EXHIBIT 32

SENJU EXHIBIT 2125
LUPIN v SENJU
IPR2015-01105

DECLARATION OF ROBERT O. WILLIAMS, III

I. QUALIFICATIONS

1. I, Robert O. Williams, III, Ph.D., submit this declaration at the request of Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. as an expert in the field of the design and evaluation of drug products. My qualifications in these areas, as well as other areas, are established below and by my *curriculum vitae*, which is attached as Appendix A.

2. I am currently the Johnson & Johnson Centennial Chair of Pharmaceutics at the University of Texas at Austin College of Pharmacy in Austin, Texas, where I have been teaching and conducting research for over fifteen years. Also, I am the Division Head of Pharmaceutics.

3. I received a B.S. degree in biology from Texas A&M University in 1979, a B.S. degree in pharmacy from the University of Texas at Austin in 1981, and a Ph.D. degree in pharmaceutics from the University of Texas at Austin in 1986. I am a licensed pharmacist.

4. I have extensive experience and expertise in pharmaceutical formulation and the use of excipients in formulating various types of drug dosage forms, including aqueous liquid preparations. I have experience with ophthalmic dosage forms including solutions. I am an expert in the field of pharmaceutical development, and I have worked almost exclusively in the field of pharmaceutical development since 1986.

5. Prior to becoming a professor, I worked in the pharmaceutical industry for several companies including Rhone-Poulenc Rorer Pharmaceuticals, Duramed Pharmaceuticals and Eli Lilly and Company. Additionally, from 1996 to 2007 I was co-founder and President of PharmaForm, a contract pharmaceutical laboratory, and from 2007 to mid-2010 I was a director of Akela Pharma. I was the Chief Scientist from 2009 to 2013 and founder of Enavail, a particle

engineering contract services company. Accordingly, I have relevant industry experience in addition to my academic qualifications.

6. My current research focuses on the development, formulation, optimization and delivery of drugs by a variety of technologies, including aqueous liquid preparations. I have extensive research experience and have authored numerous publications in this area.

7. I have authored or co-authored over 400 published papers, abstracts and book chapters related to my work in the pharmaceutical sciences. A significant number of my papers are directed specifically to pharmaceutical formulation techniques and drug dosage forms. I am a co-inventor on over 35 patents and/or patent applications that deal with drug formulation technology.

8. Over the course of my career, I have earned numerous prestigious professional awards and honors, which are described on my curriculum vitae. For example, I was elected as a fellow to the American Association of Pharmaceutical Scientists and the American Institute of Medical and Biological Engineering. I have also received the William J. Sheffield Outstanding Alumnus Award and was named a Dean's Fellow at the University of Texas at Austin College of Pharmacy.

9. I am currently the Editor-in-Chief for *AAPS PharmSciTech, a joint publication of the American Association of Pharmaceutical Scientists and Springer Publishing.* I was the Editor-in-Chief for *Drug Development and Industrial Pharmacy* from 2000 to 2014. I am a member of the Editorial Advisory Board for *The Open Drug Delivery Journal.* I also have served or currently serve as a reviewer for many scientific journals, including *International Journal of Pharmaceutics*, *Pharmaceutical Research*, *European Journal of Pharmaceutics and Biopharmaceutics*, *Journal of the Controlled Release Society*, *S.T.P. Pharma*, *Pharmaceutical*

Development and Technology, *International Journal of Pharmaceutical Compounding*, *Journal of Membrane Science*, *AAPS PharmSciTech*, *Journal of Pharmaceutical Sciences*, *Journal of Pharmaceutical and Biomedical Analysis* and *Toxicology Letters*.

10. In addition to my research and teaching duties at the University of Texas at Austin, I have consulted for pharmaceutical, chemical and biotechnology companies. I have consulted for both innovator pharmaceutical companies and generic pharmaceutical companies. Most of these consulting activities have dealt specifically with drug formulation issues.

II. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

11. I have been asked to provide my opinion on various terms and phrases in the claims of U.S. Patent Nos. 8,129,431 ("the '431 patent"), 8,669,290 ("the '290 patent"), 8,754,131 ("the '131 patent"), 8,871,813 ("the '813 patent"), and 8,927,606 ("the '606 patent") (collectively, "the patents-in-suit") as of the January 21, 2003, priority date of the patents-in-suit, based on the knowledge and understanding of a person of ordinary skill in the art, and to respond to certain proposed claim interpretations of Defendants.

12. In forming my opinions, I have reviewed the patents-in-suit and their prosecution histories. I also have considered the Joint Claim Construction and Prehearing Statement and the documents cited therein. I also have reviewed the declaration of Dr. Thomas Green. (Ex.[1] 37.) I additionally have based my opinions on my professional and academic experience in the areas of pharmaceutical development. I reserve the right to testify about these materials and experience. To the extent I am provided additional documents or information, including any declarations produced by Defendants, I may offer further opinions. In addition to these materials, I may consider additional documents and information in forming any rebuttal opinions.

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[1] "Ex. __" refers to the exhibits to the declaration of Bryan Diner in support of Plaintiffs' Opening *Markman* brief.

III. LEGAL PRINCIPLES

13. I have been informed and understand that the patent claims, and their terms and phrases, are interpreted by the Court according to their ordinary and customary meaning to a person of ordinary skill in the art at the time of invention. I understand that interpreting a term or phrase contained in a patent claim involves reading the language of the claim and considering other materials relevant to the claim, including the patent specification and the prosecution history. I understand that evidence extrinsic to the patent and its prosecution history may also be consulted, but that such materials should only be considered so long as they are not inconsistent with the claim language, the patent specification and the prosecution history.

14. I have been informed and understand that an independent patent claim does not itself refer to any other patent claim. I understand that a dependent patent claim refers to another patent claim and incorporates all of the elements of the claim to which it refers, and also adds further elements.

15. I have been informed and understand that the transition phrase "consisting essentially of" as it is used in a patent claim means that the claim encompasses the recited elements and only those non-recited elements that do not materially affect the basic and novel properties of the claimed composition. As such, any non-recited element that materially affects the basic and novel properties of the composition is excluded from the claim's scope. I further understand that the transition phrase "consisting essentially of" differs from the open transition term "comprising," which means that the claimed composition is open to non-recited elements.

IV. STATEMENT OF OPINIONS EXPRESSED AND BASES AND REASONS THEREFORE

A. Statement of Facts

16. I understand that this litigation involves the '431, '290, '131, '813, and '606 patents, which cover Plaintiffs' Prolensa® product. Prolensa® is an aqueous liquid preparation containing bromfenac[2] sodium sesquihydrate as the active pharmaceutical ingredient. (Ex. 6 at 2 ("Description").)

17. I understand that Defendants have each filed Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") to sell generic versions of Prolensa® prior to expiration of the patents-in-suit. (Exs. 8-16.)

1. The '431 Patent Claims

18. The claims of the '431 patent are directed, generally speaking, to aqueous liquid preparations of bromfenac. ('431 patent at col. 11, line 65 – col. 14, line 22.) I understand that Defendants have raised claim construction disputes regarding certain claims of the '431 patent. I understand that Plaintiffs have asserted that Defendants have infringed claims 1-4, 6-10 and 18-20 of the '431 patent.

19. Independent claim 1 of the '431 patent is directed, generally speaking, to an aqueous liquid preparation consisting essentially of two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, and where the second component is tyloxapol. The aqueous liquid preparation of claim 1 is formulated for ophthalmic administration. If a quaternary ammonium compound is included in the aqueous liquid preparation of claim 1, it is benzalkonium chloride ("BAC"). ('431 patent at col. 11, line 66 – col. 12, line 9.)

[2] The chemical name for bromfenac is 2-amino-3-(4-bromobenzoyl)phenylacetic acid. ('431 patent at col. 1, lines 24-36.)

20. Dependent claim 2 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the first component is a bromfenac sodium salt. ('431 patent at col. 12, lines 10-12.)

21. Dependent claim 3 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the second component is tyloxapol and the pharmacologically acceptable salt of bromfenac is a sodium salt, the concentration of tyloxapol is from about 0.01 w/v % to about 0.5 w/v %, the first component is a bromfenac sodium salt, and the concentration of the bromfenac sodium salt is from about 0.01 w/v % to about 0.5 w/v %. ('431 patent at col. 12, lines 13-23.)

22. Dependent claim 4 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 3, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.3 w/v % and the concentration of the bromfenac sodium salt is from about 0.05 to about 0.2 w/v %. ('431 patent at col. 12, lines 24-28.)

23. Dependent claim 6 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 4, where the concentration of tyloxapol is about 0.02 w/v %. ('431 patent at col. 12, lines 32-34.)

24. Dependent claim 7 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the formulation further includes one or more additives selected from the group consisting of a preservative, buffer, thickener, stabilizer, chelating agent, and pH controlling agent. ('431 patent at col. 12, lines 35-39.)

25. Dependent claim 8 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 7, where the preservative is benzalkonium chloride, the buffer is boric acid and/or sodium borate, the thickener is polyvinylpyrrolidone, the stabilizer is

sodium sulfite, the chelating agent is sodium edetate, and the pH controlling agent is sodium hydroxide. ('431 patent at col. 12, lines 40-46.)

26. Dependent claim 9 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 8, where the pH is from about 7 to about 9. ('431 patent at col. 12, lines 47-48.)

27. Dependent claim 10 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 8, where the pH is from about 7.5 to about 8.5. ('431 patent at col. 12, lines 49-50.)

28. Independent claim 18 of the '431 patent is directed, generally speaking, to an aqueous liquid preparation consisting essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The aqueous liquid preparation of claim 18 is formulated for ophthalmic administration, and benzalkonium chloride is the only quaternary ammonium compound included in the aqueous liquid preparation of claim 18. ('431 patent at col. 13, line 15 – col. 14, line 9.)

29. Dependent claim 19 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 18, where (a) is a bromfenac sodium salt. ('431 patent at col. 14, lines 10-12.)

30. Dependent claim 20 of the '431 patent is directed, generally speaking, to the aqueous liquid preparation of claim 19, where the concentration of bromfenac sodium salt is from about 0.01 to about 0.5% and the concentration of tyloxapol is about 0.02 w/v%. ('431 patent at col. 14, lines 13-16.)

2. **The '290 Patent Claims**

31. The claims of the '290 patent are directed, generally speaking, to stable aqueous liquid preparations of bromfenac. ('290 patent at col. 12, line 1 - col. 15, line 8.) I understand that Defendants have raised claim construction disputes regarding certain claims of the '290 patent. I understand that Plaintiffs have asserted that Defendants have infringed claims 1-4 and 6-30 of the '290 patent.

32. Independent claim 1 of the '290 patent is directed, generally speaking, to a stable aqueous liquid preparation comprising two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation, and where the second component is tyloxapol and is present in the liquid preparation in an amount sufficient to stabilize the first component. The stable aqueous liquid preparation of claim 1 is formulated for ophthalmic administration. ('290 patent at col. 12, lines 2-12.)

33. Dependent claim 2 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, further comprising a quaternary ammonium salt. ('290 patent at col. 12, lines 13-14.)

34. Dependent claim 3 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the first component is a bromfenac sodium salt. ('290 patent at col. 12, lines 15-17.)

35. Dependent claim 4 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the concentration of tyloxapol is from about 0.01 w/v% to about 0.05 w/v %, where the first component is a bromfenac sodium salt, and where the

concentration of the bromfenac sodium salt is from about 0.01 to about 0.2 w/v%. ('290 patent at col. 12, lines 18-25.)

36. Dependent claim 6 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the pH is from about 7.5 to about 8.5. ('290 patent at col. 12, lines 29-30.)

37. Dependent claim 7 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 1, where the stable aqueous liquid preparation consists essentially of (a) bromfenac sodium salt, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The stable aqueous liquid preparation of claim 7 is formulated for ophthalmic administration. The concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of claim 7 is from about 0.02 w/v % to about 0.1 w/v %. ('290 patent at col. 12, lines 31-40.)

38. Independent claim 8 of the '290 patent is directed, generally speaking, to a stable aqueous liquid preparation comprising two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation, and where the second component is tyloxapol. The stable aqueous liquid preparation of claim 8 is formulated for ophthalmic administration and is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('290 patent at col. 12, lines 41-53.)

39. Dependent claim 9 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 8, further comprising a quaternary ammonium salt. ('290 patent at col. 12, lines 54-55.)

40. Dependent claim 10 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 8, where the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('290 patent at col. 12, lines 56-60.)

41. Dependent claim 11 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 8, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, where the first component is a bromfenac sodium salt, and where the concentration of the bromfenac sodium salt is from about 0.01 to about 0.2 w/v%. ('290 patent at col. 12, lines 61-67.)

42. Dependent claim 12 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 11, where the pH is from about 7.5 to about 8.5. ('290 patent at col. 13, lines 1-2.)

43. Dependent claim 13 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 8, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The concentration of the bromfenac

sodium salt in the stable aqueous liquid preparation of claim 13 is from about 0.02 w/v % to about 0.1 w/v %. ('290 patent at col. 13, lines 3-13.)

44. Independent claim 14 of the '290 patent is directed, generally speaking, to a stable aqueous liquid preparation comprising two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation, and where the second component is tyloxapol. The stable aqueous liquid preparation of claim 14 is formulated for ophthalmic administration and does not include mannitol. ('290 patent at col. 13, lines 14-25.)

45. Dependent claim 15 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 14, further comprising a quaternary ammonium salt. ('290 patent at col. 13, lines 26-27.)

46. Dependent claim 16 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 14, where the first component is a bromfenac sodium salt. ('290 patent at col. 13, lines 28-30.)

47. Dependent claim 17 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 16, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v % and the concentration of bromfenac sodium salt is from about 0.05 to about 0.2 w/v %. ('290 patent at col. 13, lines 31-35.)

48. Dependent claim 18 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 17, where the pH is from about 7.5 to about 8.5. ('290 patent at col. 13, lines 36-37.)

49. Dependent claim 19 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 14, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of claim 19 is from about 0.02 w/v % to about 0.1 w/v %. ('290 patent at col. 13, lines 38-48.)

50. Dependent claim 20 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 14, where the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('290 patent at col. 13, lines 49-53.)

51. Dependent claim 21 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 20, further comprising a quaternary ammonium salt. ('290 patent at col. 13, lines 54-55.)

52. Dependent claim 22 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 20, where the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('290 patent at col. 13, lines 56-60.)

53. Dependent claim 23 of the '290 patent is directed, generally speaking, to the aqueous liquid preparation of claim 20, where the concentration of tyloxapol is from about 0.01

w/v % to about 0.05 w/v %, where the first component is a bromfenac sodium salt, and where the concentration of the bromfenac sodium salt is from about 0.01 to about 0.2 w/v%. ('290 patent at col. 13, lines 61-67.)

54. Dependent claim 24 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 23, where the pH is from about 7.5 to about 8.5. ('290 patent at col. 14, lines 1-2.)

55. Dependent claim 25 of the '290 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 20, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The stable aqueous liquid preparation of claim 25 is formulated for ophthalmic administration and the concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of claim 25 is from about 0.02 w/v % to about 0.1 w/v %. ('290 patent at col. 14, lines 3-14.)

56. Dependent claims 26-30 of the '290 patent are directed, generally speaking, to the aqueous liquid preparations of claims 1, 8, 14, 20, and 22, respectively, where the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows: viable cell counts of bacteria (*S. aureus, P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count

keeps the same level as that of 14 days after inoculation. ('290 patent at col. 14, line 15 – col. 15, line 8.)

3. **The '131 Patent Claims**

57. The claims of the '131 patent are directed, generally speaking, to stable aqueous liquid preparations of bromfenac. ('131 patent at col. 12, line 1 - col. 15, line 8.) I understand that Defendants have raised claim construction disputes regarding certain claims of the '131 patent. I understand that Plaintiffs have asserted that Defendants have infringed claims 1-30 of the '131 patent.

58. Independent claim 1 of the '131 patent is directed, generally speaking, to a stable aqueous liquid preparation comprising two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation and is present at a concentration from about 0.05 w/v % to about 0.2 w/v %, and where the second component is tyloxapol and is present in the liquid preparation in an amount sufficient to stabilize the first component. The stable aqueous liquid preparation of claim 1 is formulated for ophthalmic administration. ('131 patent at col. 12, lines 2-14.)

59. Dependent claim 2 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, further comprising a quaternary ammonium salt. ('131 patent at col. 12, lines 15-16.)

60. Dependent claim 3 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the first component is a bromfenac sodium salt. ('131 patent at col. 12, lines 18-20.)

61. Dependent claim 4 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the concentration of tyloxapol is from about 0.01 w/v% to about 0.05 w/v %. ('131 patent at col. 12, lines 21-23.)

62. Dependent claim 5 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the pH is from about 7.5 to about 8.5. ('131 patent at col. 12, lines 24-25.)

63. Dependent claim 6 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 1, where the stable aqueous liquid preparation consists essentially of (a) bromfenac sodium salt, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The stable aqueous liquid preparation of claim 6 is formulated for ophthalmic administration. In the stable aqueous liquid preparation of claim 6, the concentration of the bromfenac sodium salt is from about 0.02 w/v % to about 0.1 w/v %, and the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %. ('131 patent at col. 12, lines 26-36.)

64. Independent claim 7 of the '131 patent is directed, generally speaking, to a stable aqueous liquid preparation comprising two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation and is present at a concentration from about 0.05 w/v % to about 0.2 w/v %, and where the second component is tyloxapol. The stable aqueous liquid preparation of claim 7 is formulated for ophthalmic administration and is characterized in that greater than about 90% of the original amount of the first component

remains in the preparation after storage at about 60° C. for 4 weeks. ('131 patent at col. 12, lines 37-51.)

65. Dependent claim 8 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 7, further comprising a quaternary ammonium salt. ('131 patent at col. 12, lines 52-53.)

66. Dependent claim 9 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 7, where the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('131 patent at col. 12, lines 54-58.)

67. Dependent claim 10 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 7, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, where the first component is a bromfenac sodium salt, and where the concentration of the bromfenac sodium salt is from about 0.05 to about 0.1 w/v%. ('131 patent at col. 12, lines 59-65.)

68. Dependent claim 11 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 10, where the pH is from about 7.5 to about 8.5. ('131 patent at col. 12, lines 66-67.)

69. Dependent claim 12 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 7, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium

chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of claim 12 is from about 0.05 w/v % to about 0.1 w/v % and the concentration of tyloxapol is about 0.02 w/v%. ('131 patent at col. 13, lines 1-12.)

70. Independent claim 13 of the '131 patent is directed, generally speaking, to a stable aqueous liquid preparation comprising two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation and is present at a concentration from about 0.05 w/v % to about 0.2 w/v %, and where the second component is tyloxapol. The stable aqueous liquid preparation of claim 13 is formulated for ophthalmic administration and does not include mannitol. ('131 patent at col. 13, lines 13-24.)

71. Dependent claim 14 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, further comprising a quaternary ammonium salt. ('131 patent at col. 13, lines 25-26.)

72. Dependent claim 15 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, where the first component is a bromfenac sodium salt. ('131 patent at col. 13, lines 27-29.)

73. Dependent claim 16 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, and the concentration of the bromfenac sodium salt is from about 0.05 to about 0.1 w/v %. ('131 patent at col. 13, lines 30-34.)

74. Dependent claim 17 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, where the pH is from about 7.5 to about 8.5. ('131 patent at col. 13, lines 35-36.)

