

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

MDL No. 2740

THIS DOCUMENT RELATES TO ALL
CASES

SECTION "N" (5)

HON. KURT D. ENGELHARDT

ACTAVIS PHARMA, INC.'S ANSWER AND ADDITIONAL DEFENSES
TO PLAINTIFFS' FIRST AMENDED MASTER LONG FORM COMPLAINT
JURY TRIAL DEMANDED

Defendant Actavis Pharma, Inc., ("Actavis Pharma") for its Answer to plaintiffs' First Amended Master Long Form Complaint ("Amended Complaint"), states as follows:

JURISDICTION

1. Actavis Pharma admits only that plaintiffs purport to bring a lawsuit seeking "damages and such other relief deemed just and proper," but denies that plaintiffs are entitled to any relief whatsoever. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 1 of the Amended Complaint.

2. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 2 of the Amended Complaint.

3. The allegations contained in paragraph 3 of the Amended Complaint include legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in

paragraph 3 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 3 of the Amended Complaint.

INTRODUCTION

4. Actavis Pharma admits that Taxotere is a chemotherapy drug indicated for the treatment of certain kinds of cancer. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 4 of the Amended Complaint.

5. To the extent that the allegations contained in paragraph 5 of the Amended Complaint are directed to Actavis Pharma or are deemed in any way to imply causation of damages, they are denied. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 5 of the Amended Complaint.

6. To the extent that the allegations contained in paragraph 6 of the Amended Complaint are directed to Actavis Pharma or are deemed in any way to imply causation of damages, they are denied. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 6 of the Amended Complaint.

7. Actavis Pharma denies the allegations contained in paragraph 7 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7 of the Amended Complaint.

THE PARTIES

A. Plaintiffs

8. To the extent that the allegations contained in paragraph 8 of the Amended Complaint are directed to Actavis Pharma or are deemed in any way to imply causation of damages,

they are denied. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 8 of the Amended Complaint.

9. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 9 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 9 of the Amended Complaint.

10. The allegations in Paragraph 10 of the Amended Complaint are a legal conclusion, to which no response is required. To the extent a response is required, Actavis Pharma denies it has breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 10 of the Amended Complaint that are directed at Actavis Pharma. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 of the Amended Complaint.

11. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 11 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 11 of the Amended Complaint.

B. Sanofi-Related Entities

12. The allegations contained in paragraph 12 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Amended Complaint.

13. The allegations contained in paragraph 13 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of the Amended Complaint.

14. The allegations contained in paragraph 14 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Amended Complaint.

15. The allegations contained in paragraph 15 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the Amended Complaint.

16. The allegations contained in paragraph 16 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of the Amended Complaint.

17. The allegations contained in paragraph 17 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of the Amended Complaint.

18. The allegations contained in paragraph 18 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the Amended Complaint.

19. The allegations contained in paragraph 19 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of the Amended Complaint.

20. The allegations contained in paragraph 20 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of the Amended Complaint.

21. The allegations contained in paragraph 21 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of the Amended Complaint.

22. The allegations contained in paragraph 22 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Amended Complaint.

23. The allegations contained in paragraph 23 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Amended Complaint.

24. The allegations contained in paragraph 24 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of the Amended Complaint.

25. The allegations contained in paragraph 25 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 25 of the Amended Complaint.

26. The allegations contained in paragraph 26 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the Amended Complaint.

27. The allegations contained in paragraph 27 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 27 of the Amended Complaint.

28. The allegations contained in paragraph 28 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 28 of the Amended Complaint.

29. The allegations contained in paragraph 29 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 29 of the Amended Complaint.

30. The allegations contained in paragraph 30 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 30 of the Amended Complaint.

31. The allegations contained in paragraph 31 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31 of the Amended Complaint.

C. Other Brand Name Drug Sponsors, Manufacturers, Labelers, and Distributors

32. Actavis Pharma admits that Actavis Inc. n/k/a Actavis LLC obtained approval to market Docetaxel Injection Concentrate pursuant to Section 505(b)(2) of the Food, Drug, and Cosmetic Act. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 32 of the Amended Complaint.

33. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 33 of the Amended Complaint to the extent the allegations relate to other defendants. To the extent the allegations contained in paragraph 33 are directed to Actavis Pharma, the allegations are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies the allegations contained in paragraph 33 of the Amended Complaint.

34. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 34 of the Amended Complaint to the extent the allegations relate to other defendants. To the extent the allegations contained in paragraph 34 are directed to Actavis Pharma, the allegations are legal conclusions to which no response is required.

To the extent a response is required, Actavis Pharma denies the allegations contained in paragraph 34 of the Amended Complaint.

35. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 35 of the Amended Complaint to the extent the allegations relate to other defendants. To the extent the allegations contained in paragraph 35 are directed to Actavis Pharma, the allegations are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies the allegations contained in paragraph 35 of the Amended Complaint.

36. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 36 of the Amended Complaint to the extent the allegations relate to other defendants. To the extent the allegations contained in paragraph 36 are directed to Actavis Pharma, the allegations are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies the allegations contained in paragraph 36 of the Amended Complaint.

1. Sandoz

37. The allegations contained in paragraph 37 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 37 of the Amended Complaint.

38. The allegations contained in paragraph 38 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 38 of the Amended Complaint.

39. The allegations contained in paragraph 39 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 39 of the Amended Complaint.

40. The allegations contained in paragraph 40 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 40 of the Amended Complaint.

41. The allegations contained in paragraph 41 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 41 of the Amended Complaint.

42. The allegations contained in paragraph 42 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 42 of the Amended Complaint.

43. The allegations contained in paragraph 43 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 43 of the Amended Complaint.

44. The allegations contained in paragraph 44 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 44 of the Amended Complaint.

45. The allegations contained in paragraph 45 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 45 of the Amended Complaint.

46. The allegations contained in paragraph 46 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 46 of the Amended Complaint.

47. The allegations contained in paragraph 47 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 47 of the Amended Complaint.

48. The allegations contained in paragraph 48 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 48 of the Amended Complaint.

49. The allegations contained in paragraph 49 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 49 of the Amended Complaint.

50. The allegations contained in paragraph 50 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 50 of the Amended Complaint.

2. Accord Healthcare & McKesson

51. The allegations contained in paragraph 51 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 51 of the Amended Complaint.

52. The allegations contained in paragraph 52 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 52 of the Amended Complaint.

53. The allegations contained in paragraph 53 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 53 of the Amended Complaint.

54. The allegations contained in paragraph 54 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 54 of the Amended Complaint.

55. The allegations contained in paragraph 55 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 55 of the Amended Complaint.

56. The allegations contained in paragraph 56 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 56 of the Amended Complaint.

