

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

RECEIVED

AUG 02 2012

S.C. Supreme Court

State of South Carolina ex rel. Alan Wilson in his capacity
as Attorney General of the State of South Carolina,.....

Respondent,

v.

Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a
Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and
Johnson & Johnson, Inc.,

Defendants,

Of whom Ortho-McNeil-Janssen Pharmaceuticals, Inc. is....

Appellant.

APPELLANT'S DESIGNATION OF MATTER
FOR THE RECORD ON APPEAL

Pursuant to Rule 209, SCACR, Appellant Ortho-Mc-Neil-Janssen
Pharmaceuticals, Inc. designates the following material for inclusion in the record on
appeal. Undersigned counsel certifies, pursuant to Rule 209(c), SCACR, that the
designation contains no matter which is irrelevant to the appeal:

ORDERS

1. Order regarding Defendant's Motions for Summary Judgment and Parties' Motions *in Limine*, February 25, 2011
2. Penalty Order, June 3, 2011

3. Order Denying Defendant's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, December 20, 2011
4. Order Denying Defendant's Motion to Alter or Amend the Judgment and/or for a New Trial, December 20, 2011

JURY INSTRUCTIONS, VERDICT FORM, and VERDICT

5. Defendants' Requested Preliminary Jury Instructions and Memorandum of Law in Support Thereof, March 7, 2011
6. Defendants' Requested Jury Instructions, March 17, 2011
7. Plaintiff The State of South Carolina's Proposed Requests for Charge and Proposed Form of Verdict, March 17, 2011
8. Plaintiff The State of South Carolina's Request for Charge No. 1 on Elements of SCUTPA Claim; Plaintiff's Amended Request for Charge No. 6 on Statute of Limitations; Plaintiff's Request for Charge No. 7 Regarding Striking/Rejecting Certain Testimony; Plaintiff's Request for Charge No. 8 Regarding Drug Company Labeling; and Plaintiff's Amended Proposed Form of Verdict, March 18, 2011
9. Defendants' Requested Verdict Sheet, March 18, 2011
10. Defendants' Objections to Plaintiff's Proposed Requests for Charge and Proposed Verdict Sheet and Defendants' Request for Corrective Instruction, March 20, 2011
11. Verdicts as to Johnson & Johnson, Inc. and Ortho-McNeil-Janssen Pharmaceutica, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen L.P., March 22, 2011

PLEADINGS

12. Complaint, April 23, 2007
13. Amended Complaint, December 30, 2009
14. Second Amended Complaint, March 19, 2010
15. Defendants' Answer to Plaintiff's Second Amended Civil Action Complaint, April 12, 2010

TRANSCRIPTS

16. Trial Transcript, March 7, 2011 through March 22, 2011 excerpts: 1-8, 97-184, 186-191, 220-263, 356-362, 382-387, 394-650, 665-931, 935-1057, 1099-1100, 1129, 1140-1144, 1166-1169, 1172-1173, 1177, 1192, 1232-1236, 1272-1276,

1322-1323, 1367-1368, 1380-1420, 1422, 1430-1655, 1659-1783, 1803-1804, 1823-1865, 1870-1878, 1897-1907, 1969-1976, 1986-2047, 2049-2126, 2165-2177, 2184, 2191-2212, 2217-2231, 2241-2250, 2279-2290, 2296-2308, 2321-2415, 2421-2427, 2436-2437, 2442-2446, 2450-2556, 2596-2607, 2610-2679

17. Penalty Hearing Transcript, April 18, 2011 through April 19, 2011: 1-364

EXHIBITS

Plaintiff's Trial Exhibits

18. P0200 – Letter from L. Stockbridge to T. McIntyre, dated January 5, 1999
19. P0232 – Letter from T. Abrams to A. Shetty, dated April 19, 2004
20. P0280 – August 2008 Risperdal Package Insert
21. P0571 – Letter from R. Temple to R. Wasserman, dated December 29, 1993
22. P0631 – 1997 Risperdal Package Insert (published in 1997 Physicians' Desk Reference)
23. P0640 – 2006 Risperdal Package Insert
24. P0641 – March 2006 Risperdal Package Insert (published in 2007 Physicians' Desk Reference)
25. P0643 – 1994 Risperdal Package Insert
26. P0648 – July 1998 Risperdal Package Insert
27. P0649 – May 1999 Risperdal Package Insert
28. P0653 – December 2000 Risperdal Package Insert
29. P0656 – Revised July 2002 Risperdal Package Insert
30. P0657 – March 2003 Risperdal Package Insert
31. P0661 – December 2003 Risperdal Package Insert
32. P0662 – February 2005 Risperdal Package Insert
33. P0665 – October 2006 Risperdal Package Insert
34. P1027 – Letter from S. Danese to R. Wasserman, dated February 9, 1994
35. P1224 – October 2001 Risperdal Package Insert

