

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

	)	
Pharmaceutical Research and Manufacturers of America,	)	
	)	
<i>Plaintiff,</i>	)	No. 13-1974 (BAH)
	)	
v.	)	
	)	
Federal Trade Commission,	)	
	)	
<i>Defendant.</i>	)	
	)	

**DEFENDANT’S ANSWER TO COMPLAINT**

Defendant Federal Trade Commission (“FTC”) hereby answers the complaint in this matter by admitting or denying the numbered paragraphs of the complaint as follows:

1. The first sentence constitutes plaintiff’s characterization of its case to which no response is required. With respect to the second sentence, defendant admits that it issued the Rule under the Hart Scott Rodino Antitrust Improvements Act (“HSR Act”), 15 U.S.C. § 18a; the remainder of this sentence constitutes plaintiff’s legal characterization of the HSR Act to which no response is required. Defendant denies the third and fourth sentences.

2. With respect to the first sentence, defendant admits that, before this rulemaking, its Premerger Notification Office (“PNO”) treated transactions in which a patent holder licenses a patent but retains manufacturing rights as not reportable under the HSR Act. Defendant denies the second and third sentences.

3. This paragraph constitutes argument to which no response is required. To the extent this paragraph may be deemed to contain allegations of fact, they are denied.

4. Defendant admits that the quoted language in this paragraph appears in its publication of the final Rule, 78 FED. REG. 68,705, and denies the remainder of this paragraph.

5. This paragraph constitutes argument to which no response is required. To the extent this paragraph may be deemed to contain allegations of fact, they are denied.

6. Admit.

7. Admit.

8. Defendant admits that the quoted language appears in 5 U.S.C. § 706(2)(A), (C), and (D), and denies that the relief identified in this paragraph is warranted in this case.

9. Defendant lacks knowledge or information sufficient to form a belief about the truth of this paragraph.

10. Defendant lacks knowledge or information sufficient to form a belief about the truth of this paragraph.

11. Defendant lacks knowledge or information sufficient to form a belief about the truth of this paragraph.

12. Defendant lacks knowledge or information sufficient to form a belief about the truth of this paragraph.

13. Admit.

14. Defendant denies that plaintiff's members are direct targets of the Rule and admits that the quoted language appears in the Rule, 16 C.F.R. §801.2(g)(1).

15. Defendant admits that plaintiff's members would have standing to challenge the Rule in their own right, but otherwise denies this paragraph.

16. Admit.

17. Admit.

18. This paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

19. This paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

20. This paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

21. Deny.

22. Defendant admits that the FTC administers the federal premerger notification program, but otherwise denies this paragraph.

23. Defendant admits the first sentence. With regard to the second sentence, defendant admits that a 30-day waiting period applies to some, but not all, transactions subject to the HSR Act's premerger notification requirements, and otherwise denies this sentence.

24. Defendant admits that the FTC or the Department of Justice may, within the applicable waiting period, request additional information, thus extending the time during which the parties are prohibited from closing the transaction. Defendant denies the second sentence.

25. This paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

26. Defendants admits that the reporting threshold that applies to certain transaction under 15 U.S.C. §18a(a)((2)(B)(i), as adjusted in 2013, is \$70.9 million. The remainder of this paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

27. Defendant admits that the quoted language appears in the HSR Act, 15 U.S.C. 18a(d). The remainder of this paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

28. Defendant admits that the quoted language in the second sentence appears in the HSR Act, 15 U.S.C. 18a(d). The remainder of this paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required; to the extent it may be deemed to contain other allegations of fact, they are denied.

29. This paragraph constitutes argument to which no response is required.

30. This paragraph constitutes argument to which no response is required.

31. Admit.

32. This paragraph constitutes plaintiff's legal characterization of the proposed Rule to which no response is required. To the extent this paragraph is deemed to contain allegations of fact, they are denied.

33. Defendant admits that it proposed, in part, to amend 16 C.F.R. § 801.2. The remainder of this paragraph constitutes plaintiff's legal characterization of the proposed Rule to which no response is required.

34. Admit.

35. Defendant admits that it proposed, in part, to amend 16 C.F.R. §801.1 to define the terms "all commercially significant rights," "limited manufacturing rights," and "co-rights." The remainder of this paragraph constitutes plaintiff's legal characterization of the proposed Rule to which no response is required.

36. This paragraph constitutes argument to which no response is required.

37. Deny.

38. Defendant admits that the quoted language appears in the Notice of Proposed Rulemaking (“NPR”), 77 FED. REG. 50,057, and denies the remainder of this paragraph.

39. Defendant admits that the quoted language appears in the NPR and denies the remainder of this paragraph.

40. Deny.

41. Deny.

42. Defendant admits that the NPR cited the FTC’s rulemaking authority under the HSR Act, 15 U.S.C. §18a(d)(1), (2) and (3). The remainder of the paragraph constitutes plaintiff’s characterization of the Rule to which no response is required.

43. Admit.

44. This paragraph constitutes plaintiff’s characterization of its comments to the proposed Rule to which no response is required.

45. This paragraph constitutes plaintiff’s characterization of its comments to the proposed Rule to which no response is required.