75. Dependent claim 18 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 13, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of claim 18 is from about 0.02 w/v % to about 0.1 w/v %, and the concentration of tyloxapol is from about 0.02 w/v % to about 0.05 w/v %. ('131 patent at col. 13, lines 37-48.)

76. Dependent claim 19 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 13, where the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('131 patent at col. 13, lines 49-53.)

77. Dependent claim 20 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 19, further comprising a quaternary ammonium salt. ('131 patent at col. 13, lines 54-55.)

78. Dependent claim 21 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 19, where the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component

remains in the preparation after storage at about 60° C. for 4 weeks. ('131 patent at col. 13, lines 56-60.)

79. Dependent claim 22 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 21, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, where the first component is a bromfenac sodium salt, and where the concentration of bromfenac sodium salt is from about 0.05 to about 0.1 w/v%. ('131 patent at col. 13, lines 61-67.)

80. Dependent claim 23 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 22, where the pH is from about 7.5 to about 8.5. ('131 patent at col. 14, lines 1-2.)

81. Dependent claim 24 of the '131 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 13, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The stable aqueous liquid preparation of claim 24 is formulated for ophthalmic administration. The concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of claim 24 is from about 0.05 w/v % to about 0.1 w/v %. ('131 patent at col. 14, lines 3-14.)

82. Dependent claims 25-29 of the '131 patent are directed, generally speaking, to the aqueous liquid preparations of claims 1, 4, 7, 9, and 13, respectively, where the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows: viable cell counts of bacteria (*S. aureus, P. aeruginosa*) 24 hours and

7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation. ('131 patent at col. 14, line 15 – col. 15, line 4; *see* Section IV.F. below.)

83. Dependent claim 30 of the '131 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, further comprising one or more additives selected from the group consisting of a preservative, buffer, thickener, stabilizer, chelating agent, and pH controlling agent. ('131 patent at col. 15, lines 5-8.)

4. The '813 Patent Claims

84. The claims of the '813 patent are directed, generally speaking, to stable aqueous liquid preparations of bromfenac. ('813 patent at col. 11, line 29 - col. 14, line 23.) I understand that Defendants have raised claim construction disputes regarding certain claims of the '813 patent. I understand that Plaintiffs have asserted that Defendants have infringed claims 1, 3-5, 7, 9-11, 13, 15-17, and 19-22 of the '813 patent.

85. Independent claim 1 of the '813 patent is directed, generally speaking, to a stable aqueous liquid preparation consisting essentially of (a) a first component, (b) a second component, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (c) boric acid, (d) sodium tetraborate, and (e) water. The first component is the sole pharmaceutical active ingredient in the stable aqueous liquid preparation of claim 1 and is present at a concentration from about 0.05 w/v % to about 0.2 w/v %. The second component is tyloxapol and is present in the stable aqueous liquid preparation of claim 1 in an amount

sufficient to stabilize the first component. The stable aqueous liquid preparation of claim 1 is formulated for ophthalmic administration. ('813 patent at col. 11, lines 30-42.)

86. Dependent claim 3 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the first component is a bromfenac sodium salt. ('813 patent at col. 11, lines 46-48.)

87. Dependent claim 4 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %. ('813 patent at col. 11, lines 49-51.)

88. Dependent claim 5 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 1, where the pH is from about 7.5 to about 8.5. ('813 patent at col. 11, lines 52-54.)

89. Independent claim 7 of the '813 patent is directed, generally speaking, to a stable aqueous liquid preparation consisting essentially of (a) a first component, (b) a second component, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (c) boric acid, (d) sodium tetraborate, and (e) water. The first component is the sole pharmaceutical active ingredient in the stable aqueous liquid preparation of claim 7 and is present at a concentration from about 0.05 w/v % to about 0.2 w/v %. The second component is tyloxapol. The stable aqueous liquid preparation of claim 7 is formulated for ophthalmic administration and is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('813 patent at col. 11, line 64 – col. 12, line 12.)

90. Dependent claim 9 of the '813 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 7, where the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('813 patent at col. 12, lines 15-19.)

91. Dependent claim 10 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 7, where the concentration of tyloxapol is from about 0.01 w/v% to about 0.05 w/v %, the first component is a bromfenac sodium salt, and the concentration of bromfenac sodium salt is from about 0.05 w/v % to about 0.1 w/v %. ('813 patent at col. 12, lines 20-26.)

92. Dependent claim 11 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 10, where the pH is from about 7.5 to about 8.5. ('813 patent at col. 12, lines 27-28.)

93. Independent claim 13 of the '813 patent is directed, generally speaking, to a stable aqueous liquid preparation consisting essentially of (a) a first component, (b) a second component, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (c) boric acid, (d) sodium tetraborate, and (e) water. The first component is the sole pharmaceutical active ingredient in the stable aqueous liquid preparation of claim 13 and is present at a concentration from about 0.05 w/v % to about 0.2 w/v %. The second component is tyloxapol. The stable aqueous liquid preparation of claim 13 is formulated for ophthalmic administration and does not include mannitol. ('813 patent at col. 12, lines 39-50.)

94. Dependent claim 15 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, where the first component is a bromfenac sodium salt. ('813 patent at col. 12, lines 54-56.)

95. Dependent claim 16 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v % and the concentration of bromfenac sodium salt is from about 0.05 to about 0.1 w/v%. ('813 patent at col. 12, lines 57-61.)

96. Dependent claim 17 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 13, where the pH is from about 7.5 to about 8.5. ('813 patent at col. 12, lines 62-63.)

97. Dependent claim 19 of the '813 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 13, where the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('813 patent at col. 13, lines 7-11.)

98. Dependent claim 20 of the '813 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 19, where the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('813 patent at col. 13, lines 12-15.)

99. Dependent claim 21 of the '813 patent is directed, generally speaking, to the stable aqueous liquid preparation of claim 20, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, where the first component is a bromfenac sodium salt, and the

concentration of bromfenac sodium salt is from about 0.05 w/v % to about 0.1 w/v%. ('813 patent at col. 13, lines 16-21.)

100. Dependent claim 22 of the '813 patent is directed, generally speaking, to the aqueous liquid preparation of claim 21, where the pH is from about 7.5 to about 8.5. ('813 patent at col. 13, lines 22-24.)

5. The '606 Patent Claims

101. The claims of the '606 patent are directed, generally speaking, to methods of treatment for inflammatory disease of an eye with stable aqueous liquid preparations of bromfenac. ('606 patent at col. 11, line 16 - col. 14, line 31.) I understand that Defendants have raised claim construction disputes regarding certain claims of the '606 patent. I understand that Plaintiffs have asserted that Defendants have infringed claims 1-30 of the '606 patent.

102. Independent claim 1 of the '606 patent is directed, generally speaking, to a method for treating an inflammatory disease of an eye, comprising administering to the eye a stable aqueous liquid preparation that comprises two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation, and where the second component is tyloxapol and is present in the aqueous liquid preparation in an amount sufficient to stabilize the first component. The stable aqueous liquid preparation of the method of claim 1 is formulated for ophthalmic administration and is administered to the eye at a dose and a frequency effective to treat the inflammatory disease. ('606 patent at col. 11, lines 17-31.)

103. Dependent claim 2 of the '606 patent is directed, generally speaking, to the method of claim 1, where the inflammatory disease is a disease of an anterior or posterior segment of the eye. ('606 patent at col. 11, lines 32-34.)

104. Dependent claim 3 of the '606 patent is directed, generally speaking, to the method of claim 2, where the disease is postoperative inflammation. ('606 patent at col. 11, lines 35-36.)

105. Dependent claim 4 of the '606 patent is directed, generally speaking, to the method of claim 1, where the first component is a bromfenac sodium salt. ('606 patent at col. 11, lines 37-39.)

106. Dependent claim 5 of the '606 patent is directed, generally speaking, to the method of claim 1, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, the first component is a bromfenac sodium salt, and the concentration of bromfenac sodium salt is from about 0.01 to about 0.2 w/v%. ('606 patent at col. 11, lines 40-45.)

107. Dependent claim 6 of the '606 patent is directed, generally speaking, to the method of claim 5, where the concentration of bromfenac sodium salt is from about 0.02 w/v % to about 0.1 w/v %. ('606 patent at col. 11, lines 46-48.)

108. Dependent claim 7 of the '606 patent is directed, generally speaking, to the method of claim 5, where the aqueous liquid preparation further comprises a quaternary ammonium salt. ('606 patent at col. 11, lines 49-51.)

109. Dependent claim 8 of the '606 patent is directed, generally speaking, to the method of claim 5, where the concentration of the bromfenac sodium salt is about 0.1 w/v %. ('606 patent at col. 11, lines 52-54.)

110. Dependent claim 9 of the '606 patent is directed, generally speaking, to the method of claim 1, where the stable aqueous liquid preparation consists essentially of (a) bromfenac sodium salt, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The stable aqueous liquid preparation of the method of claim 9 is formulated for ophthalmic administration, and the concentration of the bromfenac sodium salt in the stable aqueous liquid preparation of the method of claim 9 is from about 0.02 w/v % to about 0.1 w/v %. ('606 patent at col. 11, lines 55-63.)

111. Dependent claim 10 of the '606 patent is directed, generally speaking, to the method of claim 1, where the dose comprises one or two drops. ('606 patent at col. 11, lines 64-65.)

112. Independent claim 11 of the '606 patent is directed, generally speaking, to a method for treating an inflammatory disease of an eye comprising administering to the eye a stable aqueous liquid preparation that comprises two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation, and where the second component is tyloxapol. The stable aqueous liquid preparation of the method of claim 11 is formulated for ophthalmic administration, is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks, and is administered to the eye at a dose and a frequency effective to treat the inflammatory disease. ('606 patent at col. 11, line 66 – col. 12, line 15.)

113. Dependent claim 12 of the '606 patent is directed, generally speaking, to the method of claim 11, where the stable aqueous liquid preparation of the method of claim 12 is

characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('606 patent at col. 12, lines 16-20.)

114. Dependent claim 13 of the '606 patent is directed, generally speaking, to the method of claim 11, where the inflammatory disease is a disease of an anterior or posterior segment of said eye. ('606 patent at col. 12, lines 21-23.)

115. Dependent claim 14 of the '606 patent is directed, generally speaking, to the method of claim 13, where the disease is postoperative inflammation. ('606 patent at col. 12, lines 24-25.)

116. Dependent claim 15 of the '606 patent is directed, generally speaking, to the method of claim 11, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, the first component is a bromfenac sodium salt, and the concentration of bromfenac sodium salt is from about 0.01 to about 0.2 w/v%. ('606 patent at col. 12, lines 26-31.)

117. Dependent claim 16 of the '606 patent is directed, generally speaking, to the method of claim 15, where the concentration of bromfenac sodium salt is from about 0.02 to about 0.1 w/v%. ('606 patent at col. 12, lines 32-34.)

118. Dependent claim 17 of the '606 patent is directed, generally speaking, to the method of claim 11, where the stable aqueous liquid preparation further comprises a quaternary ammonium salt. ('606 patent at col. 12, lines 35-36.)

119. Dependent claim 18 of the '606 patent is directed, generally speaking, to the method of claim 11, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid,

(d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The concentration of bromfenac sodium salt in the stable aqueous liquid preparation of the method of claim 18 is from about 0.02 w/v % to about 0.1 w/v %. ('606 patent at col. 12, lines 37-47.)

120. Independent claim 19 of the '606 patent is directed, generally speaking, to a method for treating an inflammatory disease of an eye comprising administering to the eye a stable aqueous liquid preparation that comprises two components, where the first component is bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, where the first component is the sole pharmaceutical active ingredient contained in the preparation, and where the second component is tyloxapol. The stable liquid preparation of the method of claim 19 is formulated for ophthalmic administration, does not include mannitol, and is administered at a dose and a frequency effective to treat the inflammatory disease. ('606 patent at col. 12, lines 48-62.)

121. Dependent claim 20 of the '606 patent is directed, generally speaking, to the method of claim 19, where the inflammatory disease is a disease of an anterior or posterior segment of said eye. ('606 patent at col. 12, lines 63-65.)

122. Dependent claim 21 of the '606 patent is directed, generally speaking, to the method of claim 20, where the disease is postoperative inflammation. ('606 patent at col. 12, lines 66-67.)

123. Dependent claim 22 of the '606 patent is directed, generally speaking, to the method of claim 19, where the first component is a bromfenac sodium salt. ('606 patent at col. 13, lines 1-3.)

124. Dependent claim 23 of the '606 patent is directed, generally speaking, to the method of claim 22, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %, and the concentration of the bromfenac sodium salt is from about 0.05 to about 0.2 w/v %. ('606 patent at col. 13, lines 4-8.)

125. Dependent claim 24 of the '606 patent is directed, generally speaking, to the method of claim 22, where the concentration of the bromfenac sodium salt is from about 0.02 to about 0.1 w/v %. ('606 patent at col. 13, lines 9-11.)

126. Dependent claim 25 of the '606 patent is directed, generally speaking, to the method of claim 20, where the stable aqueous liquid preparation consists essentially of (a) bromfenac or a pharmacologically acceptable salt or hydrate of bromfenac, where the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate and 3/2 hydrate, (b) tyloxapol, (c) boric acid, (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinylpyrrolidone, and (h) sodium sulfite. The concentration of bromfenac sodium salt in the stable aqueous liquid preparation of the method of claim 25 is from about 0.02 w/v % to about 0.1 w/v %. ('606 patent at col. 13, lines 12-22.)

127. Dependent claim 26 of the '606 patent is directed, generally speaking, to the method of claim 20, where the stable aqueous liquid preparation of the method of claim 26 is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks. ('606 patent at col. 13, lines 23-27.)

128. Dependent claim 27 of the '606 patent is directed, generally speaking, to the method of claim 20, where the concentration of tyloxapol is from about 0.01 w/v % to about 0.05

w/v %, the first component is a bromfenac sodium salt, and the concentration of bromfenac sodium salt in is from about 0.02 to about 0.1 w/v%. ('606 patent at col. 13, lines 28-33.)

129. Dependent claims 28-30 of the '606 patent are directed, generally speaking, to the methods of claims 1, 11, and 19, respectively, where the aqueous liquid preparation satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows: viable cell counts of bacteria (*S. aureus, P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation. ('606 patent at col. 14, lines 1-31.)

B. A Person of Ordinary Skill in the Art

130. Based on my review of the patents-in-suit and their file histories, I have considered the qualifications of a person of ordinary skill in the art at the time of the January 21, 2003 priority date of the patents-in-suit.

131. In my opinion, a hypothetical person of ordinary skill in the art would have had at least a bachelor's degree in pharmaceutics or pharmaceutical chemistry or a related discipline with 3-5 years of work experience in this area, or a comparable level of education and training.

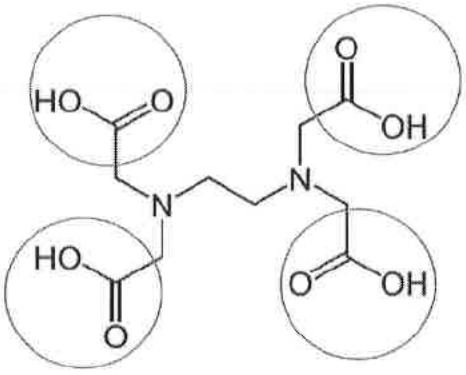
C. "EDTA sodium salt" and "sodium edetate"

132. I understand that the parties dispute the meaning of the phrase "sodium edetate" as it is used in claims 8, 14, and 17 of the '431 patent, and the meaning of the phrase "EDTA sodium salt" as it is used in claim 18 of the '431 patent, claims 7, 13, 19, and 25 of the '290 patent, claims 6, 12, 18, and 24 of the '131 patent, and claims 9, 18, and 25 of the '606 patent.

1. Background

133. EDTA is a well-known acronym for ethylenediaminetetraacetic acid. Edetate means ethylenediaminetetraacetate. (*See, e.g.*, Ex. 37 at ¶ 12.)

134. Ethylenediaminetetraacetate is a well-known chelating agent. A chelating agent strongly binds and sequesters certain metal ions in solution and is commonly used in pharmaceutical formulations. (*See, e.g.*, *id.* at ¶ 13.)



135. Ethylenediaminetetraacetic acid, or EDTA, is depicted above. It can form salts with certain metals, including sodium and calcium. (*See, e.g.*, *id.* at ¶¶ 14-15.)

136. EDTA is a tetraacetic acid, meaning it has four carboxyl groups that can be charged or ionized (circled above in red). (*See, e.g.*, *id.*) Accordingly, EDTA can form a mono-, di-, tri-, or tetra- sodium salt. (*See, e.g.*, *id.*)

2. Usage in the Claims of the Patents-In-Suit

137. In my opinion, the phrases "sodium edetate" and "EDTA sodium salt," as used in the claims of the patents-in-suit, both mean the same thing, a sodium salt of ethylenediaminetetraacetic acid. These phrases encompass, for example, the disodium salt of ethylenediaminetetraacetic acid.

138. As discussed above, edetate means ethylenediaminetetraacetate. "Sodium" used in conjunction with "edetate" would have been logically understood by a person of ordinary skill in the art to be a sodium salt of ethylenediaminetetraacetic acid.

139. As discussed above, EDTA is a well-known acronym for ethylenediaminetetraacetic acid. "Sodium salt" used in conjunction with "EDTA" would have been logically understood by a person of ordinary skill in the art to be a sodium salt of ethylenediaminetetraacetic acid.

140. The specifications and prosecution histories of the patents-in-suit confirm and are consistent with the meaning of "sodium edetate" and "EDTA sodium salt" described above.

141. The specification states that "conventional various additives such as . . . chelating agents . . . may be appropriately added to the aqueous liquid preparation of the present invention." ('431 patent at col. 6, lines 12-15.[3]) The specification further specifies that "[t]he chelating agents include sodium edetate, sodium citrate, condensed sodium phosphate and the like." (*Id.* at col. 6, lines 26-28.) The phrase "sodium edetate" is used throughout the specification and is not restricted to the tetrasodium salt. (*See, e.g., id.* at Table 2; Examples 1-3.)

142. During prosecution of the '431 patent, the Applicants equated EDTA sodium salt with sodium edetate, stating that "EDTA sodium salt is also known as sodium edetate." ('431 patent prosecution history, Mar. 24, 2010 Amendment and Remarks at 7.)

143. The prosecution history also confirms that a person of ordinary skill in the art would have understood "sodium edetate" and "EDTA sodium salt" to encompass, for example, the disodium salt of ethylenediaminetetraacetic acid. The Examiner found the phrase EDTA sodium salt to encompass "disodium EDTA," stating, while analyzing various references and the elements of the pending patent claims, "EDTA sodium salt (disodium EDTA)." ('431 patent

[3]While these citations refer to the specification of the '431 patent, the specifications of the '290, '131, '813, and '606 patents are essentially the same as the specification of the '431 patent, and the corresponding portions of these specifications further support my opinions.

prosecution history, Jun. 24, 2010 Office Action at 5.) Specifically, in initially rejecting pending claims 49, 56, and 60, reciting "sodium edetate," and pending claim 64, reciting "EDTA sodium salt," the Examiner referred to the Yanni (U.S. Patent No. 5,475,034) reference's teaching of disodium EDTA as disclosing sodium edetate and EDTA sodium salt.[4] (*Id.*)

144. In addition, three expert declarations that were filed as part of the record before the United States Patent and Trademark Office ("USPTO") in *inter partes* review ("IPR") petitions involving the patents-in-suit consistently acknowledge that "sodium edetate" and "EDTA sodium salt" include "disodium EDTA." First, Dr. Jayne Lawrence, who submitted a declaration on behalf of Lupin in the USPTO records of several of the patents-in-suit, states that Bronuck® contains sodium EDTA. (Ex. 27 at ¶¶ 80-81.) Bronuck® is described in the art as containing sodium edetate. (Ex. 56 at p. 4.) Dr. Lawrence then states that Bronuck® is identical to Xibrom®. (Ex. 27 at ¶¶ 80-81.) For the components of Xibrom®, she relies on its package insert, which specifically discloses disodium edetate at page 5, under "Inactives." (Ex. 27 at ¶ 82; Ex. 33 at 5.) Dr. Lawrence takes the same position with respect to Prolensa®, which is the NDA-approved product falling within the scope of the claims of the patents-in-suit. In particular, she states that Prolensa® contains sodium EDTA and relies on its package insert, which specifically discloses disodium edetate. (Ex. 27 at ¶ 82; Ex. 6 at 2 ("Description").) Thus, Dr. Lawrence has acknowledged that both sodium edetate and EDTA sodium salt include disodium EDTA.

