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Elmore Patent Law Group 484 Groton Road Westford, MA 01886			EXAMINER DRISCOLL, LORA E BARNHART	
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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.



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***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/019,779 .

PATENT UNDER REEXAMINATION 7919499 .

ART UNIT 3991 .

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting Request For Ex Parte Reexamination	Control No. 90/019,779	Patent Under Reexamination 7919499	
	Examiner LORA E DRISCOLL	Art Unit 3991	AIA (FITF) Status No

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

The request for *ex parte* reexamination filed 12/16/2024 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO/SB/08, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

/Lora E Barnhart Driscoll/ Patent Reexamination Specialist	/JOSEPH R KOSACK/ Patent Reexam Spec., CRU 3991	
cc:Requester (if third party requester)		

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Request for Reexamination

A request for *ex parte* reexamination of claims 1-13 of US Patent 7,919,499 was filed by a third-party requester on 12/16/24.

Decision on Request

A substantial new question of patentability (SNQ) affecting claims 1-13 is raised by the request for *ex parte* reexamination.

Scope of the Claims

The reexamination request is decided on the basis of the claims in effect at the time of the request. See MPEP 2221. In reexamination, patent claims are construed broadly. See *In re Yamamoto*, 740 F.2d 1569, 1571, 222 U.S.P.Q. 934, 936 (Fed. Cir. 1984) (claims given “their broadest reasonable interpretation consistent with the specification”).

Claims 1-13 of the '499 patent are under reexamination. Claims 1 and 14 are the independent claims. Claim 1 reads:

1. A method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation comprising about 310 mg to about 480 mg of naltrexone and a biocompatible polymer to the individual wherein the serum AUC of naltrexone is about three times greater than that achieved by 50 mg/day oral administration and wherein the biocompatible polymer is a polylactide-co-glycolide polymer.

Claim 14 reads:

14. A method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation comprising about 190 mg to about 240 mg of naltrexone and a biocompatible polymer to the individual wherein the serum AUC of naltrexone is about two times greater than that achieved by 50 mg/day oral administration and wherein the biocompatible polymer is a polylactide-co-glycolide polymer.

Priority

Application 11/083,167 was filed on 3/17/05 and claims benefit of US provisional application 60/564,542, which was filed on 4/22/04. The '499 patent issued from the '167 application on 4/5/11. The '499 patent lists no other domestic-benefit or foreign-priority claims.

Documents Submitted by Requester

Comer et al., 2002, "Depot Naltrexone: Long-Lasting Antagonism of the Effects of Heroin in Humans," *Psychopharmacology* 159(4): 351-360 ("Comer"; Ex. E)

US Patent No. 7,157,102 ("Nuwayser"; Ex. F)

Johnson et al., 2004, "A Pilot Evaluation of the Safety and Tolerability of Repeat Dose Administration of Long-Acting Injectable Naltrexone (Vivitrex®) in Patients with Alcohol Dependence," *Alcoholism: Clinical and Experimental Research* 28(9): 1356-1361 ("Vivitrex Pilot Study"; Ex. G)

Rubio et al., 2001, "Naltrexone Versus Acamprosate: One Year Follow-Up of Alcohol Dependence Treatment," *Alcohol & Alcoholism* 36(5): 419-425 ("Rubio"; Ex. W)

US Patent 6,264,987 ("Wright"; Ex. N)

The Vivitrex Pilot Study, Nuwayser, and Rubio did not appear on an information disclosure statement (IDS) and were not cited by the examiner as relevant evidence in the original prosecution, so they represent new art not previously submitted.

Comer and Wright were cited on IDSes in the '167 application but were not relied upon or discussed by the examiner in the original prosecution. ('167 application, IDS of 5/26/10, nonpatent reference 1 (Comer); '167 application, IDS of 8/29/05, US Patent reference AB (Wright); see also request at page 14, discussing Exhibits E and N; request at pages 33 and 37.)