46. Defendant admits that plaintiff attached to its comments a declaration from Dr. Thomas Varner. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remainder of this paragraph.

47. This paragraph constitutes plaintiff’s characterization of a declaration from its expert, and no response is required.

48. Admit.

49. This paragraph constitutes plaintiff’s characterization of its arguments regarding the proposed Rule to which no response is required. To the extent this paragraph may be deemed to contain allegations of fact, they are denied.

50. With respect to the first sentence, defendant admits that it issued the final Rule on November 6, 2013, but denies that this was six months after publication of the NPR. Defendant admits the second and third sentences.

51. Defendant admits the first sentence. The remainder of this paragraph constitutes plaintiff's characterization of the Rule and argument to which no response is required.

52. Admit.

53. Deny.

54. Defendant admits that the quoted language appears in its publication of the final Rule, 78 FED. REG. 68,705. The remainder of this paragraph constitutes plaintiff's characterization to which no response is required.

55. Defendant admits that the quoted language appears in its publication of the final Rule. The remainder of this paragraph constitutes plaintiff's characterization to which no response is required.

56. Deny.

57. Defendant admits that the quoted language appears in its publication of the final Rule. The remainder of this paragraph constitutes plaintiff's characterization to which no response is required.

58. Deny.

59. Defendant admits that the quoted language appears in its publication of the final Rule and denies all other factual allegations in this paragraph.

60. Deny.

61. Defendant admits that the quoted language appears in its publication of the final Rule and denies all other factual allegations in this paragraph.

62. Defendant admits that the quoted language appears in its publication of the final Rule, and that it did not discuss particular instances in which a transaction of the type covered by the Rule has been the subject of an antitrust enforcement action. The remainder of this paragraph constitutes argument to which no response is required.

63. Defendant admits that the quoted language in the second sentence appears in the HSR Act, 15 U.S.C. 18a(a). The remainder of paragraph constitutes plaintiff's legal characterization of the HSR Act to which no response is required.

64. This paragraph constitutes argument to which no response is required.

65. This paragraph constitutes argument to which no response is required.

66. This paragraph constitutes argument to which no response is required.

67. This paragraph constitutes argument to which no response is required.

68. Deny.

69. Defendant admits that the quoted language in this paragraph appears in the NPR. The remainder of paragraph constitutes argument to which no response is required; to the extent it may be deemed to contain allegations of fact, they are denied.

70. Deny.

71. This paragraph constitutes plaintiff's characterization of a declaration from its expert, and no response is required.

72. This paragraph constitutes plaintiff's characterization of a declaration from its expert, and no response is required.

73. Deny.

74. Deny.

75. Deny.

76. Defendant admits that the quoted language appears in its publication of the Rule and otherwise denies this paragraph.

77. Defendant admits that the quoted language appears in its publication of the Rule and otherwise denies this paragraph.

78. Deny.

79. Admit.

80. Deny.

81. Deny.

82. Defendant denies the first sentence. With respect to the second sentence, defendant admits that, for certain transactions, the filing fee depends on the fair market value of the transaction. With respect to the third sentence, defendant admits that the filing fee for transactions valued in excess of \$70.9 million but less than \$141.8 million is \$45,000; the filing fee for transactions valued at \$141.8 million or greater but less than \$709.1 million is \$125,000, and the filing fee for transactions valued at \$709.1 million or greater is \$280,000. With regard to the fourth sentence, defendant admits that some pharmaceutical licensing transactions reported under the HSR Act have incurred a filing fee at the higher end of this range. With regard to the fifth sentence, defendant admits that, for 30 additional filings, the total filing fees would range between \$1,350,000 and \$8,400,000.

83. Defendant denies the first, second, and fourth sentences. Defendant admits the third sentence.

84. Defendants denies the first, second, and third sentences. Defendant lacks knowledge or information sufficient to form a belief about the truth of the fourth sentence.

85. Deny.



86. Defendant lacks knowledge or information sufficient to form a belief about the truth of the first and second sentences. Defendant denies the third sentence.

87. The first sentence constitutes plaintiff's characterization of its case to which no response is required. Defendant admits the second sentence.

88. Defendant denies the first and second sentences. With regard to the third sentence, defendant admits the authority of FTC and Justice Department to investigate transactions covered by the Rule, but otherwise denies this sentence.

89. No answer to this paragraph is required.

90. Admit.

91. Deny.

92. Deny.

93. Deny.

94. No answer to this paragraph is required.

95. Admit.

96. This paragraph constitutes plaintiff's characterization of the legal standard to which no response is required.

97. This paragraph constitutes plaintiff's characterization of the legal standard to which no response is required.

98. Deny.

99. Deny.

100. Deny.

101. No answer to this paragraph is required.

102. Admit.

103. Defendant admits the first sentence. The second sentence constitutes plaintiff's characterization of the legal standard to which no response is required.

104. Deny.

105. Deny.

106. Deny.

107. No answer to this paragraph is required.

108. Deny.

109. Deny.

The remainder of this complaint constitutes plaintiff's prayer for relief to which no answer is required.

Respectfully submitted,

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Dated: February 3, 2014