



### **The Parties**

4. Plaintiff/Relator Bentley A. Hollander (“Hollander”) is an adult individual, residing at 220 West Rittenhouse Square, Apartment 18B, Philadelphia, Pennsylvania 19103.

5. Defendant Ortho is a global pharmaceutical company with headquarters located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560-20.

### **Jurisdiction and Venue**

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C. §§ 1391(c) and 1395(a), because Ortho has conducted business and continues to conduct business in this judicial district, through, among other things, the sale of products that are the subject of this action.

8. Hollander has standing to bring this action pursuant to 35 U.S.C. § 292(b), which provides that “any person” may bring action for civil money penalties for false patent marking.

### **Factual Background**

9. Defendant Ortho is a global pharmaceutical and health care products company, with annual sales in the hundreds of millions of dollars.

10. On information and belief, Defendant Ortho manufactures and sells (or causes to be manufactured and sold) hundreds of thousands of units of its products in the United States, including this judicial district.

11. Defendant Ortho is a sophisticated global healthcare business, competing with other major global healthcare concerns in this country and around the world.

12. As a highly sophisticated business entity, Ortho has extensive experience with the application for, procurement of, and publication of its patents and other intellectual property interests in the United States.

13. Defendant Ortho claims to own or have licenses under a substantial number of patents or patent applications.

#### **The Patents at Issue**

14. Ortho manufactures a number of health care related products, including prescription drugs.

15. One of Defendant's products, Risperdone, is a medication used to treat schizophrenia and other mood disturbances.

16. Defendant's product literature and labeling information describe numerous Risperdone formulations, summarized as follows:

<u>NDC No.</u>	<u>Product</u>
50458-300-01	Risperdone tablet (1 mg)(10-tablet pack)
50458-300-06	Risperdone tablet (1 mg)(60-tablet bottle)
50458-300-50	Risperdone tablet (1 mg)(500-tablet bottle)
50458-301-01	Risperdone tablet (0.25 mg)(10-tablet pack)
50458-301-04	Risperdone tablet (0.25 mg)(60-tablet bottle)
50458-301-50	Risperdone tablet (0.25 mg)(500-tablet bottle)
50458-302-01	Risperdone tablet (0.5 mg)(10-tablet pack)
50458-302-06	Risperdone tablet (0.5 mg)(60-tablet bottle)
50458-302-50	Risperdone tablet (0.5 mg)(500-tablet bottle)

50458-305-03	Risperdone solution (30 mL bottle)
50458-315-28	Risperdone orally-disintegrating tablet (1 mg)(7-tablet pack)
50458-315-30	Risperdone orally-disintegrating tablet (1 mg)(30-tablet bottle)
50458-320-01	Risperdone tablet (2 mg)(10-tablet pack)
50458-320-06	Risperdone tablet (2 mg)(60-tablet bottle)
50458-320-50	Risperdone tablet (2 mg)(500-tablet bottle)
50458-325-28	Risperdone orally-disintegrating tablet (2 mg)(7-tablet pack)
50458-330-01	Risperdone tablet (3 mg)(7-tablet pack)
50458-330-06	Risperdone tablet (3 mg)(60-tablet bottle)
50458-330-50	Risperdone tablet (3 mg)(500-tablet bottle)
50458-335-28	Risperdone orally-disintegrating tablet (3 mg)(7-tablet pack)
50458-355-28	Risperdone orally-disintegrating tablet (4 mg)(7-tablet pack)
50458-350-01	Risperdone tablet (2 mg)(10-tablet pack)
50458-350-06	Risperdone tablet (2 mg)(60-tablet bottle)
50458-395-28	Risperdone orally-disintegrating tablet (0.5 mg)(7-tablet pack)
50458-395-30	Risperdone orally-disintegrating tablet (0.5 mg)(30-tablet bottle)

17. Defendant Ortho claims that all of the Risperdone products identified above are covered by U.S. Patent No. 4,804,663 and has held them out as such and continues to hold them out as such.