57. The allegations contained in paragraph 57 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 57 of the Amended Complaint.

58. The allegations contained in paragraph 58 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 58 of the Amended Complaint.

59. The allegations contained in paragraph 59 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 59 of the Amended Complaint.

60. The allegations contained in paragraph 60 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 60 of the Amended Complaint.

61. The allegations contained in paragraph 61 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 61 of the Amended Complaint.

62. The allegations contained in paragraph 62 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 62 of the Amended Complaint.

63. The allegations contained in paragraph 63 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 63 of the Amended Complaint.

3. (The Amended Complaint omits number 3)

4. Hospira Entities

64. The allegations contained in paragraph 64 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 64 of the Amended Complaint.

65. The allegations contained in paragraph 65 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 65 of the Amended Complaint.

66. The allegations contained in paragraph 66 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 66 of the Amended Complaint.

67. The allegations contained in paragraph 67 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 67 of the Amended Complaint.

68. The allegations contained in paragraph 68 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 68 of the Amended Complaint.

69. The allegations contained in paragraph 69 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 69 of the Amended Complaint.

70. The allegations contained in paragraph 70 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 70 of the Amended Complaint.

71. The allegations contained in paragraph 71 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 71 of the Amended Complaint.

72. The allegations contained in paragraph 72 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 72 of the Amended Complaint.

73. The allegations contained in paragraph 73 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 73 of the Amended Complaint.

74. The allegations contained in paragraph 74 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 74 of the Amended Complaint.

5. *Sun Pharma Entities*

75. The allegations contained in paragraph 75 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 75 of the Amended Complaint.

76. The allegations contained in paragraph 76 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 76 of the Amended Complaint.

77. The allegations contained in paragraph 77 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 77 of the Amended Complaint.

78. The allegations contained in paragraph 78 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 78 of the Amended Complaint.

79. The allegations contained in paragraph 79 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 79 of the Amended Complaint.

80. The allegations contained in paragraph 80 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 80 of the Amended Complaint.

81. The allegations contained in paragraph 81 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 81 of the Amended Complaint.

82. The allegations contained in paragraph 82 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 82 of the Amended Complaint.

83. The allegations contained in paragraph 83 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 83 of the Amended Complaint.

84. The allegations contained in paragraph 84 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 84 of the Amended Complaint.

85. The allegations contained in paragraph 85 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 85 of the Amended Complaint.

6. *Pfizer*

86. The allegations contained in paragraph 86 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 86 of the Amended Complaint.

87. The allegations contained in paragraph 87 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 87 of the Amended Complaint.

88. The allegations contained in paragraph 88 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 88 of the Amended Complaint.

89. The allegations contained in paragraph 89 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 89 of the Amended Complaint.

90. The allegations contained in paragraph 90 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 90 of the Amended Complaint.

91. The allegations contained in paragraph 91 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 91 of the Amended Complaint.

92. The allegations contained in paragraph 92 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 92 of the Amended Complaint.

93. The allegations contained in paragraph 93 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 93 of the Amended Complaint.

94. The allegations contained in paragraph 94 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 94 of the Amended Complaint.

95. The allegations contained in paragraph 95 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 95 of the Amended Complaint.

96. The allegations contained in paragraph 96 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 96 of the Amended Complaint.

7. Actavis Entities

97. Actavis Pharma admits the allegations in paragraph 97 of the Amended Complaint.

98. Actavis Pharma admits only it is a pharmaceutical company incorporated in the State of Delaware with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey. Actavis Pharma denies the characterization that it was “acquired” by Teva Pharmaceutical Industries Ltd., but admits it became an indirect subsidiary of Teva Pharmaceutical Industries Ltd. in 2016. Actavis Pharma denies any remaining allegations in paragraph 98 of the Amended Complaint.

99. Actavis Pharma denies that it is accurate or appropriate to refer collectively to Actavis Pharma and Actavis LLC f/k/a Actavis Inc. collectively as “Actavis.” Actavis Pharma admits only that both it and Actavis LLC have conducted business, as Actavis Pharma understands that phrase, in the United States. Actavis Pharma denies the remaining allegations in paragraph 99 of the Amended Complaint.

100. Actavis Pharma admits only that it has marketed and promoted, as Actavis Pharma uses those terms, and sold docetaxel-containing products in the United States. Actavis Pharma denies the remaining allegations in paragraph 100 of the Amended Complaint.

101. Actavis Pharma admits only that FDA approved NDA 203551 for Docetaxel Injection Concentrate, effective April 12, 2013, that Actavis LLC f/k/a Actavis Inc. held the NDA at the time of approval, and that Actavis Pharma has marketed and promoted, as Actavis Pharma uses those terms, and sold Docetaxel Injection Concentrate in the United States pursuant to NDA 203551. Actavis Pharma denies the remaining allegations in paragraph 101 of the Amended Complaint.

102. Actavis Pharma admits only that Actavis LLC f/k/a Actavis Inc. filed NDA 203551 on March 14, 2012, pursuant to Section 505(b)(2) of the Food, Drug and Cosmetic Act and that Taxotere is the reference listed drug for NDA 203551. Actavis Pharma denies the remaining allegations in paragraph 102 of the Amended Complaint.

103. Actavis Pharma admits only that the Docetaxel Injection Concentrate approved pursuant to NDA 203551 is different from Taxotere, that the Docetaxel Injection Concentrate products produced pursuant to NDA 203551 contain citric acid anhydrous, Providone (kollidon 12 PF), polysorbate 80 and otherwise conform to the applicable specifications in NDA 203551, that FDA’s April 12, 2013 approval of NDA 203551 included a 140 mg/7 mL package strength, and

that a 160 mg/8 mL package strength under NDA 203551 subsequently was approved by FDA. Actavis Pharma denies the remaining allegations in paragraph 103 of the Amended Complaint.

104. Actavis Pharma admits only that April 12, 2013, is the effective date of approval of NDA 203551 and that Docetaxel Injection Concentrate 20 mg/mL, 80 mg/4 mL and 140 mg/7 ml were first marketed pursuant to that approval on or about July 1, 2013. Actavis Pharma denies the remaining allegations in paragraph 104 of the Amended Complaint.

105. Actavis Pharma admits only that the Patient Counseling Information section of the Full Prescribing Information approved by FDA on April 12, 2013, included the language in quotation marks contained in the first sentence of paragraph 105 of the Amended Complaint, and that the Patient Information approved by FDA on April 12, 2013 included the words in quotation marks contained in the second sentence of paragraph 105 of the Amended Complaint. Actavis Pharma denies the remaining allegations in paragraph 105 of the Amended Complaint.

