PATENT
Attorney Docket No. 11285.0056-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
John R. Evans et al.	)	Group Art Unit: 1628
	)	
Application No.: 12/285,887	)	Examiner: HUI, San Ming R.
	)	
Filed: October 15, 2008	)	Confirmation No.: 1199
	)	
For: FORMULATION	)	**VIA EFS-WEB**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132 OF RONALD J. SAWCHUK

I, **Ronald J. Sawchuk**, declare as follows:

Qualifications

1. My academic background and work experience are summarized in my curriculum vitae, which is attached as **Exhibit 1**.

2. Currently, I am a Professor of Pharmaceutics, Emeritus, and Morse Alumni Distinguished Teaching Professor. I am also the Director of the Bioanalytic and Pharmacokinetic Services Laboratory at the University of Minnesota.

3. I obtained a Bachelor of Science Degree in Pharmacy in 1963 from the University of Toronto. I also received a Masters of Science Degree in Pharmaceutics from the University of Toronto in 1966 and completed a Doctoral Degree (Ph. D.) in Pharmaceutical Chemistry (pharmacokinetics emphasis) at the University of California, San Francisco in 1972.

4. I joined the University of Minnesota in 1971 as an Instructor in Pharmaceutics, and served from 1972 to 1977 as an Assistant Professor of Pharmaceutics, from 1977 to 1983 as an Associate Professor of Pharmaceutics, and as a full Professor of Pharmaceutics from 1983 until my retirement in July of 2010.

5. At the University of Minnesota, I served as a member of the graduate programs in Pharmaceutics, Neurosciences, and Experimental and Clinical Pharmacology. From 1983 to 1989 and 1991 to 1994 I was the Director of Graduate Studies in Pharmaceutics at the University. From 1998 to 1999 I served as the Head of the Department of Pharmaceutics at the University of Minnesota.

6. Also, from 1982 to 1995, I served as Director of the Clinical Pharmacokinetics Laboratory at the College of Pharmacy at the University of Minnesota.

7. During my career, I received several honors, scholarships and awards, including the Weaver Medal of Honor in 2001, the Meritorious Manuscript Award from the American Association of Pharmaceutical Scientists in 1999 and the Hallie Bruce Memorial Lecture Award in 1996. In 2007, I received the American Pharmacists Association (APhA) Research Achievement Award in the Basic Pharmaceutical Sciences.

8. I am a member of numerous scientific and clinical societies. I am a Fellow of the American Association of Pharmaceutical Scientists and of the American Association for the Advancement of Science. I have been a member of the International Society of Anti-infective Pharmacology and the International Society for the Study of

Xenobiotics (ISSX). I recently served as a member-at-large on the American Association of Pharmaceutical Scientists (AAPS) Executive Council.

9. I have served on the editorial boards of scientific journals such as the Journal of Pharmaceutical Sciences and the Saudi Pharmaceutical Journal. I am currently on the Editorial Board of the AAPS Journal, and on the ISSX Journal, Xenobiotica. I have also served on numerous advisory committees and review panels.

10. I have participated in multiple research projects focused in the areas of preclinical and clinical pharmacokinetics, both publicly and privately funded. I am a named author on over 100 refereed scientific publications, in addition to several book chapters, a book that I co-edited on drug bioavailability, and over 170 abstracts which have been presented at scientific meetings. I have also given hundreds of invited lectures.

11. I have significant experience in the areas of pharmaceutical research, pharmacokinetics, and drug development. Therefore, I believe that I am qualified to render the opinions set forth in this declaration.

12. I have read the Office Action dated September 16, 2011 ("Office Action"), which is attached as **Exhibit 2**. Among other rejections, I understand that the Office Action rejects the claims pending in the captioned application as unpatentable over the following references:

a. McLeskey et al., "Tamoxifen-resistant fibroblast growth factor-transfected MCF-7 cells are cross-resistant in vivo to the antiestrogen ICI 182,780 and

two aromatase inhibitors", *Clinical Cancel Research* 4:697-711 (1998) ("*McLeskey*", attached hereto as **Exhibit 3**);

b. European Patent Specification No. EP 0 346 014, which names Michael Dukes as inventor ("*Dukes*", attached hereto as **Exhibit 4**);

c. Osborne et al., "Comparison of the effects of a pure steroidal antiestrogen with those of tamoxifen in a model of human breast cancer", *J. National Cancer Institute*, 87(20):746-750 (1995) ("*Osborne*", attached hereto as **Exhibit 5**); and

d. the abstract of Wakeling et al., "ICI 182,780, a new antioestrogen with clinical potential", *J. Steroid Biochemistry & Molecular Biology*, 43(1-3):173-177 (1992) ("*Wakeling*", attached hereto as **Exhibit 6**);

13. I have read the instant application ("the '887 application"), which I believe corresponds to U.S. Application Publication No. US 2010/0152149 (attached hereto as **Exhibit 7**.)

14. I attach hereto **Exhibit 8**, which I believe is a copy of the pending claims in the '887 application with proposed amendments. I understand the claims in **Exhibit 8** will be filed in the Patent and Trademark Office as part of the response to the Office Action.

15. I understand that the earliest priority date for the '887 application is January 10, 2000. In the paragraphs below, I will refer to the state of the art in the areas of pharmaceutical research, pharmacokinetics, and drug development prior to January 10, 2000. I will also explain how a person of ordinary skill in that art at that time

would have understood the references cited in the Office Action and how such a person would have interpreted certain experimental results related to various fulvestrant formulations.

Disclosure in *McLeskey* regarding the castor oil fulvestrant composition

16. *McLeskey* discloses two fulvestrant compositions. One composition was prepared by dissolving powdered drug in 100% ethanol and then spiking it into warmed peanut oil to give a final concentration of 50 mg/ml ("the *McLeskey* peanut oil composition"). *McLeskey* at 698, col. 2, under "Drugs". The second composition is a 50 mg/ml fulvestrant composition "in a vehicle of 10% ethanol, 15% benzyl benzoate, 10% benzyl alcohol, brought to volume with castor oil" ("the *McLeskey* castor oil composition"). *Id*. *McLeskey* does not specify whether the percentages in the castor oil composition are in weight/volume units (% w/v, as recited in the claims of the '887 application) or in volume/volume units (% v/v).

17. In a liquid composition, when a solute or cosolvent is a liquid, it is often convenient to express its concentration as a volume percent, i.e., % v/v. For the reasons that follow, I believe one of ordinary skill in the art would have concluded the *McLeskey* castor oil composition was described in volume/volume units (% v/v).

18. For example, U.S. Patent No. 3,164,520 ("the '520 patent", attached as **Exhibit 9**) entitled "Injectable Steroid Compositions Containing at least 75% Benzyl Benzoate" discloses the preparation of parenteral injections of steroid drugs in formulations containing benzyl benzoate, and often also containing castor oil or sesame oil. *See*, *e.g.*, the working examples. The '520 patent states: "The amount of benzyl

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