36. P1731 – Letter from D. Ohye to T. Abrams, dated April 28, 2004
37. P1736 – Letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated November 10, 2003
38. P2049 – September 1996 Risperdal Package Insert
39. P2061 – April 1995 Risperdal Package Insert

Plaintiff's Penalty Hearing Exhibits

40. P1 – Letter from S. Pugh to D. Coggins, dated April 13, 2011
41. P5 – Hard Drive containing sales call data produced by Defendants
42. P16 – South Carolina Department of Labor, Licensing and Regulation 2003-2004 Annual Report
43. P21 – Plaintiff's Calculations for Potential Violation Numbers
44. P2720 – Sample Quantity Data Summary
45. P2722 – Number of Sales Calls when Samples Left

Defendants' Trial Exhibits

46. D0351 – Letter from Janssen Pharmaceutica Inc. to Healthcare Providers with Risperdal Package Insert, dated November 10, 2003
47. D0352 – Wirshing, et al., J. Clin. Psychiatry 2002; 63:856-865, "The Effects of Novel Antipsychotics on Glucose and Lipid Levels"
48. D0442 – Letter from Janssen Pharmaceutica Inc. to Health Care Providers, dated July 21, 2004
49. D0498 – August 2007 Risperdal Package Insert
50. D0807 – Volume 1 of the 2000 Submission to FDA
51. D0821 – Volume 15 of the 2000 Submission to FDA
52. D0841 – Letter from R. Katz to E. Brann, dated March 3, 2002
53. D0843 – Letter from R. Katz to M. Zoschg, dated December 4, 2003
54. D0919 – Letter from S. Merchant to R. Katz, dated March 29, 2004
55. D3097 – Letter from R. Katz to V. Wagner-Weber, dated May 1, 2000

56. D3131 – Letter from R. Katz to V. Wagner-Weber, dated July 2, 1999
57. D3140 – Letter from E. Brann to R. Katz, dated September 24, 2003
58. D3175 – Letter from R. Katz to C. McGowan, dated September 11, 2003
59. D3179 – Letter from S. Merchant to R. Katz, dated November 26, 2003
60. D3180 – Letter from R. Katz to S. Merchant, dated November 21, 2003
61. D4188 – Yood, M.U., et al. The Incidence of Diabetes in Atypical Antipsychotic Users Differs According to Agent – Results from a Multisite Epidemiologic Study
62. D4337 – Chapter 4 of the 2004 Version of the FDA’s Regulatory Procedures Manual
63. D5274 – Form FDA 2253, submitted July 30, 1998 with submitted materials
64. D5350 – Form FDA 2253, submitted March 24, 2000 with submitted materials
65. D5360 – Form FDA 2253, submitted May 19, 2000 with submitted materials
66. D5380 – Form FDA 2253, submitted January 19, 2001 with submitted materials
67. D6086 – April 5, 2003 Diabetes Expert Panel Executive Summary: Antipsychotics and Diabetes/Glucose Metabolism
68. D6211 – Letter from S. Merchant to R. Katz, dated April 18, 2002
69. D6253 – Letter from M. Brony to D. Ohye, dated October 14, 2004
70. D6284 – Draft of November 10, 2003 letter from Janssen Pharmaceutica Inc. to Healthcare Providers
71. D6294 – Letter from Eli Lilly and Company to Doctors, dated October 6, 2003
72. D6305 – E-mail from I. Caers to G. Neil and others, dated September 16, 2003
73. D6366 – Promotional Review Committee Copy Approval For November 10, 2003 Mailing
74. D7008 – Expert Report of William E. Wecker, Ph.D., dated December 3, 2010 (referred to in trial transcript as “Def. Exh. A”)
75. D7174 – Chart of South Carolina Department of Health and Human Services Drug Utilization Review Program – Patient Drug History Profile

76. D7185 – “Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes,” *The Journal of Clinical and Applied Research and Education Diabetes Care*, 27:2 (2004); 596-601
77. D7186 – SC-DMH Laboratory Monitoring Guidelines for Antipsychotic Medications
78. D7252 – Undated, draft letter from W. Murray Yarbrough
79. D7262 – Wirshing, et al., “Risperidone-Associated New-Onset Diabetes” *Biol Psychiatry* 2001; 50:148-149
80. D7276 – List of South Carolina recipients of November 2003 Mailing
81. D7281 – Advertisement -01-RS-782R
82. D7294 – IND 31,931 Risperidone Tablets Annual Report July 1, 1998 – June 30, 1999
83. D7336 – W. Murray Yarbrough letter to T. Engles, dated September 19, 2002
84. D7337 – South Carolina Medicaid & SHP Claims Data, June 2003 – October 2004 (referred to in trial transcript as “Def. Exh. B”)
85. D7338 – South Carolina Medicaid & SHP Claims Data, November 2004 – December 2005 (referred to in trial transcript as “Def. Exh. C”)