106. Actavis Pharma admits only that a Supplemental New Drug Application for NDA 203551 was filed on March 21, 2014, which was approved on September 17, 2014, and that a Supplemental New Drug Application for NDA 203551 was filed on May 14, 2013, which was approved effective on November 4, 2013. Actavis Pharma denies the remaining allegations in paragraph 106 of the Amended Complaint.

107. Actavis Pharma denies the allegations in paragraph 107 of the Amended Complaint.

JURISDICTION AND VENUE

108. The allegations contained in paragraph 108 of the Amended Complaint state legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma

is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 108 of the Amended Complaint.

109. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 109 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 109 of the Amended Complaint.

110. Actavis Pharma admits only that the Judicial Panel on Multidistrict Litigation selected the Eastern District of Louisiana as the venue for MDL 2740. Actavis Pharma denies any remaining allegations in paragraph 110 of the Amended Complaint.

111. Actavis Pharma is without knowledge of information sufficient to form a belief as to the truth of the allegations in paragraph 111 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 111 of the Amended Complaint.

FACTUAL ALLEGATIONS

I. Development, Approval, and Labeling Changes for Taxotere, Docetaxel Injection, Docetaxel Injection Concentrate, and Docefrez

112. Actavis Pharma admits that Taxotere is indicated for the treatment of certain kinds of cancer. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 112 of the Amended Complaint.

113. Actavis Pharma admits that Taxotere is a chemotherapy drug indicated for the treatment of certain kinds of cancer. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 113 of the Amended Complaint.

114. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 114 of the Amended Complaint.

115. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 115 of the Amended Complaint.

116. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 116 of the Amended Complaint.

117. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 117 of the Amended Complaint.

118. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 118 of the Amended Complaint.

119. Actavis Pharma states that instructions for the use and administration of Taxotere, Docetaxel, and Docetaxel Injection Concentrate are discussed in the medical literature and in the labeling. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 119 of the Amended Complaint.

120. The allegations contained in paragraph 120 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 120 of the Amended Complaint.

121. The allegations contained in paragraph 121 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 121 of the Amended Complaint.

122. The allegations contained in paragraph 122 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 122 of the Amended Complaint.

123. The allegations contained in paragraph 123 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 123 of the Amended Complaint.

124. The allegations contained in paragraph 124 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 124 of the Amended Complaint.

125. The allegations contained in paragraph 125 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 125 of the Amended Complaint.

126. The allegations contained in paragraph 126 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 126 of the Amended Complaint.

127. The allegations contained in paragraph 127 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 127 of the Amended Complaint.

128. The allegations contained in paragraph 128 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 128 of the Amended Complaint.

129. The allegations contained in paragraph 129 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 129 of the Amended Complaint.

130. The allegations contained in paragraph 130 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 130 of the Amended Complaint.

131. The allegations contained in paragraph 131 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 131 of the Amended Complaint.

132. The allegations contained in paragraph 132 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 132 of the Amended Complaint.

133. The allegations contained in paragraph 133 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 133 of the Amended Complaint.

134. The allegations contained in paragraph 134 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 134 of the Amended Complaint.

135. The allegations contained in paragraph 135 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 135 of the Amended Complaint.

136. The allegations contained in paragraph 136 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 136 of the Amended Complaint.

137. Actavis Pharma admits only the allegations that: (i) on December 11, 2015, FDA approved sNDA 75 to NDA 020449; (ii) the Patient Counseling Information section of the Full Prescribing Information approved by FDA on December 11, 2015, for NDA 020449 included the language in quotation marks contained in the second sentence of paragraph 137 of the Amended Complaint; (iii) the Patient Information approved by FDA on December 11, 2015, for NDA 020449 included the words in quotation marks contained in the third sentence of paragraph 137 of the Amended Complaint; and (iv) the labeling approved by FDA for NDA 02049 on December 11,

2015, contained the then latest and current operative warning regarding permanent or irreversible alopecia in the Taxotere label. Actavis Pharma denies the remaining allegations in paragraph 137 of the Amended Complaint.

II. Defendants' Duties Under the FDCA and State Law

138. The allegations contained in paragraph 138 of the Amended Complaint state legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it has breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 138 directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 138 of the Amended Complaint.

139. The allegations contained in paragraph 139 of the Amended Complaint state legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it has breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 139 directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 139 of the Amended Complaint.

140. The allegations contained in paragraph 140 of the Amended Complaint state legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it has breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 140 directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 140 of the Amended Complaint.

141. The allegations contained in paragraph 141 of the Amended Complaint state legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it has breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 141 directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 141 of the Amended Complaint.

142. Actavis Pharma denies the characterizations of federal regulation contained in paragraph 142 of the Amended Complaint. To the extent a response is required, Actavis Pharma states that it complied at all times with all applicable laws and regulatory obligations with respect to docetaxel. Actavis Pharma denies any remaining allegations in paragraph 142 of the Amended Complaint.

143. Actavis Pharma denies the characterizations of federal regulation contained in paragraph 143 of the Amended Complaint. To the extent a response is required, Actavis Pharma states that it complied at all times with all applicable laws and regulatory obligations with respect to docetaxel. Actavis Pharma denies any remaining allegations in paragraph 143 of the Amended Complaint.

144. Actavis Pharma denies the characterizations of federal regulation contained in paragraph 144 of the Amended Complaint. To the extent a response is required, Actavis Pharma states that it complied at all times with all applicable laws and regulatory obligations with respect to docetaxel. Actavis Pharma denies any remaining allegations in paragraph 144 of the Amended Complaint.

145. Actavis Pharma denies the characterizations of federal regulation contained in paragraph 145 of the Amended Complaint. To the extent a response is required, Actavis Pharma

states that it complied at all times with all applicable laws and regulatory obligations with respect to docetaxel. Actavis Pharma denies any remaining allegations in paragraph 145 of the Amended Complaint.

146. Actavis Pharma denies the characterizations of federal regulation contained in paragraph 146 of the Amended Complaint. To the extent a response is required, Actavis Pharma states that it complied at all times with all applicable laws and regulatory obligations with respect to docetaxel. Actavis Pharma denies any remaining allegations in paragraph 146 of the Amended Complaint.

147. The allegations contained in paragraph 147 of the Amended Complaint are not directed toward Actavis Pharma, and therefore no response is required. To the extent a response is required, Actavis Pharma denies the allegations contained in paragraph 147 of the Amended Complaint.

III. Defendants Knew that Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate May Cause Permanent Alopecia

148. The allegations contained in paragraph 148 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 148 of the Amended Complaint.

149. To the extent plaintiffs have accurately identified a document in paragraph 149 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 149 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 149 of the Amended Complaint.

150. The allegations contained in paragraph 150 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 150 of the Amended Complaint.

151. To the extent plaintiffs have accurately identified a document in paragraph 151 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 151 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 151 of the Amended Complaint.