145. Next, Dr. Paul A. Laskar, who submitted to the USPTO a declaration on behalf of InnoPharma in the records of the '431 and '290 patents (Ex. 28; Ex. 29), similarly stated that EDTA sodium salt encompasses disodium edetate. In a claim chart analyzing various references

[4] I understand that the Applicants overcame this rejection during prosecution.

including U.S. Patent No. 4,910,225 ("Ogawa") vis-a-vis the elements of claim 18 of the '431 patent, Dr. Laskar states that "Ogawa Example 6 contains disodium edetate (EDTA sodium salt)." (Ex. 28 at 37; *see also*, Ex. 29 at 63.) In another claim chart involving claim 8 of the '431 patent, Dr. Laskar stated that the claim element sodium edetate was met by "Ogawa Example 6: disodium edetate" and "Sallmann: Example 2 - … Disodium edetate…" (Ex. 28 at 59.) Thus, Dr. Laskar has acknowledged that both sodium edetate and EDTA sodium salt encompass disodium EDTA.

146. The third declaration submitted to the USPTO in the record of the '431 and '290 patents comes from Dr. Uday B. Kompella. Like Dr. Laskar, in a claim chart analyzing various references vis-a-vis the elements of claim 18 of the '431 patent, Dr. Kompella stated that "Ogawa Example 6 contains disodium edetate (EDTA sodium salt)." (Ex. 42 at 34; *see also*, Ex. 43 at 55.) In a claim chart involving claim 8 of the '431 patent, Dr. Kompella further stated that the claim element sodium edetate was met by "Ogawa Example 6: disodium edetate" and "Sallmann: Example 2 - … Disodium edetate…" (Ex. 42 at 55.) Thus, Dr. Kompella has similarly acknowledged that both edetate sodium and EDTA sodium salt encompass disodium EDTA.

147. Extrinsic evidence further confirms the clear meaning of these phrases demonstrated in the specification and prosecution history. I have been informed that the patents-in-suit originated in Japan, based on a first filed Japanese application, and named Japanese inventors. (*See* '431, '290, '131, '813, and '606 patents at face pages.) The Japanese Pharmacopeia, which I expect a Japanese researcher in the art would have considered, uses "EDTA sodium" and "sodium edetate" to describe disodium edetate. (Ex. 45 at 913.) The U.S. Pharmacopeia as of the priority date of the patents-in-suit lists disodium edetate, not tetrasodium

edetate. (Ex. 44 at 633-34.) The Japanese Pharmacopeia and the U.S. Pharmacopeia are compendia containing monographs or descriptions of pharmaceutical formulation components and are frequently used by persons of ordinary skill in the art. A person of ordinary skill in the art, when considering the phrases "sodium edetate" and "EDTA sodium salt" as used in the claims of the patents-in-suit, would have interpreted these terms to include at least the excipient listed in compendia like the Japanese or U.S. Pharmacopeia. Thus, a person of ordinary skill in the art would have understood "sodium edetate" and "EDTA sodium salt" to at least encompass the disodium salt of EDTA.

148. In addition, in InnoPharma's Paragraph IV Notice Letter regarding the '431 patent, InnoPharma, in a claim chart analyzing Example 6 of Ogawa vis-a-vis the elements of claim 18 of the '431 patent, stated that the claim element EDTA sodium salt was met by "Disodium edetate" in Example 6 of Ogawa. (*See* Ex. 13 at 119-20.) Thus, InnoPharma has acknowledged that EDTA sodium salt encompasses disodium edetate.

149. Moreover, Burdock, ENCYCLOPEDIA OF FOOD AND COLOR ADDITIVES 916-22 (1996), a reference identified by Defendants, lists "EDTA sodium" and "Sodium ethylenediaminetetraacetate" as synonyms for "EDTA, disodium." (Ex. 46 at 916-17.) Lanigan, *Final Report on the Safety Assessment of EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, Disodium EDTA, TEA EDTA, Tetrasodium EDTA, Tripotassium EDTA, Trisodium EDTA, HEDTA, and Trisodium HEDTA*, 21 INT'L JOURNAL OF TOXICOLOGY 95-142 (2002), another reference identified by Defendants, states: "EDTA and its salts (known collectively as Edetates). . . ." (Ex. 47 at 95.) It further states that "[t]etrasodium EDTA is also known as Sodium Edetate; Tetrasodium Edetate; . . . EDTA Disodium." (*Id.* at 96-97.) Thus, a

person of ordinary skill in the art would have understood sodium edetate to encompass disodium EDTA and not be restricted to the tetrasodium salt.

150. I understand that Defendants interpret these phrases to mean "edetic acid tetrasodium salt or tetrasodium edetate." I disagree with Defendants' proposed construction, which is contrary to the plain and ordinary meaning of these phrases. For at least the reasons discussed above, a person of ordinary skill in the art would have understood these phrases to mean a sodium salt of ethylenediaminetetraacetic acid, encompassing the disodium salt of ethylenediaminetetraacetic acid.

151. I understand that Defendants have identified certain additional references including U.S. Patent No. 4,910,225 ("Ogawa"), U.S. Patent No. 7,998,942, THE MERCK INDEX (O'Neil ed., Merck & Co., Inc., 13th ed. 2001), Robert A. Lewis, Editor, LEWIS' DICTIONARY OF TOXICOLOGY (1998), Kibbe, A.H., Editor, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, Third Edition, Pharmaceutical Press and American Pharmaceutical Association, London, UK, and Washington, DC (2000), and the FDA Inactive Ingredient Database, "edetate," (2013) in connection with their proposed claim constructions. I did not see anything in these references that changes my opinion expressed above with regard to the plain and ordinary meaning that a person of ordinary skill in the art would give to "sodium edetate" and "EDTA sodium salt" as used in the claims of the patents-in-suit. As discussed above, a person of ordinary skill in the art would have understood these phrases to have encompassed a sodium salt of ethylenediaminetetraacetic acid, including the disodium salt. In my opinion, nothing in these references excludes sodium edetate or EDTA sodium salt, as those terms are used in the claims of the patents-in-suit, from encompassing the disodium salt of EDTA.

152. For example, the Ogawa specification states "[t]he chelating agent is, for example, sodium edetate, sodium citrate or sodium salt of condensed phosphoric acid." (Ogawa at col. 4, lines 33-35.) The Examples in Ogawa list "sodium edetate" and "disodium edetate." (*See id.* at Experimental Examples 3, 4, 5, 6 and Examples 1, 2, 6, and 7.) This is consistent with my opinion that "sodium edetate" and "EDTA sodium salt" are general terms that encompass a sodium salt of ethylenediaminetetraacetic acid, including disodium edetate.

153. In U.S. Patent No. 7,998,942, "disodium edetate" is listed as a stabilizer and "sodium edetate" is listed as an exemplary chelating agent. ('942 patent at col. 4, lines 1-8.) This is consistent with my opinion that "sodium edetate" and "EDTA sodium salt" are general terms that encompass a sodium salt of ethylenediaminetetraacetic acid, including disodium EDTA. Moreover, I have reviewed a translation of the Japanese Priority document for the '942 patent, and "disodium edetate" at col. 4, line 1 of the '942 patent is listed as "sodium edetate" in the priority document. (Ex. 57 at [0021]-[0022].)

154. Based on the foregoing, in my opinion, the phrase "sodium edetate" as it is used in claims 8, 14, and 17 of the '431 patent, and the phrase "EDTA sodium salt" as it is used in claim 18 of the '431 patent, claims 7, 13, 19, and 25 of the '290 patent, claims 6, 12, 18, and 24 of the '131 patent, and claims 9, 18, and 25 of the '606 patent mean a sodium salt of ethylenediaminetetraacetic acid. These phrases encompass, for example, the disodium salt of ethylenediaminetetraacetic acid.

D. "Stable"

155. I understand that the parties dispute the meaning of the term "stable" as it is used in claims 1, 7, 8, 10, 13, 14, 19, 20, 22, and 25 of the '290 patent, claims 1, 6, 7, 9, 12, 13, 18-22,

and 24 of the '131 patent, claims 1, 7, 9, 13, and 19-21 of the '813 patent, and claims 1, 9, 11, 12, 18, 19, 25, and 26 of the '606 patent.

156. In my opinion, the term "stable" as used in these claims means having sufficient resistance to degradation and having sufficient preservative efficacy to be formulated and maintained for ophthalmic use.

157. The specifications and prosecution histories of the patents-in-suit confirm and are consistent with the meaning of "stable" described above.

158. For example, the specification states that in various references, "there is no disclosure that alkyl aryl polyether alcohol type polymers or polyethylene glycol fatty acid esters [i.e., tyloxapol] are able to stabilize an aqueous liquid preparation of 2-amino-3-(4-bromobenzoyl)phenylacetic acid or its pharmacologically acceptable salt [i.e., bromfenac]." ('431 patent at col. 2, lines 4-8.) The specification further states that "the inventors of the present invention have found that, by adding, for example, [tyloxapol] to an aqueous liquid preparation of [bromfenac], the aqueous solution becomes stable within a pH range giving no irritation to eyes, and change of the [bromfenac] over time can be inhibited, and furthermore, when the aqueous solution contains a preservative, deterioration in the preservative effect of said preservative can be inhibited for a long period of time." (*Id.* at col. 2, lines 34-47.) The specification further states that "the preservative effect of composition A-04 was found to be compatible with EP-criteria A in the European Pharmacopoeia (EP), and those of compositions A-05 and A-07 were found to be compatible with EP-criteria B." (*Id.* at col. 9, lines 47-51.) Each of A-04 and A-05 contains at least bromfenac and tyloxapol. (*Id.* at Table 2.) From these passages, a person of ordinary skill in the art would understand the specification to be speaking

to the chemical stability of bromfenac and the control of microbial growth in the ophthalmic formulations for a long shelf life.

159. The specification also discloses several studies showing the resistance to degradation and preservative efficacy of aqueous liquid preparations of bromfenac and tyloxapol. (*See, e.g.*, *id.* at Experimental Examples 1–3.)

160. Experimental Example 1 and the results in Table 1 relate to the ability of tyloxapol to stabilize bromfenac by inhibiting its degradation under certain conditions. The Example shows that aqueous preparations of bromfenac and tyloxapol had 73.8% (A-02) and 89.6% (A-03) of bromfenac remaining (referred to as "Remaining rate (%)) after being stored for four weeks at 60 °C and a pH 7.0.[5] (*Id.* at col. 7, line 8 – col. 8, line 2.) These results show that the aqueous liquid preparations of bromfenac and tyloxapol demonstrated sufficient resistance to degradation to be formulated and maintained for ophthalmic use. This Example supports my opinion regarding the meaning of the term stable, as set forth above.

161. Similarly, Experimental Example 2 and the results in Table 2 show that eye drops of bromfenac each with three different concentrations of tyloxapol (compositions A-04, A-05, and A-06) showed 92.6%, 92.0%, and 90.9% of bromfenac remaining after storage for four weeks at 60 °C and a pH of about 8.15. (*Id.* at col. 8, lines 4-49.) The specification indicates that compositions A-04, A-05, and A-06 "have sufficient stability for eye drops." (*Id.* at col. 8, lines 43-49.) These results show that the aqueous liquid preparations of bromfenac and tyloxapol demonstrated sufficient resistance to degradation to be formulated and maintained for

[5] The Ogawa patent establishes that a pH of 7 severely degrades bromfenac. (Ogawa at col. 8, lines 1-22 and Table 8, demonstrating 54.2% of bromfenac remaining after storage at 3 weeks at 60 °C.)

ophthalmic use. This information from the specification also supports my opinion regarding the meaning of the term stable, as set forth above.

162. Experimental Example 3 and Tables 3-1 and 3-2 provide the results of a preservative efficacy test run in accordance with Criteria A and B of the European Pharmacopeia (EP). The details of EP Criteria A and B are provided in the specification. (*Id.* at col. 9, line 55 – col. 10, line 50.) The eye drops tested in the Example contained bromfenac with 0.02 w/v % tyloxapol (composition A-04) and with 0.05 w/v % tyloxapol (composition A-05). (*Id.* at Table 2.) The Example reports that A-04 is compatible with EP-criteria A and that A-05 is compatible with EP-criteria B. (*Id.* at col. 9, lines 47-51.) These results show that the aqueous liquid preparations of bromfenac and tyloxapol demonstrated sufficient preservative efficacy to be formulated and maintained for ophthalmic use. This information supports my opinion regarding the meaning of the term stable, as set forth above.

163. Thus, the specification read as a whole would have informed a person of ordinary skill in the art that the term "stable," as used in the claims of the patents-in-suit, means having sufficient resistance to degradation and having sufficient preservative efficacy to be formulated and maintained for ophthalmic use.

164. The prosecution history is consistent with the specification. During prosecution of the '431 patent, which has the essentially the same specification as the '290, '131, '813, and '606 patents, the applicant relied on and the Examiner credited the chemical stability test of Experimental Example 1 and the results shown in Table 1. ('431 patent prosecution history, Notice of Allowance.)

165. I understand that Defendants argue that the term "stable," as used in the claims of the patents-in-suit, is allegedly indefinite. I disagree with Defendants' argument. This term is

definite because a person of ordinary skill in the art would be reasonably certain that "stable," when read in light of the specification and the prosecution history, means having sufficient resistance to degradation and having sufficient preservative efficacy to be formulated and maintained for ophthalmic use. As discussed above, Experimental Examples 1 and 2 describe aqueous liquid preparations of bromfenac and tyloxapol demonstrating sufficient resistance to degradation to be formulated and maintained for ophthalmic use. ('431 patent at col. 7, line 7 – col. 8, line 49.) Moreover, the prosecution history discusses Example 1 relating to tyloxapol's ability to stabilize bromfenac against chemical degradation, and the Examiner credits the results shown therein. ('431 patent prosecution history, Notice of Allowance.) In addition, Experimental Example 3 demonstrates that preparations of bromfenac and tyloxapol described in Experimental Example 2 demonstrate sufficient preservative efficacy to be formulated and maintained for ophthalmic use. ('431 patent at col. 8, line 51 – col. 10, line 50.)

166. I understand that Defendants have cited EP 0306984, U.S. Patent No. 4,910,225 ("Ogawa"), and Vadas, *Stability of Pharmaceutical Products*, in Remington: The Science and Practice of Pharmacy 986-94 (Genarro, ed., 20th ed. 2000), in connection with their arguments regarding the claim term "stable." I did not see anything in these references that changes my opinion expressed above with regard to the plain and ordinary meaning that a person of ordinary skill in the art would give to "stable" as it is used in claims 1, 7, 8, 10, 13, 14, 19, 20, 22, and 25 of the '290 patent, claims 1, 6, 7, 9, 12, 13, 18-22, and 24 of the '131 patent, claims 1, 7, 9, 13, and 19-21 of the '813 patent, and claims 1, 9, 11, 12, 18, 19, 25, and 26 of the '606 patent.

E. "In an Amount Sufficient to Stabilize said First Component"

167. I understand that the parties dispute the meaning of the phrase "in an amount sufficient to stabilize said first component" as it is used in claim 1 of the '290 patent, claim 1 of the '131 patent, claim 1 of the '813 patent and claim 1 of the '606 patent.

168. In my opinion, the phrase "in an amount sufficient to stabilize said first component" as used in these claims means an amount sufficient to confer sufficient resistance to degradation to be formulated and maintained for ophthalmic use.

169. The specifications and prosecution histories of the patents-in-suit confirm and are consistent with the meaning of "in an amount sufficient to stabilize said first component" described above.

170. For example, the specification states that in various references, "there is no disclosure that alkyl aryl polyether alcohol type polymers or polyethylene glycol fatty acid esters [i.e., tyloxapol] are able to stabilize an aqueous liquid preparation of 2-amino-3-(4-bromobenzoyl)phenylacetic acid or its pharmacologically acceptable salt [i.e., bromfenac]." ('431 patent at col. 2, lines 4-8.) The specification further states that "the inventors of the present invention have found that, by adding, for example, [tyloxapol] to an aqueous liquid preparation of [bromfenac], the aqueous solution becomes stable within a pH range giving no irritation to eyes, and change of the [bromfenac] over time can be inhibited . . . ." (*Id.* at col. 2, lines 34-44.) From these passages, a person of ordinary skill in the art would understand the specification to be speaking to the chemical stability of bromfenac

171. The specification discloses several studies showing tyloxapol's ability to confer resistance to degradation of bromfenac. (*See, e.g.*, *id.* at Experimental Examples 1–2.)

172. Experimental Example 1 and the results in Table 1 relate to the ability of tyloxapol to stabilize bromfenac by inhibiting its degradation under certain conditions. The

Example shows that aqueous preparations of bromfenac and tyloxapol had 73.8% (A-02) and 89.6% (A-03) of bromfenac remaining (referred to as "Remaining rate (%)) after being stored for four weeks at 60 °C and a pH 7.0. (*Id.* at col. 7, line 8 – col. 8, line 2.) These results show that the aqueous liquid preparations of bromfenac and tyloxapol demonstrated sufficient resistance to degradation to be formulated and maintained for ophthalmic use. This Example supports my opinion regarding the meaning of the phrase "in an amount sufficient to stabilize said first component," as set forth above.

173. Similarly, Experimental Example 2 and the results in Table 2 show that eye drops of bromfenac each with three different concentrations of tyloxapol (compositions A-04, A-05, and A-06) showed 92.6%, 92.0%, and 90.9% of bromfenac remaining after storage for four weeks at 60 °C and a pH of about 8.15. (*Id.* at col. 8, lines 4–49.) The specification indicates that compositions A-04, A-05, and A-06 "have sufficient stability for eye drops." (*Id.* at col. 8, lines 43–49.) These results show that the aqueous liquid preparations of bromfenac and tyloxapol demonstrated sufficient resistance to degradation to be formulated and maintained for ophthalmic use. This information from the specification also supports my opinion regarding the meaning of the phrase "in an amount sufficient to stabilize said first component," as set forth above.

174. Thus, the specification read as a whole would have informed a person of ordinary skill in the art that the phrase "in an amount sufficient to stabilize said first component," as used in the claims of the patents-in-suit, means an amount sufficient to confer sufficient resistance to degradation to be formulated and maintained for ophthalmic use.

175. The prosecution history is consistent with the specification. During prosecution of the '431 patent, which has the essentially the same specification as the '290, '131, '813,

and '606 patents, the applicant relied on and the Examiner credited the chemical stability test of Experimental Example 1 and the results shown in Table 1. ('431 patent prosecution history, Notice of Allowance.)

