

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

First Named Inventor:	Thomas B. Ottoboni	Nonprovisional Application Number (if known):	To be assigned
Title of Invention:	METHODS OF USE OF EMULSION FORMULATIONS OF AN NK-1 RECEPTOR ANTAGONIST		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via USPTO patent electronic filing system.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- A request for continued examination has been filed with, or prior to, this form.
- If the application is a utility application, this certification and request is being filed via USPTO patent electronic filing system.
- The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature <u>/Judy M. Mohr/</u>	Date <u>2024-01-19</u>
Name (Print/Typed) <u>Judy M. Mohr</u>	Practitioner Registration Number <u>38563</u>

Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*

☒ *Total of 1 forms are submitted.

**ELECTRONIC ACKNOWLEDGEMENT RECEIPT**APPLICATION #
18/418,030RECEIPT DATE / TIME
01/19/2024 06:33:42 PM Z ETATTORNEY DOCKET #
092459-0423/8032.US06**Title of Invention**

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

Application InformationAPPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 9379

FILED BY Judy Steinkraus

PATENT CENTER # 64020839

FILING DATE -

CUSTOMER # 108547

FIRST NAMED Thomas B. Ottoboni
INVENTORCORRESPONDENCE -
ADDRESS

AUTHORIZED BY Judy Mohr

Documents**TOTAL DOCUMENTS: 9**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
ADSaia0014-ADS_jls.pdf	9	Application Data Sheet	2174 KB
Track-1_aia0424.pdf	1	Track One Request	183 KB
Application_Transmittal_Nonp rov.pdf	2	Transmittal of New Application	564 KB
Parent_Signed_Declarations. pdf	2	Oath or Declaration filed	180 KB
New_POA_to_File.pdf	1	Power of Attorney	105 KB
373c_thru_2024_aia0096.pdf	6	Miscellaneous Incoming Letter	344 KB

Drawings_mdr.pdf	4	Drawings-only black and white line drawings	966 KB
0423_8032US06_Specificatio n_19 Jan 2024_jmm- APP.TEXT.docx	46	Application body structured text document	110 KB

Warning: All artifacts (SmartArt, Drawings, Charts, etc) have been replaced with images. Bookmarks were found and have been removed. Images have been detected in the abstract section. Please review. You may be missing a drawing heading.

0423_8032US06_Specificatio n_19 Jan 2024_jmm.pdf	46	Auxiliary PDF of Application	278 KB
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Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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0423_8032US06_Specification_ 19 Jan 2024_jmm- APP.TEXT.docx	FC161D96D1D4C1931DB6FAEF554CB237BC40B16986C5DA31 CA2D23D46E1640ACB9E39762D16F2776655F435B64FDD358D EA28D2A76FA62A7718785033C2BB3B2
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/418,030	01/19/2024	Thomas B. Ottoboni	092459-0423/8032.US06	9379
108547	7590	02/26/2024	EXAMINER	
McDermott Will & Emery LLP			CENTRAL, DOCKET	
500 North Capitol Street NW			ART UNIT	PAPER NUMBER
Washington, DC 20001-1531			OPAP	
			NOTIFICATION DATE	DELIVERY MODE
			02/26/2024	ELECTRONIC

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):

ipdocketmwe@mwe.com

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 18/418,030	Applicant(s) Ottoboni et al.	
	Examiner ANDREA SMITH	Art Unit OPET	AIA (FITF) Status Yes
1. THE REQUEST FILED <u>19 January 2024</u> IS GRANTED . The above-identified application has met the requirements for prioritized examination A. ☒ for an original nonprovisional application (Track I). B. ☐ for an application undergoing continued examination (RCE). 2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs: A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim; C. filing a <u>request for continued examination</u> ; D. filing a notice of appeal; E. filing a request for suspension of action; F. mailing of a notice of allowance; G. mailing of a final Office action; H. completion of examination as defined in 37 CFR 41.102; or I. abandonment of the application. Telephone inquiries with regard to this decision should be directed to ANDREA SMITH at (571)272-3226. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.			
/ANDREA M SMITH/ Lead Paralegal Specialist, OPET			



