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APPLICATION #
18/408,486

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Title of Invention

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

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5991	FILED BY	Judy Steinkraus
PATENT CENTER #	63894091	AUTHORIZED BY	Peter Brunovskis
CUSTOMER #	108547	FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Thomas B. Ottoboni

Payment Information

PAYMENT METHOD DA / 500417	PAYMENT TRANSACTION ID E202419K39588020	PAYMENT AUTHORIZED BY Judy Steinkraus
PRE-AUTHORIZED ACCOUNT 500417	PRE-AUTHORIZED CATEGORY 37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.21 (Miscellaneous fees and charges)	

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	56.00	1	56.00
2817	REQUEST FOR PRIORITIZED EXAMINATION	1680.00	1	1680.00
2111	UTILITY PATENT APPL. SEARCH FEE	280.00	1	280.00
4011	BASIC FILING FEE- UTILITY	64.00	1	64.00

Azurity Ex. 1022
PGR Petition – USP 12,115,254

2311	EXAMINATION OF ORIGINAL PATENT APPLICATION	320.00	1	320.00
2202	EACH CLAIM IN EXCESS OF 20	40.00	10	400.00
			TOTAL AMOUNT:	\$2,800.00

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

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WHAT IS CLAIMED IS:

1. An injectable pharmaceutical emulsion, comprising:
about 0.7-0.8 wt% aprepitant;
an emulsifier;
an oil;
a co-surfactant; and
water,
wherein the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1 (wt/wt%).
2. The emulsion of claim 1, wherein the emulsifier is a phospholipid.
3. The emulsion of claim 2, wherein the phospholipid is present in the emulsion at about 16 wt/wt%.
4. The emulsion of claim 2, wherein the phospholipid is present in the emulsion at about 17 wt/wt%.
5. The emulsion of claim 1, wherein the emulsifier is an egg lecithin.
6. The emulsion of claim 5, wherein the egg lecithin is present in the emulsion at about 16 wt/wt%.
7. The emulsion of claim 5, wherein the phospholipid is present in the emulsion at about 17 wt/wt%.
8. The emulsion of claim 1, wherein the oil is selected from the group consisting of coconut oil, olive oil, soybean oil, safflower oil, triglycerides, octyl and decyl glycerate, ethyl oleate, glyceryl linoleate, ethyl linoleate, glyceryl oleate, cholesteryl oleate, cholesteryl linoleate, and mixtures thereof.
9. The emulsion of claim 8, wherein the oil is present at a concentration of about 9 wt/wt % to 10 wt/wt %.
10. The emulsion of claim 1, wherein the co-surfactant comprises an alcohol.

11. The emulsion of claim 10, wherein the alcohol is present in the emulsion at less than 10 wt/wt%.
12. The emulsion of claim 10, wherein the co-surfactant is ethanol.
13. The emulsion of claim 1, further comprising an osmotic agent.
14. The emulsion of claim 13, wherein the osmotic agent is selected from the group consisting of glycerol, sorbitol, xylitol, mannitol, glucose, trehalose, maltose, sucrose, raffinose, lactose, dextran, polyethylene glycol, or propylene glycol.
15. The emulsion of claim 14, wherein the osmotic agent is present at a concentration of about 3 wt/wt % to 8 wt/wt %.
16. The emulsion of claim 1, further comprising a pH modifier.
17. The emulsion of claim 16, wherein the pH modifier is oleic acid or a salt thereof.
18. The emulsion of claim 1, wherein the emulsifier is egg lecithin.
19. The emulsion of claim 1, wherein the co-surfactant is ethanol.
20. The emulsion of claim 1, further comprising sucrose.
21. The emulsion of claim 1, further comprising sodium oleate
22. An injectable pharmaceutical emulsion, comprising:
about 0.7-0.8 wt% aprepitant;
an emulsifier;
an oil;
a co-surfactant; and
water,
wherein the ratio of the emulsifier to aprepitant ranges about 23:1 (wt/wt%).
23. The emulsion of claim 22, wherein the emulsifier is a phospholipid.
24. The emulsion of claim 23, wherein the phospholipid is selected from the group consisting of egg phospholipids and soy phospholipids.

