**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
J. Michael Ramstack, Ph.D., *et al.*

Application No.: 10/259,949-Conf. #5406 Group Art Unit: 1615

Filed: September 30, 2002 Examiner: R. Bennett

For: PREPARATION OF INJECTABLE SUSPENSIONS HAVING IMPROVED INJECTABILITY

## TRANSMITTAL LETTER

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

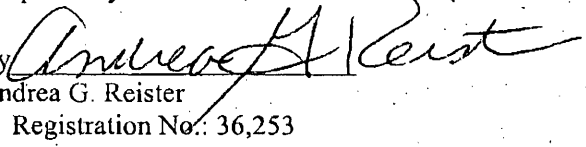
1. Amendment Transmittal (in duplicate);
2. Fee Transmittal;
3. Reply Under 37 C.F.R. § 1.111;
4. Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Patent;
5. Statement Under 37 CFR 3.73(b);
6. Copy of Declaration of Mark A. Tray, Ph.D. Under 37 C.F.R. § 1.132 filed in parent Appl. No. 09/577,875;
7. Check No. 312256 in the amount of $110 to cover the fee for the Terminal Disclaimer; and

8. Return receipt postcard.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-0740, referencing our Docket No. 000166.0073-US01. A duplicate copy of this paper is enclosed.

Dated: May 14, 2003

Respectfully submitted,

By 

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Bet 5-23-03

**REPLY UNDER 37 C.F.R. § 1.111**

Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action dated April 9, 2003 (Paper No. 4), Applicants provide the following remarks.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-0740 referencing our Docket No. 000166.0073-US01.

**REMARKS/ARGUMENTS**

Reconsideration of this Application is respectfully requested. Claims 1-21, 41, and 42 are currently pending for the examiner's consideration, with claim 1 being the only independent claim. Based on the following Remarks, Applicants respectfully request that the examiner reconsider all outstanding objections and rejections and they be withdrawn.

***Obviousness-Type Double Patenting***

The Examiner has rejected claims 1-21, 41, and 42 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 ("the '164 patent"). Filed herewith is a Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Patent executed by the assignee of the above-captioned application for the '164 patent ("Disclaimer"). A Statement Under 37 C.F.R. § 3.73(b) establishing the right to act on behalf of the assignee with regard to the above-captioned application is also filed herewith. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the proprietary of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991). The filing of a terminal disclaimer serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection. *Id.*; M.P.E.P. § 804.02. Based upon filing of the Disclaimer and accompanying fee, Applicants respectfully submit that the obviousness-type double patenting rejection should be withdrawn.

***Rejection Under 35 U.S.C. § 103(a)***

The examiner has rejected claims 1-21, 41, and 42 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,656,299 to Kino *et al.* ("the Kino patent") in view of U.S. Patent No. 5,540,912 to Roorda *et al.* ("the Roorda patent"). Applicants respectfully submit that none of the cited documents or other documents of record discloses or suggests the relationship between increased viscosity and improved injectability, or the claimed methods by which the compositions having improved injectability are produced. For at least this reason Applicants respectfully submit that the § 103 rejection cannot properly be maintained.

As noted by the Examiner in paragraph 5 of the Office Action, the Kino patent "does not disclose the viscosity to be greater than about 60 cp and less than about 600 cp." In fact, the Kino patent does not explicitly disclose the viscosity of the injection vehicles used in the Test Examples, nor does the Kino patent provide any information about injectability, or the relationship between injectability and viscosity of the injection vehicle. This is evident from paragraph 3 of the Declaration of Mark A. Tracy, Ph.D. Under 37 C.F.R. § 1.132 ("the Tracy Declaration") filed in parent application number 09/577,875 (now U.S. Patent No. 6,495,164), a copy of which is filed herewith.

As evident from the Tracy Declaration, all of the injection vehicles of the Test Examples of the Kino patent have a viscosity significantly less than 20 cp at 20°C. Particularly, as stated in paragraph 4 of the Tracy Declaration, the viscosity of the physiological saline injection vehicle as the fluid phase of a suspension containing the microspheres of each of Test Examples 1, 3, and 4 of the Kino patent is approximately one (1) cp at 20°C. As stated in paragraph 5 of the Tracy Declaration, the viscosity of the carboxymethyl cellulose (CMC) injection vehicle as the fluid phase of a suspension containing the microspheres of Test Example 2 of the Kino patent is less than 7 cp at 20°C.

The Examiner is taking the position that, "absent unexpected results regarding the criticality of the viscosity, Kino discloses all the limitations of the instant claims." However, as noted above, the Examiner recognizes that the Kino patent does not disclose the viscosity to be greater than about 60 cp and less than about 600 cp, and the Tracy Declaration evidences that all of the Test Examples of the Kino patent have a viscosity significantly less than 20 cp.

Applicants respectfully submit that the "criticality" of the viscosity to the improvements in injectability of the present invention is discussed throughout the above-captioned application as originally filed. For example, as noted on page 8, lines 12-16 of the above-captioned application:

> "The inventors have unexpectedly discovered that injectability is improved, and *in vivo* injectability failures significantly and unexpectedly reduced, by increasing the viscosity of the fluid phase of an injectable suspension. This is in contrast to conventional teachings that an increase in the viscosity hinders injectability and syringeability."

Moreover, as noted on page 12, line 15, through page 18, line 7 of the above-captioned application as originally filed, the *in vivo* studies "showed a dramatic improvement in injectability with increased injection vehicle viscosity." Based on the experiments and data reported in these pages of the application, it is evident that viscosities of at least about 20 cp are necessary for successful and medically acceptable injectability rates. At viscosities of less than or equal to about 11 cp, *in vivo* injectability failures increase significantly.

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