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Title of Invention:	METHODS OF USE OF EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST
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37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

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37 CFR 1.19 (Document supply fees)
 37 CFR 1.20 (Post Issuance fees)
 37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	New_POA_to_File.pdf	107291	no	1
			e30ffefea5db5c33a42b87aacd789d82f2e8d0c		
Warnings:					
Information:					
2	Oath or Declaration filed	Parent_Signed_Declarations.pdf	184417	no	2
			035394277d6bf4f69e7a5488f23988b93431e3c4		
Warnings:					
Information:					
3	Drawings-only black and white line drawings	Drawings.pdf	254515	no	4
			b97566b275ae1919ac83dbd35adfb2ca72b46927		
Warnings:					
Information:					
4		0340_Specification.pdf	287619	yes	45
			0fe16ccd37f520d194786546da8ae9a349070556		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Abstract		45	45	
	Claims		43	44	
	Specification		1	42	
Warnings:					
Information:					
5	Assignee showing of ownership per 37 CFR 3.73	373c_to_file.pdf	535249	no	8
			f110ca3b356858a9192f76b06326a9c71a3e2d2f5		

Warnings:					
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6	Application Data Sheet	ADS.pdf	1822758 b5cb979b6047a124e7f2d18d9e954a00c8350639	no	9
Warnings:					
Information:					
7	Transmittal of New Application	Application_Transmittal.pdf	265349 c6a9a03f69ce88847c7101085239a184a70cc19b4	no	1
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	35098 89ca33bd7a471a1931f00fd53c14c9eb80bf96f1	no	2
Warnings:					
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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.

WHAT IS CLAIMED IS:

1. A method for preventing post-operative nausea and vomiting in a subject, comprising:
administering an injectable pharmaceutical emulsion comprising:
a neurokinase-1 (NK-1) receptor antagonist;
an emulsifier;
an oil;
a co-surfactant; and
an aqueous phase,
wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%).
2. The method according to claim 1, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%).
3. The method according to claim 1, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%).
4. The method according to claim 1, wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier.
5. The method according to claim 1, wherein the emulsifier is a phospholipid.
6. The method according to claim 1, wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase.
7. The method according to claim 1, wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant.
8. The method according to claim 1, wherein the pH modifier is oleic acid or a salt thereof.
9. The method according to claim 1, wherein the pH modifier is a buffer.
10. The method according to claim 9, wherein the buffer is Tris buffer.

11. The method according to claim 1, wherein the oil is soybean oil.
12. The method according to claim 1, wherein the alcohol is ethanol.
13. The method according to claim 12, wherein the ethanol is present in the emulsion at less than 10 wt/wt%.
14. The method according to claim 1, wherein the NK-1 receptor antagonist is aprepitant.



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for Thomas B. Ottoboni and examiner information for ABDALHAMEED, MANAHIL MIRGHANI ALI.

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):

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Priority

This application, filed on 02/19/2021, is a continuation of U.S. Application No. 16/820,311, filed 03/16/2020 (now U.S. Patent No. 11,173,118) which is a continuation of U.S. Application No. 15/965,638, filed 04/27/2018 (now U.S. Patent No. 10,624,850), which is a continuation of U.S. Application No. 15/012,532, filed 02/1/2016 (now U.S. Patent No. 9,974,742).

Information Disclosure Statement

The information disclosure statement (IDS) filed on 05/19/2021, complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits, except where noted.

Claim Objections

Claim is objected to because of the following informalities:

Claim 1 recites a "neurokinase-1 (NK-1)". It appears that the recitation "neurokinase" is a typographical error and the claim intended to recite neurokinin-1 (NK-1).

Appropriate correction is required.

