

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: TAXOTERE (DOCETAXEL)) MDL No. 2740
PRODUCTS LIABILITY LITIGATION)
) Section: "N" (5)
)
THIS DOCUMENT RELATES TO:)
ALL CASES)

**SUN PHARMACEUTICAL INDUSTRIES, INC. f/k/a CARACO PHARMACEUTICAL
LABORATORIES, LTD.'S ANSWER AND AFFIRMATIVE DEFENSES TO
PLAINTIFFS' FIRST AMENDED MASTER LONG FORM COMPLAINT**

Defendant Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. ("Sun" or "Defendant")¹, by its undersigned attorneys responds to the Plaintiffs' First Amended Master Long Form Complaint ("FAMLFC") as follows:

PRELIMINARY STATEMENT

Many of the paragraphs of the FAMLFC and of the individual allegations contained therein are addressed jointly to Sun and the other Defendants, or without distinction between them. Sun and the other Defendants are unrelated. In general, Sun has no knowledge, actual, constructive or otherwise, as to actions, conduct, business practices or corporate behavior of the other Defendants. Accordingly, in the responses that follow, Sun responds solely on its own behalf, and denies knowledge or information as to the truth of any and all allegations as to the other Defendants, except insofar as expressly averred otherwise, and therefore, denies the same.

¹ Plaintiffs have also named Sun Pharma Global FZE in the Master Long Form Complaint but Sun Pharma Global FZE is a foreign company incorporated under the laws of the United Arab Emirates and has not been served with process, has not agreed to accept service of process in this litigation and consequently, Sun Pharma Global FZE is not appearing in this matter or joining in this Answer. The responses in this Answer are on behalf of Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. only.

Sun denies each and every allegation of the FAMLFC except as expressly admitted or otherwise responded to herein, and in response to each of the numbered paragraphs of Plaintiffs' FAMLFC, states as follows:

1. Sun admits that it distributed a Docefrez product approved under Section 505(b) of the Federal Food, Drug, and Cosmetic Act and denies the remaining allegations contained in Paragraph 1 directed to it. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

2. Sun avers that Paragraph 2 does not contain a factual allegation directed toward it, and thus no further response is required. To the extent a response is required, Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and therefore denies the same.

3. Sun avers that Paragraph 3 does not contain a factual allegation directed toward it, and thus no further response is required. To the extent a response is required, Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and therefore denies the same.

INTRODUCTION²

4. Sun admits that Taxotere is a chemotherapy drug administered to many who suffer primarily from breast cancer. Except as thus stated, Sun denies the remaining allegations of Paragraph 4 directed to it. Sun specifically denies any wrongdoing or liability to Plaintiffs whatsoever..

² Headings and subheadings throughout this Answer are taken directly from the FAMLFC and are included solely for ease of reference. They do not constitute admissions by Sun, and any portion of a heading or subheading that may be construed as a factual allegation is specifically denied.

5. Sun denies the allegations contained in Paragraph 5 directed to it. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

6. Sun denies the allegations contained in Paragraph 6 and specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

7. Sun denies the allegations contained in Paragraph 7. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

THE PARTIES

A. Plaintiffs

8. Sun denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs or their spouses, children, parents, decedents, wards, or heirs. Sun lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 8, and on that basis denies the same.

9. Sun denies the allegations contained in Paragraph 9.

10. The allegations in Paragraph 10 call for a legal conclusion, to which no response is required. To the extent a response is required, Sun denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever. Sun lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 10, and therefore denies the same.

11. Sun denies the allegations contained in Paragraph 11.

B. Sanofi-Related Entities

12-31 The allegations contained in Paragraphs 12-31 are directed to other defendants and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 12-31, and on that basis denies the same.

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

32. Sun admits that it distributed a Docefrez product approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 355(b)(2).

33-36. The allegations in Paragraphs 33-36 call for a legal conclusion, to which no response is required. To the extent a response is required, Sun denies the allegations contained in Paragraphs 33-36 and states that federal statutes and regulations speak for themselves.

1. Sandoz

37-50. The allegations contained in Paragraphs 37-50 are directed to another defendant and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 37-50, and on that basis denies the same.

2. Accord Healthcare & McKesson

51-63. The allegations contained in Paragraphs 51-63 are directed to other defendants and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 51-63, and on that basis denies the same.