176. I understand that Defendants argue the phrase "in an amount sufficient to stabilize said first component" is allegedly indefinite. I disagree with Defendants' argument. This phrase is definite because a person of ordinary skill in the art would be reasonably certain that "in an amount sufficient to stabilize said first component," when read in light of the specification and the prosecution history, means an amount sufficient to confer sufficient resistance to degradation to be formulated and maintained for ophthalmic use. As discussed above, Experimental Examples 1 and 2 and describe aqueous liquid preparations of bromfenac and tyloxapol having an amount of tyloxapol sufficient to confer sufficient resistance to degradation to be formulated and maintained for ophthalmic use. ('431 patent at col. 7, line 7 – col. 8, line 49.) Moreover, the prosecution history discusses Example 1 relating to tyloxapol's ability to stabilize bromfenac against chemical degradation, and the Examiner credits the results shown therein. ('431 patent prosecution history, Notice of Allowance.)

177. I understand that Defendants have cited EP 0306984, U.S. Patent No. 4,910,225 ("Ogawa"), and Vadas, *Stability of Pharmaceutical Products*, in Remington: The Science and Practice of Pharmacy 986-94 (Genarro, ed., 20th ed. 2000), in connection with their arguments regarding the claim phrase "in an amount sufficient to stabilize said first component." I did not see anything in these references that changes my opinion expressed above with regard to the plain and ordinary meaning that a person of ordinary skill in the art would give to "in an amount sufficient to stabilize said first component" as it is used in claim 1 of the '290 patent, claim 1 of the '131 patent, claim 1 of the '813 patent and claim 1 of the '606 patent.

E. "Consisting Essentially of" and "Consists Essentially of"

178. I understand that the parties dispute the meaning of the phrase "consisting essentially of" as it is used in claims 1 and 18 of the '431 patent and claims 1, 7, and 13 of the '813 patent, and the phrase "consists essentially of" as it is used in claims 7, 13, 19, and 25 of the '290 patent, claims 6, 12, 18, and 25 of the '131 patent, and claims 9, 18, and 25 of the '606 patent.

179. In my opinion, the phrases "consisting essentially of" and "consists essentially of" as used in these claims mean encompassing the recited elements of the claims and additional unrecited elements only to the extent such unrecited elements do not materially affect the basic and novel characteristics of the claimed preparations. These phrases exclude, for instance, any other active ingredient besides the bromfenac active ingredient recited in the claims.

180. The specifications and prosecution histories of the patents-in-suit confirm and are consistent with the ordinary meaning of consisting essentially of" and "consists essentially of" described above.

181. The claims of the '431 patent started out in prosecution with the open-ended transition term "comprising," reciting a preparation comprising at least bromfenac and tyloxapol. ('431 patent prosecution history, Mar. 20, 2007 Preliminary Amendment at 2-5.) The Examiner initially rejected claims "comprising" bromfenac and tyloxapol as obvious in view of the Gamache reference, which discloses compositions containing a combination of a 5-HT agonist or 1B/ID agonist and bromfenac as active ingredients. ('431 patent prosecution history, Sept. 27, 2007 Office Action at 7-8.) The Applicants subsequently added claims that included the transition phrase "consisting essentially of" instead of "comprising." ('431 patent prosecution history, Jan. 15, 2009 Amendment at 6-9.) In that context, the Applicants stated that "consisting

essentially of" is open to the specified ingredients and additional ones that do not materially affect the basic and novel characteristics of the claimed invention. (*Id.* at 13.) The Applicants identified "the principal 1B/ID agonist of the Gamache composition" as an active ingredient that "would affect the basic novel properties of the claimed preparation." (*Id.*) The Examiner then withdrew the obviousness rejections of these claims based on Gamache. ('431 patent prosecution history, June 3, 2009 Office Action.)

182. Of record during the prosecution of the '431 patent was U.S. Patent No. 6,395,746 to Cagle et al. (Ex. 53.) Like Gamache, Cagle discloses combination compositions containing other active ingredients (*e.g.*, antibiotics) and bromfenac. (*Id.*) After the patent claims reciting aqueous liquid preparations "consisting essentially of" bromfenac and tyloxapol were added, the Examiner considered the Cagle reference ('431 patent prosecution history, Apr. 8, 2010 Information Disclosure Statement) but did not reject the claims based on it. That the Examiner did not reject the "consisting essentially of" claims in view of Cagle would logically indicate to a person of ordinary skill in the art that the "consisting essentially of" language excludes from the claim any active ingredient besides bromfenac.

183. I understand that Defendants interpret these phrases to mean "includes the specified ingredients, and may include additional ingredients that do not materially affect the basic and novel properties of the claimed preparation." Defendant Lupin, in its invalidity contentions regarding the '431 patent, argues that "[o]ther, unidentified ingredients, whether active or inactive, are permitted, provided that they do not materially affect the basic and novel characteristics of the invention." (Ex. 31 at 9.) I disagree with Defendants' proposed construction, which is contrary to the plain and ordinary meaning of these phrases. For the

reasons discussed above, these phrases exclude at least any other active ingredient besides the bromfenac active ingredient recited in the claims.

184. In addition, I have reviewed InnoPharma's Paragraph IV Notice Letter and invalidity contentions regarding the '431 patent. (Ex. 13; Ex. 30.) Based on the prosecution history of the '431 patent described above, InnoPharma concludes that "Claim 1 excludes active ingredients other than bromfenac." (Ex. 13 at 104; Ex. 30 at 23.) InnoPharma further concludes that "Claim 18 excludes active ingredients other than bromfenac." (Ex. 13 at 119.) This confirms and is consistent with my opinion described above that these phrases exclude at least any other active ingredient besides the bromfenac active ingredient recited in the claims.

185. I understand that Defendants have cited various portions of the '431 patent specification and '431 patent prosecution history. I did not see anything in these documents that changes my opinion expressed above with regard to the ordinary meaning that a person of ordinary skill would give to "consisting essentially of" as it is used in claims 1 and 18 of the '431 patent and claims 1, 7, and 13 of the '813 patent, or "consists essentially of" as it is used in claims 7, 13, 19, and 25 of the '290 patent, claims 6, 12, 18, and 25 of the '131 patent, and claims 9, 18, and 25 of the '606 patent.

F. "Satisfies the Preservative Efficacy Standard of US Pharmacopoeia as follows: Viable Cell Counts of Bacteria (*S. aureus, P. aeruginosa*) 24 Hours and 7 Days after Inoculation Decrease to Not More than 1/10 and Not More than 1/1000, Respectively, and Thereafter, the Cell Count Levels Off or Decreases; and Viable Cell Count of Fungi (*C. albicans, A. niger*) 14 Days after Inoculation Decreases to Not More than 1/10, and Thereafter, The Cell Count Keeps the Same Level as that of 14 days After Inoculation"

186. I understand that the parties dispute the meaning of the phrase "satisfies the preservative efficacy standard of US Pharmacopoeia as follows: viable cell counts of bacteria (*S. aureus, P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and

not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation" as it is used in claims 25-29 of the '131 patent.

187. In my opinion, this claim phrase actually means it satisfies EP-criteria B, which is viable cell counts of bacteria (*S. aureus, P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation.

188. The '131 patent specification and prosecution history confirms and is consistent with the ordinary meaning of this phrase described above.

189. Based on the specification, which clearly describes the claimed preservative efficacy tests as those required to meet EP-Criteria B, a person of ordinary skill in the art would have understood that the recitation in the claims of "US Pharmacopoeia" was clearly an error and would have read these claims in light of the specification to refer to preservative efficacy as determined by EP-Criteria B. The specification describes the EP-Criteria B test exactly as recited in the claims. ('131 patent at col. 9, line 63 – col. 10, line 49.) In Tables 3-2 and 3-3, it is shown that "compositions A-05 and A-07 were found to be compatible with EP-criteria B." (*Id.* at Experimental Example 3; col. 9, lines 49-50.) The U.S. Pharmacopeia is not mentioned anywhere in the specification. And similar claims in the other patents-in-suit all correctly recite EP-criteria B of the European Pharmacopeia. (*See, e.g.*, '290 patent at claims 26-30; '606 patent at claims 28-30.)

190. In addition, claims 25-29 (formerly application claims 43-47) of the '131 patent were added in a preliminary amendment. ('131 patent prosecution history, Jan. 28, 2014 Preliminary Amendment.) The Examiner rejected the claims only for double patenting, and upon entry of terminal disclaimers, the Examiner allowed them. ('131 patent prosecution history, Mar. 13, 2014 Office Action, Mar. 20, 2014 Response, Notice of Allowance.) This supports my opinion that a person of ordinary skill in the art would have understood that the recitation in the claims of "US Pharmacopoeia" was a simple error and would have read these claims in light of the specification to refer to preservative efficacy as determined by EP-Criteria B.

191. I understand that Defendants consider this phrase to be indefinite. I disagree with Defendants' position. This phrase is definite because a person of ordinary skill in the art would have understood, in light of the claim language and specification, that clearly an error occurred and that these claims refer to the EP-Criteria B test. Moreover, the prosecution history does not suggest a different interpretation of the claims.

192. I understand that Defendants have cited United States Pharmacopeia Rev. 25 at section <51> (2001), European Pharmacopoeia, 4th ed. At 5.1.3 (2001), and Moser et al., *Comparison of Compendial Antimicrobial Effectiveness Tests: A Review*, AAPS PharmSciTech, vol. 12, no. 1 at 222-26 (2011), in connection with their arguments regarding this phrase. I did not see anything in these references that changes my opinion expressed above with regard to the ordinary meaning a person of ordinary skill in the art would give to "satisfies the preservative efficacy standard of US Pharmacopoeia as follows: viable cell counts of bacteria (*S. aureus, P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10,

and thereafter, the cell count keeps the same level as that of 14 days after inoculation" as it is used in claims 25-29 of the '131 patent, in light of the specification and prosecution history.

V. COMPENSATION

193. I will be compensated for my time preparing for and testifying in this matter at the rate of $600/hour. No part of my compensation is contingent upon the outcome of this matter or any issue in it.

8/10/15
Date

Robert O. Williams, III, Ph.D.

APPENDIX A

CURRICULUM VITAE
Robert O. (Bill) Williams III

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(512) 306-8396

I. Personal

Born September 11, 1956 in Beaumont, Texas. Citizen of the United States. Married; two children.

II. Education

May 75 – May 79	Texas A&M University, College Station, Texas Bachelor of Science in Biology, Graduated with special honors
Sep 79 – Dec 81	University of Texas at Austin, Austin, Texas. Bachelor of Science in Pharmacy, Graduated with special honors Registered Pharmacist – State of Texas
Aug 82 – May 86	University of Texas at Austin, Austin, Texas Doctor of Philosophy, Pharmaceutics Major Professor: James W. McGinity, Ph.D.

III. Positions Held

1. January, 1982 to August, 1982 – Registered, Pharmacist, Walgreen's Pharmacy, Beaumont, TX.
2. August, 1986 to December, 1988 - Group Leader for Eli Lilly and Company, Indianapolis, IN.
3. January, 1989 to December, 1990 - Director for Duramed Pharmaceuticals, Cincinnati, OH.
4. January, 1991 to April, 1992 - Section Manager for Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA.

5. April, 1992 to January, 1993 - Department Manager for Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA.
6. January, 1993 to August, 1995 - Director for Rhone-Poulenc Rorer Pharmaceuticals, Collegeville, PA.
7. September, 1995 to August, 1999 - Assistant Professor of Pharmaceutics, College of Pharmacy, University of Texas at Austin, Austin, TX.
8. January, 1996 to January, 2007 – President, PharmaForm LLC, Austin, TX.
9. January, 2007 – June, 2010 – Consultant, PharmaForm LLC, Austin, TX.
10. January, 2007 to June, 2010 – Board of Directors, Akela Pharma, Inc., Montreal, Canada
11. September, 1999 to August, 2004 – Associate Professor of Pharmaceutics, College of Pharmacy, University of Texas at Austin, Austin, TX.
12. September, 2004 to 2013 – Professor of Pharmaceutics, Johnson & Johnson Centennial Professor, College of Pharmacy, University of Texas at Austin, Austin, TX.
13. September, 2007 to present – Division Head, Division of Pharmaceutics, College of Pharmacy, University of Texas at Austin, Austin, TX.
14. 2009-2013, Founder and Chief Scientist, Enavail LLC, Austin, TX.
15. January, 2013 to present – Visiting Professor, University of Chile, Santiago, Chile.
16. September, 2013 to present – Professor of Pharmaceutics, Johnson & Johnson Centennial Chair, College of Pharmacy, University of Texas at Austin, Austin, TX.

IV. Graduate and Undergraduate Courses Presented

Pharmaceutics, PHR 356C and PHR 156P - UT Austin
Advanced Manufacturing Pharmacy, PGS 381G - UT Austin
Recent Advances in Pharmaceutics, PGS 382R - UT Austin
Advanced Product Development, PGS 381D - UT Austin
Advanced Pharmaceutical Processing, PGS 380Q - UT Austin
Pharmaceutical Entrepreneurship, PHR 261J/PGS 280M – UT Austin

V. Professional Memberships

American Association of Pharmaceutical Scientists 1985 - present
(Sections of Pharmaceutical Technology, and Pharmaceutics and Drug Delivery)
- Member, Planning Committee, Pharmaceutical Technology Section (1997-1998)
- Member, Strategic Planning Committee (1999-2000)
- Reviewer, Pharmaceutical Technology Screening Committee (2003, 2004)
- Co-Chair, Strategic Visioning Process (2003-2004)
- Reviewer, Annual Meeting and Exposition Abstract Screening Committee (2006)
- Member, Pharmaceutical Technology Education Committee (2007-present)

Controlled Release Society 1995 - present

Association de Pharmacie Galenique Industrielle (APGI)	1998 - present
American Association of Colleges of Pharmacy	1995 - present
Rho Chi (Pharmacy Honor Society)	1982 - present
Kappa Psi (Graduate Chapter, Pharmacy Professional Fraternity),	1979 - present
Grand Council Deputy - President	1998 – present
International Academy of Compounding	1999 – 2004
European Federation of Biotechnology	2002 – 2013
Product Quality Research Institute	2004 – 2005
(AAPS representative on Drug Product Technical Committee)	
Center for Microencapsulation and Drug Delivery,	2003-2013
Texas A&M University (Member – Strategic Advisory Board)	
Austin Technology Incubator University Development Portfolio,	2014-present
Member	

VI. Current Research Interests

1. Small particle technology to enhance dissolution rates and bioavailability.
2. Formulation of novel liquid and semisolid drug delivery systems.
3. Study of novel controlled-release aqueous coating formulations.
4. Preformulation and formulation of novel delivery systems for pulmonary, nasal and buccal delivery.
5. Modified release oral dosage forms.

VII. Honors and Awards

1. University Undergraduate Honors Fellow, Texas A&M University; 1978
2. Distinguished Student Award, Texas A&M University; 1979
3. Lemmon Award, University of Texas at Austin; 1981
4. Amaric Corporation Pre-doctoral Fellowship, University of Texas at Austin; 1983 - 1985
5. Professional Development Award, University of Texas at Austin; 1985
6. Texas Excellence Teaching Award, University of Texas at Austin; 1998
7. Phi Lambda Sigma, the Pharmacy Leadership Society, Elected member - 1998

8. Leadership Fellow, American Association of Colleges of Pharmacy Academic Leadership Fellows Program, 2004-2005.

9. Paper awarded the Penwest Award for Best Scientific Paper, Novel Curing Process for Cellulose Acetate Phthalate Coated Beads. Proceedings of the 20th Pharmaceutical Technology Conference and Exhibition, Liverpool, UK, April, 2001.

10. Dean's Fellow, College of Pharmacy, University of Texas at Austin, 2004-2005.

11. Fellow, Elected by the American Association of Pharmaceutical Scientists, 2006.

12. Paper awarded the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award, Improved Dissolution Rate and Bioavailability Through the Formation of a Highly Miscible Binary Mixture, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.

13. Paper nominated for the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award, Rapid Release, High Potency Itraconazole Formed by Evaporative Precipitation Into Aqueous Solution, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.

14. Outstanding Thesis Award, Barbara Jean Hoeben, M.S. (May, 2005) – Thesis Title: Comparison of Commercial Itraconazole to Aerosolized Nanoparticle Itraconazole in a Murine Model for the Prevention of Invasive Pulmonary Aspergillosis (IPA).

15. Elected "Fellow" of the American Association of Pharmaceutical Scientists, 2006.

16. Elected "Fellow" of the American Institute of Medical and Biological Engineering, 2008.

17. Received the 2009 William J. Sheffield Outstanding Alumnus Award, Pharmacy Alumni Association, The University of Texas at Austin.

18. Invited paper by W. Yang, J. I. Peters and R. O. Williams III was recognized as one of the Top-10 most cited articles published in *International Journal of Pharmaceutics* during the period 2008-2010 (Elsevier Publishers; September 2010).

VIII. Committees

Academic Performance Committee - 1996 – present, Chairman and Member
Faculty Retreat Planning Committee, Chair - 1996-1997, 2007, 2011
Committee on Committees - 1995 – 1997, 2004 – 2005, 2006
Pharmacy Honors Course - Coordinator for Pharmaceutics - 1996 - 2001
Honors and Awards Committee - 1995 - 2001

Internship Region Assignment Committee, Chairman, 1998 - 2004
Staff Excellence Awards Committee - 1998 – 2000
Financial Aid Committee – 1999 – 2000
College Accreditation Committee – 2002 – present
Admissions and Registration Committee (University Committee) – 2001 – 2003
Intellectual Property Committee (University Committee) – 2003- 2013
Co-Chair – Life Sciences (2004-2005)
Faculty Advisor to: Kappa Psi Pharmaceutical Fraternity
Pharmaceutical Association of Compounding
Drug Product Technical Committee, PQRI – representative for AAPS, 2004-2006
Post-Tenure Review Committee – Chairman; 2005-2007
College of Pharmacy, Dean Search Committee – Co-Chairman; 2007
College of Pharmacy, Executive Committee – Chairman; 2008 – 2013
University of Texas at Austin, Office of Technology Commercialization and Associate Vice President for Research for Commercialization Search Committee; 2008-2010
Graduate Studies Committee, Pharmacy Doctoral Program (1995 – present)
Graduate Studies Committee, Translational Science Doctoral Program (2011- 2013)

IX. Editorial Responsibilities

1. *AAPS PharmSciTech* – Editor-in-Chief (2014 – present)
2. *Drug Development and Industrial Pharmacy* – Editor-in-Chief (2000 – 2014)
3. *International Journal of Pharmaceutics* – reviewer
4. *Pharmaceutical Research* – reviewer
5. *European Journal of Pharmaceutics and Biopharmaceutics* – reviewer
6. *Journal of the Controlled Release Society* – reviewer
7. *S. T. P. Pharma. Sciences* – reviewer
8. *Pharmaceutical Development and Technology* – reviewer
9. Pharmaceutical Technology Conference - International Advisory Board Member
10. *International Journal of Pharmaceutical Compounding* – reviewer
11. *Journal of Membrane Science* – reviewer
12. *AAPS PharmSciTech* – reviewer
13. *Journal of Pharmaceutical Sciences* – reviewer
14. *Journal of Pharmaceutical and Biomedical Analysis* – reviewer
15. *Toxicology Letters* – reviewer
16. National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Pharmaceutical and Chemical Resources for AIDS Drug Development,* invited reviewer.
17. *The Open Drug Delivery Journal*, Member, Editorial Advisory Board, 2008-present.
18. *Journal of Pharmaceutical Research & Clinical Practice*, Editorial Advisory Board, 2010-present.
19. *British Journal of Pharmaceutical Research*, Editorial Advisory Board, 2013-present.