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/418,030	01/19/2024	Thomas B. Ottoboni	092459-0423/8032.US06	9379
108547	7590	04/08/2024		
McDermott Will & Emery LLP 500 North Capitol Street NW Washington, DC 20001-1531			EXAMINER ABDALHAMEED, MANAHIL MIRGHANI ALI	
			ART UNIT	PAPER NUMBER
			1622	
			NOTIFICATION DATE	DELIVERY MODE
			04/08/2024	ELECTRONIC

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):

ipdocketmwe@mwe.com

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 01/09/2024 is a continuation of U.S. Application No. 18/535,853, filed 12/11/2023, which is a continuation of U.S. Application No. 17/180,593, filed 02/19/2021 (now U.S. Patent No. 11878074), which 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 02/01/2016 (now U.S. Patent No. 9,974,742).

Information Disclosure Statement

The information disclosure statement (IDS) filed on 03/27/2024 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.

DETAILED ACTION

Claims 1-30 are pending.

Rejections 35 U.S.C. 112(b)

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.

Claims 13, 15-16, 18-19, 21, 23-29 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 applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

The claims are rejected for insufficient antecedent basis. For example, claim 13 recites “the emulsion of **claim 11**, wherein the **soybean oil** is present at a concentration of about 9 wt/wt% to 10 wt/wt%”. However, claim 11 is directed to **egg lecithin** not soybean oil. Similarly claim 15 recites “the emulsion of claim 13 wherein the ethanol is present in the emulsion at less than 10 wt/wt%, whereas claim 13 is directed to the amount of soybean not ethanol. The lack of antecedent basis is repeated throughout claims 15-16, 18-19, 21, 23-29. Applicant may overcome this rejection by changing the dependency of the claims.

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.

Double Patenting Rejection over US9561229B2

Claims 1-30 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-surfactant (ethanol); and water, wherein the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1

(wt/wt %); and wherein the injectable emulsion further comprises an osmotic agent (sucrose); and pH modifier (sodium oleate).

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. The US9561229B2 ratio of egg yolk lecithin to aprepitant (calculates 1:15 to 1:32.5) overlaps with the range in present claim 1. Thus, the range recited in present claim 1 is obvious over the amount of emulsifier and aprepitant claimed in the US9561229B2. Therefore, the conflicting claims 1-21 of US9561229B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over US9808465B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 8-9, 12-15 of U.S. Patent No. US9808465B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from

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about 20:1 to 25:1 (wt/wt %).

US9808465B2 recited in claims 1-6, 8-9, 12-15, 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, 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 pH of the emulsion ranges from about 7.5-9.0, wherein the ethanol is less than 10 wt%, and wherein the emulsifier is an egg lecithin, wherein the pH modifier is sodium oleate, wherein the oil is soybean oil, wherein the alcohol in the emulsion is ethanol, and wherein the tonicity modifier in the emulsion is sucrose. The amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 11-15% of egg lecithin (calculates to 0.6-0.8wt%). Therefore, the conflicting claims 1-6, 8-9, 12-15 of US9808465B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over US9974742B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 9, and 12-14 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from

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about 20:1 to 25:1 (wt/wt %).

US9974742B2 recited in claims 1-6, 9, and 12-14, 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 ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt %), wherein the pH of the emulsion ranges from about 7.5-9.0, 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 pH modifier is oleic acid or a salt thereof, 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 %. The amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 11-15% of egg lecithin (calculates to 0.6-0.8wt%). Therefore, the conflicting claims 1-6, 9, and 12-14 of US9974742B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over US9974793B2

Claims 1-30 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from

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about 20:1 to 25:1 (wt/wt %).

US9974793B2 recited in claims 1-22, a physically stable pharmaceutical emulsion, comprising 0.4-1.0 wt/wt% aprepitant; an emulsifier (egg yolk lecithin); an oil (soybean 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 comprises 0.7 wt/wt % aprepitant; wherein the pH of the emulsion ranges from about 7.5-9.0, wherein the composition comprises 11 wt/wt % to 15 wt/wt % emulsifier; wherein the composition comprises 9 wt/wt % to 10 wt/wt % oil; wherein the composition further comprises sodium oleate as a pH modifier; wherein composition further comprises 3 wt/wt % to 8 wt/wt % sucrose; wherein the composition further comprises 6 wt/wt % ethanol. Therefore, the conflicting claims 1-22 of US9974793B2 meets the limitations of instant claims 1-30.