4. Hospira Entities³

64-74. The allegations contained in Paragraphs 64-74 are directed to other defendants and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 64-74, and on that basis denies the same.

5. Sun Pharma Entities⁴

³ The numbering of the Subsections in Plaintiffs' FAMLFC erroneously skips to number 4 here instead of continuing at number 3. For consistency, Sun's Answer contains the same numbering as Plaintiffs' FAMLFC.

75. Sun admits the allegations contained in paragraph 75.
76. Sun admits the allegations contained in paragraph 76.
77. Sun admits that it has conducted business on behalf of Sun Pharma Global FZE in the United States. Sun denies the remaining allegations contained in Paragraph 77.
78. Sun admits that Sun Pharma Global FZE designs generic drugs and further admits that Sun sells and/or distributes generic drugs in certain markets in the United States. Except as thus stated, Sun denies the remaining allegations contained in Paragraph 78. Sun specifically denies the characterization of its revenue in Paragraph 78.
79. Sun admits that Sun Pharma Global FZE designed and tested the FDA-approved Docefrez and further admits that Sun sold and/or distributed the FDA-approved Docefrez. Sun states that FDA approved Sun Pharma Global FZE's New Drug Application for Docefrez on May 3, 2011 and Sun began selling Docefrez on or around May 16, 2011. Sun further admits that Docefrez was approved by FDA under New Drug Application number 022534. Except as thus stated, Sun denies the remaining allegations contained in Paragraph 79.
80. New Drug Application number 022534 and the applicable FDA authority speak for themselves and Sun avers that the allegations Paragraph 80 seeks to characterize the NDA 022534 submission. To the extent any allegations are set forth in Paragraph 81, Sun denies those allegations.
81. New Drug Application number 022534 and the applicable FDA authority speak for themselves and Sun avers that the allegations in Paragraph 81 seek to characterize the Docefrez

⁴ Sun herein again states that Sun Pharma Global FZE, a foreign company, has not been served with process, has not agreed to accept service of process in this litigation and consequently, Sun Pharma Global FZE is not appearing in this matter or joining in this Answer. The responses in this Answer are on behalf of Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. only.

formulation. To the extent any allegations are set forth in Paragraph 81, Sun denies those allegations.

82. Sun admits the allegations contained in paragraph 82.

83. Sun admits only that this paragraph purports to refer to and quote portions of the FDA-approved Patient Information for Docefrez, which speaks for itself, and Plaintiffs' attempt to quote, paraphrase, or construe the information is denied.

84. Sun admits that a Changes Being Effectuated ("CBE") Supplemental New Drug Application ("sNDA") (S-002) submitted on July 28, 2011, was approved on July 13, 2012, and a CBE sNDA (S-004) on May 22, 2014, that was approved on October 30, 2014. Except as thus stated, Sun avers that the remaining allegations in Paragraph 84 seek to characterize the labeling changes submitted in CBE sNDA S-002 and S-004. Sun denies the remaining allegations of Paragraph 84 and states that the labeling submissions speak for themselves.

85. Sun admits that it ceased distributing Docefrez in November 2015 and further avers that the remaining allegations in Paragraph 85 seek to characterize the Docefrez labeling. Sun denies the remaining allegations in Paragraph 85 and states that the Docefrez labeling speaks for itself.

6. *Pfizer*

86-96. The allegations contained in Paragraphs 86-96 are directed to other defendants and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 86-96, and on that basis denies the same.

7. *Actavis Entities*

97-107. The allegations contained in Paragraphs 97-107 are directed to other defendants and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 97-107, and on that basis denies the same.

JURISDICTION AND VENUE

108. The allegations in Paragraph 108 state a legal conclusion, to which no response is required. To the extent a response is required, Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 108 relating to the citizenship of other parties, and therefore denies the same. Sun denies the remaining allegations in Paragraph 108.

109. The allegations in Paragraph 109 state a legal conclusion, to which no response is required. To the extent a response is required, Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 109, and therefore denies the same.

110. Sun admits the allegations in Paragraph 110.

111. The allegations in Paragraph 111 state a legal conclusion, to which no response is required. To the extent a response is required, Sun denies the allegations in Paragraph 111 directed to it.

FACTUAL ALLEGATIONS

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

112. Sun admits the allegations in Paragraph 112.

113. Sun admits the allegations in Paragraph 113.

114. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 114, and therefore denies the same.

115. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 115, and therefore denies the same.

116. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 116, and therefore denies the same.

117. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 117, and therefore denies the same.

118. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 118, and therefore denies the same.

119. Sun avers that Paragraph 119 seeks to characterize the use and administration of Docefrez. Sun denies the characterization of the use and administration of Docefrez in Paragraph 119 and states that the medical literature and labeling discussing the use and administration of Docefrez speak for themselves. Sun lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 119, and therefore denies the same.

120. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 120 directed to other parties, and therefore denies the same.

121. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 121 directed to another Defendant, and therefore denies the same.

122. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 122 directed to another Defendant, and therefore denies the same.

123. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 123 directed to another Defendant, and therefore denies the same.

124. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 124 directed to another Defendant, and therefore denies the same.

125. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 125 directed to another Defendant, and therefore denies the same.

126. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 126 directed to another Defendant, and therefore denies the same.

127. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 127 directed to another Defendant, and therefore denies the same.

128. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 128 directed to another Defendant, and therefore denies the same.

129. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 129 directed to another Defendant, and therefore denies the same.

130. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 130 directed to another Defendant, and therefore denies the same.

131. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 131 directed to another Defendant, and therefore denies the same.

132. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 132 directed to another Defendant, and therefore denies the same.

133. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 133 directed to another Defendant, and therefore denies the same.

134. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 134 directed to another Defendant, and therefore denies the same.

135. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 135 directed to another Defendant, and therefore denies the same.

136. The allegations in paragraph 136 are directed at a defendant other than Sun and therefore, no responsive pleading is required. To the extent a response is deemed necessary, Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 136 and for that reason deny each of them.

137. Paragraph 137 does not set forth any allegation directed to Sun that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, Sun admits only that paragraph 137 purports to quote, paraphrase or construe portions of the Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to quote, paraphrase or

characterize the labeling is denied. Sun is without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 137 and for that reason deny each of them.

II. Defendants' Duties under the FDCA and State Law

138. Allegations contained in Paragraph 138 state a legal conclusion, to which no response is required. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

139. Allegations contained in Paragraph 139 state a legal conclusion to which no response is required. To the extent a response is required, Sun denies the same. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

140. Allegations contained in Paragraph 140 state a legal conclusion to which no response is required. To the extent a response is required, Sun denies the same. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

141. Allegations contained in Paragraph 141 state a legal conclusion to which no response is required. To the extent a response is required, Sun denies the same. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

142. Paragraph 142 seeks to characterize federal statutes and regulations. Sun denies the characterization of the cited federal statutes and regulations in Paragraph 142, and states that the federal statutes and regulations speak for themselves. To the extent a response is required, Sun

affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

143. Paragraph 143 seeks to characterize federal regulations. Sun denies the characterization of the cited federal regulations in Paragraph 143, and states that the federal regulations speak for themselves. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

144. Paragraph 144 seeks to characterize federal regulations. Sun denies the characterization of the cited federal regulations in Paragraph 144, and states that the federal regulations speak for themselves. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

145. Paragraph 145 seeks to characterize federal regulations. Sun denies the characterization of the cited federal regulations in Paragraph 145, and states that the federal regulations speak for themselves. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

146. Paragraph 146 seeks to characterize federal regulations. Sun denies the characterization of the cited federal regulations in Paragraph 146, and states that the federal regulations speak for themselves. Sun denies the remaining allegations in Paragraph 146. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

147. Sun denies the allegations in Paragraph 147.

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

148. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 148 directed to another Defendant, and therefore denies the

same. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 148 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 148.

149. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 149 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 149.

150. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 150 directed to another Defendant, and therefore denies the same. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 150 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 150.

151. Sun states that Plaintiffs' interpretations of and conclusions drawn from the publications referenced in Paragraph 151 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 151.

152. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 152 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 152.

153. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 153 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 153.

154. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 154 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 154.

155. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 155 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 155.

156. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 156 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 156.

157. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 157 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 157.

158. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 158 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 158.

159. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies, presentations, and publications referenced in Paragraph 159 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 159.

160. Sun states that Plaintiffs' interpretations of and conclusions drawn from the publications referenced in Paragraph 160 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 160.

161. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 161 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 161.

162. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 162 directed to another Defendant, and therefore denies the same.

163. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 163 directed to another Defendant, and therefore denies the same.

164. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 164 directed to another Defendant, and therefore denies the same.

165. Sun admits the allegations in Paragraph 165.

166. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 166 directed to another Defendant, and therefore denies the same.

167. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 167 directed to another Defendant, and therefore denies the same.

168. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 168 directed to another Defendant, and therefore denies the same.

169. The allegations in paragraph 169 are directed at a defendant other than Sun and therefore, no responsive pleading is required. To the extent a response is deemed necessary, Sun admits only that paragraph 169 purports to refer to a FDA regulatory request that Sanofi submitted on

November 25, 2015, which speaks for itself, and Plaintiffs' attempt to characterize the request is denied.

170. Paragraph 170 does not set forth any allegation directed to Sun that is susceptible to admission or denial and therefore no response is required. To the extent a response is deemed necessary, Sun admits only that paragraph 170 purports to refer to and quote from certain Taxotere labeling, which speaks for itself, and Plaintiffs' attempt to characterize the labeling is denied.

171. Sun denies the allegations contained in Paragraph 171 directed to it. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

172. Sun denies the allegations contained in Paragraph 172 directed to it. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

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

173. Sun admits that chemotherapy can cause hair loss, which in some cases is temporary. Sun lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 173, and therefore denies the same.

174. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 174, and therefore denies the same.

175. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 175, and therefore denies the same.

176. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 176, and therefore denies the same.

177. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 177, and therefore denies the same.

178. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 178, and therefore denies the same.

179. Sun states that Plaintiffs' interpretations of and conclusions drawn from the publications referenced in Paragraph 179 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 179.

180. Sun avers that Paragraph 180 attempts to characterize the side effects associated with Docefrez. Sun denies the characterization of the side effects of Docefrez in Paragraph 180, and states that the medical literature and Docefrez labeling discussing the side effects of this drug speak for themselves. Sun denies the remaining allegations in Paragraph 180.

181. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 181 directed to another Defendant, and therefore denies the same.

182. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 182 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 182.

183. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 183 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 183.

184. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 184 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 184.

185. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 185 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 185.

186. Sun states that Plaintiffs' interpretations of and conclusions drawn from the presentations and publications referenced in Paragraph 186 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 186.

187. Sun denies the allegations contained in Paragraph 187 directed to it. Sun specifically denies any wrongdoing or liability to Plaintiffs whatsoever.

188. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies and publications referenced in Paragraph 188 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 188.

189. Sun denies the allegations contained in Paragraph 189 directed to it. Sun specifically denies any wrongdoing or liability to Plaintiffs whatsoever.

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

190-212. The allegations contained in Paragraphs 190-212 are directed to other defendants and Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 86-96, and on that basis denies the same.

VI. Permanent Alopecia is Devastating for Plaintiffs.

213. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 213 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 213.

214. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 214 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 214.

215. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 215, and therefore denies the same.

216. Sun lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 216, and therefore denies the same.

217. Sun states that Plaintiffs' interpretations of and conclusions drawn from the studies referenced in Paragraph 217 are erroneous and/or taken out of context, and the same are therefore denied. Sun denies the remaining allegations in Paragraph 217.

218. Sun denies the allegations set forth in Paragraph 218.

219. Sun denies the allegations set forth in Paragraph 219. Sun specifically denies any wrongdoing or liability to Plaintiffs whatsoever.

FIRST CLAIM FOR RELIEF

(Strict Products Liability – Failure to Warn – Against All Defendants)

220. Sun restates and incorporates by reference its answers to all prior paragraphs of the FAMLFC, as if fully set forth herein.

221. Sun admits that Sun Pharma Global FZE developed and tested and Sun distributed and/or sold FDA-approved Docefrez product in compliance with all applicable legal duties, laws, and regulations. Except as thus stated, Sun denies the remaining allegations in Paragraph 221 directed to Sun.

222. Sun denies the allegations contained in Paragraph 222. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

223. Sun lacks knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 223 directed to another Defendant and nonparty, and therefore denies the same.

224. Sun denies the allegations contained in Paragraph 224.

225. Sun denies the allegations contained in Paragraph 225.

226. Sun denies the allegations contained in Paragraph 226.

227. Paragraph 227 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun denies the allegations contained in Paragraph 227.

228. Paragraph 228 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun denies the allegations contained in Paragraph 228.