X. Students Currently Being Supervised

Chris Brough – Ph.D. Candidate
Siyuan Huang – Ph.D. Candidate
Soraya Hengsawas – Ph.D. Candidate
Justin LaFontaine – Ph.D.
Leena Prasad – Ph.D.
Julien Maincent – Ph.D.
Zachary Warnken – PharmD/Ph.D.
Daniel Ellenberger – Ph.D.

XI. Personnel Supervised (and Starting Position; if available)

1. Mongkol Sriwongjanya, Ph.D. (1996 – 1997; Post-doctoral Research Fellow) Senior Research Scientist, Andrx Pharmaceuticals, Fort Lauderdale, FL

2. Jie Liu, Ph.D. (August, 1998) Senior Research Scientist, Baxter Healthcare, New Providence, NJ. Dissertation Title: Development, Characterization and Optimization of Pressurized Metered-Dose Inhalers Formulated to Delivery Small Organic Drugs or Proteins with Hydrofluoroalkane Propellants.

3. Chengjiu Hu, Ph.D. (August, 1999) Senior Research Scientist, DuPont Pharmaceuticals, Garden City, NY. Dissertation Title: Investigation of Factors Influencing the Development of Pressurized Metered Dose Inhalers.

4. Melisa K. Barron, Ph.D. (August, 2000) Senior Scientist, Dey Laboratories, Napa, CA. Dissertation Title: Investigation of Formulation and Processing Technique on the Characteristics of Polymeric Powders Produced for Suspension Type Pressurized Metered Dose Inhalers Systems.

5. Jiping Liu, Ph.D. (August, 2001) Research Investigator, Sanofi-Synthelabo, Philadelphia, PA. Dissertation Title: Applications of Cellulose Acetate Phthalate Aqueous Dispersion (Aquacoat CPD) for Enteric Coating.

6. Bobby J. Truong, M.S. (August, 2001). Thesis Title: Development of Insulin Pressurized Meter-Dose Inhaler for the Pulmonary Drug Delivery by Spray-Freezing into Cryogenic Vapor.

7. Marazban Sarkari, Ph.D. (2000-2001; Post-doctoral Research Fellow) Senior Scientist, RxKINETIX, Boulder, CO

8. Vorapann Mahaguna, Ph.D. (December, 2001) Senior Research Scientist, DuPont Pharmaceuticals, Garden City, NY. Dissertation Title: Investigation of Cellulose Ether Polymers in Controlled Drug Delivery.

9. Raouf Ghaderi, Ph.D. (2001-2002; Post-doctoral Research Fellow) Senior Research Scientist, KOS Pharmaceuticals, NJ

10. True L. Rogers, Ph.D. (June, 2002) Senior Research Scientist, The Dow Chemical Company, Midland, MI. Dissertation Title: A Novel Cryogenic Particle Engineering Technology to Micronize Water-Insoluble Drugs and Enhance Their Dissolution Properties: Spray-Freezing Into Liquid.

11. Jiahui Hu, Ph.D. (July, 2003) – Senior Research Scientist, Forest Laboratories, Garden City, NY. Dissertation Title: A Nanoparticle Engineering Process: Spray-Freezing into Liquid to Enhance the Dissolution of Poorly Water Soluble Drugs.

12. Bradi L. Jones, Pharm.D., M.S. (August, 2003) – Pharmacist, University of Texas Health Science Center at San Antonio, San Antonio, TX. Thesis Title – Investigation of Pulmonary and Oral Delivery of Itraconazole Produced by Evaporative Precipitation into Aqueous Solution and Spray Freezing into Liquid Technology in a Murine Model.

13. Thomas W. Leach, Ph.D. (2002-2004 – Post-doctoral Research Fellow) Senior Research Scientist, Curagen Inc., New Haven, CT

14. Zhongshui Yu, Ph.D. (July, 2004) – Senior Research Scientist, Hoffmann-La Roche Pharmaceuticals, Nutley, NJ. Dissertation Title: Spray Freezing into Liquid to Produce Protein Microparticles.

15. Xiaoxia Chen, Ph.D. (July, 2004) – Senior Research Scientist, Hoffmann-La Roche Pharmaceuticals, Nutley, NJ. Dissertation Title: Nanoparticle Engineering Processes: Evaporative Precipitation into Aqueous Solution (EPAS) and Anitsolvent Precipitation to Enhance the Dissolution Rates of Poorly Water Soluble Drugs.

16. Thiago Cardoso Carvalho, R.Ph. (July, 2004) – Visiting Scientist, Universidade Federal De Minas Gerais, Brazil.

17. Barbara Jean Hoeben, M.S. (May, 2005) – Pharmacist, United States Air Force, San Antonio, TX. Thesis Title: Comparison of Commercial Itraconazole to Aerosolized Nanoparticle Itraconazole in a Murine Model for the Prevention of Invasive Pulmonary Aspergillosis (IPA).

18. Jason M. Vaughn, Ph.D. (June, 2005) – Associate Director and Senior Research Scientist, PharmaForm LLC, Austin, TX. Dissertation Title: Improved Bioavailability and Site Specific Delivery of Poorly Water Soluble Drugs through the Production of Stabilized Drug Nanoparticles.

19. Jason T. McConville, Ph.D. – (2003-2006; Post-doctoral Research Fellow) – Assistant Professor of Pharmaceutics, University of Texas at Austin, Austin, TX.

20. Prapasri Sinswat, Ph.D. (August, 2006) – Assistant Professor of Pharmaceutics, Chulalongkorn University, Bangkok, Thailand. Dissertation Title: Enhancing the Delivery of Poorly Water Soluble Drugs Using Particle Engineering Technologies.

21. Kirk A. Overhoff, Ph.D. (August, 2006) – Senior Pharmaceutical Scientist, Schering Corporation, Kenilworth, NJ. Dissertation Title: Improved Oral Bioavailability of Poorly Water Soluble Drugs Using Rapid Freezing Processes.

22. Josh D. Engstrom, Ph.D. (August, 2007) – Senior Pharmaceutical Scientist, Bristol Meyers Squibb, Princeton, NJ. Dissertation Title: Stable Submicron Protein Particles: Formation, Properties and Pulmonary Applications.

23. Keat Chow, Ph.D. (2007-2008; Post-doctoral Research Fellow).

24. Masao Nagao, M.S. (2007-2008; Visiting Research Scholar; Takeda Pharmaceuticals, Japan).

25. Dave A. Miller, Ph.D. (August, 2007) – Senior Pharmaceutical Scientist, Hoffman La Roche, Nutley, NJ. Dissertation Title: Improved Oral Absorption of Poorly Water Soluble Drugs by Advanced Solid Dispersion Systems.

26. Michal P. Matteucci, Ph.D. (August, 2007) – Dissertation Title: Highly Supersaturated Aqueous Solutions by Design of Amorphous Pharmaceutical Nanoparticles.

27. Troy P. Purvis, Ph.D. (August, 2007) – Senior Pharmaceutical Scientist, Azaya Therapeutics, San Antonio, TX. Dissertation Title: Nanoparticle Formulations of Poorly Water Soluble Drugs and their Action In Vivo and In Vitro.

28. Yosuhiro Tsutsumi, Ph.D. (2008-2009; Visiting Research Scholar; Daiichi Sankyo Co., Ltd., Pharmaceutical Technology, Japan).

29. Rui Jia, Ph. D. (2008-2009); Visiting Research Scholar; China.

30. Justin A. Tolman, Pharm.D., Ph.D. (January, 2009) – Assistant Professor of Pharmaceutics, School of Pharmacy and Health Professions, Creighton University, Omaha, Nebraska. Dissertation Title: Pulmonary Delivery of Aqueous Voriconazole Solution.

31. Alan B. Watts, Ph.D (July 2009) – Senior Scientist, Microdose Inc., Princeton, NJ, Dissertation Title: Pulmonary Delivery of Tacrolimus for Lung Transplant and Asthma Therapy.

32. Wei Yang, Ph.D. (July 2009) – Senior Scientist, Enavail, LLC, Austin, TX, Dissertation Title: Improvement of Bioavailability of Poorly Water-Soluble Drug via Pulmonary Delivery of Nanoparticles.

33. James C. DiNunzio (July 2009) – Senior Scientist, PharmaForm LLC, Austin, TX, Dissertation Title: Formulation and Processing Technologies for Enhanced Oral Bioavailability of Poorly Water Soluble Compounds.

34. Ikumasa Ohno, Ph.D. (2010-2010; Visiting Research Scholar, Daiichi Sankyo Co., Ltd., Pharmaceutical Technology, Japan).

35. Nicole A. Beinborn, Ph.D. (August 2011) – Senior Scientist, Aptalis, Dayton, OH, Dissertation Title: Inhaled Voriconazole Formulations for Invasive Fungal Infections in the Lungs.

36. Meimei Zhang (2009-2011) – Visiting Chinese Graduate Student Scholar, (Professor Chuanbin Wu) Department of Pharmaceutics, School of Pharmaceutical Sciences R&D Center of Pharmaceutics, Sun Yat-sen University, Guangzhou, Guangdong, China, Dissertation Title: Amorphous Fenobibrate Solid Dispersions Prepared by Thin-Film Freezing.

37. Houli Li (2009-2011) – Visiting Chinese Graduate Student Scholar, (Professor Ruichen Guo) Institute of Clinical Pharmacology, Qilu Hospital of Shandong University, Jinan, Shandong, China, Dissertation Title: Modified Release Carbamazepine Compositions Prepared by Thin-Film Freezing.

38. Kevin P. O'Donnell, Ph.D. (December 2011) – Senior Scientist, The Dow Chemical Company, Midland, MI, Dissertation Title: Pharmaceutical Technologies for Improving Drug Loading in the Formulation of Solid Dispersions.

39. Helene L. Dugas, Ph.D. (May 2012) – Territory Manager, Laboratory Sales, Wheaton Industries, Houston, TX, Dissertation Title: Mycophenolate Mofetil Inhaled Formulation for the Prevention of Lung Transplant Rejection.

40. Stephanie Bosselmann, Ph.D. (May 2012) – Senior Scientist, Berlin Chemie, Berlin, Germany, Dissertation Title: Nanoparticle Engineering for Enhanced Drug Delivery.

41. Javier O. Morales, Ph.D. (November 2012) – Assistant Professor, University of Santiago, Santiago, Chile, Dissertation Title: Mucoadhesive Films for the Buccal Delivery of Insulin.

42. Shih-Fan Jang, Ph.D. (January 2013) – Dissertation Title: Development of Lower Intestine Targeting Mucoadhesive Platform of Oral Drug Delivery.

43. Bo Lang, Ph.D. (June 2013) – Formulation Scientist, Mylan Pharmaceuticals, Morgantown, WV, Dissertation Title: Advanced Formulation and Processing Technologies in the Oral Delivery of Poorly Water Soluble Drugs.

44. Yi-Bo Wang, Ph.D. (November 2013) – Reviewer, Food and Drug Administration, Division of Bioequivalence, Washington D.C., Dissertation Title: Pulmonary Delivery of Brittle Matrix Powders Produced by Thin Film Freezing.

45. Simone Raffa Carvalho, Ph.D. (November 2013) – Dissertation Title: Improved Inhalation Therapies of Brittle Powders.

46. Justin M. Keen, Ph.D. (November 2013) – Formulation Scientist, DisperSol Technologies, LLC, Austin, TX. Dissertation Title: Novel Formulations and Thermal Processes for Bioavailability Enhancement of Soluble and Poorly Soluble Drugs.

47. Ryan C. Bennett, Ph.D. (March 2014) – Pharmaceutical Scientist, Freund-Vector Corporation, Cedar Rapids, IA. Dissertation Title: Thermal Processing Cyclodextrins

and Thermoplastic Polymers for Bioavailability Enhancement of Poorly Water-Soluble Drugs.

XII. Publications

1. R.O. Williams III and J.W. McGinity, The Use of Tableting Indices to Study the Compaction Properties of Powders, *Drug Development and Industrial Pharmacy*, 14(1988) 1823-1844.

2. R.O. Williams III and J.W. McGinity, Compaction Properties of Microcrystalline Cellulose and Sodium Sulfathiazole in Combination with Talc or Magnesium Stearate, *Journal of Pharmaceutical Sciences*, 78(1989) 1025-1034.

3. M. Schulze, R.O. Williams III, and J.W. McGinity, Compaction Properties of Acrylic Resin Polymers with Plastic and Brittle Drugs, *Drug Development and Industrial Pharmacy*, 16(1990) 741-754.

4. R.O. Williams III, J. Dorrell, K. Corti, and M. Connolly, Significance of Interactions of a Novel Anti-Emetic Drug and Packaging Components During Clinical Trials, *Drug Development and Industrial Pharmacy*, 18(1992) 2145-2161.

5. K. S. Balaji, R.O. Williams III, and E. R. Christensen, Comparison of Milling Process: Ball Mill versus Air Classifying Mill, *Drug Development and Industrial Pharmacy*, 20(1994) 841-851.

6. S. Li, M. Karth, K. Feld, L. DiPaolo, C. Pendharkar, and R. O. Williams III, Evaluation of Bilayer Tablet Machines — A Case Study, *Drug Development and Industrial Pharmacy*, 21(1995) 571-590.

7. S. Li, R. Felt, L. DiPaolo, M. Huang, and R.O. Williams III, Development and In Vitro - In Vivo Evaluation of a Multiparticulate Sustained Release Formulation of Diltiazem, *Pharmaceutical Research*, 12(1995) 1338-1342.

8. R. O. Williams III, M. Sriwongjanya, and J. Liu, An In Vitro Method to Investigate Food Effects on Drug Release From Film Coated Beads, *Pharmaceutical Development and Technology*, 2(1997) 1-9.

9. R. O. Williams III, M. Sriwongjanya, and M. Barron, Compaction Properties of Microcrystalline Cellulose Using Tableting Indices, *Drug Development and Industrial Pharmacy*, 23(1997) 695-704.

10. R. O. Williams III, J. Liu, and J. J. Koleng, Influence of Metering Chamber Volume and Water Level on the Emitted Dose of a Suspension-Based pMDI Containing Propellant 134a, Pharm. Res., *Pharmaceutical Research*,14(1997) 438-443.

11. R. O. Williams III and M. Sriwongjanya, Determination of Benzalkonium Chloride and Nonoxynol-9 by HPLC During a Preformulation Study, *S.T.P. Pharma. Sciences*, 7(1997) 241-247.

12. R. O. Williams III, V. Mahaguna, and M. Sriwongjanya, Determination of Diazolidinyl Urea in a Topical Cream by High-performance Liquid Chromatography, *Journal of Chromatography B, Biomedical Applications*, 696(1997) 303-306.

13. R. O. Williams III and C. Hu, A Study of an Epoxy Aerosol Can Lining Exposed to Hydrofluoroalkane Propellants, *European Journal of Pharmaceutics and Biopharmaceutics*, 44(1997) 195-203.

14. R. O. Williams III and V. Mahaguna, Preformulation studies on Freund's Incomplete Adjuvant Emulsion, *Drug Development and Industrial Pharmacy*, 24(1998) 157-162.

15. R. O. Williams III, M. Repka, and J. Liu, Influence of Propellant Composition on Drug Delivery From a Pressurized Metered-dose Inhaler, *Drug Development and Industrial Pharmacy*, 24(1998) 763-770.

16. R. O. Williams III and M. Barron, Influence of Temperature on the Emitted Dose of an Oral Metered Dose Inhaler, *Drug Development and Industrial Pharmacy*, 24(1998) 1043-1048.

17. R. O. Williams III and J. Liu, Influence of Formulation Additives on the Vapor Pressure of Hydrofluoroalkane Propellants, *International Journal of Pharmaceutics*, 166(1998) 99-103.

18. R. O. Williams III and J. Liu, Formulation of a Protein with Propellant HFA 134a for Aerosol Delivery, *European Journal of Pharmaceutical Sciences*, 7(1998) 137-144.

19. R. O. Williams III, V. Mahaguna and M. Sriwongjanya, Characterization of an Inclusion Complex of Cholesterol and Hydroxypropyl-□□ cyclodextrin, *European Journal of Pharmaceutics and Biopharmaceutics*, 46(1998) 355-360.

20. R. O. Williams III, J. Brown, and J. Liu, Influence of Micronization Method on the Performance of a Suspension TAA pMDI Formulation, *Pharmaceutical Development and Technology*, 4(1999) 167-179.

21. R. O. Williams III, M. K. Barron, M. J. Alonso and C. Remunan-Lopez, Investigation of a pMDI System Containing Chitosan Microspheres and P134a, *International Journal of Pharmaceutics*, 174(1998) 209-222.

22. R. O. Williams III and J. Liu, Influence of Formulation Technique for Hydroxypropyl-beta-cyclodextrin on the Stability of Aspirin in HFA 134a, *European Journal of Pharmaceutics and Biopharmaceutics*, 47(1999) 145-152.

23. R. O. Williams III, T. Rogers, and J. Liu, Study of Solubility of Steroids in Hydrofluoroalkane Propellants, *Drug Development and Industrial Pharmacy*, 25(1999) 1227-1234.

24. R. O. Williams III, M. A. Repka, and M. K. Barron, Application of Co-Grinding to Formulate a Model pMDI Suspension, *European Journal of Pharmaceutics and Biopharmaceutics*, 48(1999) 131-140.

25. R. O. Williams III and C. Hu, Moisture Uptake and Its Influence on Pressurized Metered-Dose Inhalers, *Pharmaceutical Development and Technology*, 5(2000) 153-162.

26. R. O. Williams III, T. A. Wheatley and J. Liu, Influence of Plasticization and Curing Conditions on the Mechanical Properties of Aqueous Based Cellulose Acetate Phthalate Films, *S. T. P. Pharma Sciences*, 9(1999) 545-553.

27. R. O. Williams III and J. Liu, Influence of Processing and Curing Conditions on Beads coated with an Aqueous Dispersion of Cellulose Acetate Phthalate, *European Journal of Pharmaceutics and Biopharmaceutics*, 49(2000) 243-252.

28. R. O. Williams III and C. Hu, Investigation of Moisture Scavengers in Pressurized Metered Dose Inhalers, *S. T. P. Pharma Sciences*, 10(2000) 243-250.

29. R. O. Williams III, A. M. Patel, M. K. Barron and T. L. Rogers, Investigation of Some Commercially Available Spacer Devices for the Delivery of Glucocorticoid Steroids from a pMDI, *Drug Development and Industrial Pharmacy*, 27(2001) 401-412.

30. R. O. Williams III and J. Liu, The Influence of Plasticizer on Heat-Humidity Curing of Cellulose Acetate Phthalate Coated Beads, *Pharmaceutical Development and Technology*, 6(2001) 607-619.

31. R. O. Williams III, M. Sykora and V. Mahaguna, Method to Recover a Lipophilic Drug From Hydroxypropyl Methylcellulose Matrix Tablets, *AAPS PharmSci Tech*, 2(2001) 1-9.

32. M. Sarkari, J. Brown, X. Chen, S. Swinnea, R. O. Williams III and K. Johnston, Enhanced Drug Dissolution Using Evaporative Precipitation into Aqueous Solution, *International Journal of Pharmaceutics*, 243(2002) 17-31.

33. T. L. Rogers, K. Johnston and R. O. Williams III, A Comprehensive Review – Solution Based Particle Formation of Pharmaceutical Powders by Supercritical or Compressed Fluid Carbon Dioxide and Cryogenic Spray-Freezing Technologies, *Drug Development and Industrial Pharmacy*, 27(2001) 1003-1015.