A substantial new question of patentability may be based solely on old art where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier examination(s), in view of a material new argument or interpretation presented in the request. Such material new argument or interpretation may be based solely on claim scope of the patent being reexamined. MPEP 2242(II)(A).

A proposed SNQ (ground 1; request at page 15) is therefore based solely on patents and/or printed publications already cited/considered in an earlier concluded examination or review of the patent being reexamined, or has been raised to or by the Office in a pending reexamination or supplemental examination of the patent. On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., “old art,” does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. In the present instance, there exists a SNQ based solely on Comer. Comer was cited on an IDS in the '167 application but was not relied upon or discussed by the examiner in the original prosecution. Comer has therefore been presented and viewed in a new light and a different way than in the original prosecution.

Requester presented additional exhibits including patent and nonpatent references, documents from USPTO proceeding IPR2018-00943 (“the IPR proceeding”), declarations from the original prosecution and from the IPR proceeding, and Office actions and responses from the original prosecution. These are not relied upon in the proposed SNQs.

Requester's Proposed SNQs

Ground 1: Comer

The request presents a substantial new question of patentability of claims 1, 3-5, and 12 of the '499 patent based on Comer. The request relies on Nuwayser in this SNQ solely for the definition of the art-recognized trademark DEPOTREX. (Request at pages 39-40.)

Comer discloses treating addicts and alcoholics with depot formulations of naltrexone. (Request at pages 38-39.) Comer administers DEPOTREX®, a known depot formulation, to administer 384 mg of naltrexone. (Request at pages 39-41.)

Comer's DEPOTREX® contains polylactide-co-glycolide (PLGA) as a biocompatible polymer. (Request at pages 39-41.)

Regarding claims 3 and 4, Comer teaches release for "a month." (Request at page 44; see '499 patent, column 4, line 56, identifying "every four weeks" as one example of "monthly" administration.)

Regarding claim 5, Comer administers the same formulation as that recited in claim 5. (Request at page 44.)

Regarding claim 12, Comer teaches injection of the depot formulation through an 18-gauge needle. (Request at page 44.)

For "a substantial new question of patentability" to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in an earlier concluded examination or review of the patent, raised to or by the Office in a pending reexamination or supplemental examination of the patent, or decided in a final holding of invalidity (after all appeals) by a federal court in a decision on the merits involving the claim. MPEP 2242.

Regarding (A), an examiner would have found Comer's teachings important in assessing patentability. Regarding (B), the same question of patentability has not been decided by the Office in an earlier concluded review because IPR2018-00943 was terminated before the PTAB could issue a final written decision.

Ground 2: The Vivitrex Pilot Study

The request presents a substantial new question of patentability of claims 1, 3-5, and 10-12 of the '499 patent based on the Vivitrex Pilot Study. The request discusses whether the '499 patent is entitled to the benefit of its '542 provisional application's filing date and discusses the teachings of the Vivitrex Pilot Study. The request establishes a substantial likelihood that a reasonable examiner would consider the Vivitrex Pilot Study to be important in deciding whether or not the claims are patentable.

The request contends that the '542 provisional application does not provide support under 35 U.S.C. 112, first paragraph, for the claimed increase in naltrexone serum AUC compared to that yielded by oral administration. (Request at pages 45-48.) The underlying '167 application adds material beyond the disclosure of the '542 provisional application (specifically, examples 3-5 at columns 18-20), so it is analogous to a continuation-in-part of that provisional application. See MPEP 2152.01 (analysis of effective filing date not changed by AIA and referencing MPEP 2133.01). "[A]ny claim that contains a limitation that is only supported as required by pre-AIA 35 U.S.C. 112, first paragraph, by the disclosure of the CIP application will have the effective filing date of the CIP application." MPEP 2133.01. See also MPEP 2218:

[W]here the patent for which reexamination is requested is a continuation-in-part of a parent application, the requester would notify the Office of the application number of the parent application and its status if the asserted substantial new question of patentability relates to a proposed rejection based on an intervening art and the question of whether the claimed subject matter in the patent has support in the parent application is relevant.