152. To the extent plaintiffs have accurately identified a document in paragraph 152 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 152 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 152 of the Amended Complaint.

153. To the extent plaintiffs have accurately identified a document in paragraph 153 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 153 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 153 of the Amended Complaint.

154. To the extent plaintiffs have accurately identified a document in paragraph 154 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 154 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 154 of the Amended Complaint.

155. To the extent plaintiffs have accurately identified a document in paragraph 155 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 155 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 155 of the Amended Complaint.

156. To the extent plaintiffs have accurately identified a document in paragraph 156 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 156 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 156 of the Amended Complaint.

157. To the extent plaintiffs have accurately identified a document in paragraph 157 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 157 that are

directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 157 of the Amended Complaint.

158. To the extent plaintiffs have accurately identified a document in paragraph 158 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 158 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 158 of the Amended Complaint.

159. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 159 of the Amended Complaint.

160. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 160 of the Amended Complaint.

161. To the extent plaintiffs have accurately identified a document in paragraph 161 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 161 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 161 of the Amended Complaint.

162. The allegations contained in paragraph 162 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 162 of the Amended Complaint.

163. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 163 of the Amended Complaint.

164. To the extent plaintiffs have accurately identified a document in paragraph 164 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 164 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 164 of the Amended Complaint.

165. Actavis Pharma states only that the label says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 165 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 165 of the Amended Complaint.

166. The allegations contained in paragraph 166 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 166 of the Amended Complaint.

167. Actavis Pharma states only that the label says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 167 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 167 of the Amended Complaint.

168. Actavis Pharma states only that the label says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 168 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 168 of the Amended Complaint.

169. The allegations contained in paragraph 169 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 169 of the Amended Complaint.

170. Actavis Pharma admits only the allegations that: (i) on December 11, 2015, FDA approved sNDA 75 to NDA 020449; (ii) the Patient Counseling Information section of the Full Prescribing Information approved by FDA on December 11, 2015, for NDA 020449 included the language in quotation marks contained in the second sentence of paragraph 170 of the Amended Complaint; (iii) the Patient Information approved by FDA on December 11, 2015, for NDA 020449 included the words in quotation marks contained in the third sentence of paragraph 170 of the Amended Complaint; and (iv) the labeling approved by FDA for NDA 02049 on December 11, 2015, contained the then latest and current operative warning regarding permanent or irreversible alopecia in the Taxotere label. Actavis Pharma denies the remaining allegations in paragraph 170 of the Amended Complaint.

171. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 171 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 171.

172. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 172 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 172.

IV. Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate Caused Permanent Alopecia in Many Breast Cancer Patients

173. Actavis Pharma admits that chemotherapy can cause hair loss, and that the hair loss may be temporary in some cases. Actavis Pharma denies any allegations contained in paragraph 173 of the Amended Complaint directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 173 of the Amended Complaint.

174. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 174 of the Amended Complaint.

175. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 175 of the Amended Complaint.

176. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 176 of the Amended Complaint.

177. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 177 of the Amended Complaint.

178. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 178 of the Amended Complaint.

179. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 179 of the Amended Complaint.

180. Actavis Pharma denies any allegations contained in paragraph 180 of the Amended Complaint directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 180 of the Amended Complaint.

181. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 181 of the Amended Complaint.

182. To the extent plaintiffs have accurately identified a document in paragraph 182 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 182 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 182 of the Amended Complaint.

183. To the extent plaintiffs have accurately identified a document in paragraph 183 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 183 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 183 of the Amended Complaint.

184. To the extent plaintiffs have accurately identified a document in paragraph 184 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 184 that are

directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 184 of the Amended Complaint.

185. To the extent plaintiffs have accurately identified a document in paragraph 185 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 185 that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 185 of the Amended Complaint.

186. To the extent plaintiffs have accurately identified a document in paragraph 186 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 186 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 186 of the Amended Complaint.

187. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 187 of the Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 187 of the Amended Complaint.

188. To the extent plaintiffs have accurately identified a document in paragraph 188 of the Amended Complaint, Actavis Pharma states only that the document says what it says, but denies plaintiffs' characterization of the document. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 188 of the

Amended Complaint that are directed to other defendants. Actavis Pharma denies the remaining allegations contained in paragraph 188 of the Amended Complaint.

189. To the extent the allegations contained in paragraph 189 of the Amended Complaint are directed to Actavis Pharma, the allegations are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies the allegations contained in paragraph 189 of the Amended Complaint. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 189 of the Amended Complaint that are directed to other defendants.

V. Sanofi Marketed & Promoted Taxotere Despite Knowing It Caused Permanent Alopecia

190. The allegations contained in paragraph 190 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 190 of the Amended Complaint.

191. The allegations contained in paragraph 191 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 191 of the Amended Complaint.

192. The allegations contained in paragraph 192 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 192 of the Amended Complaint.

193. The allegations contained in paragraph 193 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 193 of the Amended Complaint.

194. The allegations contained in paragraph 194 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 194 of the Amended Complaint.

195. The allegations contained in paragraph 195 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 195 of the Amended Complaint.

196. The allegations contained in paragraph 196 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 196 of the Amended Complaint.

197. The allegations contained in paragraph 197 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 197 of the Amended Complaint.

198. The allegations contained in paragraph 198 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 198 of the Amended Complaint.

199. The allegations contained in paragraph 199 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 199 of the Amended Complaint.

200. The allegations contained in paragraph 200 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 200 of the Amended Complaint.

201. The allegations contained in paragraph 201 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 201 of the Amended Complaint.

202. The allegations contained in paragraph 202 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 202 of the Amended Complaint.

203. The allegations contained in paragraph 203 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 203 of the Amended Complaint.

204. The allegations contained in paragraph 204 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 204 of the Amended Complaint.

205. The allegations contained in paragraph 205 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 205 of the Amended Complaint.

206. The allegations contained in paragraph 206 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 206 of the Amended Complaint.

207. The allegations contained in paragraph 207 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 207 of the Amended Complaint.

208. The allegations contained in paragraph 208 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 208 of the Amended Complaint.

209. The allegations contained in paragraph 209 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response it required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 209 of the Amended Complaint.

210. The allegations contained in paragraph 210 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 210 of the Amended Complaint.

211. The allegations contained in paragraph 211 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 211 of the Amended Complaint.

212. The allegations contained in paragraph 212 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 212 of the Amended Complaint.

VI. Permanent Alopecia is Devastating for Plaintiffs.

213. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 213 of the Amended Complaint.

214. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 214 of the Amended Complaint.

215. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 215 of the Amended Complaint.

216. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 216 of the Amended Complaint.

217. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 217 of the Amended Complaint.