34. R. O. Williams III, T. D. Reynolds, T. D. Cabelka, M. Sykora and V. Mahaguna, Investigation of Excipient Type and Level on Drug Release from Controlled Release Tablets Containing HPMC, *Pharmaceutical Development and Technology*, 7(2002) 181-193.

35. R. O. Williams III, B. Browne, C. Augustine, B. Stewart, J. Kimble, T. Rogers, and J. Brown, Influence of Propeller Gas Composition on the Delivery of Drug by Air-Jet Nebulization, *S.T.P. Pharma Sciences*, 11(2001) 443-448.

36. X. Chen, T. Young, M. Sarkari, R. O. Williams III, and K. Johnston, Preparation of Cyclosporine A Nanoparticles by Evaporative Precipitation into Aqueous Solution, *International Journal of Pharmaceutics*, 242(2002) 3-14.

37. T.L. Rogers, J. Hu, Z. Yu, K. Johnston, and R.O. Williams III, A Novel Particle Engineering Technology: Spray-Freezing into Liquid, *International Journal of Pharmaceutics*, 242(2002) 93-100.

38. J. Liu and R. O. Williams III, Long-term Stability of Heat-Humidity Cured Cellulose Acetate Phthalate Coated Beads, *European Journal of Pharmaceutics and Biopharmaceutics*, 53(2002) 167-173.

39. Z. Yu, T. Rogers, J. Hu, K. P. Johnston and R. O. Williams III, Preparation and Characterization of Microparticles Containing Peptide Produced by a Novel Process: Spray Freezing Into Liquid, *European Journal of Pharmaceutics and Biopharmaceutics*, 54(2002) 221-228.

40. J. Hu, T. Rogers, J. Brown, T. Young, K. Johnston, and R. O. Williams III, Improvement of Dissolution Rates of Poorly Water Soluble APIs Using the Novel Spray Freezing Into Liquid Technology, *Pharmaceutical Research*, 19(2002) 1278-1284.

41. T. L. Rogers, A. C. Nelson, J. Hu, J. N. Brown, M. Sarkari, T. J. Young, K. P. Johnston and R. O. Williams III, A Novel Particle Engineering Technology to Enhance Dissolution of Poorly Water Soluble Drugs: Spray-Freezing Into Liquid, *European Journal of Pharmaceutics and Biopharmaceutics*, 54(2002) 271-280.

42. J. Liu and R. O. Williams III, Properties of Heat-Humidity Cured Cellulose Acetate Phthalate Free Films, *European Journal of Pharmaceutical Sciences*, 17(2002) 31-41.

43. T. L. Rogers, K. P. Johnston and R. O. Williams III, Physical Stability of Micronized Powders Produced by Spray-Freezing into Liquid (SFL) to Enhance the Dissolution of an Insoluble Drug, *Pharmaceutical Development and Technology*, 8(2003) 187-197.

44. T. L. Rogers, A. C. Nelsen, M. Sarkari, T. J. Young, K. P. Johnston and R. O. Williams III, Enhanced Aqueous Dissolution of a Poorly Water Soluble Drug by Novel Particle Engineering Technology: Spray-Freezing into Liquid with Atmospheric Freeze-Drying, *Pharmaceutical Research*, 20(2003) 485-493.

45. T. L. Rogers, K. A. Overhoff, P. Shah, P. Santiago, J. Yacaman, K. P. Johnston and R. O. Williams III, Micronized Powders of a Poorly Water Soluble Drug Produced by

a Spray-Freezing into Liquid Emulsion Process, *European Journal of Pharmaceutics and Biopharmaceutics*, 55(2003) 161-172.

46. M.K. Barron, T.J. Young, K.P. Johnston and R.O. Williams III, Investigation of Processing Parameters of Spray Freezing Into Liquid to Prepare Polyethylene Glycol Polymeric Particles for Drug Delivery, *AAPS PharmSciTech*, 4(2003) 90-102.

47. X. Chen, R.O. Williams III and K.P. Johnston, Rapid Dissolution of High Potency Danazol Particles Produced by Evaporative Precipitation from Aqueous Solution, *Journal of Pharmaceutical Sciences*, 93(2004) 1867-1878.

48. J. Hu, K. P. Johnston and R. O. Williams III, Spray Freezing into Liquid (SFL) Particle Engineering Technology to Enhance Dissolution of Poorly Water Soluble Drugs: Organic vs. Aqueous-organic Co-solvent Systems, *European Journal of Pharmaceutical Sciences*, 20(2003) 295-303..

49. V. Mahaguna, R. L. Talbert, J. I. Peters, S. Adams, T. D. Reynolds, F. Y. W. Lam, and R. O. Williams III, Influence of Hydroxypropyl Methylcellulose Polymer on In Vitro and In Vivo Performance of Controlled Release Tablets Containing Alprazolam, *European Journal of Pharmaceutics and Biopharmaceutics*, 56(2003) 461-468.

50. Z. Yu, A. S. Garcia, K. P. Johnston, and R. O. Williams III, Spray Freezing Into Liquid for Highly Stable Protein Nanostructured Microparticles, *European Journal of Pharmaceutics and Biopharmaceutics*, 58(2004) 529-537.

51. J. Hu, K. P. Johnston and R. O. Williams III, Rapid Dissolving High Potency Danazol Powders Produced by Spray Freezing into Liquid Process with Organic Solvents, *International Journal of Pharmaceutics*, 271(2004) 145-154.

52. J. Hu, K. P. Johnston and R. O. Williams III, Rapid Release Tablet Formulation of Micronized Danazol Powder Produced by Spray Freezing into Liquid, *Journal of Drug Delivery Science and Technology*, 14(2004)305-311.

53. J. Hu, K. P. Johnston and R. O. Williams III, Stable Amorphous Danazol Nanostructured Powders with Rapid Dissolution Rates Produced by Spray Freezing into Liquid, *Drug Development and Industrial Pharmacy*, 30(2004)695-704.

54. X. Chen, Z. Benhayoune, R. O. Williams III, and K. P. Johnston, Rapid Dissolution of High Potency Itraconazole Particles Produced by Evaporative Precipitation into Aqueous Solution, *Journal of Drug Delivery Science and Technology*, 14(2004)299-304.

55. W. T. Leach, D. Simpson, T. N. Val, E. C. Anuta, Z. Yu, R. O. Williams III, and K. P. Johnston, Uniform Encapsulation of Stable Protein Nanoparticles by Spray Freezing for the Reduction of Burst Release, *Journal of Pharmaceutical Sciences*, 94(2005)56-69.

56. J. Hu, K. P. Johnston, and R. O. Williams III, Nanoparticle Engineering Processes for Enhancing the Dissolution Rates of Poorly Water Soluble Drugs – A Review, *Drug Development and Industrial Pharmacy*, 30(2004)247-258.

57. Z. Yu, K. P. Johnston and R. O. Williams III, Spray Freezing into Liquid Versus Spray Freeze Drying: Influence of Atomization on Protein Aggregation and Biological Activity, *European Journal of Pharmaceutical Sciences*, 27(2006)9-18.

58. P. Sinswat, X. Gao, M. J. Yacaman, R. O. Williams III and K. P. Johnston, Stabilizer Choice for Rapid Dissolving High Potency Itraconazole Particles Formed by Evaporative Precipitation into Aqueous Solution, *International Journal of Pharmaceutics*, 302(2005)113-124.

59. J. M. Vaughn, K. Gao, M.-J. Yacaman, K. P. Johnston, and R. O. Williams III, Comparison of Powder Produced by Evaporative Precipitation into Aqueous Solution (EPAS) and Spray Freezing into Liquid (SFL) Processes Using Novel Z-Contrast STEM and Complimentary Techniques, *European Journal of Pharmaceutics and Biopharmaceutics*, 60(2005)81-89.

60. X. Chen, C. Y-L Lo, M. Sarkari, R. O. Williams III, and K. P. Johnston, Ketoprofen Nanoparticle Gels Formed by Evaporative Precipitation into Aqueous Solution, *AIChE Journal*, 52(2006)2428-2435.

61. T. W. Leach, R. O. Williams III, and K. P. Johnston, Encapsulation of Protein Nanoparticles into Uniform-Sized Microspheres Formed in a Spinning Oil Film, *AAPS PharmSciTech*, 6(2005)605-617.

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15. Intravenous and Intradermal In Vivo Assays for Screening Local Tolerance of Injectable. Seventh Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, November, 1992.
16. Evaluation of Effect of Film Coating Formulations on the Quality of Tablet Printing: Solvent versus Aqueous In Systems, Science Expo 1993, Rhone-Poulenc Rorer, Collegeville, PA, October, 1993.
17. Influence of Loading Temperature of the Metering Chamber on Product Performance of a pMDI, Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Seattle, WA, October, 1996.
18. Comparison of Bonding Indices of Different Microcrystalline Cellulose Products, Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Seattle, WA, October, 1996.
19. Investigation of Water Uptake into Metered-Dose Inhaler Products, Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Seattle, WA, October, 1996.
20. Minimization of Food Effect on Drug Release From Aquacoat Coated Pellets, Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Seattle, WA, October, 1996.
21. A Method For Detection of Residual Tween 80 From Aerosol Componentry Using Thin-Layer Chromatography, Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Seattle, WA, October, 1996.
22. Formulation Aspects of Freund's Incomplete Adjuvant Emulsion, Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Seattle, WA, October, 1996.
23. The Influence of Metering Chamber Volume on the Dose Delivery and the Aerodynamic Particle Size Distribution from a pMDI Formulated with P-134a Propellant, Proceedings of the 16th Pharmaceutical Technology Conference, Athens, Greece, April, 1997.
24. The Influence of Water on the Emitted Dose of a pMDI Containing P-134a Propellant, Proceedings of the 16th Pharmaceutical Technology Conference, Athens, Greece, April, 1997.
25. Optimization of Drug Delivery From a MDI with Propellants 134a and 227, Proceedings of the 24th International Symposium on Controlled Release of Bioactive Materials, Stockholm, Sweden, June, 1997.
26. Influence of Food Effects on Drug Release From Aquacoat Coated Beads, Proceedings of the 24th International Symposium on Controlled Release of Bioactive Materials, Stockholm, Sweden, June, 1997.
27. Influence of Micronization Technique on the Delivery of Drug From a Metered-Dose Inhaler Formulation Using Propellant HFA 134a. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
28. Characterization of Chitosan Microspheres as Protein Carriers for Lung Delivery. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.

29. Pulmonary Delivery of Proteins by Inhalation Aerosols Formulated with HFA 134a Propellant. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
30. Influence of Temperature on the Integrity of Aerosol Can Linings Following Exposure to Hydrofluoroalkane Propellants. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
31. Influence of Propellant Type on the Solubility of Triamcinolone Acetonide and Beclomethasone Dipropionate. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
32. Formulation and Characterization of an Inclusion Complex of Cholesterol and Hydroxypropyl-beta-cyclodextrin. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
33. Optimization of a Matrix Tablet Formulation Containing a Liquid Active Ingredient Using HPMC. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Boston, MA, November, 1997.
34. Optimization of Granulations Containing Nonoxynol-9 Using Hydroxypropyl-methylcellulose. Proceedings of the 17th Pharmaceutical Technology Conference, Dublin, Ireland, March, 1998.
35. Influence of Hydroxypropyl-beta-cyclodextrin on the Chemical Stability of Aspirin in HFA 134a. Proceedings of the Respiratory Drug Delivery VI Conference, Hilton Head, South Carolina, May, 1998.
36. Modeling the Stability of Aspirin in a pMDI Formulation Containing HFA 134 and Hydroxypropyl-beta-cyclodextrin. Proceedings of the 2nd World Meeting on Pharmaceutics, Biopharmaceutics, and Pharmaceutical Technology, Paris, France, May, 1998.
37. Influence of Propellant Type on Drug Solubility. Proceedings of the 25th International Symposium on Controlled Release of Bioactive Materials, Las Vegas, NV, June, 1998.
38. Optimization of a Matrix Tablet Formulation Containing a Liquid Active Ingredient Using Cellulose Ethers. Proceedings of the 25th International Symposium on Controlled Release of Bioactive Materials, Las Vegas, NV, June, 1998.
39. Evaluation of the Impact of Eudragit Enteric Resin Coating Systems on the Pharmacokinetic Characteristics of Diltiazem Extended-Release Tablets. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
40. Chitosan Microspheres for Mucosal Delivery of Insulin. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
41. Influence of Co-Grinding of Drug and a Polymeric Surfactant on Performance of a Pressurized Metered Dose Inhaler Suspension Formulation. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
42. Investigation of Some Commercially Available Spacer Devices on the Delivery of a Glucocorticoid Steroid from a Pressurized Metered Dose Inhaler. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.

43. Aerosol Delivery of Insulin via a Pressurized Metered Dose Inhaler Formulated with HFA 134a. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
44. Study of Solubility of Steroids in Hydrofluoroalkane Propellants. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
45. Influence of Curing Conditions on Drug Release from Ethylcellulose Coated Matrix Bead Formulations. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
46. Use of Cellulose Ethers in a Vaginal Tablet Containing Nonoxynol-9. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
47. Moisture Uptake and its Effect on the Performance of pMDIs. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
48. Effect of Plasticizers and Curing Conditions on the Mechanical Properties of Aqueous Based Cellulose Acetate Phthalate Films. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
49. Chitosan Microspheres for Mucosal Delivery of Insulin. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, San Francisco, CA, November, 1998.
50. Co-processing and its Influence on a Model pMDI Formulation Containing Triamcinolone Acetonide and Pluronic F77, Proceedings of the 26th International Symposium on Controlled Release of Bioactive Materials, Boston, MA, June, 1999.
51. Feasibility Study of Buccal Delivery of Insulin Using Propellant-Driven Metered-Dose Applicators. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.
52. Development of Moisture Scavenger Systems for Controlling the Water Level in pMDIs. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.
53. Influence of Coating Variables on Drug Release from Beads Coated with Cellulose Acetate Phthalate Aqueous Dispersion. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.
54. Influence of Processing Parameters on Drug Release from Ethylcellulose Coated Matrix Bead Formulations. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.
55. Use of Heliox to Deliver Albuterol by Nebulization – An In Vitro Evaluation. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.
56. Cryogenic Spray Process for the Preparation of Microparticles. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.
57. Development and Validation of a Reverse-Phase HPLC Stability-Indicating Assay for Insulin. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November, 1999.

58. Investigation of Excipient Type on the Release of Alprazolam from Hydrophilic Matrix Tablets. Proceedings of the Pharmacy Student Research Conference, Denver, CO, June, 2000.
59. Investigation of the Use of Pore Formers to Modify Drug Release from Ethylcellulose Coated Beads. Proceedings of the Pharmacy Student Research Conference, Denver, CO, June, 2000.
60. Method to Recover a Lipophilic Drug from Hydroxypropyl Methylcellulose Matrix Tablets. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
61. Use of Pore Formers to Modify Drug Release from Ethylcellulose Coated Beads. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
62. Investigation of Excipient type and Level on Drug Release from HPMC Controlled Release Tablets. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
63. Influence of Plasticizers on Heat-Humidity Curing of Cellulose Acetate Phthalate. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
64. Buccal Delivery of Insulin Using Perosulin Pressurized Metered-Dose Applicator. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
65. Comparison of the Aerodynamic Particle Size Distribution of pMDIs Obtained Using the Aerosizer and Andersen Cascade Impactor. Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October, 2000.
66. Novel Curing Process for Cellulose Acetate Phthalate Coated Beads. Proceedings of the 20th Pharmaceutical Technology Conference and Exhibition, Liverpool, UK, April, 2001.
    a. Received the Penwest Award for best scientific paper
67. Buccal Delivery of Insulin to Type I Diabetic Patients with Perosulin Formulation. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
68. Stabilization of a Ketoprofen/PLO Formulation. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
69. Utilization of a Novel Cryogenic Spray-freezing into Liquid Process to Enhance the Dissolution of Danazol. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
70. Improvement of Dissolution Rate of Poorly Water Soluble Drugs Using the Novel Spray-freezing into Liquid Technology. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
71. Evaporative Precipitation into Aqueous Solutions (EPAS) – A New Technology to Enhance Bioavailability for Poorly Water Soluble Drugs. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
72. Amorphous Nifedipine Nanoparticles for Enhanced Bioavailability Formed by Evaporative Precipitation into Aqueous Solution (EPAS). Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.

73. Pharmacodynamics of Alprazolam Formulated in HPMC Controlled Release Tablets. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
74. Formulation Development and Pharmacokinetics Study of Alprazolam Contained in HPMC Controlled Release Tablets. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
75. Comparison of Cascade Impaction and Time-of-flight Methods for Characterizing Nebulizer Output. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
76. A Process for the Production of Protein Loaded Microparticles Using a Novel Cryogenic Process. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
77. Properties of Heat-Humidity Cured Cellulose Acetate Phthalate Free Films Prepared by the Spray Method. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
78. Enteric Release Stability of Heat-Humidity Cured Cellulose Acetate Phthalate Coated Beads. Proceedings of the American Association of Pharmaceutical Scientists, Denver, CO, October, 2001.
79. Particle Design for Enhanced Dissolution Rates of Poorly Water Soluble Drugs. Proceedings of the 76th Colloid and Surface Science Symposium, University of Michigan, Ann Arbor, MI, June, 2002.
80. Evaporative Precipitation into Aqueous Solution to Enhance Dissolution of Poorly Water Soluble Drugs. Proceedings of the 4th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy, April, 2002.
81. Utilization of a Novel Spray-Freezing Into Liquid (SLF) and Atmospheric Freeze Drying (ATMFD) Particle Engineering Technology to Enhance the Dissolution of a Poorly Water Soluble Model Drug. Proceedings of the 4th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Florence, Italy, April, 2002.
82. A Novel Particle Engineering Technology: Spray Freezing into Liquid To Enhance the Dissolution of Poorly Water Soluble Drugs. Proceedings of the Controlled Release Society Meeting, Seoul, South Korea, July, 2002.
83. A New Process for the Production of Protein Loaded Microparticles Using a Novel Cryogenic Process. Proceedings of the Controlled Release Society Meeting, Seoul, South Korea, July, 2002.
84. A Novel Technique to Enhance Dissolution of Poorly Water Soluble Compounds: Evaporative Precipitation into Aqueous Solution (EPAS). Proceedings of the Controlled Release Society Meeting, Seoul, South Korea, July, 2002.
85. Particle Design for Enhanced Dissolution Rates of Water Insoluble Drugs. Proceedings of the American Institute for Chemical Engineering, Indianapolis, IN, November, 2002.
86. Novel Spray Freezing Process for the Production of Protein Loaded Microparticles. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
87. Novel Process to Prepare Microparticles for Depot Delivery: Spray Freezing Double Emulsion Into Liquid. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.