Double Patenting Rejection over US9974794B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 9974794B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

US9974794B2 recited in claims 1-11, a physically stable emulsion pharmaceutical composition, comprising 0.4-1.0 wt/wt% aprepitant; 13-15 wt/wt% egg yolk lecithin); 9-10 wt/wt% soybean oil; sodium oleate as a pH modifier; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1, wherein the composition comprises 0.7 wt/wt % aprepitant; wherein the pH of the emulsion ranges from about 7.5-9.0, wherein the composition comprises 9 wt/wt % to 10 wt/wt % oil; wherein the composition further comprises wherein composition further comprises 3 wt/wt % to 8 wt/wt % sucrose; wherein the composition further comprises 6 wt/wt % ethanol. Therefore, the conflicting claims 1-11 of US9974794B2 meets the limitations of instant claims 1-30.

Double Patenting Rejection over US10500208B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 7-9, 11-13 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

US10500208B2 recited in claims 1-5, 7-9, and 11-13, 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 ratio of the emulsifier to the aprepitant in the emulsion ranges from about 15:1 to 30:1 (wt/wt %), wherein the ratio of the oil to the aprepitant in the emulsion ranges from about 11:1 to 15:1 (wt/wt %), wherein the pH of the emulsion ranges from about 7.5-9.0, wherein the emulsifier is an egg lecithin, wherein the pH modifier is sodium oleate, wherein the oil is soybean oil, wherein the alcohol is less than 10 wt/wt % ethanol. The amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 11-15% of egg lecithin (calculates to 0.7-1.0wt%). Therefore, the conflicting claims 1-5, 7-9, and 11-13 of US10500208B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over US10624850B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 9, and 12-16 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

US10624850B2 recited in claims 1-6, 9, and 12-16 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 (egg lecithin); an oil (soybean oil); a co-surfactant which comprises less than 10 wt/wt %

ethanol; a tonicity agent; a pH modifier (oleic acid or a salt thereof); and water, wherein the ratio of the emulsifier to the NK-1 receptor antagonist ranges from about 18:1 to 22:1 (wt/wt %), wherein the pH of the emulsion ranges from about 7.5-9.0, wherein the ratio of the oil to the NK-1 receptor antagonist ranges from about 5:1 to 15:1 (wt/wt %). The instant specification defined aprepitant as NK-1 receptor antagonist. The amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 11-15% of egg lecithin (calculates to 0.6-0.8wt%). Therefore, the conflicting claims 1-6, 9, and 12-16 of US10624850B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over US10953018B2

Claims 1-30 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

US10953018B2 recited in claims 1-18, a physically stable pharmaceutical emulsion, comprising 0.4-1.0 wt/wt% aprepitant; an emulsifier (11-15 wt/wt% egg yolk lecithin); an oil (9-10 wt/wt% soybean oil); and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1; wherein the composition comprises 0.7 wt/wt % aprepitant; wherein the composition further

comprises sodium oleate as a pH modifier; wherein the pH of the emulsion ranges from about 7.5-9.0, 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 1-30.

Double Patenting Rejection over US11173118B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8, 11-12, and 14-17 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 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

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 (egg lecithin); an oil (soybean oil); a co-surfactant (ethanol); 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 aqueous phase comprises water and a tonicity agent and a pH modifying agent (oleate or a salt thereof). US11173118B2 1-8, 11-12, and 14-17 recites all the instant claimed elements including the pH modifier sodium oleate, and the US11173118B2 specification recited that the pH of the composition is 7.5-9. [Col. 6, ln. 15]. Therefore, the conflicting

claims 1-8, 11-12, and 14-17 of US11173118B2 meets the limitations of instant claims 1-30.

