

APPENDIX II

Materials Considered By Mansoor M. Amiji, Ph.D., RPH

1. U.S. Patent No. 8,679,544
2. File History of U.S. Patent No. 8,679,544
3. U.S. Patent No. 8,99,387
4. File History of U.S. Patent No. 8,99,387
5. U.S. Patent No. 9,017,721
6. File History of U.S. Patent No. 9,017,721
7. PCT Publication No. WO2008/000042, published January 3, 2008 (Meiser)
8. Novartis Package Insert for Cataflam®, Voltaren®, and Voltaren®-XR, dated May 2000
9. United States Pharmacopeia 30, Section <711> (2007)
10. United States Pharmacopeia 30, Section <1092> (2007)
11. Chuasuwan *et al.*, “Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms Diclofenac Sodium and Diclofenac Potassium,” 98(4):1206-1219 (2009)
12. PCT Publication No. WO2006/133954, published December 21, 2006 (Reiner)
13. PCT Publication No. WO2006/069419, published July 6, 2006 (Payne)
14. Moore, “Diclofenac Potassium 12.5mg Tablets for Mild to Moderate Pain and Fever: A Review of Its Pharmacology, Clinical Efficacy and Safety,” 27(3):163-195 (2007)
15. U.S. Patent No. 5,256,699 (Murphy)
16. Dokoumetzidis *et al.*, “A century of dissolution research: From Noyes and Whitney to the Biopharmaceutics Classification System,” Int’l Journal of Pharmaceutics 321:1-11 (2006)
17. Kesisoglou *et al.*, “Nanosizing – Oral Formulation Development and Biopharmaceutical Evaluation,” Advanced Drug Delivery Reviews, 59:631-644 (2007)
18. U.S. Patent No. 5,202,129 (Samejima)

19. U.S. Patent Publication 2006/0159628 (Liversidge)
20. Vogt et al., "Dissolution enhancement of Fenofibrate by Micronization, Cogrounding and Spray-drying: Comparison with Commercial Preparations," *European Journal of Pharmaceutics and Biopharmaceutics* 68:283-288 (2008)
21. U.S. Patent Publication 2006/0204588 (Liversidge)
22. U.S. Patent No. 8,808,751 (Cammarano)
23. Iroko F-1 Prospectus filed with the Securities and Exchange Commission on June 18, 2013
24. Khazaeinia *et al.*, "A Comparison of Gastrointestinal Permeability Induced by Diclofenac-phospholipid complex with Diclofenac Acid and its Sodium Salt," *Journal of Pharmaceutical Sciences* 6(3):352-359 (2003)
25. iCeutica Press Release, "iCeutica Receives Key Patent for SoluMatrix Fine Particle Technology Platform" (Sept. 24, 2014)
26. Memorandum dated April 6, 2005, from John Jenkins, M.D., at FDA re: "Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk"
27. U.S. Dep't of Health & Human Servs., Food and Drug Admin., CDER, Guidance for Indus., Dissolution Testing of Immediate Release Solid Oral Dosage Forms (1997)
28. Royal Hanson *et al.*, Handbook of Dissolution Testing 1-53 (3rd ed. 2004)
29. iCeutica Press Release dated April 28, 2011: iCeutica Announces Sale to Partner Iroko; 10X uplift on original value
30. FDA Orangebook listing for Zorvolex; available at: http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=204592&TABLE1=OB_Rx; and http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=204592&Product_No=001&table1=OB_Rx (accessed November 2, 2015)
31. Loewenstein and Roberts, "The Ionization of Citric Acid Studied by the Nuclear Magnetic Resonance Technique" *J. of Am. Chem. Soc.* 82(11) 2705-2710 (1960)
32. Rune and Viskum, "Duodenal pH values in normal controls and in patients with duodenal ulcer," *Gut* 10:569-571 (1969)