88. Formulation of Danazol Micronized by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
89. Enhanced Aqueous Dissolution of a Poorly Water Soluble Drug by Novel Particle Engineering Technologies: Spray-Freezing into Liquid Dried by Atmospheric Freeze-Drying. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
90. A Novel Cryogenic Spray Process to Enhance Dissolution of Poorly Water Soluble Drug: Organic Solvent vs. Aqueous-Organic Co-solvent Systems. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
91. High Potency Danazol with Enhanced Dissolution Rates by Evaporative Precipitation into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
92. Release Mechanism of Alprazolam from Controlled Release Tablets Containing HPMC and Various Excipients. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
93. Quantitation of Plasticizers from Cellulose Acetate Phthalate Films by High-Performance Liquid Chromatography (HPLC) – Separation. Proceedings of the American Association of Pharmaceutical Scientists Meeting, Toronto, Canada, November 2002.
94. High Potency Danazol with Enhanced Dissolution Rates by Evaporative Precipitation into Aqueous Solution. Proceedings of the Controlled Release Society, Winter Meeting, Salt Lake City, UT, March 2003.
95. Improvement of Dissolution Rate of Poorly Water Soluble Drug Utilizing a Novel Spray Freezing into Liquid Process: Organic Solvent vs. Aqueous-Organic Co-solvent Systems. Proceedings of the Controlled Release Society, Winter Meeting, Salt Lake City, UT, March 2003.
96. A Novel Particle Engineering Technology: Spray Freezing Into Liquid to Enhance the Dissolution of Poorly Water Soluble Drugs. Proceedings of the 21st Pharmaceutical Technology Conference, Dublin, Ireland, March 2003.
97. Enhancement of Danazol Potency by Spray Freezing into Liquid (SFL) Using Organic Solvents. Proceedings of the 30th Controlled Release Society Meeting, Glasgow, Scotland, July 2003.
98. Enhanced Dissolution by Evaporative Precipitation into Aqueous Solution and Formulation of the Processed Dispersions. Proceedings of the 30th Controlled Release Society Meeting, Glasgow, Scotland, July 2003.
99. Spray Freezing into Liquid for Protein Microparticle Preparation: Influence of Process Parameters on Physicochemical Stability of Protein. Proceedings of the 30th Controlled Release Society Meeting, Glasgow, Scotland, July 2003.
100. Encapsulation of Protein Solids Produced by Spray Freezing into Liquid into Biodegradable Microparticles for Controlled Release. Proceedings of the 30th Controlled Release Society Meeting, Glasgow, Scotland, July 2003.
101. Micronized Powders of a Poorly Water Soluble Drug Produced by a Spray Freezing into Liquid Emulsion Process. Proceedings of the 30th Controlled Release Society Meeting, Glasgow, Scotland, July 2003.

102. Protein Processing via Spray Freezing into Liquid to Achieve Low Burst During Protein Delivery from Biodegradable Polymeric Microspheres. Proceedings of the American Institute for Chemical Engineering, San Francisco, CA, November, 2003.
103. Physicochemical Properties of Itraconazole Produced by Spray-Freezing into Liquid Process. Proceedings of the First EUFEPS Conference, Versailles, France, October, 2003.
104. Stability of Amorphous Danazol Powders Produced by Spray Freezing Into Liquid Technology: Influence of Excipient Type and Glass Transition Temperature. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
105. Low Burst Biodegradable Microspheres Using Protein Solids Prepared Via Spray Freezing Into Liquid Technology. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
106. The Stability of Protein Powder: Spray Freezing Into Liquid Versus Spray Freeze Drying. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
107. The Influence of Process Parameters on the Stability of Protein Nanoparticles Produced by Spray Freezing Into Liquid. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
108. Nebulization of a Suspension Containing Itraconazole Prepared by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
109. Spray Freezing Into Liquid of Itraconazole for Pulmonary Delivery. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
110. High Potency Itraconazole with Enhanced Dissolution Rates Produced by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
111. Influence of Stabilizer Type on Dissolution Properties of Itraconazole Produced by Evaporative Precipitation Into Aqueous Solution. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
112. Rapid Release High Potency Danazol Powders Produced by Spray Freezing Into Liquid (SFL) – Organic Solvent Process. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
113. Controlling Particle Characteristics of Itraconazole Powders Produced by Spray-Freezing Into Liquid – Organic Solution Versus Emulsion Liquid Feed Solutions. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
114. Evaporative Precipitation Into Aqueous Solution Process: Investigation of Processing Parameters to Enhance Dissolution of Danazol. Proceedings of the American Association of Pharmaceutical Scientists, Salt Lake City, UT, October 2003.
115. Stability and Delivery of Protein Powders Prepared by the Spray Freezing into Liquid Nitrogen Technology, Abstracts of Papers, 227th American Chemical Society Meeting, Anaheim, CA, March, 2004.
116. Comparison of Particle Formation Processes, Spray Freezing into Liquid and Evaporative Precipitation into Aqueous Solution: How Particle Formation Impacts Morphology and Performance, Proceedings of the 30th Controlled Release Society Meeting, Honolulu, HI, June, 2004.

117. Enhanced Solubility and Dissolution of Itraconazole Prepared by the Spray Freezing into Liquid Technique, Proceedings of the 30th Controlled Release Society Meeting, Honolulu, HI, June, 2004.
118. Stable Amorphous Danazol Nanostructured Powders Produced by Spray Freezing into Liquid Technology, Proceedings of the 30th Controlled Release Society Meeting, Honolulu, HI, June, 2004.
119. Homogenous Encapsulation of Protein Nanoparticles into Uniform Size Microspheres, Proceedings of the National Biotechnology Meeting, Boston, MA, June 2004.
120. Controlled Precipitation of Naproxen Nanoparticles, Proceedings of the American Institute of Chemical Engineers Meeting, Austin, TX, November, 2004.
121. Spray Freezing into Liquid Versus Spray Freeze Drying: The Influence of Atomization on Protein Aggregation and Biological Activity, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
122. Insulin Loaded Polymeric Microparticles: Formulation, Characterization, and Release Characteristics, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
123. The Use of Antioxidants to Stabilize Ethyl Lactate, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
124. Ultrarapid Freezing to Micronize Water Insoluble Drugs – A Comparison to Spray Freezing into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
125. Design of a Restraint-Free Small Animal Dosing Chamber for Inhalation and Investigation of Drug Distribution Within the Chamber, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
126. Comparison of Powder Produced by Evaporative Precipitation into Aqueous Solution and Spray Freezing into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
127. Rapid Release Tablet Formulation Containing Micronized Danazol Powder Produced by Spray Freezing into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
128. Morphology of Poorly Water Soluble Drug Nanoparticles by a Cryogenic SEM Technique, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
129. Miscibility of Hydrophilic Polymers and Surfactants with Polyethylene Oxide in Hot-melt Extruded Tablets Containing Poorly Water Soluble Drug, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
130. Influence of Processing on Stability of Insulin – Spray Freezing Into Liquid, Proceedings of the American Association of Pharmaceutical Scientists, Baltimore, MD, November, 2004.
131. Delivery of Poorly Water Soluble Drugs Using Nebulization, Proceedings of the15th Drug Delivery to the Lungs Conference, Aerosol Society, London, England, December, 2004.
132. Comparison of Commercial Itraconazole to Aerosolized Nanoparticle Itraconazole in a Murine Model for the Prevention of Invasive Pulmonary Aspergillus, Proceedings of Alcalde XIX Southwest Leadership Conference, Austin, Texas, April, 2005.

133. Novel Treatment of Pulmonary Aspergillosis Using Nebulized Itraconazole Nanoparticles in the Murine Model, Proceedings of the Respiratory Drug Delivery – Europe 2005 Conference, Paris, France, May, 2005.
134. Improved Dissolution Rate and Bioavailability Through the Formation of a Highly Miscible Binary Mixture, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.
    a. Paper awarded the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award
135. Rapid Release, High Potency Itraconazole Formed by Evaporative Precipitation Into Aqueous Solution, Proceedings of the Controlled Release Society Annual Meeting, Miami, FL, June, 2005.
    a. Paper nominated for the Controlled Release Society's Innovative Aspects of Oral Drug Delivery and Absorption Graduate/Post-Doc Award
136. Particle Engineering for Rapid Dissolution Rates of Poorly Water Soluble Drugs, Proceedings of the American Institute of Chemical Engineers 2005 Annual Meeting, Cincinnati, OH, October, 2005.
137. Cryogenic Liquids, Nanoparticles and Microencapsulation, Proceedings of the 15th Symposium on Microencapsulation, Parma, Italy, September, 2005.
    a. Invited Speaker
138. Improved Danazol Supersaturation and Oral Bioavailability via Formulation into an Amorphous Solid Solution, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
139. Characterization of Nebulized Itraconazole Nanoparticles and Delivery to the Murine Lung, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
140. Treatment of Acute Pulmonary Aspergillosis with Nebulized Itraconazole in the Murine Model, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
141. Poorly Water Soluble Drug Nanoparticles by Anitsolvent Precipitation: Mixing Energy Versus Surfactant Stabilization, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
142. On-Line Turbidimetric Dissolution Rates of Poorly Water Soluble Drug Nano-structured Particles, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
143. Improvement of Dissolution Rate of Repaglinide Using Controlled Precipitation, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
144. Novel Processes for the Enteric Coating of Empty Gelatin Capsules, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
145. Rapid Dissolving Repaglinide Powders Produced by Ultra-Rapid Freezing Process, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.
146. Investigation of Dissolution Properties of Microcrystalline or Stabilized Amorphous Particles of Itraconazole in Melt Extruded Solid Dispersions, Proceedings of the American Association of Pharmaceutical Scientists Meeting, Nashville, TN, November, 2005.

147. In vivo Efficacy of Aerosolized Nano-structured Itraconazole Formulations for the Prevention of Invasive Pulmonary Aspergillosis, Proceedings of the 45th Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, D.C., December 2005.
148. Murine Airway Histology and Alveolar Macrophage Uptake of Inhaled Amorphous Itraconazole, Proceedings of the American Thoracic Society Meeting, San Diego, CA, May, 2006.
149. Particle Engineering and Formulation for Enhanced Bioavailability of Poorly Water Soluble Drugs, Proceedings of Particles 2006, Medical/Biochemical Diagnostic, Pharmaceutical and Drug Delivery Applications of Particle Technology, Orlando, FL, May 2006.
150. Single Dose Variability and Multi-Dose Studies of Nebulized Itraconazole in a Murine Model, Proceedings of Respiratory Drug Delivery X, Boca Raton, FL, April 2006.
151. Poorly Water Soluble Drug Nanoparticles by Anitsolvent Precipitation: Mixing Energy Versus Surfactant Stabilization, Proceedings of the Controlled Release Society Meeting, Vienna, Austria, July 2006.
152. Sustained Lung Concentrations of Itraconazole Using Nebulized Dispersions in a Murine Model, Proceedings of the Controlled Release Society Meeting, Vienna, Austria, July 2006.
153. Evaluation of the USP Enteric Test Method A for Delayed-Release Dosage Forms Using PLIF, Proceedings of the Controlled Release Society Meeting, Vienna, Austria, July 2006.
154. Evaluation of the USP Dissolution Test Method A for Enteric Coated Articles by Planer Laser Induced Fluorescence, Proceedings of the World Congress of Pharmacy and Pharmaceutical Sciences 2006, 66th International Congress of FIP, Salvatore, Brazil, August 2006.
155. Aerosolized Itraconazole (ITZ) as Prophylaxis Against Invasive Pulmonary Aspergillosis (IPA) Due to *Aspergillus fumigatus*, Proceedings of the Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, September, 2006.
156. Aerosolized Itraconazole as Prophylaxis Against Invasive Pulmonary Aspergillosis Due to Aspergillus Fumigatus, Proceedings of the American College of Clinical Pharmacy, St. Louis, MO, October, 2006.
157. In-vitro and In-vivo Comparison of Melt Extruded Particulate Dispersions of PVP and HPMC-Stabilized Nano-Structured Amorphous Particles of Itraconazole, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
158. Formation of Stable Submicron Protein Particles by Thin Film Freezing, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
159. Anti-solvent Precipitation of Cyclosporin A Nanoparticles for Enhanced Pulmonary Delivery, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
160. In-vitro and In-vivo Validation of a High Concentration Preclinical Rodent Dosing Apparatus for Inhalation, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.

161. Development of a Modified Release System Containing Itraconazole Using the Ultra-Rapid Freezing Technology, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
162. Stable Supersaturated Solutions from Nanoparticle Dissolution, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
163. Evaluation of the USP Dissolution Test Method A for Enteric-Coated Articles by Planar Laser Induced Fluorescence, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
164. Optimization of Rapidly Disintegrating and Dissolving Tablets Containing Itraconazole Nanoparticles Formed by Evaporative Precipitation Into Aqueous Solution, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
165. Immunological Response and Alveolar Macrophage Uptake of Inhaled Amorphous ITZ, Proceedings of the American Association of Pharmaceutical Scientists, San Antonio, TX, October 2006.
166. Engineered Particles for Targeted Drug Delivery, Proceedings 15th International Symposium on Microencapsulation, Lexington, Kentucky, September 2007.
167. In Vitro Efficacy and In Vivo Safety of Inhaled Nanoparticles of Tacrolimus, Proceedings of the American College of Chest Physicians, Chicago, IL, October, 2007.
168. Effect of Stabilizer on the Maximum Degree and Extent of Supersaturation and Oral Absorption of Tacrolimus Nanoparticles Made by Ultra-rapid Freezing, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
169. Improved Bioavailability of Itraconazole via Pulmonary Administration of Nanoparticles Produced by Ultra-rapid Freezing, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
170. Preformulation and Formulation Studies of Rapidly Dissolving Powders of Sirolimus Produced by the Ultra-Rapid Freezing Process, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
171. Multiple Dose Pharmacokinetic Study of Tacrolimus Nanoparticles Delivered by Nebulization to Mice, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
172. The Influence of Hydrophilic and Enteric Polymers in Targeting *In Vitro* Supersaturation of Itraconazole from Engineered Particles, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
173. Influence of Cyclodextrin on Viscosity and Aerosolization by Nebulization, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
174. Amphotericin B Formulation Containing Insoluble Aggregates Dispersed in a Lyoprotectant Carrier for Pulmonary Delivery, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
175. Supersaturation of Itraconazole in Neutral pH from Engineered Particles and Enteric Dispersions of Engineered Particles Produced by Hot-Melt Extrusion, Proceedings of the American Association of Pharmaceutical Scientists, San Diego, CA, November, 2007.
176. Design of Pharmaceutical Nanoparticles for Enhanced Therapies, Proceedings of the American Institute of Chemical Engineering Meeting, Salt Lake City, UT, November, 2007.

177. Suspension of Protein and Poorly Water Soluble Drug Particles for High Dosages with Pressurized Metered Dose Inhalers, Proceedings of the Respiratory Drug Delivery Conference, Scottsdale, AZ, May, 2008.
178. K. P. Johnston, J. Engstrom, J. Tam, M. Matteucci, A. Mazuski, L. Ma, Robert O. Williams III, T. Milner and M. Feldman, Design of Pharmaceutical Nanoparticles for Drug Delivery, Proceedings of the National American Chemical Society Meeting, Philadelphia, PA, August, 2008.
179. A. R. Saad, A. Cline, A. B. Watts, G. Hsiung, J. I. Peters, L. Angel, R. O. Williams III and S. B. Johnson, Nanoparticle Tacrolimus Inhalation in Rat Lung Transplant Model, Proceedings of the American College of Chest Physicians, Philadelphia, PA, October, 2008.
180. J. A. Tolman, N. P. Wiederhold, J. T. McConville, L. K. Najvar, J. R. Graybill, J. J. Coalson, R. Bocanegra, T. F. Patterson and R. O. Williams III, Aerosolized Voriconazole (VRC) as Prophylaxis Against Invasive Pulmonary Aspergillosis (IPA) due to *Aspergillus fumigatus*, Proceedings of the Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington D.C., October 2008.
181. M. A. Mazuski, M. E. Matteucci, R. O. Williams III and K. P. Johnston, Flocculated Amorphous Nanoparticles for Enhanced Bioavailability of Poorly-Water Soluble Drugs: In Vitro and In Vivo Studies, American Institute of Chemical Engineering, Philadelphia, PA, November 2008.
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186. J. DiNunzio, C. Brough, R. O. Williams III and J. W. McGinity, Production of Plasticizer Free Itraconazole Solid Dispersions for Enhanced Solid State Properties Using KinetiSol Dispersion, Proceedings of the American Association of Pharmaceutical Scientists, Atlanta, GA, November 2008.
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188. Y. Tsutsumi, K. T. Chow, W. Yang and R. O. Williams III, Preparation and Characterization of Solid Dispersions of Itraconazole and Enteric Polymers Made by

Spray Freezing into Liquid Technology, Proceedings of the American Association of Pharmaceutical Scientists, Atlanta, GA, November 2008.

189. K. O'Donnell, R. O. Williams III, C. Wah and J. T. McConville, Investigation of Nebulized Dose and Inhaled Dose of Itraconazole Dispersions in a Nose Only Rodent Dosing Chamber, Proceedings of the American Association of Pharmaceutical Scientists, Atlanta, GA, November 2008.
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192. K. T. Chow, W. Yang and R. O. Williams III, Dissolution Enhancement of Itraconazole Prepared by a Modified Spray Freezing into Liquid Process with Template Emulsion, Proceedings of the American Association of Pharmaceutical Scientists, Atlanta, GA, November 2008.
193. M. Nagao, S. Bosselmann and R. O. Williams III, Preparation of Itraconazole Nanoparticles by Advanced Evaporative Precipitation into Aqueous Solution, Proceedings of the American Association of Pharmaceutical Scientists, Atlanta, GA, November 2008.
194. J. Tolman, N. Nelson, S. Bosselmann, N. Wiederhold and R. O. Williams III, Pharmacokinetic Profile Following Multiple Doses of Inhaled Voriconazole Solution in Mice, Proceedings of the American Association of Pharmaceutical Scientists, Atlanta, GA, November 2008.
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198. S. Bosselmann, D. Owens, M. Herpin, R. Kennedy and R. O. Williams III, Enhanced Stability of Itraconazole Hot-Melt Extrudates Through the Deposition of a Hydrophobic Plasma-Polymerized Film, Proceedings of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November 2009.
199. K. O'Donnell, R. O. Williams III, H. Lirola and J. T. McConville, Investigation of Nebulized Itraconazole Dispersions: In-Vitro-In-Vivo Comparison of Dose Administered to Mice in a Nose-only Dosing Apparatus, Proceedings of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November 2009.

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201. W. Yang, K. Chow, B. Lang, K. P. Johnston and R. O. Williams III, Pharmacokinetic Study of Inhaled Nebulized Itraconazole as Cyclodextrin Solubilized Solution or Colloidal Dispersion in Mice, Proceedings of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November 2009.
202. K. Chow, W. Yang, Y. Tsutsumi and R. O. Williams III, Particle Engineering Studies for Solubility Enhancement of Itraconazole Using Fine Emusion Templating and Cosolvent Approaches with Ultra-rapid Freezing, Proceedings of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November 2009.
203. J. DiNunzio, C. Brough, J. Hughey, R. O. Williams III and J. W. McGinity, Solid Dispersion Production Containing a Temperature Sensitive Drug via Hote Melt Extrusion and KinetiSol Dispersing, Proceedings of the American Association of Pharmaceutical Scientists, Los Angeles, CA, November 2009.
204. S. Bosselmann,, D. E. Owens III, R. L. Kennedy, M. J. Herpin and R. O. Williams III, Enhanced Stability of Amorphous Ketoprofen Made by Rapid Freezing Through the Deposition of Hydrophobic Plasma-Polymerized Films, Proceedings of Particles 2010: Medical/Biochemical Diagnostic, Pharmaceutical and Drug Delivery Applications of Particle Technology, Orlando, FL, May, 2010.
205. S. Bosselmann, M. Nagao, K. T. Chow and R. O. Williams III, Formulation and Characterization of Itraconazole Nanoparticles Made by Advanced Evaporative Precipitation Into Aqueous Solution, Proceedings of Particles 2010: Medical/Biochemical Diagnostic, Pharmaceutical and Drug Delivery Applications of Particle Technology, Orlando, FL, May, 2010. (Invited)
206. B. Windsor, D. E. Owens III, W. Yang, A. B. Watts and R. O. Williams III, Benefits of Nanostructured Compositions Made by Rapid Freezing to Drug Delivery, Proceedings of Particles 2010: Medical/Biochemical Diagnostic, Pharmaceutical and Drug Delivery Applications of Particle Technology, Orlando, FL, May, 2010. (Invited)
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208. S. Bosselmann, D. E. Owens III, R. L. Kennedy, M. J. Herpin and R. O. Williams III, Novel Plasma Deposited Stability Enhancement Coating for Amorphous Ketoprofen, Proceedings of the 240th American Chemical Society Meeting (Polymeric Materials: Science and Engineering), Boston, MA, August, 2010. (Invited)
209. K. P. O'Donnell, P. Schmerler and R. O. Williams III, Investigation of a Novel Solvent Removal Technique, Atmospheric Freeze Drying, on the Physico-chemical Properties of Pharmaceutical Powders, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 2010.
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for Dry Powder Inhalation, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 2010.