Double Patenting Rejection over US11744800B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 11744800B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

US11744800B2 recited in claims 1-21 an injectable pharmaceutical emulsion comprising aprepitant, about 14-15 wt/wt % egg lecithin (an emulsifier, phospholipid); about 9-10 wt/wt % soybean oil (an oil); about 3 wt/wt% ethanol (a co-surfactant); about 3-8 wt/wt % sucrose (an osmotic agent); sodium oleate (a pH modifier); and water, wherein the ratio of the egg lecithin to aprepitant ranges from about 18:1 to 22:1 (wt/wt %). The amount of aprepitant appears to be met considering the ratio between aprepitant to egg lecithin and 14-15% of egg lecithin (calculates to 0.78-0.8wt%). US11744800B2 1-21 recites all the instant claimed elements including the pH modifier sodium oleate, and the US11744800B2 specification recited that the pH of the composition is 7.5-9. [Col. 6, ln. 21]. Therefore, the conflicting claims 1-21 of US11744800B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over US11878074B2

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 11878074B2. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

11878074B2 recites in claims 1-5, 7-9, and 11-14, an injectable pharmaceutical emulsion comprising: aprepitant; 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 emulsion comprises between about 11 wt/wt% to 15 wt/wt% of an emulsifier; wherein the emulsifier is a phospholipid; wherein the pH modifier is oleic acid or a salt thereof; wherein the oil is soybean oil; the alcohol is ethanol. The amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 11-15% of egg lecithin (calculates to 0.6-0.8wt%). 11878074B2 1-5, 7-9, and 11-14 recites all the instant claimed elements including the pH modifier sodium oleate, and the 11878074B2 specification recited that the pH of the composition is 7.5-9. [Col. 6, ln. 15]. Therefore, the conflicting claims 1-5, 7-9, and 11-14 of 11878074B2 reads on the limitations of instant claims 1-30.

Double Patenting Rejection over U.S. co-pending Application No. 17/194,114

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19, 21-28 of co-pending Application No. 17/194,114 (US20210186981A1). Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

Co-pending Application No. 17/194,114 recites in claims 1-19 and 21-28, a physically stable pharmaceutical emulsion 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 pH of the emulsion ranges from about 7.5-9.0, wherein the composition comprises 11-15 wt/wt % emulsifier; wherein the emulsifier is egg yolk lecithin; wherein the composition comprises 9 -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 3-8 wt/wt % sucrose; wherein the composition further comprises 6 wt/wt % ethanol. The amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 11-15% of egg lecithin (calculates to 0.6-0.8wt%). Therefore, the conflicting claims 1-19 and 21-28 of co-pending Application No. 17/194,114 reads on the limitations of instant claims 1-30.

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

Double Patenting Rejection over U.S. co-pending Application No. 16/261,459

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 31, 39-46, 51, 54-62 and 65-71 of co-pending Application No. 16/261,459 (US20190231688A1). Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

Co-pending Application No. 16/261,459 recites in claims 31, 39-46, 51, 54-62 and 65-71, an emulsion comprising 100-200 mg of aprepitant; 10-20 wt/wt% of an emulsifier; an oil; less than 10 wt/wt% ethanol; a tonicity agent; a pH modifier and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 20:1 to 25:1, wherein the ratio of the oil to the aprepitant ranges from about 10:1 to 15:1 wt/wt%; wherein the pH of the emulsion ranges from about 7.5-9.0, wherein the emulsifier is 17 wt/wt % of phospholipid egg lecithin; wherein the oil is soybean oil; wherein the pH modifier sodium is oleate. The claimed amount of aprepitant, 0.7-0.8wt% appears to be obvious considering the amount of aprepitant and emulsifier recited in claims 45 (calculates to 0.5:1 to 0.4:0.8). Therefore, the conflicting claims 31, 39-46, 51, 54-62 and 65-71 of co-pending Application No. 16/261,459 reads on the limitations of instant claims 1-30.