218. Actavis Pharma denies any allegations contained in paragraph 218 of the Amended Complaint directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 218 of the Amended Complaint.

219. Actavis Pharma denies any allegations contained in paragraph 219 of the Amended Complaint directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 219 of the Amended Complaint.

FIRST CLAIM FOR RELIEF
(Strict Products Liability – Failure to Warn – Against All Defendants)

220. Actavis Pharma incorporates by reference its responses to all preceding paragraphs of the Amended Complaint as if fully set forth herein.

221. Actavis Pharma admits only that it has marketed and promoted, as Actavis Pharma uses those terms, and sold Docetaxel Injection Concentrate under NDA 203551. Actavis Pharma denies any remaining allegations in paragraph 221 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 221 of the Amended Complaint.

222. Actavis Pharma denies the allegations in paragraph 222 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 222 of the Amended Complaint.

223. The allegations contained in paragraph 223 of the Amended Complaint are not directed toward Actavis Pharma and therefore no response is required. To the extent a response is

required, Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 223 of the Amended Complaint.

224. Actavis Pharma denies the allegations in paragraph 224 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 224 of the Amended Complaint.

225. Actavis Pharma denies the allegations in paragraph 225 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 225 of the Amended Complaint.

226. Actavis Pharma denies the allegations in paragraph 226 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 226 of the Amended Complaint.

227. Actavis Pharma denies the allegations in paragraph 227 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 227 of the Amended Complaint.

228. Actavis Pharma denies the allegations in paragraph 228 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 228 of the Amended Complaint.

229. Actavis Pharma denies the allegations in paragraph 229 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 229 of the Amended Complaint.

230. Actavis Pharma denies the allegations in paragraph 230 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 230 of the Amended Complaint.

SECOND CLAIM FOR RELIEF
(Strict Products Liability for Misrepresentation – Against All Defendants)

Count 2 of the Amended Complaint was dismissed pursuant to Pretrial Order No. 61, and therefore Actavis Pharma is not required to respond to the allegations set forth in second claim for relief (Paragraphs 231 through 238 of the Amended Complaint).

THIRD CLAIM FOR RELIEF
(Negligence – Against All Defendants)

239. Actavis Pharma incorporates by reference its responses to all preceding paragraphs of the Amended Complaint as if fully set forth herein.

240. The allegations contained in paragraph 240 of the Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 240 of the Amended Complaint directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 240.

241. Actavis Pharma denies the allegations in paragraph 241 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 241 of the Amended Complaint.

242. Actavis Pharma denies the allegations in paragraph 242 of the Amended Complaint that are directed to it, including all subparts. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 242 of the Amended Complaint.

243. Actavis Pharma denies the allegations in paragraph 243 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 243 of the Amended Complaint.

244. Actavis Pharma denies the allegations in paragraph 244 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 244 of the Amended Complaint.

245. Actavis Pharma denies the allegations in paragraph 245 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 245 of the Amended Complaint.

246. Actavis Pharma denies the allegations in paragraph 246 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 246 of the Amended Complaint.

FOURTH CLAIM FOR RELIEF
(Negligent Misrepresentation – Against All Defendants)

247. Actavis Pharma incorporates by reference its responses to all preceding paragraphs of the Amended Complaint as if fully set forth herein.

248. The allegations contained in paragraph 248 of the Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies it breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 248 of the Amended Complaint directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 248 of the Amended Complaint.

249. Actavis Pharma denies the allegations in paragraph 249 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 249 of the Amended Complaint.

250. Actavis Pharma denies the allegations in paragraph 250 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 250 of the Amended Complaint.

251. Actavis Pharma denies the allegations in paragraph 251 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 251 of the Amended Complaint.

252. Actavis Pharma denies the allegations in paragraph 252 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 252 of the Amended Complaint.

253. Actavis Pharma denies the allegations in paragraph 253 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 253 of the Amended Complaint.

254. Actavis Pharma denies the allegations in paragraph 254 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 254 of the Amended Complaint.

255. Actavis Pharma denies the allegations in paragraph 255 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 255 of the Amended Complaint.

256. Actavis Pharma denies the allegations in paragraph 256 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 256 of the Amended Complaint.

257. Actavis Pharma denies the allegations in paragraph 257 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 257 of the Amended Complaint.

FIFTH CLAIM FOR RELIEF
(Fraudulent Misrepresentation – Against All Defendants)

258. Actavis Pharma incorporates by reference its responses to all preceding paragraphs of the Amended Complaint as if fully set forth herein.

259. Actavis Pharma denies the allegations in paragraph 259 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 259 of the Amended Complaint.

260. Actavis Pharma denies the allegations in paragraph 260 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 260 of the Amended Complaint.

261. Actavis Pharma denies the allegations in paragraph 261 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 261 of the Amended Complaint.

262. Actavis Pharma denies the allegations in paragraph 262 of the Amended Complaint that are directed to it, including all subparts. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 262 of the Amended Complaint.

263. Actavis Pharma denies the allegations in paragraph 263 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 263 of the Amended Complaint.

264. Actavis Pharma denies the allegations in paragraph 264 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 264 of the Amended Complaint.

265. Actavis Pharma denies the allegations in paragraph 265 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 265 of the Amended Complaint.

SIXTH CLAIM FOR RELIEF
(Fraudulent Concealment – Against All Defendants)

266. Actavis Pharma incorporates by reference its responses to all preceding paragraphs of the Amended Complaint as if fully set forth herein.

267. Actavis Pharma denies the allegations in paragraph 267 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 267 of the Amended Complaint.

268. Actavis Pharma denies the allegations in paragraph 268 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 268 of the Amended Complaint.

269. Actavis Pharma denies the allegations in paragraph 269 of the Amended Complaint that are directed to it, including all subparts. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 269 of the Amended Complaint.

270. Actavis Pharma denies the allegations in paragraph 270 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 270 of the Amended Complaint.

271. Actavis Pharma denies the allegations in paragraph 271 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 271 of the Amended Complaint.

272. Actavis Pharma denies the allegations in paragraph 272 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 272 of the Amended Complaint.

273. Actavis Pharma denies the allegations in paragraph 273 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 273 of the Amended Complaint.

274. Actavis Pharma denies the allegations in paragraph 274 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 274 of the Amended Complaint.

275. Actavis Pharma denies the allegations in paragraph 275 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 275 of the Amended Complaint.

SEVENTH CLAIM FOR RELIEF
(Fraud and Deceit – Against All Defendants)

276. Actavis Pharma incorporates by reference its responses to all preceding paragraphs of the Amended Complaint as if fully set forth herein.

277. Actavis Pharma denies the allegations in paragraph 277 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 277 of the Amended Complaint.