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 conflicting claims 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); *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 nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b). The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon

submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-5, 7-9, and 11-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 9561229B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US9561229B2 recited in claims 1-21 an injectable pharmaceutical emulsion comprising 0.4 wt/wt % to 1.0 wt/wt % aprepitant; 13 wt/wt % to 15 wt/wt % egg yolk lecithin; 9 wt/wt % to 10 wt/wt % soybean

oil; and a pH modifier, wherein the pH modifier is sodium oleate; wherein the pH of the emulsion ranges from 7.5 to 9.0, wherein the emulsion comprises 0.7 wt/wt % aprepitant, wherein the emulsion comprises 14 wt/wt % egg yolk lecithin, wherein the emulsion further comprises 3 wt/wt % to 8 wt/wt % sucrose, wherein the emulsion further comprises 2 wt/wt % to 6 wt/wt % ethanol. US9561229B2 further recited a method for treating nausea and vomiting in a subject in need thereof comprising administering to the subject the pharmaceutical emulsion according to claim 1, wherein the nausea and vomiting is chemotherapy induced nausea and vomiting, wherein the administering is intravenous. The US9561229B2 ratio of egg yolk lecithin to aprepitant appears to meet the claimed ratio of 18:1 to 22:1. Therefore, the conflicting claims 1-21 of US9561229B2 meets the limitations of instant claims 1-5, 7-9, and 11-14.

Claims 1-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 9808465B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist

is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US9808465B2 recited in claims 1-15, a method for preventing or treating a subject at risk of or suffering from emesis, comprising administering to the subject a composition comprising an injectable physically stable emulsion wherein the emulsion comprises aprepitant; 11 wt/wt % to 15 wt/wt % of an emulsifier; an oil; a co-emulsifier which is an alcohol; a tonicity modifier; a pH modifier; and water; wherein the ratio of emulsifier : aprepitant ranges from about 18:1 to 22:1, and wherein the pH of the emulsion ranges from about 7.5 to 9.0, wherein the emesis is induced by chemotherapy, wherein the ratio of the oil to the aprepitant within the oil phase of the emulsion ranges from about 10:1 to 15:1 (wt/wt %), wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the emulsifier is an egg lecithin, wherein the pH modifier is sodium oleate; wherein the buffer is Tris buffer; wherein the oil is soybean oil, wherein the alcohol in the emulsion is ethanol, and wherein the tonicity modifier in the emulsion is sucrose. Therefore, the conflicting claims 1-15 of US9808465B2 meets the limitations of instant claims 1-14.

Claims 1-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 9974742B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US9974742B2 recited in claims 1-14, an injectable pharmaceutical emulsion comprising 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 %), wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt %), wherein the emulsifier is an egg lecithin; wherein the emulsion further comprising dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant,

befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof, wherein the pH modifier is Tris buffer; wherein the oil is soybean oil, wherein the alcohol is ethanol, wherein the ethanol is present in the emulsion at less than 10 wt/wt %. Therefore, the conflicting claims 1-14 of US9974742B2 meets the limitations of instant claims 1-14.

Claims 1-5, 7-9, and 11-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 9974793B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US9974793B2 recited in claims 1-22, a physically stable pharmaceutical composition, comprising aprepitant; an emulsifier; an oil; and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1, wherein the ratio of the oil to aprepitant (wt %:wt %) ranges from about 11:1 to 15:1, wherein the composition is an emulsion; wherein the composition comprises 0.4 wt/wt % to 1.0 wt/wt % aprepitant; wherein the composition comprises 0.7 wt/wt % aprepitant; wherein the composition comprises 11 wt/wt % to 15 wt/wt % emulsifier; wherein the composition comprises 14 wt/wt % emulsifier; wherein the emulsifier is egg yolk lecithin; wherein the composition comprises 9 wt/wt % to 10 wt/wt % oil; wherein the oil is soybean oil; wherein the composition further comprises sodium oleate as a pH modifier; wherein the pH of the composition ranges from 7.5 to 9.0; wherein composition further comprises 3 wt/wt % to 8 wt/wt % sucrose; wherein the composition further comprises 5 wt/wt % sucrose, wherein the composition further comprises 2 wt/wt % to 6 wt/wt % ethanol. Therefore, the conflicting claims 1-22 of US9974793B2 meets the limitations of instant claims 1-5, 7-9, and 11-14.