The request states that the '542 provisional application nowhere provides data demonstrating possession of the claimed increased serum AUC from the claimed range of naltrexone dose. (Request at page 48.) The request further states that the person of ordinary skill in the art would have understood that serum AUC depends on several factors and would therefore not have concluded that the '542 provisional application teaches the claimed increase. (Request at pages 47-48.)

Based on the request's analysis of the '499 patent's benefit claim, a reasonable examiner could reasonably conclude that the '499 patent's effective filing date is its actual filing date, 3/17/05. In that case, then, the examiner would find that the Vivitrex Pilot Study of September 2004 is important in assessing patentability. (See request at pages 45-46.)

Regarding claim 1, the Vivitrex Pilot Study administers 400 mg naltrexone intramuscularly in a formulation comprising PLGA. (Request at pages 48-49.) An examiner would have found these teachings important in assessing patentability.

Regarding claims 3 and 4, the Study teaches multiple "1-month treatment cycles." (Request at pages 49-50; see '499 patent, column 4, line 56, identifying "every four weeks" as one example of "monthly" administration.)

Regarding claim 5, the Study administers the same formulation as that recited in claim 5. (Request at page 50.)

Regarding claim 10, the Study's patients were alcohol-dependent. (Request at page 50.)

Regarding claim 11, the Study's patients received the first dose of naltrexone on day 0 of the pilot. (Request at page 50.)

Regarding claim 12, the Study teaches intramuscular injection of the depot formulation. (Request at page 50.)

For "a substantial new question of patentability" to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in an earlier concluded examination or review of the patent, raised to or by the Office in a pending reexamination or supplemental examination of the patent, or decided in a final holding of invalidity (after all appeals) by a federal court in a decision on the merits involving the claim. MPEP 2242.

Regarding (A), an examiner would have found the Vivitrex Pilot Study's teachings important in assessing patentability because they are relevant to the claim limitations. Regarding (B), the same question of patentability has not been decided by the Office in an earlier concluded review because the Vivitrex Pilot Study was not before the PTAB in IPR2018-00943.

Ground 3: Comer in view of Nuwayser, Rubio, and Wright

The request presents a substantial new question of patentability of claims 1-13 of the '499 patent based on Comer in view of Nuwayser, Rubio, and Wright. Comer discloses treating addicts and alcoholics with depot formulations of naltrexone. (Request at pages 38-39.) Comer administers DEPOTREX®, a known depot formulation, to administer 384 mg of naltrexone. (Request at pages 39-41.) Comer's

DEPOTREX® contains polylactide-co-glycolide (PLGA) as a biocompatible polymer.

(Request at pages 39-41.) Nuwayser teaches a formulation that achieves acceptable delivery of naltrexone via a depot formulation. (Request at pages 51-52.) An examiner would have found these teachings important in assessing patentability.

Regarding claims 3-5 and 12, see the discussion of Comer provided under Ground 1. (Request at pages 56 and 58.)

Regarding claim 2, Comer teaches administering over a year, and Rubio teaches of 12-month treatment protocols in alcoholics. (Request at pages 56-57.)

Regarding claims 7-9, Comer and Nuwayser both teach weekly administration. (Request at page 57.)

Regarding claim 10, Comer discusses the use of depot naltrexone in alcoholics, as does Rubio. (Request at pages 57-58.)

Regarding claim 11, Comer specifically states that oral naltrexone is not necessary prior to depot injection. (Request at page 58.)

Regarding claim 13, Nuwayser's formulation exemplifies 54.4% naltrexone by weight and Wright teaches that drug loading may be in the range of 30-75% by weight. (Request at page 58, citing Ex. N (Wright).)

For "a substantial new question of patentability" to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in an

earlier concluded examination or review of the patent, raised to or by the Office in a pending reexamination or supplemental examination of the patent, or decided in a final holding of invalidity (after all appeals) by a federal court in a decision on the merits involving the claim. MPEP 2242.

