APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/259,949	09/30/2002	J. Michael Ramstack	000166.0073-US01	5406

26853 7590 04/09/2003

COVINGTON & BURLING
ATTN: PATENT DOCKETING
1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401

EXAMINER
BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
1615	4

DATE MAILED: 04/09/2003

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

PTO-90C (Rev. 07-01)

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21, 41-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 41-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

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)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The examiner acknowledges receipt of Amendment A filed 1/8/03.

Election/Restrictions

1. Applicant's election of Group I in Paper No. 3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

2. 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. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-21, 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, of U.S. Patent No. 6,495,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a composition suitable for injection through a needle into a host, comprising: microparticles comprising a polymeric binder, and injection vehicle, wherein the microparticles are suspended in said injection vehicle at a concentration of greater than 30 mg/ml to form a suspension, wherein a fluid phase of said suspension has a viscosity greater than about 60cp and less than about 600 cp at 20 deg C., wherein the viscosity of said fluid phase of said suspension

provides injectablility of the composition through a needle ranging in diameter from 18-22 gauge.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-21, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kino et al. (5656299), and further in view of Roorda et al. (US 5540912).

Kino discloses a sustained release microsphere preparation, which is produced by including a hydrophobic antipsycotic drug into a base composed of a high molecular weight polymeric binder such as polylactic acid, poly(lactic-co-glycolic) acid or the like and a process for the production (abstract). The microspheres have an average particle size of about 0.5 to 400μm (see col. 2 lines 30-34). The hydrophobic antipsychotic drug may be risperidone (see col. 2 lines 38-49). The poly(lactic-co-glycolic) acid is used in a compositional ratio of lactic acid to glycolic acid in a ratio from about 100:0 to 50:50 (see col. 3 lines 10-18). A viscosity enhancing agent, such as sodium carboxymethylcellulose, may be added to the microspheres, along with an density enhancing agent, such as sorbitol or a tonicity adjusting agent such as sodium chloride. Polysorbate 80 may also be added as a wetting agent. The sustained release microsphere preparation may be used preferably in the form of an aqueous suspension (see col. 4 lines 38-60). The preparation is intramuscularly or subcutaneously administered to a patient in need thereof (see col. 7 lines 35-45 and col. 8 lines 1-8). Sustained release injections of the microspheres can

be made into more stable injections by further adding a filler, such as sorbitol, dispersing the mixture and then subjecting the dispersion to freeze drying or spray drying to obtain a solid preparation which can be used by adding distilled water for injection or an appropriate dispersion medium at the time of injection (see col. 4 lines 52-60). The process for producing the microspheres comprises making an oil layer comprising a polymeric binder containing the antipsychotic drug, adding the oil layer to a water layer, subjecting the resulting mixture to an emulsification treatment to obtain an O/W type emulsion and subsequently removing the solvent in the oil layer by an in-water drying method (see col. 3 lines 27-50). Kino does not disclose the viscosity to be greater than about 60 cp and less than about 600 cp.

Absent unexpected results, it would have been obvious to one having ordinary skill in the art at the time of the invention to determine the optimal viscosity for application. The desired viscosity for any given formulation or use may vary, for example, according to the preference of the physician, the manner of application and type of applicator used, the amount of formulation needed, the area to which the formulation is applied, and similar considerations. The desired viscosity will also vary with the concentration of the particles in the suspension, since the presence of the particles contributes to the viscosity of the suspension. Both the prior art and the instant claims are drawn to a composition suitable for injection through a needle host comprising microparticles comprising a polymeric binder in combination with a viscosity enhancing agent, a density enhancing agent, a tonicity adjusting agent, a wetting agent and an active agent. Therefore, absent unexpected results regarding the criticality of the viscosity, Kino discloses all the limitations of the instant claims.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.