229. Sun denies the allegations contained in Paragraph 229.

230. Sun denies the allegations contained in Paragraph 230. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

SECOND CLAIM FOR RELIEF

(Strict Products Liability for Misrepresentation – Against All Defendants)

Sun states that Count 2 of Plaintiffs' FAC was dismissed by the Court in Pretrial Order No. 61, dated September 27, 2017, and therefore no answer is required. To the extent an answer is required, Sun denies the allegations contained in Paragraphs 231 – 238 of Plaintiffs' FAMLFC.

THIRD CLAIM FOR RELIEF

(Negligence – Against All Defendants)

239. Sun restates and incorporates by reference its answers to all prior paragraphs of the FAMLFC, as if fully set forth herein.

240. Paragraph 240 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

241. Sun denies the allegations in Paragraph 241.

242. Sun denies the allegations contained in Paragraph 242 and all subparts thereof.

243. Sun denies the allegations contained in Paragraph 243.

244. Sun denies the allegations contained in Paragraph 244.

245. Sun denies the allegations in Paragraph 245.

246. Sun denies the allegations contained in Paragraph 246. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

FOURTH CLAIM FOR RELIEF

(Negligent Misrepresentation – Against All Defendants)

247. Sun restates and incorporates by reference its answers to all prior paragraphs of the FAMLFC, as if fully set forth herein.

248. Paragraph 248 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to docetaxel.

249. Paragraph 249 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun denies the allegations in Paragraph 249.

- 250. Sun denies the allegations contained in Paragraph 250.
- 251. Sun denies the allegations contained in Paragraph 251.
- 252. Sun denies the allegations contained in Paragraph 252.
- 253. Sun denies the allegations in Paragraph 253.
- 254. Sun denies the allegations in Paragraph 254.
- 255. Sun denies the allegations in Paragraph 255.
- 256. Sun denies the allegations in Paragraph 256.
- 257. Sun denies the allegations in Paragraph 257. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

FIFTH CLAIM FOR RELIEF

(Fraudulent Misrepresentation – Against All Defendants)

- 258. Sun restates and incorporates by reference its answers to all prior paragraphs of the FAMLFC, as if fully set forth herein.
- 259. Sun admits that it sold Docefrez, which was accompanied by its FDA-Approved labeling, which discussed the risks and benefits of the medication. Except as thus stated, Sun denies the allegations contained in Paragraph 259.
- 260. Sun denies the allegations in Paragraph 260.
- 261. Sun denies the allegations in Paragraph 261.
- 262. Sun denies the allegations contained in Paragraph 262 and all subparts therein.
- 263. Sun denies the allegations contained in Paragraph 263.
- 264. Sun denies the allegations contained in Paragraph 264.

265. Sun denies the allegations contained in Paragraph 265. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

SIXTH CLAIM FOR RELIEF

(Fraudulent Concealment – Against All Defendants)

266. Sun restates and incorporates by reference its answers to all prior paragraphs of the FAMLFC, as if fully set forth herein.

267. Sun denies the allegations contained in Paragraph 267.

268. Sun denies the allegations contained in Paragraph 268.

269. Sun denies the allegations contained in Paragraph 269 and all subparts therein.

270. Sun denies the allegations contained in Paragraph 270.

271. Sun denies the allegations contained in Paragraph 271.

272. Sun denies the allegations contained in Paragraph 272.

273. Sun denies the allegations contained in Paragraph 273.

274. Sun denies the allegations contained in Paragraph 274.

275. Sun denies the allegations contained in Paragraph 275. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

SEVENTH CLAIM FOR RELIEF

(Fraud and Deceit Against All Defendants)

276. Sun restates and incorporates by reference its answers to all prior paragraphs of the FAMLFC, as if fully set forth herein.

277. Sun denies the allegations contained in Paragraph 277.

278. Sun denies the allegations contained in Paragraph 278.

279. Sun denies the allegations contained in Paragraph 279.

280. Sun denies the allegations contained in Paragraph 280.

281. Paragraph 281 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

282. Paragraph 282 calls for a legal conclusion, to which no response is required. To the extent a response is required, Sun affirmatively states that it complied at all times with all applicable legal duties, laws and regulatory obligations with respect to Docefrez.