Claims 1-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 10500208B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the

ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US10500208B2 recited in claims 1-13, an injectable emulsion comprising aprepitant; 11 wt/wt % to 15 wt/wt % of an emulsifier; an oil; a co emulsifier which is an alcohol; a tonicity modifier; a pH modifier; and water; wherein the pH of the emulsion ranges from about 7.5 to 9.0, wherein the emulsion is physically stable, wherein the ratio of the oil to the aprepitant in the emulsion ranges from about 11:1 to 15:1 (wt/wt %); further comprising dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the ratio of the emulsifier to the aprepitant in the emulsion ranges from about 15:1 to 30:1 (wt/wt %), wherein the ratio of emulsifier to oil ranges from about 1:1 to 3:1 (wt/wt %), wherein the emulsifier is an egg lecithin, further comprising a buffer, wherein the pH modifier is sodium oleate, wherein the buffer is Tris buffer; wherein the oil is soybean oil, wherein the alcohol is ethanol. Therefore, the conflicting claims 1-13 of US10500208B2 meets the limitations of instant claims 1-14.

Claims 1-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 10624850B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US10624850B2 recited in claims 1-6, 9, and 12-16 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 wherein the subject is at risk of or is suffering from nausea and/or vomiting; wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt %); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt %); wherein the ratio of emulsifier to oil ranges from about 1:1 to 3:1 (wt/wt %); wherein the emulsifier is an egg lecithin; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is Tris buffer; wherein the oil is soybean oil; wherein the alcohol is ethanol; wherein the nausea and/or vomiting is induced by chemotherapy, surgery, or radiotherapy. Therefore, the conflicting claims 1-14 of US10624850B2 meets the limitations of instant claims 1-14.

Claims 1-5, 7-9, and 11-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 10953018B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a

phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US10953018B2 recited in claims 1-18, a method for treating nausea and vomiting in a subject in need thereof comprising administering to the subject a physically stable pharmaceutical composition, comprising aprepitant; an emulsifier; an oil; and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1; wherein the ratio of the oil to aprepitant (wt %:wt %) ranges from about 11:1 to 15:1, and wherein the composition is an emulsion; wherein the nausea and vomiting is chemotherapy induced nausea and vomiting; wherein the administering is intravenous; wherein the composition comprises 0.4 wt/wt % to 1.0 wt/wt % aprepitant; wherein the composition comprises 0.7 wt/wt % aprepitant; wherein the composition comprises 11 wt/wt % to 15 wt/wt % emulsifier; wherein the emulsifier is egg yolk lecithin; wherein the composition comprises 9 wt/wt % to 10 wt/wt % oil; wherein the oil is soybean oil; wherein the composition further comprises sodium oleate as a pH modifier; wherein the pH of the composition ranges from 7.5 to 9.0; wherein the composition further comprises 3 wt/wt % to 8 wt/wt % sucrose. Therefore, the conflicting claims 1-18 of US10953018B2 meets the limitations of instant claims 1-5, 7-9, and 11-14.

Claims 1-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 11173118B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

US11173118B2 recited in claims 1-8, 11-12, and 14-17, an injectable pharmaceutical emulsion comprising, a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase; wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt %); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt %); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to

15:1 (wt/wt %); wherein the aqueous phase comprises water and a tonicity agent; wherein the aqueous phase further comprises a pH modifying agent; wherein the ratio of emulsifier to oil ranges from about 1:1 to 3:1 (wt/wt %); wherein the emulsifier is an egg lecithin; wherein the emulsion further comprising dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is an oleate or a salt thereof; wherein the pH modifier is Tris buffer; wherein the pH modifier is a buffer; wherein the oil is soybean oil; wherein the co-surfactant is ethanol. Therefore, the conflicting claims 1-17 of US11173118B2 meets the limitations of instant claims 1-14.

Claims 1-14 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19, 21-28 of copending Application No. 17/194,114. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist

is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

Copending Application No. 17/194,114 recites in claims 1-28, a method for preventing nausea and vomiting in a subject in need thereof, comprising administering to the subject a physically stable pharmaceutical composition comprising aprepitant; an emulsifier; an oil; and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1, wherein the ratio of the oil to aprepitant (wt %:wt %) ranges from about 11:1 to 15:1, and wherein the composition is an emulsion; wherein the nausea and vomiting is chemotherapy induced nausea and vomiting; wherein the administering is intravenous; wherein the composition comprises 11 wt/wt % to 15 wt/wt % emulsifier; wherein the emulsifier is egg yolk lecithin; wherein the emulsion further comprising dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in an aqueous phase of the emulsion; wherein the composition comprises 9 wt/wt % to 10 wt/wt % oil; wherein the oil is soybean oil; wherein the composition further comprises sodium oleate as a pH modifier; wherein the composition further comprises 3 wt/wt % to 8 wt/wt % sucrose; wherein the composition further comprises 2 wt/wt % to 6 wt/wt % ethanol. Therefore, the conflicting claims 1-28 of Copending Application No. 17/194,114 meets the limitations of instant claims 1-14.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 1-5, 8, and 11-14, are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-30 of copending Application No. 17/979,577. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-14 recite a method for preventing post-operative nausea and vomiting in a subject, comprising: administering an injectable pharmaceutical emulsion comprising: a neurokinase-1 (NK-1) receptor antagonist; an emulsifier; an oil; a co-surfactant; and an aqueous phase, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt%); wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 10:1 to 15:1 (wt/wt%); wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase; wherein the NK-1 receptor antagonist is selected from the group consisting of aprepitant, rolapitant, netupitant, ezlopitant, vestipitant, serlopitant, maropitant, casopitant, befetupitant, and orvepitant; wherein the pH modifier is oleic acid or a salt thereof; wherein the pH modifier is a buffer; wherein the buffer is Tris buffer; wherein the oil is soybean oil; the alcohol is ethanol; wherein the ethanol is present in the emulsion at less than 10 wt/wt%; and wherein the NK-1 receptor antagonist is aprepitant.

Copending Application No. 17/979,577 recites in claims 1-30 recite an injectable pharmaceutical emulsion comprising aprepitant, about 14 wt/wt % to 15 wt/wt % egg lecithin; about 9 wt/wt % to 10 wt/wt % soybean oil; about 2 wt/wt % to 3 wt/wt ethanol; about 3 wt/wt % to 8 wt/wt % sucrose; about 0.4 wt/wt % to 0.5 wt/wt % sodium oleate; wherein the ratio of the egg lecithin to aprepitant ranges from

about 18:1 to 22:1 (wt/wt %); wherein the ratio of soybean oil to aprepitant ranges from about 13:1 to 14:1 wt/wt %; and wherein the ratio of (egg lecithin plus soybean oil) to aprepitant ranges from about 32:1 to 34:1. Copending Application No. 17/979,577 recites a method for preventing post-operative nausea and vomiting in a subject, comprising intravenously administering the injectable pharmaceutical emulsion of claim 1. Therefore, the conflicting claims 1-30 of Copending Application No. 17/979,577 meets the limitations of instant claims 1-5, 8, and 11-14

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANAHIL MIRGHANI ALI ABDALHAMEED whose telephone number is (571)272-1242. The examiner can normally be reached M-F 7:30 am - 5:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and

Art Unit: 1622

<https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M.M.A./

Examiner, Art Unit 1622

/BRANDON J FETTEROLF/

Supervisory Patent Examiner, Art Unit 1622

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: THOMAS B. OTTOBONI, *ET AL.*

APPLICATION NO.: 17180593

FILED: FEBRUARY 19, 2021

FOR: METHODS OF USE OF EMULSION
FORMULATIONS OF AN NK-1 RECEPTOR
ANTAGONIST

EXAMINER: ABDALHAMEED,
MANAHIL MIRGHANI ALI

ART UNIT: 1622

CONF. NO.: 1222

Amendment Under 37 C.F.R. § 1.111

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

Sir:

The present communication responds to the Office Action dated May 4, 2023 in the above-identified application.

Please amend the application as follows:

Amendments to the Claims begin on page 2.

Remarks begin on page 4.

[The remainder of this page is intentionally left blank.]

Amendments to the Claims

The following Listing of Claims, in which deleted text appears ~~struck through~~ or [[double-bracketed]] and inserted text appears underlined, will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A method for preventing post-operative nausea and vomiting in a subject, comprising:

administering an injectable pharmaceutical emulsion comprising:

a neurokinin-1 ~~neurokinase-1~~ (NK-1) receptor antagonist;

an emulsifier;

an oil;

a co-surfactant; and

an aqueous phase,

wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt%).

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

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

4. (Original) The method according to claim 1, wherein the emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier.

5. (Original) The method according to claim 1, wherein the emulsifier is a phospholipid.