278. Actavis Pharma denies the allegations in paragraph 278 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 278 of the Amended Complaint.

279. Actavis Pharma denies the allegations in paragraph 279 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 279 of the Amended Complaint.

280. Actavis Pharma denies the allegations in paragraph 280 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 280 of the Amended Complaint.

281. The allegations in paragraph 281 of the Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 281 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 281 of the Amended Complaint.

282. The allegations in paragraph 281 of the Amended Complaint are legal conclusions to which no response is required. To the extent a response is required, Actavis Pharma denies that it breached any legal duties, if any, to plaintiffs. Actavis Pharma denies any remaining allegations contained in paragraph 281 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 281 of the Amended Complaint.

283. Actavis Pharma denies the allegations in paragraph 283 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 283 of the Amended Complaint.

284. Actavis Pharma denies the allegations in paragraph 284 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 284 of the Amended Complaint.

285. Actavis Pharma denies the allegations in paragraph 285 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 285 of the Amended Complaint.

286. Actavis Pharma denies the allegations in paragraph 286 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 286 of the Amended Complaint.

287. Actavis Pharma denies the allegations in paragraph 287 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 287 of the Amended Complaint.

288. Actavis Pharma denies the allegations in paragraph 288 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 288 of the Amended Complaint.

289. Actavis Pharma denies the allegations in paragraph 289 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 289 of the Amended Complaint.

290. Actavis Pharma denies the allegations in paragraph 290 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 290 of the Amended Complaint.

291. Actavis Pharma denies the allegations in paragraph 291 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 291 of the Amended Complaint.

292. Actavis Pharma denies the allegations in paragraph 292 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 292 of the Amended Complaint.

293. Actavis Pharma denies the allegations in paragraph 293 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 293 of the Amended Complaint.

294. Actavis Pharma denies the allegations in paragraph 294 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 294 of the Amended Complaint.

295. Actavis Pharma denies the allegations in paragraph 295 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 295 of the Amended Complaint.

296. Actavis Pharma denies the allegations in paragraph 296 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 296 of the Amended Complaint.

297. Actavis Pharma denies the allegations in paragraph 297 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 297 of the Amended Complaint.

298. Actavis Pharma denies the allegations in paragraph 298 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 298 of the Amended Complaint.

299. Actavis Pharma denies the allegations in paragraph 299 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 299 of the Amended Complaint.

300. Actavis Pharma denies the allegations in paragraph 300 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 300 of the Amended Complaint.

301. Actavis Pharma denies the allegations in paragraph 301 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a

belief as to the truth of the remaining allegations contained in paragraph 301 of the Amended Complaint.

302. Actavis Pharma denies the allegations in paragraph 302 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 302 of the Amended Complaint.

303. Actavis Pharma denies the allegations in paragraph 303 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 303 of the Amended Complaint.

304. Actavis Pharma denies the allegations in paragraph 304 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 304 of the Amended Complaint.

305. Actavis Pharma denies the allegations in paragraph 305 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 305 of the Amended Complaint.

306. Actavis Pharma denies the allegations in paragraph 306 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 306 of the Amended Complaint.

307. Actavis Pharma denies the allegations in paragraph 307 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 307 of the Amended Complaint.

308. Actavis Pharma denies the allegations in paragraph 308 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 308 of the Amended Complaint.

309. Actavis Pharma denies the allegations in paragraph 309 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 309 of the Amended Complaint.

310. Actavis Pharma denies the allegations in paragraph 310 of the Amended Complaint that are directed to it. Actavis Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 310 of the Amended Complaint.

EIGHTH CLAIM FOR RELIEF
(Breach of Express Warranty – Against Sanofi-Related Entities Only)

Count 8 of the Amended Complaint was dismissed pursuant to Pretrial Order No. 61, and therefore Actavis Pharma is not required to respond to the allegations set forth in eighth claim for relief (Paragraphs 311 through 318 of the Amended Complaint).

PRAYER FOR RELIEF

319. Actavis Pharma admits only that plaintiffs pray for damages, but denies that plaintiffs are entitled to any damages whatsoever. Actavis Pharma denies the remaining allegations in paragraph 319 of the Amended Complaint.

JURY DEMAND

320. Actavis Pharma admits only that plaintiffs purport to demand a trial by jury. Actavis Pharma denies any remaining allegations in paragraph 320 of the Amended Complaint.

321. Actavis Pharma denies all allegations contained in headings and captions of the Amended Complaint.

322. Actavis Pharma denies all allegations contained in the Amended Complaint, unless expressly admitted in this answer.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to Actavis Pharma in this matter. Actavis Pharma accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Actavis Pharma may withdraw any of these additional defenses as may be appropriate. Actavis Pharma further reserves the right to amend its Answer and defenses, and to assert additional defenses and other claims, as this matter proceeds.

Further answering, and by way of additional defense, Actavis Pharma states as follows:

1. Plaintiffs' Amended Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted.
2. Plaintiffs' Amended Complaint fails to state a claim for fraud, misrepresentation, deception, and/or deceit and fails to allege the circumstances constituting fraud with particularity required by the Federal Rules of Civil Procedure.

3. Plaintiffs' Amended Complaint should be dismissed due to the transferor Court's lack of personal jurisdiction over defendant.

4. This Court is an improper venue for the trial of this action.

5. This Court is not the proper forum for the trial of this action and is not a convenient forum for the just adjudication of plaintiffs' claims.

6. Plaintiffs have failed to obtain proper process or sufficient service of process.

7. Some or all of plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.

8. With respect to each and every cause of action, plaintiffs are not entitled to recover because of the fundamental unfairness and prejudice due to the delay from the date of the alleged use of the products allegedly sold by Actavis Pharma and the assertion of plaintiffs' claims against Actavis Pharma.

9. Plaintiffs' claims against Actavis Pharma are barred, in whole or in part, by laches, waiver, estoppel, unclean hands, res judicata, release of claims and/or ratification.

10. If plaintiffs, or any third party not within the control of Actavis Pharma, have failed to preserve evidence, and as a result of such spoliation Actavis Pharma has been prejudiced, then plaintiffs' causes of action should be barred.

11. Plaintiffs' claims are barred, in whole or in part, by plaintiffs' failure to mitigate plaintiffs' alleged damages.

12. The acts and omissions of plaintiffs caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiffs' recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.

13. Actavis Pharma is entitled to contribution from any person and/or entity whose negligence or other fault contributed to plaintiffs' alleged injuries and damages if plaintiffs receive a verdict against Actavis Pharma.

14. The liability of Actavis Pharma, if any, to the plaintiffs for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom plaintiffs could have obtained personal jurisdiction with due diligence.

