b>Applicant(s)</b> Ottoboni et al.	
	<b>Examiner</b> DENNIS HEYER	<b>Art Unit</b> 1628	<b>AIA (FITF) Status</b> Yes

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to remarks, claim amendments and the terminal disclaimer filed 9/18/2019.  
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
2.  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
3.  The allowed claim(s) is/are 29-43 and 45 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a)  All      b)  Some      \*c)  None of the:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
 including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_ .  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Examiner's Amendment/Comment                             |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>9/18/2019</u> . | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material _____.               | 7. <input type="checkbox"/> Other _____.   |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date. _____.   |  |

/DENNIS HEYER/  
Primary Examiner, Art Unit 1628

Art Unit: 1628

*The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.*

## **DETAILED ACTION**

Acknowledgement is made of Applicant's remarks and amendments in the response filed September 18, 2019. Acknowledgement is made of Applicant's cancellation of Claim 44.

### ***Priority***

This application, 15/965,638, filed 04/27/2018 is a division of 15/012,532, filed 02/01/2016, now U.S. Patent 9,974,742.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on September 18, 2019 was filed after the mailing date of the non-Final Office Action on March 19, 2019. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### ***Terminal Disclaimer***

The terminal disclaimer filed on September 18, 2019 disclaiming the terminal portion of any patent granted on this application which would extend beyond the

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expiration date of US patents 9,561,229 and 9,808,465 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### **Withdrawn Rejections**

#### ***Claim rejections – 35 USC § 112***

The rejection of Claims 29 – 43 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite is rendered moot and is withdrawn in response to Applicant's amendment incorporating the limitation of Claim 44 into independent Claim 29.

#### ***Double Patenting***

The rejection of Claims 29 – 37 and 40 – 45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 12 – 21 of US patent 9,561,229 and Claims 1 – 15 of US patent 9,808,465 is withdrawn in response to the Terminal Disclaimer filed on September 18, 2019 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patents 9,561,229 and 9,808,465.

#### ***Rejoinder***

It is noted that upon the allowance of a generic claim, applicant is entitled to claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. Accordingly,

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method Claims 38 and 39 previously withdrawn in reply to the response to the election/restriction requirement filed March 19, 2019, are rejoined with the allowed method Claims 29 – 37, 40 – 43 and 45.

Because a claimed specie previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the specie election requirement as set forth in the Office action mailed on January 11, 2019 is hereby withdrawn.** In view of the withdrawal of the specie election requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the specie election requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: The claimed subject matter drawn to a method for treating a subject, comprising administering to the subject an injectable pharmaceutical emulsion, wherein the emulsion comprises: a neurokinase-1 (NK-1) receptor antagonist; 11 wt/wt% to 15 wt/wt% of an emulsifier; an oil; a co-surfactant which comprises an alcohol; a tonicity agent; a pH modifier; and water; wherein the pH of the emulsion ranges from about 7.5 to 9.0, and the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%) and

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wherein the subject is at risk of or is suffering from nausea and/or vomiting; is allowed as being neither anticipated by nor obvious over the closest prior art.

Zhou *et al.* in CN 102379845 (IDS dated 10/8/2018, Foreign Patent Cite No. 12) is representative of the closest prior art. Zhou teaches injectable emulsion formulations comprising the NK-1 antagonist aprepitant, the emulsifier egg lecithin, the oil, soybean oil, glycerin (a tonicity agent), the alcohol, ethanol and a pH modifier, wherein the NK-1 antagonist aprepitant is used to treat patients at risk of vomiting (emesis) induced by cancer chemotherapy. However, the ratio of emulsifier to aprepitant (the NK-1 antagonist) is significantly below the ratio required by the claimed invention. Accordingly, there would have been no motivation by one of ordinary skill to modify the ratio to those recited by the claimed invention.

Further, as discussed in the Declaration submitted by Thomas Ottoboni (heretofore the "Ottoboni Declaration") in US application serial No. 15/083,071 (now US patent 9,561,229) cited by Applicant in the Remarks filed 9/6/2017 of said US application, the claimed injectable emulsion formulations exhibit surprising and unexpected properties compared to the emulsions of Zhou (Example 4, disclosed in the instant specification) which contains less than 11 wt/wt% of the emulsifier egg yolk lecithin (specifically, 9.95 wt/wt%; outside the scope of the claimed invention) results in crystal formation 4 days after preparation at room temperature. By comparison, Examples 1, 2, 3 and 6 (Table 7, pages 31 – 32 of the present specification) which contain between 11.7 and 14.3 wt/wt% of the emulsifier (within the range recited in instant Claim 1) were stable; i.e. no observable crystal formation after storage at room temperature for at least 2 months.

As such, the claimed emulsion formulations exhibit stability that is surprising and unexpected compared to the closest prior art. See MPEP 716.02(b): Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

*\*It is noted that, in order to further clarify the record, Applicant should submit a copy of the Ottoboni Declaration into the prosecution file history of this application.*

### **Conclusion**

Claims 29 – 43 and 45 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on 7-7 EST Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WINSTON SHEN can be reached at (571)272-3157. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/DENNIS HEYER/

Primary Examiner, Art Unit 1628