18. U.S. Patent No. 4,804,663 expired on December 29, 2007.

19. Defendant Ortho has falsely marked and continues to falsely mark its Risperdone products with an expired patent.

20. Ortho knows or reasonably should know that it is falsely marking its Risperdone products with an expired patent.

21. Defendant Ortho also manufactures Nizoral, a medicated dandruff shampoo.

22. Nizoral is marked with U.S. Patent No. 4,335,125.

23. U.S. Patent No. 4,335,125 expired on June 15, 2000.

24. Defendant Ortho also manufactures Terconazole, an antifungal agent used to treat vaginal yeast infections.

25. Terconazole comes in three different formulations, as follows:

<u>NDC No.</u>	<u>Product</u>
0062-5350-01	Terconazole cream (45g tube)
0062-5356-01	Terconazole cream (20g tube)
0062-5351-01	Terconazole suppository (80g)

26. Defendant Ortho claims and holds out each of these Terconazole products as covered by U.S. Patent No. D279,504.

27. U.S. Patent No. D279,504 expired on July 2, 1999.

28. Defendant Ortho also manufactures Ofloxacin, a synthetic chemotherapeutic antibiotic of the fluoroquinoline drug class.

29. Ofloxacin comes in three different product formulations, as follows:

<u>NDC No.</u>	<u>Product</u>
0062-1540-02	Ofloxacin tablets (200 mg)
0062-1541-02	Ofloxacin tablets (300 mg)
0062-1542-02	Ofloxacin tablets (400 mg)

30. Defendant Ortho has held out and continues to hold out each of the Ofloxacin products as being covered by U.S. Patent No. 4,382,892.

31. U.S. Patent No. 4,382,892 expired on September 2, 2003.

32. Defendant Ortho also manufactures Reminyl – now called Razadyne – a drug used for the treatment of mild to moderate dementia associated with Alzheimer's Disease.

33. Razadyne comes in several different product formulations, as follows:

<u>NDC No.</u>	<u>Product</u>
50458-387-30	Galantamine hydrobromide capsules (8 mg)
50458-388-30	Galantamine hydrobromide capsules (16 mg)
50458-389-30	Galantamine hydrobromide capsules (24 mg)
50458-390-10	Galantamine hydrobromide solution (100 mL)
50458-396-60	Galantamine hydrobromide tablets (4 mg)

50458-397-60 Galantamine hydrobromide tablets (8 mg)  
50458-398-60 Galantamine hydrobromide tablets (12 mg)

34. Defendant Ortho has marked each of the above Razadyne products, and continues to mark these products, with U.S. Patent No. 4,663,318.

35. U.S. Patent No. 4,663,318 expired on December 14, 2008.

36. Defendant Ortho knows or reasonably should know of the requirements and provisions of 35 U.S.C. §292.

37. Ortho knows or reasonably should know that the purpose of marking a product with a patent number is to put competitors and the public on notice of exclusive and legally enforceable rights as to that product.

38. Upon information and belief, Defendant Ortho has marked and continues to mark many of its products with expired patents for the purpose of deceiving the public and its competitors.

39. By knowingly marking and continuing to mark what are likely millions of units of products with expired patents, Defendant Ortho has injured the sovereign interests of the United States and has discouraged or deterred honest competition and innovation.

40. By knowingly marking and continuing to mark what are likely millions of units of products with expired patents, Defendant Ortho has profited significantly and unjustly, in amounts to be determined during discovery in this case.

**COUNT I**  
**False Marking of**  
**50458-300-01 Risperdone tablet (1 mg)(10-tablet pack)**

41. The preceding paragraphs are incorporated here by reference.

42. Defendant Ortho manufactures and sells a product identified as 50458-300-01 RISPERDONE TABLET (1 mg)(10-TABLET PACK).

43. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

44. U.S. Patent 4,804,663 expired on December 29, 2007.

45. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

46. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT II**  
**False Marking of**  
**50458-300-06 Risperdone tablet (1 mg)(60-tablet bottle)**

47. The preceding paragraphs are incorporated here by reference.

48. Defendant Ortho manufactures and sells a product identified as 50458-300-06 RISPERDONE TABLET (1 mg)(60-TABLET BOTTLE).

49. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

50. U.S. Patent 4,804,663 expired on December 29, 2007.

51. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

52. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT III**  
**False Marking of**  
**50458-300-50 Risperdone tablet (1 mg)(500-tablet bottle)**

53. The preceding paragraphs are incorporated here by reference.

54. Defendant Ortho manufactures and sells a product identified as 50458-300-50 RISPERDONE TABLET (1 mg)(500-TABLET BOTTLE).

55. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

56. U.S. Patent 4,804,663 expired on December 29, 2007.

57. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

58. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT IV**  
**False Marking of**  
**50458-301-01 Risperdone tablet (0.25 mg)(10-tablet pack)**

59. The preceding paragraphs are incorporated here by reference.

60. Defendant Ortho manufactures and sells a product identified as 50458-301-01 RISPERDONE TABLET (0.25 mg)(10-TABLET PACK).

61. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

62. U.S. Patent 4,804,663 expired on December 29, 2007.

63. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.



64. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT V**  
**False Marking of**  
**50458-301-04 Risperdone tablet (0.25 mg)(60-tablet bottle)**

65. The preceding paragraphs are incorporated here by reference.

66. Defendant Ortho manufactures and sells a product identified as 50458-301-04 RISPERDONE TABLET (0.25 mg)(60-TABLET BOTTLE).

67. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

68. U.S. Patent 4,804,663 expired on December 29, 2007.

69. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

70. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT VI**  
**False Marking of**  
**50458-301-50 Risperdone tablet (0.25 mg)(500-tablet bottle)**

71. The preceding paragraphs are incorporated here by reference.

72. Defendant Ortho manufactures and sells a product identified as 50458-301-50 RISPERDONE TABLET (0.25 mg)(500-TABLET BOTTLE).

73. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

74. U.S. Patent 4,804,663 expired on December 29, 2007.

75. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

76. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT VII**  
**False Marking of**  
**50458-302-01 Risperdone tablet (0.5 mg)(10-tablet pack)**

77. The preceding paragraphs are incorporated here by reference.

78. Defendant Ortho manufactures and sells a product identified as 50458-302-01 RISPERDONE TABLET (0.5 mg)(10-TABLET PACK).

79. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

80. U.S. Patent 4,804,663 expired on December 29, 2007.

81. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

82. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT VIII**  
**False Marking of**  
**50458-302-06 Risperdone tablet (0.5 mg)(60-tablet bottle)**

83. The preceding paragraphs are incorporated here by reference.

84. Defendant Ortho manufactures and sells a product identified as 50458-302-06 RISPERDONE TABLET (0.5 mg)(60-TABLET BOTTLE).

85. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

86. U.S. Patent 4,804,663 expired on December 29, 2007.

87. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

88. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT IX**  
**False Marking of**  
**50458-302-50 Risperdone tablet (0.5 mg)(500-tablet bottle)**

89. The preceding paragraphs are incorporated here by reference.

90. Defendant Ortho manufactures and sells a product identified as 50458-302-50 RISPERDONE TABLET (0.5 mg)(500-TABLET BOTTLE).

91. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

92. U.S. Patent 4,804,663 expired on December 29, 2007.

93. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

94. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT X**  
**False Marking of**  
**50458-305-03 Risperdone solution (30 mL bottle)**

95. The preceding paragraphs are incorporated here by reference.

96. Defendant Ortho manufactures and sells a product identified as  
50458-305-03 RISPERDONE SOLUTION (30 mL bottle)

97. Defendant Ortho has marked and has continued to mark each unit of  
this product with the U.S. Patent No. 4,804,663.

98. U.S. Patent 4,804,663 expired on December 29, 2007.

99. Since December 29, 2007, Defendant Ortho knew or reasonably  
should have known that this product was not covered by U.S. Patent 4,804,663.

100. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a)  
by marking or causing to be marked each unit of this product with an expired patent  
for the purpose of deceiving the public.

**COUNT XI**  
**False Marking of**  
**50458-315-28 Risperdone orally-disintegrating tablet (1 mg)(7-tablet pack)**

101. The preceding paragraphs are incorporated here by reference.

102. Defendant Ortho manufactures and sells a product identified as  
50458-315-28 RISPERDONE ORALLY-DISINTEGRATING TABLET (1 mg)(7-tablet  
pack).

103. Defendant Ortho has marked and has continued to mark each unit of  
this product with the U.S. Patent No. 4,804,663.

104. U.S. Patent 4,804,663 expired on December 29, 2007.

105. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

106. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XII**  
**False Marking of**  
**50458-315-30 Risperdone orally-disintegrating tablet**  
**(1 mg)(30-tablet bottle)**

107. The preceding paragraphs are incorporated here by reference.

108. Defendant Ortho manufactures and sells a product identified as 50458-315-30 RISPERDONE ORALLY-DISINTEGRATING TABLET (1 mg)(30-TABLET BOTTLE).

109. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

110. U.S. Patent 4,804,663 expired on December 29, 2007.

111. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

112. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XIII**  
**False Marking of**  
**50458-320-01 Risperdone tablet (2 mg)(10-tablet pack)**

113. The preceding paragraphs are incorporated here by reference.

114. Defendant Ortho manufactures and sells a product identified as 50458-320-01 RISPERDONE TABLET (2 mg)(10-TABLET PACK).

115. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

116. U.S. Patent 4,804,663 expired on December 29, 2007.

117. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

118. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XIV**  
**False Marking of**  
**50458-320-06 Risperdone tablet (2 mg)(60-tablet bottle)**

119. The preceding paragraphs are incorporated here by reference.

120. Defendant Ortho manufactures and sells a product identified as 50458-320-06 RISPERDONE TABLET (2 mg)(60-TABLET BOTTLE).

121. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

122. U.S. Patent 4,804,663 expired on December 29, 2007.

123. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

124. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XV**  
**False Marking of**  
**50458-320-50 Risperdone tablet (2 mg)(500-tablet bottle)**

125. The preceding paragraphs are incorporated here by reference.

126. Defendant Ortho manufactures and sells a product identified as 50458-320-50 RISPERDONE TABLET (2 mg)(500-TABLET BOTTLE).

127. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

128. U.S. Patent 4,804,663 expired on December 29, 2007.

129. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

130. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XVI**  
**False Marking of**  
**50458-325-28 Risperdone orally-disintegrating tablet**  
**(2 mg)(7-tablet pack)**

131. The preceding paragraphs are incorporated here by reference.

132. Defendant Ortho manufactures and sells a product identified as 50458-325-28 RISPERDONE ORALLY-DISINTEGRATING TABLET (2 mg)(7-TABLET PACK).

133. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

134. U.S. Patent 4,804,663 expired on December 29, 2007.

135. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

136. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XVII**  
**False Marking of**  
**50458-330-01 Risperdone tablet (3 mg)(10-tablet pack)**

137. The preceding paragraphs are incorporated here by reference.

138. Defendant Ortho manufactures and sells a product identified as 50458-330-01 RISPERDONE TABLET (3 mg)(10-TABLET PACK).

139. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

140. U.S. Patent 4,804,663 expired on December 29, 2007.

141. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

142. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XVIII**  
**False Marking of**  
**50458-330-06 Risperdone tablet (3 mg)(60-tablet bottle)**

143. The preceding paragraphs are incorporated here by reference.

144. Defendant Ortho manufactures and sells a product identified as 50458-330-06 RISPERDONE TABLET (3 mg)(60-TABLET BOTTLE).



145. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

146. U.S. Patent 4,804,663 expired on December 29, 2007.

147. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

148. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XIX**  
**False Marking of**  
**50458-330-50 Risperdone tablet (3 mg)(500-tablet bottle)**

149. The preceding paragraphs are incorporated here by reference.

150. Defendant Ortho manufactures and sells a product identified as 50458-330-50 RISPERDONE TABLET (3 mg)(500-TABLET BOTTLE).

151. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

152. U.S. Patent 4,804,663 expired on December 29, 2007.

153. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

154. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XX**  
**False Marking of**  
**50458-335-28 Risperdone orally-disintegrating tablet (3 mg)(7-tablet pack)**

155. The preceding paragraphs are incorporated here by reference.

156. Defendant Ortho manufactures and sells a product identified as 50458-335-28 RISPERDONE ORALLY-DISINTEGRATING TABLET (3 mg)(7-TABLET PACK).

157. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

158. U.S. Patent 4,804,663 expired on December 29, 2007.

159. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

160. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXI**  
**False Marking of**  
**50458-355-28 Risperdone orally-disintegrating tablet (4 mg)(7-tablet pack)**

161. The preceding paragraphs are incorporated here by reference.

162. Defendant Ortho manufactures and sells a product identified as 50458-355-28 RISPERDONE ORALLY-DISINTEGRATING TABLET (4 mg)(7-TABLET PACK).

163. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

164. U.S. Patent 4,804,663 expired on December 29, 2007.

165. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

166. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXII**  
**False Marking of**  
**50458-350-01 Risperdone tablet (2 mg)(10-tablet pack)**

167. The preceding paragraphs are incorporated here by reference.

168. Defendant Ortho manufactures and sells a product identified as 50458-350-01 RISPERDONE TABLET (2 mg)(10-TABLET PACK).

169. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

170. U.S. Patent 4,804,663 expired on December 29, 2007.

171. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

172. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXIII**  
**False Marking of**  
**50458-350-06 Risperdone tablet (2 mg)(60-tablet bottle)**

173. The preceding paragraphs are incorporated here by reference.

174. Defendant Ortho manufactures and sells a product identified as 50458-350-06 RISPERDONE TABLET (2 mg)(60-TABLET BOTTLE).

175. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

176. U.S. Patent 4,804,663 expired on December 29, 2007.

177. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

178. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXIV**  
**False Marking of**  
**50458-395-28 Risperdone orally-disintegrating tablet (0.5 mg)(7-tablet pack)**

179. The preceding paragraphs are incorporated here by reference.

180. Defendant Ortho manufactures and sells a product identified as 50458-395-28 RISPERDONE ORALLY-DISINTEGRATING TABLET (0.5 mg)(7-TABLET PACK).

181. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

182. U.S. Patent 4,804,663 expired on December 29, 2007.

183. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

184. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXV**  
**False Marking of**  
**50458-395-30 Risperdone orally-disintegrating tablet**  
**(0.5 mg)(30-tablet bottle)**

185. The preceding paragraphs are incorporated here by reference.

186. Defendant Ortho manufactures and sells a product identified as 50458-395-30 RISPERDONE ORALLY-DISINTEGRATING TABLET (0.5 mg)(30-TABLET BOTTLE).

187. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,804,663.

188. U.S. Patent 4,804,663 expired on December 29, 2007.

189. Since December 29, 2007, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,804,663.

190. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXVI**  
**False Marking of**  
**50458-680-08 Ketocoazole shampoo (120 mL bottle)**

191. The preceding paragraphs are incorporated here by reference.

192. Defendant Ortho manufactures and sells a product identified as 50458-680-08 KETOCOANZOLE SHAMPOO (120 mL BOTTLE), also known as NIZORAL.

193. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,335,125.

194. U.S. Patent 4,335,125 expired on June 15, 2000.

195. Since June 15, 2000, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,335,125.

196. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXVII**  
**False Marking of**  
**0062-5350-01 Terconazole Cream (45g tube)**

197. The preceding paragraphs are incorporated here by reference.

198. Defendant Ortho manufactures and sells a product identified as 0062-5350-01 TERCONAZOLE CREAM (45g TUBE), aka TERAZOL.

199. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. D279,504.

200. U.S. Patent D279,504 expired on July 2, 1999.

201. Since July 2, 1999, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent D279,504.

202. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXVIII**  
**False Marking of**  
**0062-5356-01 Terconazole Cream (20g tube)**

203. The preceding paragraphs are incorporated here by reference.

204. Defendant Ortho manufactures and sells a product identified as 0062-5356-01 TERCONAZOLE CREAM (20g TUBE), aka TERAZOL.

205. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. D279,504.

206. U.S. Patent D279,504 expired on July 2, 1999.

207. Since July 2, 1999, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent D279,504.

208. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXIX**  
**False Marking of**  
**0062-5351-01 Terconazole Suppository (80 mg)**

209. The preceding paragraphs are incorporated here by reference.

210. Defendant Ortho manufactures and sells a product identified as 0062-5351-01 TERCONAZOLE SUPPOSITORY (80 mg), aka TERAZOL.

211. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. D279,504.

212. U.S. Patent D279,504 expired on July 2, 1999.

213. Since July 2, 1999, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent D279,504.

214. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXX**  
**False Marking of**  
**0062-1540-02 Ofloxacin tablets (200 mg)**

215. The preceding paragraphs are incorporated here by reference.

216. Defendant Ortho manufactures and sells a product identified as 0062-1540-02 OFLOXACIN TABLETS (200 mg).

217. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,382,892.

218. U.S. Patent 4,382,892 expired on September 2, 2003.

219. Since September 2, 2003, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,382,892.

220. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXI**  
**False Marking of**  
**0062-1541-02 Ofloxacin tablets (300 mg)**

221. The preceding paragraphs are incorporated here by reference.

222. Defendant Ortho manufactures and sells a product identified as 0062-1541-02 OFLOXACIN TABLETS (300 mg).

223. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,382,892.

224. U.S. Patent 4,382,892 expired on September 2, 2003.

225. Since September 2, 2003, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,382,892.

226. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.



**COUNT XXXII**  
**False Marking of**  
**0062-1542-02 Ofloxacin tablets (400 mg)**

227. The preceding paragraphs are incorporated here by reference.

228. Defendant Ortho manufactures and sells a product identified as 0062-1542-02 OFLOXACIN TABLETS (400 mg).

229. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,382,892.