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

Double Patenting Rejection over U.S. co-pending Application No. 18/408,463

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-28 of co-pending Application No. 18/408,463. Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

Co-pending Application No. 18/408,463 recites in claims 1-28, an injectable emulsion comprising aprepitant; 13-20 wt/wt% of an emulsifier (17 wt/wt% egg lecithin); an 9-10 wt/wt% oil (soybean oil); co-emulsifier (less than 10 wt/wt% ethanol); a tonicity modifier (3-8 wt/wt% sucrose); a pH modifier (sodium oleate); and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 20:1 to 25:1. wherein the pH of the emulsion ranges from about 7.5-9.0. The claimed amount of aprepitant appears to be obvious considering the ratio between aprepitant to egg lecithin and 13-20% of egg lecithin (calculates to 0.65-0.8wt%). Therefore, the conflicting claims 1-19 and 21-28 of co-pending Application No. 17/194,114 reads on the limitations of instant claims 1-30.

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

Double Patenting Rejection over U.S. co-pending Application No. 18/408,486

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim claims 1-30 of co-pending Application No. 18/408,486 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

Co-pending Application No. 18/408,486 recites in claims 1-30, an injectable emulsion comprising 0.7-0.8 wt/wt% aprepitant; 13-20 wt/wt% of an emulsifier (17 wt/wt% egg lecithin); an 9-10 wt/wt% oil (soybean oil); co-emulsifier (less than 10 wt/wt% ethanol); a tonicity modifier (3-8 wt/wt% sucrose); a pH modifier (sodium oleate); and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 20:1 to 25:1. Co-pending Application No. 18/408,486 claims 1-30 recites all the instant claimed elements including the pH modifier sodium oleate, and the co-pending Application No. 18/408,486 specification recited that the pH of the composition is 7.5-9. [page 7, 0047] Therefore, the conflicting claims 1-30 of co-pending Application No. 18/408,486 reads on the limitations of instant claims 1-30.

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

Double Patenting Rejection over U.S. co-pending Application No. 18/535,853

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of co-pending Application No. 18/535,853 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because:

The instant claims 1-30 recite an injectable pharmaceutical emulsion comprising 0.7-0.8wt% aprepitant, 13-20 wt/wt% of an emulsifier (phospholipid, egg lecithin); an oil (olive oil, soybean oil, etc.); a co-emulsifier (ethanol); a tonicity modifier (sucrose); a pH modifier (sodium oleate); and water, wherein the pH of the emulsion ranges from about 7.5-9.0, the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt %).

Co-pending Application No. 18/535,853 recites in claims 1-20, an injectable emulsion comprising 0.7-0.8 wt/wt% aprepitant; 11-15 wt/wt% of an emulsifier (egg lecithin); an 9-10 wt/wt% oil (soybean oil); co-emulsifier (6 wt/wt% ethanol); a tonicity modifier (3-8 wt/wt% sucrose); a pH modifier (sodium oleate); and water; wherein the ratio of the emulsifier to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1, wherein the pH of the emulsion ranges from about 7.5-9.0. Therefore, the conflicting claims 1-20 of co-pending Application No. 18/535,853 meets the limitations of instant claims 1-30.

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, Robert Havlin can be reached on 571-272-9066. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/BAHAR CRAIGO/
Primary Examiner, Art Unit 1699

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: THOMAS B. OTTOBONI, et al.

APPLICATION NO.: 18/418,030

FILED: JANUARY 19, 2024

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

EXAMINER: ABDALHAMEED,
MANAHIL MIRGHANI ALI

ART UNIT: 1622

CONF. NO: 9379

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 April 8, 2024 in the above-identified application.

Please amend the application as follows:

Amendments to the Claims begin on page 2.

Remarks begin on page 5 of this paper.

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. (Original) An injectable emulsion, comprising:
0.7-0.8 wt% aprepitant;
13 wt/wt% to 20 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.
2. (Original) The emulsion of claim 1, wherein the emulsifier is a phospholipid.
3. (Original) The emulsion of claim 2, wherein the phospholipid is present in the emulsion at about 17 wt/wt%.
4. (Original) The emulsion of claim 2, wherein the phospholipid is present in the emulsion at about 18 wt/wt%.
5. (Original) The emulsion of claim 1, wherein the emulsifier is an egg lecithin.
6. (Original) The emulsion of claim 5, wherein the egg lecithin is present in the emulsion at about 17 wt/wt%.
7. (Original) The emulsion of claim 5, wherein the egg lecithin is present in the emulsion at about 18 wt/wt%.
8. (Original) The emulsion of claim 5, wherein the ratio of egg lecithin to aprepitant is between about 20:1 to 25:1.