25. The emulsion of claim 22, wherein the oil is selected from the group consisting of coconut oil, olive oil, soybean oil, safflower oil, triglycerides, octyl and decyl glycerate, ethyl oleate, glyceryl linoleate, ethyl linoleate, glyceryl oleate, cholesteryl oleate, cholesteryl linoleate, and mixtures thereof.
26. The emulsion of claim 22, wherein the co-surfactant comprises an alcohol present in the emulsion at less than 10 wt/wt%.
27. An injectable pharmaceutical emulsion, comprising:
about 0.7-0.8 wt% aprepitant;
an emulsifier;
an oil;
a co-surfactant; and
water,
wherein the ratio of the emulsifier to aprepitant ranges about 24:1 (wt/wt%).
28. The emulsion of claim 27, wherein the emulsifier is a phospholipid.
29. The emulsion of claim 27, wherein the phospholipid is selected from the group consisting of egg phospholipids and soy phospholipids.
30. The emulsion of claim 27, wherein the oil is selected from the group consisting of coconut oil, olive oil, soybean oil, safflower oil, triglycerides, octyl and decyl glycerate, ethyl oleate, glyceryl linoleate, ethyl linoleate, glyceryl oleate, cholesteryl oleate, cholesteryl linoleate, and mixtures thereof.



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for 18/408,486 and 108547, inventor Thomas B. Ottoboni, and examiner 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 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

Claims 1-30 are pending.

Claim objections

Claim 7 is objected to because of the following informalities:

Claim 7 recites "The emulsion of claim 5, wherein the **phospholipid** is present in the emulsion at about 17 wt/wt%." Claim 5 recites "The emulsion of claim 1, wherein the emulsifier is an **egg lecithin**." However, while claim 1 recites that the injectable emulsion comprises "an emulsifier", claim 1 perse does not define the emulsifier as phospholipid (dependent claims 2-4 define the emulsifier as phospholipid). While the egg lecithin is known in the art as a phospholipid, it would be better if Applicant use consistent

claim dependency language. That is, claim 7 recite “wherein the egg lecithin” instead of “wherein the phospholipid” or change the dependency of claim 7.

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

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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, 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).

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 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, 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).

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 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, 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).

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 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, 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).

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 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, 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

Art Unit: 1622

modifier (sodium oleate).

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 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, 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).

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 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, 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).

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 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, 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).

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). 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, 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).

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%). Therefore, the conflicting claims 1-21 of US11744800B2 meets 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, 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).

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%). 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, 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).

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 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 claimed 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, 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).

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 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 (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, 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).

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. 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. 18/418,030

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. 18/418,030 (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, 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).

Co-pending Application No. 18/418,030 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. Therefore, the conflicting claims 1-30 of co-pending Application No. 18/418,030 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.

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, 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).

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. 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.

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

/BAHAR CRAIGO/
Primary Examiner, Art Unit 1699

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: THOMAS B. OTTOBONI
APPLICATION NO.: 18/408,486
FILED: JANUARY 9, 2024
FOR: METHODS OF USE OF EMULSION
FORMULATIONS OF AN NK-1 RECEPTOR
ANTAGONIST

EXAMINER: ABDALHAMEED,
MANAHIL MIRGHANI ALI
ART UNIT: 1622
CONF. NO: 5991

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 March 26, 2024 in the above-identified application.

Please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims beginning on page 2.

Remarks begin on page 5.

[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 pharmaceutical emulsion, comprising:
about 0.7-0.8 wt% aprepitant;
an emulsifier;
an oil;
a co-surfactant; and
water,
wherein the ratio of the emulsifier to aprepitant ranges from about 20:1 to 25:1
(wt/wt%).
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 16 wt/wt%.
4. (Original) The emulsion of claim 2, wherein the phospholipid is present in the emulsion at about 17 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 16 wt/wt%.
7. (Currently amended) The emulsion of claim 5, wherein the egg lecithin
~~phospholipid~~ is present in the emulsion at about 17 wt/wt%.
8. (Original) The emulsion of claim 1, wherein the oil is selected from the group consisting of coconut oil, olive oil, soybean oil, safflower oil, triglycerides, octyl and decyl glycerate, ethyl oleate, glyceryl linoleate, ethyl linoleate, glyceryl oleate, cholesteryl oleate, cholesteryl linoleate, and mixtures thereof.

9. (Original) The emulsion of claim 8, wherein the oil is present at a concentration of about 9 wt/wt % to 10 wt/wt %.
10. (Original) The emulsion of claim 1, wherein the co-surfactant comprises an alcohol.
11. (Original) The emulsion of claim 10, wherein the alcohol is present in the emulsion at less than 10 wt/wt%.
12. (Original) The emulsion of claim 10, wherein the co-surfactant is ethanol.
13. (Original) The emulsion of claim 1, further comprising an osmotic agent.
14. (Original) The emulsion of claim 13, wherein the osmotic agent is selected from the group consisting of glycerol, sorbitol, xylitol, mannitol, glucose, trehalose, maltose, sucrose, raffinose, lactose, dextran, polyethylene glycol, or propylene glycol.
15. (Original) The emulsion of claim 14, wherein the osmotic agent is present at a concentration of about 3 wt/wt % to 8 wt/wt %.
16. (Original) The emulsion of claim 1, further comprising a pH modifier.
17. (Original) The emulsion of claim 16, wherein the pH modifier is oleic acid or a salt thereof.
18. (Original) The emulsion of claim 1, wherein the emulsifier is egg lecithin.
19. (Original) The emulsion of claim 1, wherein the co-surfactant is ethanol.
20. (Original) The emulsion of claim 1, further comprising sucrose.
21. (Original) The emulsion of claim 1, further comprising sodium oleate
22. (Original) An injectable pharmaceutical emulsion, comprising:
about 0.7-0.8 wt% aprepitant;
an emulsifier;
an oil;

a co-surfactant; and

water,

wherein the ratio of the emulsifier to aprepitant ranges about 23:1 (wt/wt%).