15. Actavis Pharma reserves its right to make a written election of credit for settlements under the applicable law. Actavis Pharma also demands that its fault or responsibility be compared to other parties and non-parties to this suit, including plaintiffs, as provided by any governing statutory or common law scheme of comparative fault, comparative responsibility and contribution.

16. To the extent plaintiffs seek to recover only economic loss in tort, plaintiffs' claims are barred by the economic loss doctrine.

17. Plaintiffs, knowing the nature and properties of docetaxel-containing products, consented to use docetaxel-containing products, and accordingly Actavis Pharma cannot be held liable.

18. Plaintiffs' common law claims are subsumed by state Product Liability Acts.

19. Actavis Pharma pleads all defenses available under the UCC.

20. Actavis Pharma did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Actavis Pharma, and/or by plaintiffs' failure to give Actavis Pharma timely notice of the alleged breach of warranty.

21. Plaintiffs have failed to sufficiently plead a claim for punitive damages.

22. Punitive damages may not be recovered for breach of warranty claims.

23. Actavis Pharma denies any conduct for which punitive or exemplary damages could or should be awarded and denies that sufficient evidence has been produced to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.

24. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad and would violate Actavis Pharma's constitutional rights as secured by the Fifth and Seventh Amendments to the United States Constitution, would violate its rights to due process and equal protection under the Fourteenth Amendment of the United States Constitution and the prohibition against excessive fines in the United States Constitution, and the Commerce Clause of the United States Constitution, in that such an award would constitute, if imposed, an undue and unreasonable burden on interstate commerce and would contravene other provisions of the United States Constitution and any applicable state constitution.

25. Plaintiffs cannot recover punitive or exemplary damages against Actavis Pharma because such an award, which is penal in nature, would violate Actavis Pharma's constitutional rights under the United States Constitution and any applicable state constitution, unless Actavis Pharma is afforded the same procedural safeguards as are criminal defendants, including but not limited to the right to avoid self-incrimination, the right to forego production and disclosure of incriminating documents and the right to the requirement of a level of proof beyond a reasonable doubt.

26. Plaintiffs' demand for punitive damages is barred by state Product Liability Acts.

27. Plaintiffs' claim for punitive damages cannot be sustained to the extent it seeks to punish Actavis Pharma for alleged harm to non-parties and/or persons who are not before the court.

28. Actavis Pharma moves to bifurcate those punitive damage issues provided for by applicable law.

29. An award of punitive damages based on conduct or acts committed by those who are not Actavis Pharma's vice-principals would violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution as well as the applicable state constitution.

30. With respect to plaintiffs' demand for punitive or exemplary damages, Actavis Pharma specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under applicable state law or other applicable law.

31. Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

32. Claims brought pursuant to state statutes that are insufficiently definite to provide adequate or fair notice of the conduct proscribed are unconstitutional, and accordingly plaintiffs' claims pursuant to such statutes are barred.

33. Claims brought pursuant to state statutes that unconstitutionally burden interstate business practices are barred.

34. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to docetaxel is protected under the First Amendment of the United States Constitution and the applicable state constitution.

35. The advertisements, if any, with respect to the product at issue were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and applicable state constitution(s).

36. Any claims by plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

37. Any communications and/or actions between any Actavis Pharma and the FDA and/or any governmental agency or entity are constitutionally protected under the *Noerr-Pennington* Doctrine and the First Amendment to the United States Constitution.

38. To the extent juries are not given any rules, standards, or guidelines upon which to rely in calculating mental anguish or emotional distress damage awards, an award of pain and suffering, mental anguish, or emotional distress damages in this case will violate Actavis Pharma's due process and equal protection rights guaranteed by the United States Constitution and any applicable state constitution.

39. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling, and including but not limited to pursuant to the holdings of the United States Supreme Court as set forth in *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567, *reh'g denied*, 132 S. Ct. 55 (2011); *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013).

40. To the extent that plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

41. The Amended Complaint fails to state a cause of action upon which relief can be granted because the federal government has preempted the field of law applicable to the product alleged to have caused plaintiffs' injuries, including by not limited to preemption, in whole or in part, by the Federal Food, Drug, and Cosmetic Act. The granting of relief prayed for in the Amended Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law.

42. The alleged injuries sustained by plaintiffs, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which Actavis Pharma has no legal responsibility.

43. If any injury or damage was sustained by plaintiffs, which is expressly denied, some or all of the alleged damages were based on pre-existing and/or congenital and/or hereditary conditions, which were not under the control of Actavis Pharma.

44. If plaintiffs suffered injuries as alleged in the Amended Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by plaintiffs' assumption of the risk.

45. If the injuries claimed by plaintiffs were related to the use of docetaxel, which is expressly denied, any such injuries were the result of an idiosyncratic or allergic reaction to docetaxel.

46. The injuries and damages claimed by plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Actavis Pharma was not the proximate and/or competent producing cause of such alleged injuries and damages.

47. The injuries and damages claimed by plaintiffs, if any, are barred or must be reduced because those damages arose from the acts or omissions of persons or entities other than Actavis Pharma for whom Actavis Pharma has no legal responsibility.

48. Any injuries or damages sustained by plaintiffs were directly and proximately caused by failure of plaintiffs to heed warnings and instructions. Therefore, no recovery is available to plaintiffs against Actavis Pharma.

49. Plaintiffs' claims may be barred because there is no evidence that plaintiffs' health care providers would have heeded any different warnings than what were provided.

50. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling or other unforeseeable misuse, or use inconsistent with the labeling of docetaxel. Plaintiffs' recovery is accordingly barred. Plaintiffs' claims are barred to the extent their injuries relate to a modified product.

51. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Actavis Pharma.

52. Plaintiffs' claims are barred because the benefits of docetaxel outweigh the risks, if any, that might be associated with the product. The product conformed to the reasonable expectation of the consumer.

53. The claims in the Amended Complaint are barred in whole or in part by the learned intermediary doctrine.

54. Actavis Pharma gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Amended Complaint, Actavis Pharma intends to rely upon same in defense of this action.

55. Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the distribution of docetaxel, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package inserts and other literature, conformed to the applicable state of the art. Docetaxel, including its labeling approved by the FDA, complied with the state of scientific and medical knowledge available at the time. Plaintiffs' recovery accordingly is barred.

56. At all times relevant hereto, the state of scientific knowledge and the state of the art of design and manufacture of docetaxel-containing products were such that Actavis Pharma did not know and/or could not have reasonably known that docetaxel-containing products presented any risk to plaintiffs.

57. Plaintiffs' claims are barred because docetaxel was neither defective nor unreasonably dangerous in its distribution, and docetaxel was reasonably safe and reasonably fit for its intended uses, thereby barring plaintiffs' recovery.