9. (Original) The emulsion of claim 5, wherein the ratio of egg lecithin to aprepitant is about 23:1.
10. (Original) The emulsion of claim 5, wherein the ratio of egg lecithin to aprepitant is about 24:1.
11. (Original) The emulsion of claim 5, wherein the ratio of egg lecithin to aprepitant is about 25:1.
12. (Original) The emulsion of claim 1, wherein the oil in the emulsion is soybean oil.
13. (Currently Amended) The emulsion of claim 12 [[11]], wherein the soybean oil is present at a concentration of about 9 wt/wt % to 10 wt/wt %.
14. (Original) The emulsion of claim 1, wherein the alcohol in the emulsion is ethanol.
15. (Currently Amended) The emulsion of claim 14 [[13]], wherein the ethanol is present in the emulsion at less than 10 wt/wt%.
16. (Currently Amended) The emulsion of claim 14 [[13]], wherein the ethanol is present in the emulsion at a concentration of about 2 wt/wt % to 3 wt/wt %.
17. (Original) The emulsion of claim 1, wherein the tonicity modifier in the emulsion is sucrose.
18. (Original) The emulsion of claim 16, wherein the sucrose is present at a concentration of about 3 wt/wt % to 8 wt/wt %.
19. (Original) The emulsion of claim 16, wherein the sucrose is present at a concentration of about 5 wt/wt %.
20. (Original) The emulsion of claim 1, wherein the pH modifier in the emulsion is sodium oleate.

21. (Original) The emulsion of claim 19, wherein the sodium oleate is present at a concentration of about 0.4 wt/wt % to 0.5 wt/wt %.
22. (Original) The emulsion of claim 1, wherein the aprepitant is present in the emulsion at about 0.7 wt/wt%.
23. (Original) The emulsion of claim 21, wherein the phospholipid is an egg lecithin.
24. (Original) The emulsion of claim 21, wherein the ratio of phospholipid to aprepitant is between about 20:1 to 25:1.
25. (Original) The emulsion of claim 21, wherein the phospholipid is present at a concentration of about 17 wt/wt %.
26. (Original) The emulsion of claim 21, wherein the phospholipid is present at a concentration of about 18 wt/wt %.
27. (Original) The emulsion of claim 21, wherein the ratio of phospholipid to aprepitant is about 23:1.
28. (Original) The emulsion of claim 21, wherein the ratio of phospholipid to aprepitant is about 24:1.
29. (Original) The emulsion of claim 21, wherein the ratio of phospholipid to aprepitant is about 25:1.
30. (Original) An injectable pharmaceutical emulsion, comprising:
 - about 0.7-0.8 wt% aprepitant;
 - an egg phospholipid emulsifier;
 - an oil;
 - a co-surfactant;
 - water; and
 - a pH modifier,wherein the ratio of the emulsifier to aprepitant is about 20:1 to 25:1 (wt/wt%).

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated April 8, 2024 are respectfully requested.

I. Amendments

Claims 13, 15, and 16 are amended to provide antecedent basis for a recited element. No new matter has been added. Claims 1-30 are pending in the instant application.

II. Rejections Under 35 U.S.C. § 112

Claims 13, 15-16, 18-19, 21, and 23-29 are rejected under 35 U.S.C. § 112(b) as indefinite for lack of antecedent basis. This rejection is traversed in view of the following.

The dependency of claims 13, 15, and 16 are amended to provide antecedent basis for the recited claim element. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112.

III. Obviousness Type Double-Patenting Rejection

The proffered nonstatutory double patenting rejections are grouped below according to Applicant's response.