6. (Original) The method according to claim 1, wherein the emulsion further comprises dexamethasone sodium phosphate, wherein the dexamethasone sodium phosphate is present in the aqueous phase.

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

8. (Original) The method according to claim 1, wherein the pH modifier is oleic acid or a salt thereof.

9. (Original) The method according to claim 1, wherein the pH modifier is a buffer.

10. (Original) The method according to claim 9, wherein the buffer is Tris buffer.

11. (Original) The method according to claim 1, wherein the oil is soybean oil.

12. (Original) The method according to claim 1, wherein the alcohol is ethanol.

13. (Original) The method according to claim 12, wherein the ethanol is present in the emulsion at less than 10 wt/wt%.

14. (Original) The method according to claim 1, wherein the NK-1 receptor antagonist is aprepitant.

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated May 4, 2023 are respectfully requested.

I. Amendments

Claim 1 is amended to correct a typographical error. Claims 1-14 are pending in the application. No new matter has been added.

II. Claim Objections

Claim 1 was objected to for a typographical error. Applicant has amended claim 1 to recite “neurokinin-1”. Therefore, withdrawal of the objection is respectfully requested.

III. Double-Patenting Rejections

Claims 1-5, 7-9, and 11-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 9,561,229 B2.

Claims 1-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 9,808,465 B2.

Claims 1-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 9,974,742 B2.

Claims 1-5, 7-9, and 11-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 9,974,793 B2.

Claims 1-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 10,500,208 B2.

Claims 1-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 10,624,850 B2.

Claims 1-5, 7-9, and 11-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 10,953,018 B2.

Claims 1-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 11,173,118 B2.

Claims 1-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19 and 21-28 of copending Application No. 17/194,114.

Claims 1-5, 8, and 11-14 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-30 of copending Application No. 17/979,577.

The Examiner noted that a timely filed Terminal Disclaimer in compliance with 36 C.F.R. §1.321(c) would overcome an actual or provisional rejection on this ground. Without conceding to the validity of these rejections, Applicant herewith submits an executed Terminal Disclaimer filed in accordance with C.F.R. §1.321(b) and (c) which disclaims the terminal portion of any Patent issuing on the instant application that extends beyond the expiration of U.S. Patent Nos.: 9,561,229 B2; 9,808,465 B2; 9,974,742 B2; 9,974,793 B2; 10,500,208 B2; 10,624,850 B2; 10,953,018 B2; 11,173,118 B2 and beyond the expiration of any patent that issues from U.S. Patent Application Nos. 17/194,114 and 17/979,577.

The applicant submits that the Terminal Disclaimer filed herewith overcomes the rejections for obviousness-type double patenting. Therefore, withdrawal of the rejections is respectfully requested.

IV. Conclusion

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

In view of the foregoing, a Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 815-7630.

Respectfully submitted,
MCDERMOTT WILL & EMERY LLP

Date August 2, 2023

/Judy Mohr/

Judy Mohr
Registration No. 38,563

Correspondence Address:
Customer No. 108547



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NOTICE OF ALLOWANCE AND FEE(S) DUE

108547 7590 09/11/2023
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001-1531

Table with 2 columns: EXAMINER, ART UNIT, PAPER NUMBER. Values: ABDALHAMEED, MANAHIL MIRGHANI ALI; 1622

DATE MAILED: 09/11/2023

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Values: 17/180,593; 02/19/2021; Thomas B. Ottoboni; 092459-0340/8032.US02; 1222

TITLE OF INVENTION: METHODS OF USE OF EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE. Values: nonprovisional; SMALL; \$480; \$0.00; \$0.00; \$480; 12/11/2023

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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.

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

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108547 7590 09/11/2023
McDermott Will & Emery LLP
 500 North Capitol Street NW
 Washington, DC 20001-1531

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.
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17/180,593 02/19/2021 Thomas B. Ottoboni 092459-0340/8032.US02 1222

TITLE OF INVENTION: METHODS OF USE OF EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional SMALL \$480 \$0.00 \$0.00 \$480 12/11/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
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ABDALHAMEED, 1622 424-400000

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/AIA/122 or PTO/SB/122) attached.
- "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 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 _____
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- 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)

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

- Electronic Payment via Patent Center or EFS-Web Enclosed check Non-electronic payment by credit card (Attach form PTO-2038)
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- Applicant changing to regular undiscounted fee status.