58. The warnings and instructions accompanying docetaxel at the time of the occurrence or injuries alleged by plaintiffs were legally adequate warnings and instructions.

59. The prescription drug docetaxel complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous. Plaintiffs' recovery is accordingly barred.

60. Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for docetaxel.

61. At the time the docetaxel product at issue left Actavis Pharma's control, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm, if any, for which plaintiffs seek to recover damages, without substantially impairing the reasonably anticipated or intended function of the product. Further, all reasonable precautions consistent with legal duties and obligations were taken to protect third parties from any dangers posed by the inherent characteristics of the product.

62. Actavis Pharma is not a proper party to this lawsuit.

63. All or some of Plaintiffs' claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

64. Plaintiffs' causes of action are or may be barred, in whole or in part, by lack of standing.

65. Plaintiffs' claims for equitable relief are barred because there is an adequate remedy at law.

66. Docetaxel has been approved by the FDA. Plaintiffs' claims that Actavis Pharma is strictly liable are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

67. The public interest and benefit in the availability of docetaxel-containing products preclude liability of Actavis Pharma for the risks, if any, which were unavoidable given the state of human knowledge at the time. With respect to plaintiffs' claims, if it is determined that there is a risk inherent in docetaxel-containing products, then such risk, if any, is outweighed by the benefits of docetaxel-containing products.

68. Plaintiffs cannot recover for the claims asserted because plaintiffs have failed to comply with the conditions precedent necessary to bring this action.

69. Actavis Pharma cannot be held jointly liable for any judgment entered against any other actor, party, or defendant in this matter and that its liability is several only in nature.

70. Actavis Pharma's products were at all times in conformity with governmental requirements.

71. Dangers associated with Actavis Pharma's product were open and obvious.

72. The docetaxel-containing products complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations creates a rebuttable presumption that docetaxel-containing products were not defective and that there was no negligence.

73. To the extent of any collateral source benefits, remuneration or compensation received, the amount of damages claimed by plaintiffs should be reduced.

74. The prescription drugs docetaxel-containing products complied with the applicable federal and/or state safety codes, statutes, rules, regulations or standards. Compliance with such codes, statutes, rules, regulations and standards demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of these prescription drugs, and that Actavis Pharma is entitled to a presumption that the products are neither defective nor unreasonably dangerous. Plaintiffs' claims and any recovery are accordingly barred.

75. Plaintiffs' claims are barred by the doctrine of avoidable consequences.

76. Plaintiffs failed to exercise ordinary care on his own behalf for his own safety which caused or contributed to the alleged injury or damage, if any.

77. Plaintiffs' common law claims are subsumed by state Product Liability Acts.

78. Since the utility of docetaxel-containing products outweighs the danger allegedly created thereby, plaintiffs' claims are barred as a matter of public policy.

79. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect, since the docetaxel-containing products that plaintiffs allegedly ingested were properly prepared in accordance with the applicable standard of care.

80. To the extent that plaintiffs allege a continuing duty to warn, such cause of action is barred under applicable law.

81. Docetaxel-containing products were approved for safety and efficacy by the FDA. These products were never under the control of Actavis Pharma.

82. If docetaxel-containing products were unsafe, which Actavis Pharma expressly denies, they were unavoidably unsafe. The apparent benefits of these pharmaceutical products also exceed any apparent risks given the scientific knowledge available when the products were sold.

83. Plaintiffs' recovery, if any, of medical bills is limited to the amounts accepted as payment in full by the applicable medical providers.

84. If the injuries claimed by plaintiffs were related to the use of docetaxel-containing products, which is expressly denied, the claims in the Amended Complaint based upon warranty are barred in whole or in part because there is no warranty to a person who is unusually susceptible or unusually allergic to the use of the product. To the extent that plaintiffs were unusually susceptible or unusually allergic to docetaxel-containing products, plaintiffs' claims are either barred or reduced.

85. Plaintiffs used docetaxel-containing products after they knew, or should have known, of the alleged defects, the existence of which Actavis Pharma expressly denies, and plaintiffs are, therefore, barred from any recovery herein.

86. Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

87. Plaintiffs cannot state a claim upon which relief may be granted with regard to warnings and labeling for prescription drugs because the remedy sought by plaintiffs is subject to the exclusive regulation of the FDA.

88. Plaintiffs or plaintiffs' physicians were aware or should have been aware of any potential hazards reported to be associated with the use of docetaxel-containing products, and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings provided with respect to docetaxel-containing products and/or generally available in the medical and scientific literature. Therefore, Actavis Pharma had no duty to warn of any alleged danger or defect.

89. To the extent that Plaintiffs' Amended Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Amended Complaint, such benefits are not recoverable in this action under applicable law.

90. Notwithstanding the claims and contentions of plaintiffs, plaintiffs received all or substantially all of the benefit from the subject products that plaintiffs hoped and intended to receive and, to that extent, any damages and/or restitution that plaintiffs might be entitled to recover from Actavis Pharma must be correspondingly reduced.

91. To the extent that plaintiffs' claims have been settled or plaintiffs will in the future settle with any person or entity with respect to the injuries asserted in the Amended Complaint, the liability of Actavis Pharma, if any, should be reduced accordingly.

92. Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted as to costs, attorneys' fees, interest, double damages, unjust enrichment, disgorgement, restitution, or successor liability.

93. Plaintiffs' Amended Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

94. Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted for several or joint and several liability.

95. The injuries alleged in the Amended Complaint may be and should be reasonably apportioned among the defendants and others, as each defendant's alleged acts and omissions is divisible and distinct. Therefore, no defendant is jointly and severally liable to plaintiffs for any claim.

96. Applicable state law precludes any out-of-state plaintiffs from maintaining a cause of action in this forum that he or she could not otherwise bring in their state of residence.

97. To the extent not incorporated above, Actavis Pharma raises all defenses applicable under Louisiana law and any other state law deemed to apply to the individual plaintiffs' claims. Actavis Pharma hereby gives notice that it intends to rely on any additional defenses that become available or apparent during discovery, and thus reserves the right to amend this Answer to assert such defenses in accordance with the Federal Rules of Civil Procedure.

98. Actavis Pharma adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Actavis Pharma's defenses pleaded in this Answer.

WHEREFORE, Actavis Pharma requests that the Amended Complaint be dismissed with prejudice, that judgment be entered in favor of Actavis Pharma and against plaintiffs, and that

Actavis Pharma be awarded the costs of this action, together with such other and further relief as may be appropriate.

JURY DEMAND

Actavis Pharma hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

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CERTIFICATION

I hereby certify that the foregoing was electronically filed with the Clerk of Court using the CM/ECF system and served on all counsel of record electronically as a result thereof on this 16th day of October, 2017.

/s/ Michael J. Suffern
Michael J. Suffern