33. Countdown to the 10th Anniversary Scrip Awards, available at: https://ibiawards.com/scrip-awards/wp-content/uploads/sites/41/2014/11/script_shottlist_ad6_141125_16.pdf (accessed November 2, 2015)
34. U.S. Patent No. 3,558,690
35. United States Pharmacopeia 30, Official Monographs for Diclofenac Potassium and Diclofenac sodium, ¶ 1921 (2007)
36. Remington's Pharmaceutical Handbook Excerpt, 18th ed., pp. 715-716 (1990)
37. HPPS Operators Guide, Malvern Instruments, 2.0 (2003)
38. U.S. Provisional Application No. 61/172,291
39. Australian Provisional Application No. 2009901748
40. U.S. Patent No. 5,145,684 (Liversidge)
41. Rohrs, Brian, "Dissolution Method Development for Poorly Soluble Compounds," Dissolution Technologies (Aug. 2001)
42. January 10, 2008 email string from Adrian Russell to Felix Meiser and Aaron Dodd Re: Lab mill for API and excipient (ICT0085082-085)
43. November 3, 2014 email from Bill Bosch to Seamus Mulligan Re: Introduction to iCeutica (ICT0006103-104)
44. iCeutica Pty Ltd and Iroko Pharmaceuticals, LLC's Opening Claim Construction Brief (D.I. 67)
45. Declaration of Elizabeth M. Flanagan in Support of iCeutica Pty Ltd and Iroko Pharmaceuticals, LLC's Opening Claim Construction Brief, and all exhibits attached thereto (D.I. 68)
46. Opadry[®] Enteric Application Data, "Development of Diclofenac Sodium Delayed Release Tablets USP Opadry[®] Enteric (94 Series)," Colorcon Technical Literature (2010)
47. Semalty, *et al.*, Development and physicochemical evaluation of pharmacosomes of diclofenac," *Acta Pharm.* 59:335-344 (2009)
48. Cristofolletti, *et al.*, "Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms: Efavirenz," *J. of Pharm. Scis.*, Vol. 102, No. 2 (February 2013)
49. Gowthamarajan, *et al.*, "Dissolution Testing for Poorly Soluble Drugs: A Continuing Perspective," *Dissolution Technologies* (Aug. 2010)

50. List of Drugs in the FDA Dissolution Methods database, available at: <http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm> (accessed Sept, 18, 2015)
51. Malvern Instruments Ltd. Product Brochure Re: Mastersizer 3000, Smarter Particle Sizing
52. Hackley and Clogston, NIST - NCL Joint Assay Protocol, PCC-1 (Version 1.1), "Measuring the Size of Nanoparticles in Aqueous Media Using Batch-Mode Dynamic Light Scattering," Nat'l Institute of Standards and Technology (Nov. 2007, rev. Feb. 2010)
53. Horiba Scientific, "A Guidebook to Particle Size Analysis," (2002)
54. Pobudkowska, et al., "Study of pH-Dependent Drugs Solubility in Water," Chem. Ind. Chem. Eng. Q. 20 (1) 115-126 (2014)
55. Martin, *et al.*, "Selection of Dissolution Medium for QC Testing of Drug Products," J. of Validation Technology (Summer 2011)
56. Singla, *et al.*, "A Discriminatory and Biorelevant Dissolution Test Method for Simvastatin Drug Products," Dissolution Technologies (Nov. 2009)
57. Noory, *et al.*, "Steps for Development of a Dissolution Test for Sparingly Water-Soluble Drug Products," Dissolution Technologies, Article 3 (Feb. 2000)
58. Zhao, *et al.*, "Effect of Sodium Lauryl Sulfate in Dissolution Media on Dissolution of Hard Gelatin Capsule Shells," Pharm. Research, Vol. 21, No. 1 (Jan. 2004)
59. Jamzad, *et al.*, "Role of Surfactant and pH on Dissolution Properties of Fenofibrate and Glipizide—A Technical Note," AAPS PharmSciTech 2006; 7 (2) Article 33