Regarding (A), an examiner would have found the teachings of Comer, Nuwayser, Rubio, and Wright important in assessing patentability because they are relevant to the claim limitations. Regarding (B), the same question of patentability has not been decided by the Office in an earlier concluded review because IPR2018-00943 was terminated before the PTAB could issue a final written decision.

Ground 4: The Vivitrex Pilot Study in view of Nuwayser, Rubio, and Wright

The request presents a substantial new question of patentability of claims 1-13 of the '499 patent based on the Vivitrex Pilot Study in view of Nuwayser, Rubio, and Wright.

Regarding claim 1, the Vivitrex Pilot Study administers 400 mg naltrexone intramuscularly in a formulation comprising PLGA. (Request at pages 59-60.) An examiner would have found that teaching important in assessing patentability.

Regarding claims 3-5 and 10-12, a reasonable examiner would have found the Study important in assessing patentability for the reasons provided under Ground 2. (Request at pages 61-63.)

Regarding claims 2 and 6, the Study treated patients every 4 weeks for 16 weeks, while both Rubio teaches administration for a year or more. (Request at pages

60-61.) An examiner would have found these teachings important in assessing patentability.

Regarding claims 7-9, the Study teaches weekly administration. (Request at page 62.) An examiner would have found these teachings important in assessing patentability.

Regarding claim 10, the Study discusses the use of depot naltrexone in alcoholics, as does Rubio. (Request at pages 62-63.) An examiner would have found these teachings important in assessing patentability.

Regarding claim 11, the Study does not teach providing an initial oral dose of naltrexone. (Request at page 63.) An examiner would have found that teaching important in assessing patentability.

Regarding claim 13, Wright's formulation may be in the range of 30-75% by weight. (Request at page 63.) An examiner would have found that teaching important in assessing patentability.

For "a substantial new question of patentability" to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in an earlier concluded examination or review of the patent, raised to or by the Office in a pending reexamination or supplemental examination of the patent, or decided in a final

holding of invalidity (after all appeals) by a federal court in a decision on the merits involving the claim. MPEP 2242.

Regarding (A), an examiner would have found the teachings of the Vivitrex Pilot Study, Nuwayser, Rubio, and Wright important in assessing patentability because they are relevant to the claim limitations. Regarding (B), the same question of patentability has not been decided by the Office in an earlier concluded review because the Vivitrex Pilot Study was not before the PTAB in IPR2018-00943.

35 U.S.C. 325(d)

35 USC 325(d) states in part, "...[i]n determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." Thus in order for the Director to exercise discretion as to whether to Order a reexamination under chapter 30, the request must first be determined to be based on the same or substantially the same prior art or arguments that previously were presented to the Office.

A review of the post grant history of the '499 patent indicates that the patent was the subject of a single prior Office post grant challenge filed before the filing of this Request (90/019,779).

IPR2018-00943

On 4/20/18, Petitioner Amneal Pharmaceuticals LLC, being different from the Requester in this application's Request, filed a petition for *inter partes* review of claims

1-13 of the '499 patent (IPR2018-00943) which asserted the following grounds as raising a reasonable likelihood of prevailing (RLP):

RLP Ground	Claims	Basis	References
#1	1, 3-5, 10-12	§ 102(b)	Comer
#2	1, 3-5, 10-12	§ 102(b)	Nuwayser
#3	1-13	§ 103(a)	Comer, Nuwayser, Rubio, and Wright
#4	1-13	§ 103(a)	Nuwayser, Comer, Rubio, and Wright
#5	1-13	§ 103(a)	Nuwayser, Kranzler, Rubio, and Wright
#6	3	§ 103(a)	Alkermes 10-K, Vivitrex Specimen, Wright, and Rubio

On 11/7/18, the Patent Trial and Appeal Board (PTAB) mailed a Decision instituting *inter partes* review holding that the Petitioner showed a reasonable likelihood of prevailing on all grounds. See Decision Granting Institution, page 41.