23. (Original) The emulsion of claim 22, wherein the emulsifier is a phospholipid.

24. (Original) The emulsion of claim 23, wherein the phospholipid is selected from the group consisting of egg phospholipids and soy phospholipids.

25. (Original) The emulsion of claim 22, wherein the oil is selected from the group consisting of coconut oil, olive oil, soybean oil, safflower oil, triglycerides, octyl and decyl glycerate, ethyl oleate, glyceryl linoleate, ethyl linoleate, glyceryl oleate, cholesteryl oleate, cholesteryl linoleate, and mixtures thereof.

26. (Original) The emulsion of claim 22, wherein the co-surfactant comprises an alcohol present in the emulsion at less than 10 wt/wt%.

27. (Original) An injectable pharmaceutical emulsion, comprising:
about 0.7-0.8 wt% aprepitant;

an emulsifier;

an oil;

a co-surfactant; and

water,

wherein the ratio of the emulsifier to aprepitant ranges about 24:1 (wt/wt%).

28. (Original) The emulsion of claim 27, wherein the emulsifier is a phospholipid.

29. (Original) The emulsion of claim 27, wherein the phospholipid is selected from the group consisting of egg phospholipids and soy phospholipids.

30. (Original) The emulsion of claim 27, wherein the oil is selected from the group consisting of coconut oil, olive oil, soybean oil, safflower oil, triglycerides, octyl and decyl glycerate, ethyl oleate, glyceryl linoleate, ethyl linoleate, glyceryl oleate, cholesteryl oleate, cholesteryl linoleate, and mixtures thereof.

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated March 26, 2024 are respectfully requested.

I. Claim Amendment

Claim 7 is amended to address the objection in the Office Action. In accordance with the Examiner's suggestion, claim 7 has been amended to substitute "phospholipid" with "egg lecithin."

II. Obviousness Type Double-Patenting Rejections

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. 18/418,030.

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, 18/418,030, and 18/535,853. Withdrawal of the nonstatutory double patenting rejections is respectfully requested.

GROUP 2: REJECTION OVER A NOW ABANDONED APPLICATION

Claims 1-30 were 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.

Application No. 17/194,114 is abandoned. A Notice of Abandonment was mailed by the USPTO on March 7, 2024. Withdrawal of the rejection is respectfully 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.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

108547 7590 06/20/2024
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: 06/20/2024

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Values: 18/408,486, 01/09/2024, Thomas B. Ottoboni, 092459-0422/8032.US05, 5991

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, 09/20/2024

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.

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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.

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108547 7590 06/20/2024
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(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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18/408,486 01/09/2024 Thomas B. Ottoboni 092459-0422/8032.US05 5991

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 09/20/2024

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

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

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- "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.**

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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.

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

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

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- The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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

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

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

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

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 18/408,486, 01/09/2024, Thomas B. Ottoboni, 092459-0422/8032.US05, 5991
Row 2: 108547, 7590, 06/20/2024, McDermott Will & Emery LLP, 500 North Capitol Street NW, Washington, DC 20001-1531
Row 3: EXAMINER ABDALHAMEED, MANAHIL MIRGHANI ALI
Row 4: ART UNIT 1622, PAPER NUMBER
Row 5: DATE MAILED: 06/20/2024

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. 18/408,486	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 05/24/2024.
 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 _____.

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

/BAHAR CRAIGO/
Primary Examiner, Art Unit 1699

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 05/24/2024 have been received and its contents have been carefully considered. Claim 7 was amended. Claims 1-30 are pending.

EXAMINER COMMENT AND REASONS FOR ALLOWANCE

Withdrawal Claim Objections

Objection of claim 7 is withdrawn in view of Applicant's amendment submitted on 05/24/2024.

Withdrawal Claim Objections – 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. 18/418,030, claims 1-20 of co-pending Application No. 18/535,853, is withdrawn in view of the Terminal Disclaimer submitted by the Applicant on 05/24/2024.

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, 18/418,030, 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.

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, 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

Art Unit: 1622

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

/BAHAR CRAIGO/

Primary Examiner, Art Unit 1699