GROUP 1: REJECTIONS ADDRESSED BY FILING A TERMINAL DISCLAIMER

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 9,561,229.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 8-9, and 12-15 of U.S. Patent No. 9,808,465.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 9, and 12-14 of U.S. Patent No. 9,974,742.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 9,974,793.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 9,974,794.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, 7-9, and 11-13 of U.S. Patent No. 10,500,208.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6, 9, and 12-16 of U.S. Patent No. 10,624,850.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 10,953,018.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-8, 11-12, and 14-17 of U.S. Patent No. 11,173,118.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 11,744,800.

Claims 1-30 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 11,878,074.

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-28 of co-pending Application No. 18/408,463.

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claim claims 1-30 of co-pending Application No. 18/408,486.

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of co-pending Application No. 18/535,853.

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; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; 11,173,118; 11,744,800; and 11,878,074; and beyond the expiration of any patent that issues from, 18/408,463, 18/408,486, and 18/535,853.

GROUP 2: REJECTION OVER A NOW ABANDONED APPLICATION

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19 and 21-28 of co-pending Application No. 17/194,114. This application is abandoned; a Notice of Abandonment was mailed on March 7, 2024. Withdrawal of the rejection is requested.

GROUP 3: REJECTION OVER A LATER-FILED APPLICATION

Claims 1-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 31, 39-46, 51, 54-62, and 65-71 of co-pending Application No. 16/261,459.

Reconsideration and withdrawal is requested. The instant application has a patent term filing date of February 1, 2016. Application No. 16/261,459 has a patent term filing date of January 29, 2019, and is therefore later filed than the instant application. In accord with M.P.E.P. § 804, and in view of the terminal disclaimer filed herewith to resolve the other rejections, the nonstatutory double patenting rejection over Application No. 16/261,459 is the only remaining rejection. Since the instant case has an earlier patent term filing date the rejection should be withdrawn. (*See*, M.P.E.P. § 804 (I)(B)(1)(b)(i) “If a provisional nonstatutory double patenting rejection is the only rejection remaining in an application having the earlier patent term filing date, the examiner should withdraw the rejection in the application having the earlier patent term filing date and permit that application to issue as a patent, thereby converting the provisional nonstatutory double patenting rejection in the other application into a nonstatutory double patenting rejection upon issuance of the patent.”).

IV. Conclusion

No fees are believed due with this communication. However, 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, the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. 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 (202) 756-8934.

Respectfully submitted,
McDERMOTT WILL & EMERY LLP

Date: **July 2, 2024**

Correspondence Address:

Customer No. 108547

/Peter Brunovskis/
Peter Brunovskis, Ph.D.
Registration No. 52,441

DM_US 205241961-3.092459.0423



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

108547 7590 08/02/2024
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001-1531

EXAMINER	
ABDALHAMEED, MANAHIL MIRGHANI ALI	
ART UNIT	PAPER NUMBER
1622	

DATE MAILED: 08/02/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/418,030	01/19/2024	Thomas B. Ottoboni	092459-0423/8032.US06	9379

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
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	11/04/2024

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.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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

108547 7590 08/02/2024

McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001-1531

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.

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 the USPTO patent electronic filing system 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.
18/418,030	01/19/2024	Thomas B. Ottoboni	092459-0423/8032.US06	9379

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
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	11/04/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABDALHAMEED,	1622	707-750000

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 _____

(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)

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

☐ Electronic Payment via the USPTO patent electronic filing system ☐ 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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/418,030	01/19/2024	Thomas B. Ottoboni	092459-0423/8032.US06	9379
108547	7590	08/02/2024	EXAMINER	
McDermott Will & Emery LLP 500 North Capitol Street NW Washington, DC 20001-1531			ABDALHAMEED, MANAHIL MIRGHANI ALI	
			ART UNIT	PAPER NUMBER
			1622	
DATE MAILED: 08/02/2024				

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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

<https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf>

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
- 3) a contractor of the USPTO having need for the information in order to perform a contract;
- 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
- 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
- 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) 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));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and
- 10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/418,030	Applicant(s) Ottoboni 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 07/02/2024.
☐ 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 1-30. 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. ☒ Notice of References Cited (PTO-892) 2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____ 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____	5. ☐ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____
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/M.M.A./ Examiner, Art Unit 1622	/ROBERT H HAVLIN/ Supervisory Patent Examiner, Art Unit 1622
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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 01/09/2024 is a continuation of U.S. Application No. 18/535,853, filed 12/11/2023, which is a continuation of U.S. Application No. 17/180,593, filed 02/19/2021 (now U.S. Patent No. 11878074), which 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 02/01/2016 (now U.S. Patent No. 9,974,742).