On 7/31/19, prior to the issuance of any final written decision, the PTAB issued a decision terminating the proceeding in view of a joint settlement agreement between the parties. The PTAB noted that on August 16, 2024, Petitioner and Patent Owner filed a Joint Motion to Terminate and thus, the proceeding was terminated under 35 USC § 317(a). See Termination Decision entered 7/31/19.

A comparison between the prior art and arguments presented in the instant request and the earlier IPR petition, indicates that ground 3 presented in the instant reexamination request is based on the same art and arguments as presented in RLPs 3 and 4 of IPR2018-00943.

As indicated above, the current request asserts the following grounds as raising a substation new question of patentability (SNQ) of the '499 patent.

90/019,779

SNQ Ground	Claims	Basis	References
1	1, 3-5, 12	35 U.S.C. 102(b)	Comer as evidenced by Nuwayser
2	1, 3-5, 10-12	35 U.S.C. 102(a)	Vivitrex Pilot Study
3	1-13	35 U.S.C. 103(a)	Comer in view of Nuwayser, Rubio, and Wright
4	1-13	35 U.S.C. 103(a)	Vivitrex Pilot Study in view of Comer, Rubio, and Wright

Because at least one ground in the instant Request e.g., ground #3, is based on the same prior art previously presented to the Office in the prior IPR petition, the statutory threshold under 325(d) is met for the Director to exercise discretion in deciding whether to reject the 90/019,779 request.

However, in view of the fact that the prior instituted IPR petition was terminated after institution based on a joint settlement agreement and the PTAB did not fully evaluate the prior art presented in the petition, the Examiner as delegated by the Director declines to exercise such discretion to reject the reexamination request,

Accordingly, *ex parte* reexamination is ordered for the '499 patent, in view of the determination above that a substantial new question of patentability has been raised in the instant Request for Reexamination.

Conclusion

In view of the analysis above, the request for reexamination is **GRANTED**.
Claims 1-13 of US Patent 7,919,499 will be reexamined.

Duty to Disclose

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent

proceeding, involving US Patent 7,919,499 throughout the course of this reexamination proceeding. See MPEP 2207, 2282, and 2286.

Amendment in Reexamination Proceedings

Any proposed amendment to the specification and/or claims in the reexamination made by the patent owner must comply with 37 CFR 1.530(d)-(j), must be formally presented as directed by 37 CFR 1.52(a) and (b), and must be accompanied by any fees required by 37 CFR 1.20(c).

Waiver of Right to File Patent Owner Statement

In a reexamination proceeding, patent owner may waive the right under 37 CFR 1.530 to file a Patent Owner Statement. The document must contain a statement that patent owner waives the right under 37 CFR 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 CFR 1.248 because the request for reexamination was made by a third party. See 37 CFR 1.550(f).

Service of Papers

After the filing of a request for reexamination by a third-party requester, any document filed by either the patent owner or the third-party requester must be served on the other party (or parties, where two or more third-party requester proceedings are merged) in the reexamination proceeding in the manner provided by 37 CFR 1.228. See 37 CFR 1.550(f).

Extension of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136(a) apply only to “an applicant” and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that

ex parte reexamination proceedings “will be conducted with special dispatch.” See 37 CFR 1.550(a). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORA E BARNHART DRISCOLL, whose telephone number is (571)272-1928. The examiner can normally be reached M-F 7:00-4:00 p.m. ET.

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, Jean Witz, can be reached on 571-272-0927.

All correspondence relating to this *ex parte* reexamination proceeding may be submitted:

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For Patent Center transmissions, 37 CFR 1.8(a)(1)(i)(C) and (ii) state that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4) , and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

/Lora E Barnhart Driscoll/
Patent Reexamination Specialist, Art Unit 3991

Conferees:

/JOSEPH R KOSACK/
Patent Reexamination Specialist, Art Unit 3991

/T.M.S/
Supervisory Patent Examiner, Art Unit 3991