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212. H. Li, M. Zhang, B. Lang, K. P. O'Donnell and R. O. Williams III, Modified Release Carbamazepine Compositions Prepared by Thin Film Freezing, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 2010.
213. R. Bennett, J. Hughey, C. Brough, R. O. Williams III and J. W. McGinity, Solid Dispersion Comparisons of Griseofulvin in Eudragit L100-55 Carrier Processed by Hot Melt Extrusion and KinetiSol Dispersing, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 2010.
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215. B. Lang and R. O. Williams III, Influence of Excipient Type on Itraconazole Compositions Made by Thin Film Freezing-Emulsion Process, Proceedings of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 2010.
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219. S. M. Levine, H. Singh, K. P. O'Donnell, B. Lang, W. Yang, A. Anzueto, R. O. Williams III and J. I. Peters, Safety and Tolerability of Single Dose Inhaled Tacrolimus in Healthy Subjects, Proceedings of the American College of Chest Physicians, Honolulu, Hawaii, CHEST 2011, October, 2011.
220. J. D. Simmons, A. M. Cline, Y-B. Wang, K. P. O'Donnell, C. E. Baisden, J. J. Coalson, E. G. Brooks, J. H. Calhoon, R. O. Williams III, J. I. Peters and S. B. Johnson, The Efficacy of Inhaled Nanoparticle Tacrolimus in Preventing Rejection in an Orthotopic Rat lung Transplant Model, Proceedings of the American Association for Thoracic Surgery, San Francisco, CA, May 2012.
221. H. Lirola and R. O. Williams III, Development and Validation of HPLC Method for the Separation of Mycophenolate Mofetil, Mycophenolic Acid and Mycophenolic Acid Glucuronide, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.

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223. K. P. O'Donnell, J. Morales, S. Raffa Carvalho, L. Hudson, R. Goodall, J. T. McConville and R. O. Williams III, Investigation of Sustained Drug delivery Through a Novel Implantable Personalized Molecular Drug Delivery System in the Presence of Particulate Matter, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
224. I. Ohno, S. Bosselmann and R. O. Williams III, Modified Evaporative Precipitation into Aqueous Solution Process to Prepare Mefenamic Acid Nanoparticle Compositions, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
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227. K. P. O'Donnell, J. Morales, S. Raffa Carvalho, L. Hudson, R. Goodall, J. T. McConville, R. O. Williams III, E. Tuzun, T. Fossum and J. Grinde, Pilot Investigation of Sustained Leuprolide Delivery Through a Novel Implantable Personalized Molecular Drug Delivery System with 3-nanometer Nanochannels, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
228. R. Bennett, C. Brough, K. P. O'Donnell, J. Hughey, J. Keen, R. O. Williams III and J. W. McGinity, Preparation of Solid Dispersions by KinetiSol Dispersing: An Approach to Enhance Solubility of a Poorly Water Soluble Plant Extract, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
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230. M. Zhang, H. Li, B. Lang, K. P. O'Donnell, Y. Wang, C. Wu and R. O. Williams III, Amorphous Fenofibrate Solid Dispersions Prepared by Thin-film Freezing Combined with Template Emulsion, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
231. A. B. Watts, Y. Wang and R. O. Williams III, Aerosolized Brittle Matrices for Pulmonary Delivery, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
232. Y. Wang, J. I. Peters, S. Levine, H. Singh, W. Yang, K. P. O'Donnell and R. O. Williams III, In Vitro and In Vivo Study of Inhaled Tacrolimus Colloidal Dispersion in Healthy Human Volunteers, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
233. N. Beinborn and R. O. Williams III, Effect of Process Variables on Aerodynamic Properties of Voriconazole Formulations Produce by Thin Film Freezing for Dry Powder

Inhalation, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.

234. N. Beinborn, J. Du, H. Smyth and R. O. Williams III, Dry Powder Insufflation of Crystalline and Amorphous Voriconazole Formulations Produced by Think Film Freezing to Mice, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
235. H. Li, M. Zhang, B. Lang, K. P. O'Donnell, R. Guo and R. O. Williams III, Modified Release Carbamazepine Compositions Prepared by Thin-Film Freezing, Proceedings of the American Association of Pharmaceutical Scientists, Washington D.C., October 2011.
236. P. Shivshankar, H. Payan, C. Calhoun, J. I. Peters, R. O. Williams III and Claude J. LeSaux, Inhaled Tacrolimus Protects Mice from Bleomycin-Induced Lung Fibrosis, Proceedings of the American Thoracic Society International Conference, May, 2012.
237. A. B. Watts, Y. B. Wang, S. M. Levine, J. I. Peters and R. O. Williams III, Development of Inhaled Tacrolimus: Human Safety and Formulation Improvements. Proceedings of the Respiratory Drug Delivery Meeting, Phoenix, AZ, May, 2012.
238. J. D. Simmons, N. A. Das, A. M. Cline, Y. B. Wang, K. P. O'Donnell, D. T. DeArmond, C. E. Baisden, J. J. Coalson, E. G. Brooks, J. H. Calhoon, R. O. Williams III, J. I. Peters and S. B. Johnson, The Efficacy of Inhaled Nanoparticle Tacrolimus in Preventing Rejection in an Orthotopic Rat Lung Transplant Model, Proceedings of the American College of Surgeons 98th Annual Clinical Congress, Chicago, IL, September, 2012.
239. J. Bayer, N. A. Das, C. E. Baisden, M. Rani, M. G. Schwacha, R. O. Williams III, J. I. Peters and S. B. Johnson, Effect of Inhaled Tacrolimus on Ischemia Reperfusion Injury in Rat Lung Transplant Model, Proceedings of the 49th Annual Meeting of the Society of Thoracic Surgeons, Los Angeles, CA, May, 2013.
240. J. W. McGinity, R. O. Williams III, J. R. Hughey, J. C. DiNunzio and D. A. Miller, Kinetisol: A Novel Process for the Production of Pharmaceutical Solid Dispersion Systems, Proceedings of the Gattfossee Meeting, St. Remy, France, June 2012.
241. P. Du, R. O. Williams III and H. Smyth, Engineered Lactose with Various Physicochemical Properties by Ultra Rapid Freezing, Proceedings of the American Association of Pharmaceutical Scientists, Chicago, IL, October 2012.
242. Y. Wang, A. B. Watts and R. O. Williams III, Brittle Matrices for Pulmonary Delivery of Tacrolimus, Proceedings of the American Association of Pharmaceutical Scientists, Chicago, IL, October 2012.
243. H. Dugas, J. I. Peters and R. O. Williams III, Pulmonary Bioavailability of an Inhaled Mycophenolate Mofetil Suspension: Comparison with the Nebulization of IV Cellcept Solution, Proceedings of the American Association of Pharmaceutical Scientists, Chicago, IL, October 2012.
244. B. Lang, J. W. McGinity and R. O. Williams III, Ternary Solid Dispersions Comprising Itraconazole and Surfactants to Improve the Dissolution Rate and the Degree of Supersaturation, Proceedings of the American Association of Pharmaceutical Scientists, Chicago, IL, October 2012.
245. B. Lang, J. W. McGinity and R. O. Williams III, Dissolution Enhancement of Itraconazole by Hot-Melt Extrusion Alone and the Combination of Hot-melt Extrusion and Rapid Freezing – Identification of Critical Formulation and Process Attributes and

Composition Optimization, Proceedings of the American Association of Pharmaceutical Scientists, Chicago, IL, October 2012.

246. A. B. Watts, Yi-Bo Wang, S. Carvalho, Jay I. Peters and R. O. Williams III, A DPI Platform for Delivery of Small Molecules and Biologics (ID 39297), Proceedings of the American Thoracic Society Meeting, Philadelphia, PA, May 2013.

247. R. O. Williams III, B. Lang, J. W. McGinity and D. A. Miller, Thermal Processing for the Delivery of Water-Insoluble Drugs: Hot-Melt Extrusion and Kinetisol® Dispersing, Proceedings of the American Institute of Chemical Engineering Annual Meeting 2013, November 2013 (invited presentation).

248. N. A. Das, J. Simmons, A. Cline, Y. Wang, K. O'Donnell, J. I. Peters, S. Johnson, and R. O. Williams III, Efficacy of Inhaled Nanoparticle Tacrolimus in Preventing Rejection in an Orthotopic Rat Lung Transplant Model, Proceedings of the Society of Thoracic Surgeons 50th Annual Meeting, January 2014 (accepted as podium presentation).

249. R. C. Bennett, C. Brough, D. A. Miller, J. M. Keen, R. O. Williams III and J. W. McGinity, Comparison of Physical Stability of Solid Dispersions Containing an Insoluble Plant Extract Prepared by Rotary Evaporation, Hot Melt Extrusion, and KinetiSol Dispersing, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Antonio, TX, November 2013.

250. Y-B. Wang, A. B. Watts and R. O. Williams III, Brittleness Assessment of Inhalation Powders Produced by Think Film Freezing, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Antonio, TX, November 2013.

251. S. Carvalho, M. Do, A. B. Watts and R. O. Williams III, Influence of Thin Film Freezing Parameters on Aerosolization of Rapamycin Formulation, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Antonio, TX, November 2013.

252. S. Carvalho, A. B. Watts, M. Do and R. O. Williams III, Use of Thin Film Freezing to Produce Aerosolized Brittle Matrices of Rapamycin for Dry Powder Inhalation, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Antonio, TX, November 2013.

253. Y. B. Wang, A. B. Watts and R. O. Williams III, Brittleness Assessment of Inhalation Powders Produced by Thin Film Freezing, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Antonio, TX, November 2013.

254. S. Hengsawas, J. Keen, S. Huang, J. W. McGinity and R. O. Williams III, Miscibility Modeling of Amorphous Solid Dispersions, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.

255. S. Huang, K. P. O'Donnell, J. Keen and R. O. Williams III, Evaluation of an Extrudable Form of Hypromellose – Affinisol HPMC HME, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.

256. S. Thakkar, X. Li, R. o. Williams III and Z. Cui, A Method of Preparing Dry Powder Vaccines Adjuvanted with Aluminum Salts, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.

257. J. Maincent, S. Huang, L. Najvar, W. Kirkpatrick, T. Patterson, N. Wiederhold, J. Peters and R. O. Williams III, Enteric Polymer and Hydrophilic Additive Processed by Hot-Melt Extrusion to Improve Bioavailability of Itraconazole, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.

258. J. LaFontaine, L. Prasad, C. Brough, K. Ford, R. O. Williams III and J. W. McGinity, Processing and Characterization of PVP- and HPMC-Based Amorphous Solid Dispersions: A Comparison of Hot Melt Extrusion and KinetiSol® Dispersing, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.

XIV. Invited Talks

1. Proprietes de Compaction de Poudres, Servier Laboratories, Orleans, France, June, 1985.

2. A Study of the Influence of Magnesium Stearate or Talc on the Compaction Properties of Aspirin and Sodium Sulfathiazole Using Tableting Indices, Proceedings of the Fourth International Conference on Pharmaceutical Technology, Paris, France, June, 1986.

3. Tableting - An Industrial Viewpoint, Pharmaceutics Series, University of Cincinnati, Cincinnati, OH, October, 1990.

4. Utilization of Sodium Chloride, Fructose, and Urea to Modify the Surface Tension of RG-12915A Solutions, The University of Texas at Austin, Austin, TX, September, 1991.

5. Tableting Indices in Compaction Studies, Proc. Midwest Regional Meeting, American Association of Pharmaceutical Scientists, Chicago, IL, May, 1992.

6. Theory and Practical Applications of Tableting Indices in Compaction Studies, Proc. Fifth Annual Meeting, Proceedings of the American Association of Pharmaceutical Scientists, Las Vegas, NV, November, 1990.
   a. Invited Speaker

7. Current Issues and Trends in Technology Transfer, Sixth International Congress for Pharmaceutical Engineering, International Society for Pharmaceutical Engineering, Philadelphia, PA, May, 1994.
   a. Invited Speaker

8. Simulated Food Effects on Drug Release from Film Coated Pellets, Proceedings of the 15th Pharmaceutical Technology Conference, Oxford, England, March, 1996.

9. Optimization of Metered-Dose Inhaler Suspension Formulations, Fachbereich Pharmazie, Freie Universitat Berlin, Berlin, Germany, March, 1996.

10. Formulation and Stability of a Three Component Suspension, Horizon Pharmaceuticals, Louisville, KY, May, 1996.

11. Optimization of a Matrix Tablet Formulation Containing Nonoxynol-9 Using Cellulose Ethers, The Dow Chemical Company, Cellulosics Division, Midland, MI, November, 1997.

12. Delivering Steroids to the Nose Using an Aqueous Based Pump System, Honduran Medical Association, Tegucigalpa, Honduras, Central America, October, 1998.
    a. Invited Plenary Speaker

13. Preparation of Chitosan Microspheres for Nasal and Pulmonary Release of Therapeutic Macromolecules, Proceedings of the Association of Pharmaceutical Technology Professors of Spain, Santiago, Spain, February, 1999.

14. The Effect of Co-Grinding Drug and a Polymeric Surfactant on a Model pMDI Suspension, Proceedings of the 18th Pharmaceutical Technology Conference, Utrecht, The Netherlands, April, 1999.
    a. Invited Speaker

15. Buccal Delivery of Insulin Via Aerosol Spray, Proceedings of the Third World Meeting On Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Berlin, Germany, April, 2000.
    a. Session Chair – Scientific Program

16. Introduction to Pharmaceutical Development and Technology, Invited Short Course, International Society of Pharmaceutical Engineers, Philadelphia, PA, May, 2001.
    a. Invited Speaker

17. Utilization of a Novel Cryogenic Spray-freezing Into Liquid (SFL) Process to Encapsulate Danazol, Proceedings of the 13th International Symposium on Microencapsulation, Angers, France, September, 2001.
    a. Session Chair – Scientific Program

18. Austin's Road to Bio: Where We Are and Where We're Going – Drug Delivery and Nanotechnology. Austin Chamber of Commerce, Austin, TX, January, 2003.
    a. Invited Expert Panel – Speaker

19. Improvement of Dissolution Rates of Poorly Water Soluble Drugs Using A New Particle Engineering Technology – Spray Freezing into Liquid. Proceedings of the American Chemical Society, Polymeric Drug Delivery: Science and Application, New York, NY, September, 2003.
    a. Invited Speaker
    b. Session Chair – Engineered Drug Particles

20. Enabling Technologies Helping to Expand Drug Delivery in the Pharmaceutical Industry: Nanotechnology. International Conference on Drug Development, Austin, Texas, February, 2004.
    a. Invited Speaker

21. Novel Processes to Enhance Dissolution and Bioavailability of Poorly Water Soluble Drugs, Barnett International Conference on Strategies for Improving Solubility, Philadelphia, PA, June 2004.
    a. Invited Speaker

22. Recent Advances in Particle Engineering Processes – Precipitation and Freezing, Short Course, Advances in Controlled Release and Drug Delivery Technologies, The Center for Microencapsulation & Drug Delivery, College Station, TX, October 2004.
    a. Invited Speaker

23. Solid Dispersions and Nanotechnology Systems for Poorly Water Soluble Drugs, Second Annual Anthony P. Simonelli Conference in Pharmaceutical Sciences, Long Island University, New York, NY, June, 2005.
    a. Invited Speaker

24. Cryogenic Liquids, Nanoparticles and Microencapsulation, 15th International Symposium on Microencapsulation, Parma, Italy, September 2005.
    a. Invited Lecture

25. Nanoparticles for Pharmaceutical Applications, DPT Laboratories, LTD., San Antonio, TX, October 2005.
    a. Invited Lecture

26. Texas Life Sciences: More Than Just Your Medicine Cabinet, Proceedings of the Bio Texas Summit 06 Meeting, Austin, TX, February, 2006.
    a. Invited Lecture and Panelist

27. Enabling Technologies Helping to Expand Drug Delivery in the Pharmaceutical Industry: Nanotechnology, Committee of Emerging Technology and Telecommunications, City of Austin, Austin, TX, July 2006.
    a. Invited Lecture

28. Manufacturing Challenges for Production of Nanoparticles. Proceedings of the World Congress of Pharmacy and Pharmaceutical Sciences 2006, 66th International Congress of FIP, Salvatore, Brazil, August 2006.
    a. Invited Lecture

29. An Alternative Route of Delivery for Antifungal Drugs to Treat Fungal Infections – Pulmonary Drug Delivery. Asuragen Inc., Austin, TX, January 2007.
    a. Invited Lecture

30. Positioning Investors for the Nest Wave in Pain Management, Fentanyl Taifun – Inhaled Fentanyl for Breakthrough Pain, Oppenheimer Healthcare, New York City, NY, March, 2007.
    a. Invited Lecture

31. Advances in Pulmonary Drug Delivery – Inhaled Nanoparticles, Distinguished Faculty Seminar, Celebrating Research Achievements, University of Texas at Austin, College of Pharmacy, Austin, Texas, April, 2007.
    a. Invited Lecture

32. Pharmaceutical Development in a Collaborative Setting: A Successful Formula, Proceedings of the International Biotechnology Congress and Exhibition: BioMonterrey 08, Monterrey, Mexico, October 2008.
    a. Invited Lecture
33. Pulmonary Delivery of Itraconazole Nanoparticles to Treat Life Threatening Fungal Infections, School of Pharmacy, University of Kansas, Lawrence, KS, April 2009.
    a. Invited Lecture
34. Formulation and Characterization of Itraconazole Nanoparticles Made by Advanced Evaporative Precipitation Into Aqueous Solution, Proceedings of Particles 2010, Orlando, FL, May, 2010.
    a. Invited Lecture
35. Novel Plasma Deposited Stability Enhancement Coating for Amorphous Ketoprofen, Proceedings of the 240th American Chemical Society Meeting (Polymeric Materials: Science and Engineering), Boston, MA, August, 2010.
    a. Invited Lecture – Stephanie Bosselmann
36. Novel Particle Engineering Technologies for Enhancing Bioavailability, February, 2010
    a. Merck & Company, Kenilworth, NJ
    b. Hoffmann LaRoche, Nutley, NJ
    c. Columbia Laboratories, Inc., Livingston, NJ
    d. ThePharmaNetwork, West Orange, NJ
37. Steps to Getting Published in a Research Journal, Proceedings of the American Association of Pharmaceutical Scientists Meeting, San Diego, CA, November 2014.

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