Defendant’s Penalty Hearing Exhibits

86. D1 – “Second-Generation (Atypical) Antipsychotics and Metabolic Effects: A Comprehensive Literature Review,” John W. Newcomer
87. D2 – 2007 Zyprexa Package Insert (Offer of proof; not admitted into evidence)
88. D3 – 2009 Zyprexa Package Insert (Offer of proof; not admitted into evidence)
89. D4 – 2010 Latuda Package Insert (Offer of proof; not admitted into evidence)
90. D5 – South Carolina Fee for Service, State Health Plan, and HMO Claims Data – Antipsychotic Prescriptions by Month
91. D6 – Calculation of Net Cost of Risperdal to the State (Columns 1-7 admitted)
92. D7 – Janssen Compilation of Rebates to South Carolina

Court’s Exhibits

93. C-1 – Note from Juror

94. C-2 – Federal Regulations
95. C-3 – Objections to Openings
96. C-4 – Offer of Proof
97. C-5 – Charge by the Court
98. C-6 – Question from the Jury
99. C-7 – Question from the Jury

MISCELLANEOUS AND OTHER MOTIONS

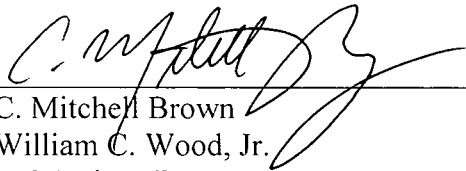
100. Plaintiff The State of South Carolina's Motion to Exclude the Testimony of Certain Risperdal Prescribers at Trial, July 2, 2010
101. Defendants' Motion *in Limine* and Memorandum of Law in Support Thereof to Preclude the Introduction into Evidence of the April 19, 2004 DDMAC Letter and Any Evidence of or Reference to the Letter at Trial, January 7, 2011
102. Plaintiff The State of South Carolina's Motion to Exclude the Expert Testimony of Dr. William E. Wecker, January 13, 2011
103. Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Testimony of Certain Risperdal Prescribers at Trial, January 20, 2011
104. Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Expert Testimony of Sheldon Bradshaw, January 20, 2011
105. Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Expert Testimony of Dr. William E. Wecker, January 21, 2011
106. Defendants' Objections to Plaintiff's Opening Statement, March 8, 2011
107. Defendants' Motion for a Directed Verdict and Memorandum of Law in Support Thereof, March 14, 2011
108. Defendants' Reply in Support of Motion for a Directed Verdict, March 15, 2011
109. Defendants' Memorandum in Opposition to Plaintiff's Motion to Exclude the Testimony of Dr. Robert Bank and Dr. Brenda Ratliff, March 16, 2011
110. Defendants' Offer of Proof for the Expert Testimony of Dr. William E. Wecker, March 21, 2011
111. Defendants' Offer of Proof for the Post-2007 FDA-Approved Package Insert for Zyprexa and the 2010 FDA-Approved Package Insert for Latuda, March 21, 2011

112. Defendants' Renewed Motion for a Direct Verdict and Memorandum of Law in Support Thereof, March 21, 2011
113. Plaintiff The State of South Carolina's Motion for a Directed Verdict as to Defendants' Eighth Affirmative Defense on Statute of Limitations, March 21, 2011
114. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion and Memorandum in Support Thereof for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, April 1, 2011
115. Defendants' Response in Opposition to Plaintiff's Motion to Enforce This Court's February 11, 2011 Order and For Sanctions, April 4, 2011
116. Janssen's Penalty Hearing Brief, April 15, 2011
117. Defendants' Offer of Proof for the Testimony of Prescriber Physicians; and Robert L. Bank, M.D., and Brenda Ratliff, M.D., April 18, 2011
118. Defendant Ortho-McNeil Janssen Pharmaceuticals, Inc.'s Post-Penalty Hearing Brief, May 3, 2011
119. Reply Memorandum of Law in Support of Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, May 3, 2011
120. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion and Memorandum of Law in Support Thereof to Alter or Amend the Judgment and/or for a New Trial, June 13, 2011

121. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Reply in Support of its Motion to Alter or Amend the Judgment and/or for a New Trial, July 15, 2011
122. Appellant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Notice of Appeal, January 18, 2012

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Columbia, South Carolina
August 2, 2012

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Roger L. Couch, Circuit Court Judge

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Ortho-McNeill-Janssen Pharmaceuticals, Inc., f/k/a
Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and
Johnson & Johnson, Inc., Defendants.

Of whom Ortho-McNeill-Janssen Pharmaceuticals, Inc.
is Appellant.

PROOF OF SERVICE

I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for Appellant, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States Mail, postage prepaid, to the following address(es):

Pleadings: **Appellant's Designation of Matter for the Record
on Appeal**

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