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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.

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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.

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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 17/180,593 filed 02/19/2021 by Thomas B. Ottoboni, attorney docket 092459-0340/8032.US02, confirmation 1222. Examiner: ABDALHAMEED, MANAHIL MIRGHANI ALI. Art Unit: 1622. Date Mailed: 09/11/2023.

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. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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.

Notice of Allowability	Application No. 17/180,593	Applicant(s) Ottononi et al.	
	Examiner MANAHIL M ABDALHAMEED	Art Unit 1622	AIA (FITF) Status 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 08/02/2023.
 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 1-14. 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 or send an inquiry to 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 checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____. | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material _____. | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date. _____. | |

/BRANDON J FETTEROLF/
Supervisory Patent Examiner, Art Unit 1622

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

The Amendments and Applicant's Arguments submitted on 08/02/2023 have been received and its contents have been carefully considered. Claim 1 was amended. Claims 1-14 are pending.

EXAMINER COMMENT AND REASONS FOR ALLOWANCE

Withdrawal Claim Objections

Objection of claim 1 is withdrawn in view of Applicant's amendment submitted on 08/02/2023.

Withdrawal Claim Objections – Double Patenting

Rejection of claims 1-14 rejected under the nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 9561229B2, claims 1-15 of U.S. Patent No. 9808465B2, claims 1-14 of U.S. Patent No. 9974742B2, claims 1-22 of U.S. Patent No. 9974793B2, claims 1-13 of U.S. Patent No. 10500208B2, claims 1-14 of U.S. Patent No. 10624850B2, claims 1-18 of U.S. Patent No. 10953018B2, claims 1-17 of U.S. Patent No. 11173118B2, claims 1-19, 21-28 of copending Application No. 17/194,114, and claims 1-30 of copending Application No. 17/979,577, is withdrawn in view of the Terminal Disclaimer submitted by the Applicant on 08/02/2023.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The closest prior art is considered to be W. Zhou et al. (CN102379845A, 03/21/2012).

Zhou teaches NK-1 antagonist, aprepitant microemulsion for injection, consisting of 0.05% ~ 2% aprepitant, 5% ~ 30% injection oil, 0.5% ~ 10% emulsification Agent, 1-10% emulsion aid, 5% -20% protective agent; 60-80% water for injection. Zhou teaches that the emulsifier is egg yolk phospholipid, the oil is soybean oil, and teaches that the emulsion comprises alcohol (ethanol) and a pH modifier, wherein the NK-1 antagonist aprepitant is used to treat patients at risk of vomiting induced by cancer chemotherapy.

However, Zhou's ratio of emulsifier to aprepitant (the NK-1 antagonist) is below the ratio required by the claimed invention. It appears that the amount of emulsifier is critical in the claimed emulsion because, according to the instant specification, the aprepitant emulsion possess favorable stability properties when the amount of emulsifier in the oil phase is greater than the amount of oil, wherein the amount of emulsifier have been found to impart greater stability on a final emulsion compared to a similar aprepitant emulsion with the oil phase comprises emulsifier less than the claimed amount. [Instant specification, pg. 16, 0099]. For example, the instant specification provides preparation of an alternate aprepitant emulsion, wherein the ratio of aprepitant: emulsion is 1: 14.8, wherein with 4 days post preparation, crystals were observed which indicates less stable emulsion. [Instant Specification, Example 4, pg. 28].

In order to arrive at the claimed composition, one of ordinary skill in the art would have to modify Zhou's aprepitant emulsion to increase the ratio of the emulsifier to the NK-1 receptor antagonist to about 18:1 to 22:1 (wt/wt%). However, neither Zhou's disclosure, nor this disclosure provides sufficient guidance and motivation to one of ordinary skill in the art to perform the modification to arrive at instantly claimed emulsion.

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.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANAHIL MIRGHANI ALI ABDALHAMEED whose telephone number is (571)272-1242. The examiner can normally be reached M-F 7:30 am - 5:00 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M.M.A./
Examiner, Art Unit 1622

/BRANDON J FETTEROLF/
Supervisory Patent Examiner, Art Unit 1622