DETAILED ACTION

The Amendments and Applicant's Arguments submitted on 07/02/2024 have been received and its contents have been carefully considered. Claims 13, 15 and 16 were amended. Claims 1-30 are pending.

EXAMINER COMMENT AND REASONS FOR ALLOWANCE

Withdrawal Claim Rejections – 35 U.S.C. 112(b)

Rejection of claims 13, 15-16, 18-19, 21, 23-29 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA) for insufficient antecedent basis, is withdrawn in view of Applicant's amendment to claims 13, 15 and 16 submitted on 07/02/2024.

Withdrawal Claim Rejections – Double Patenting

Rejection of claims 1-30 rejected under the nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 9561229B2, claims 1-6, 8-9, 12-15 of U.S. Patent No. US9808465B2, claims 1-6, 9, and 12-14 of U.S. Patent No. 9974742B2, claims 1-22 of U.S. Patent No. 9974793B2, claims 1-11 of U.S. Patent No. 9974794B2, claims 1-5, 7-9, 11-13 of U.S. Patent No. 10500208B2, claims 1-6, 9, and 12-16 of U.S. Patent No. 10624850B2, claims 1-18 of U.S. Patent No. 10953018B2, claims 1-8, 11-12, and 14-17 of U.S. Patent No. 11173118B2, claims 1-21 of U.S. Patent No. 11744800B2, claims 1-21 of U.S. Patent No. 11878074B2, claims 1-28 of co-pending Application No. 18/408,463, claims 1-30 of co-pending Application No. 18/408,486, claims 1-20 of co-pending Application No. 18/535,853, is withdrawn in view of the Terminal Disclaimer submitted by the Applicant on 07/02/2024.

Rejection of claims 1-30 rejected under the nonstatutory double patenting as being unpatentable over claims 1-19, 21-28 of copending Application No. 17/194,114, is withdrawn because Application No. 17/194,114 is abandoned on 03/7/2024.

Rejection of claims 1-30 rejected under the nonstatutory double patenting as being unpatentable over claims 31, 39-46, 51, 54-62 and 65-71 of co-pending Application No. 16/261,459, is withdrawn because the co-pending Application No. 16/261,459 has patent term filing date of 01/29/2019, whereas the instant application has a patent term filing date of 02/01/2016, and Pursuant to MPEP 1490, the nonstatutory double patenting rejections over copending applications No. 16/261,459 is withdrawn because the instant application has an earlier patent term filing date.

Terminal Disclaimer

The terminal disclaimer filed on 05/24/2024 disclaiming the terminal portion of any patent

granted on this application which would extend beyond the expiration date of any patent granted on U.S. Patent No. US9561229B2, US9808465B2, US9974742B2, US9974793B2, US9974794B2, US10500208B2, US10624850B2, US10953018B2, US11173118B2, US11744800B2, US11878074B2, and U. S. Application Number 18/408,463, 18/408,486, and 18/535,853 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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. [Zhou, translated Espacenet document, page 3].

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 amount of phospholipid to 13-20 wt/wt% and increase the ratio of the emulsifier to the NK-1 receptor antagonist to about 20:1 to 25:1 (wt/wt%). However, Zhou's disclosure does not provide sufficient guidance and motivation to one of ordinary skill in the art to perform the modification to arrive at instantly claimed emulsion. Therefore, Zhou's disclosure does not anticipate or render the instant claims obvious.

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,

Art Unit: 1622

Robert Havlin can be reached on 571-272-9066. 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

/ROBERT H HAVLIN/

Supervisory Patent Examiner, Art Unit 1622