

In re application of: Ramstack *et al.*
Appl. No.: 09/577,875
Filed: May 25, 2000
For: **Preparation of Injectable
Suspensions Having Improved
Injectability**

Art Unit: 1615
Examiner: R. Bennett
Atty. Docket: 00166.0073.US00

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AMB
7/21/03

**Declaration of Mark A. Tracy, Ph.D.
Under 37 C.F.R. § 1.132**

Commissioner for Patents
Washington, D.C. 20231

I, Mark A. Tracy, Ph.D., hereby declare and state as follows.

1. I have a B.S. degree in Chemical Engineering, an M.S. degree in Chemical Engineering, and a Ph.D. degree in Physical Chemistry. I have over fifteen years experience in chemical engineering, chemistry, and controlled drug delivery technology. I am currently employed by Alkermes, Inc. ("Alkermes") as a Director of Formulation Development. I have been employed by Alkermes since July 1992. A copy of my *curriculum vitae* is attached.

2. The above-captioned U.S. Patent Application No. 09/577,875 ("the '875 application") is owned by Alkermes Controlled Therapeutics Inc. I, a subsidiary of Alkermes. I have read and understood the '875 application. I am familiar with the technology of the invention disclosed in the '875 application through my education and my work at Alkermes.

3. I have read and understood U.S. Patent No. 5,656,299 to Kino *et al.* ("the Kino patent"). The Kino patent does not explicitly disclose the viscosity of the injection vehicles used

in the Test Examples. The Kino patent does not provide any information about injectability, or the relationship between injectability and viscosity of the injection vehicle.

4. Test Examples 1, 3, and 4 of the Kino patent use physiological saline as the injection vehicle. Based upon my knowledge and experience, 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) centipoise (cp) at 20°C.

5. Test Example 2 of the Kino patent uses a 0.5% sodium carboxymethyl cellulose (CMC) solution isotonized with mannitol as the injection vehicle. Based upon my knowledge and experience, the CMC is the viscosity-controlling component of the injection vehicle of Test Example 2 of the Kino patent. That CMC is the viscosity-controlling component is exemplified by the two injection vehicles disclosed on page 10, lines 10-17 of the '875 application as originally filed. The Formula 1 injection vehicle described on page 10 of the '875 application contains 1.5% CMC, and has a viscosity of approximately 27 cp at 20°C. The Formula 2 injection vehicle described on page 10 of the '875 application contains 0.75% CMC, and has a viscosity of approximately 7 cp at 20°C. By reducing the CMC from 1.5% to 0.75%, the viscosity dropped from 27 cp to 7 cp. Based upon my knowledge and experience, and the disclosure on page 10, lines 10-17 of the '875 application, the viscosity of the 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.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so

Sates Code and that such willful false statements may jeopardize the validity of the above-captioned patent application or any patent issued thereon.

Mark A. Tracy
Mark A. Tracy

Date: May 17, 2002