230. U.S. Patent 4,382,892 expired on September 2, 2003.

231. Since September 2, 2003, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,382,892.

232. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXIII**  
**False Marking of**  
**50458-387-30 Galantamine hydrobromide capsules (8 mg)**

233. The preceding paragraphs are incorporated here by reference.

234. Defendant Ortho manufactures and sells a product identified as 50458-387-30 GALANTAMINE HYDROBROMIDE CAPSULES (8 mg).

235. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

236. U.S. Patent 4,663,318 expired on December 14, 2008.

237. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

238. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXIV**  
**False Marking of**  
**50458-388-30 Galantamine hydrobromide capsules (16 mg)**

239. The preceding paragraphs are incorporated here by reference.

240. Defendant Ortho manufactures and sells a product identified as 50458-388-30 GALANTAMINE HYDROBROMIDE CAPSULES (16 mg).

241. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

242. U.S. Patent 4,663,318 expired on December 14, 2008.

243. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

244. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXV**  
**False Marking of**  
**50458-389-30 Galantamine hydrobromide capsules (24 mg)**

245. The preceding paragraphs are incorporated here by reference.

246. Defendant Ortho manufactures and sells a product identified as 50458-389-30 GALANTAMINE HYDROBROMIDE CAPSULES (24 mg).

247. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

248. U.S. Patent 4,663,318 expired on December 14, 2008.

249. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

250. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXVI**  
**False Marking of**  
**50458-390-10 Galantamine hydrobromide solution (100 mL)**

251. The preceding paragraphs are incorporated here by reference.

252. Defendant Ortho manufactures and sells a product identified as 50458-390-10 GALANTAMINE HYDROBROMIDE SOLUTION (100 mL).

253. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

254. U.S. Patent 4,663,318 expired on December 14, 2008.

255. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

256. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXVII**  
**False Marking of**  
**50458-396-60 Galantamine hydrobromide capsules (4 mg)**

257. The preceding paragraphs are incorporated here by reference.

258. Defendant Ortho manufactures and sells a product identified as 50458-396-60 GALANTAMINE HYDROBROMIDE CAPSULES (4 mg).

259. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

260. U.S. Patent 4,663,318 expired on December 14, 2008.

261. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

262. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXVIII**  
**False Marking of**  
**50458-397-60 Galantamine hydrobromide capsules (8 mg)**

263. The preceding paragraphs are incorporated here by reference.

264. Defendant Ortho manufactures and sells a product identified as 50458-397-60 GALANTAMINE HYDROBROMIDE CAPSULES (8 mg).

265. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

266. U.S. Patent 4,663,318 expired on December 14, 2008.

267. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

268. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**COUNT XXXIX**  
**False Marking of**  
**50458-398-60 Galantamine hydrobromide capsules (12 mg)**

269. The preceding paragraphs are incorporated here by reference.

270. Defendant Ortho manufactures and sells a product identified as 50458-398-60 GALANTAMINE HYDROBROMIDE CAPSULES (12 mg).

271. Defendant Ortho has marked and has continued to mark each unit of this product with the U.S. Patent No. 4,663,318.

272. U.S. Patent 4,663,318 expired on December 14, 2008.

273. Since December 14, 2008, Defendant Ortho knew or reasonably should have known that this product was not covered by U.S. Patent 4,663,318.

274. Defendant Ortho has violated and continues to violate 35 U.S. § 292(a) by marking or causing to be marked each unit of this product with an expired patent for the purpose of deceiving the public.

**Prayer for Relief**

WHEREFORE, Plaintiff/Relator Hollander respectfully requests that this Court:

- a. Find that Defendant Ortho's manufacture, advertising, and sale of products with false patent markings or false patent assertions violate 35 U.S.C. § 292(a);
- b. Enter judgment against Ortho and in favor of Hollander;
- c. Determine an appropriate fine, of not more than \$500 per offense, but sufficient to penalize Ortho for violations of § 292(a) and to deter Ortho and others

similarly situated from violating § 292(a) in the future, for each offense of false marking, one half of which shall be paid over to the United States;

- d. Award Hollander the costs associated with this litigation;
- e. Determine that this case is “exceptional” under 35 U.S.C. § 285 and, based on such determination, award Hollander reasonable attorney fees; and
- f. Grant Hollander such other and further relief as the Court may deem just and equitable.

### **Request for Jury Trial**

Pursuant to Fed.R.Civ.P. 38(b)(1), Hollander hereby demands a jury trial on all issues so triable.

Respectfully submitted,

**LAYSER & FREIWALD, P.C.**

/s/Aaron J. Freiwald AF8799

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Attorneys for Plaintiff/Relator  
Bentley A. Hollander

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