283. Sun denies the allegations contained in Paragraph 283.

284. Sun denies the allegations contained in Paragraph 284.

285. Sun denies the allegations contained in Paragraph 285.

286. Sun denies the allegations contained in Paragraph 286.

287. Sun denies the allegations contained in Paragraph 287.

288. Sun denies the allegations contained in Paragraph 288.

289. Sun denies the allegations contained in Paragraph 289.

290. Sun denies the allegations contained in Paragraph 290.

291. Sun denies the allegations contained in Paragraph 291.

292. Sun denies the allegations contained in Paragraph 292.

293. Sun denies the allegations contained in Paragraph 293.

294. Sun denies the allegations contained in Paragraph 294.

295. Sun denies the allegations contained in Paragraph 295.

296. Sun denies the allegations contained in Paragraph 296.

297. Sun denies the allegations contained in Paragraph 297.
298. Sun denies the allegations contained in Paragraph 298.
299. Sun denies the allegations contained in Paragraph 299.
300. Sun denies the allegations contained in Paragraph 300.
301. Sun denies the allegations contained in Paragraph 301.
302. Sun denies the allegations contained in Paragraph 302.
303. Sun denies the allegations contained in Paragraph 303.
304. Sun denies the allegations contained in Paragraph 304.
305. Sun denies the allegations contained in Paragraph 305.
306. Sun denies the allegations contained in Paragraph 306.
307. Sun denies the allegations contained in Paragraph 307.
308. Sun denies the allegations contained in Paragraph 308.
309. Sun denies the allegations contained in Paragraph 309.
310. Sun denies the allegations contained in Paragraph 310. Sun specifically denies that it or its product caused Plaintiffs' alleged injuries and damages, and denies any wrongdoing or liability to Plaintiffs whatsoever.

EIGHTH CLAIM FOR RELIEF

(Breach of Express Warranty –Against Sanofi Related Entities Only)

Sun states that Count 8 of Plaintiffs' FAC was dismissed by the Court in Pretrial Order No. 61, dated September 27, 2017, and therefore no answer is required. Sun further states that Count 8 sets forth claims directed to other Defendants, to which no answer is required. To the extent an answer is required, Sun lacks knowledge or information sufficient to form a belief as to the truth

of allegations contained in Paragraphs 311 – 318 of Plaintiffs' FAMLFC directed to other Defendants, and therefore denies the same.

PRAYER FOR RELIEF

319. Sun denies that it is liable to Plaintiffs in any manner whatsoever, and denies each and every allegation of the Paragraph to the extent said allegations imply any wrongdoing by Sun. Sun further denies Plaintiffs are entitled to any of the relief requested.

JURY DEMAND

320. Sun avers that Paragraph 320 does not contain any factual allegations directed toward Sun, and thus no further response is required.

DEMAND FOR JURY TRIAL

Now comes Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd. and files this JURY DEMAND and requests that this case be set for trial before a jury of twelve persons.

Any allegation heretofore neither admitted nor denied is now hereby expressly denied.

AFFIRMATIVE DEFENSES AND RIGHT TO AMEND

FIRST DEFENSE

Plaintiffs' FAMLFC fails to state a claim of action, or right of action, upon which relief can be granted against Sun.

SECOND DEFENSE

All or part of Plaintiffs' claims may be barred, in whole or in part, by the doctrine of federal preemption pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription medications.

THIRD DEFENSE

The FAMLFC and each and every cause of action asserted therein may be, as a matter of law, preempted in whole or in part by federal law, pursuant to *Mutual Pharmaceuticals. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

FOURTH DEFENSE

Plaintiffs' claims may be barred, in whole in part, by *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), and its progeny.

FIFTH DEFENSE

Sun alleges that jurisdiction over the defendants or over the subject matter may be improper and specifically preserves those exceptions/defenses.

SIXTH DEFENSE

Plaintiffs' claims are subject to dismissal on the grounds that they are barred by the applicable statute of limitations and/or applicable statute of repose.

SEVENTH DEFENSE

Plaintiffs' claims are subject to dismissal because they fail to state with required particularity the circumstances allegedly constituting conspiracy and fraud by Sun as required by the Rules of Civil Procedure.

EIGHTH DEFENSE

Plaintiffs' claims against Sun are barred by laches, waiver, and/or estoppel.

NINTH DEFENSE

The Plaintiffs' claims are barred, in whole or in part, by the Plaintiffs' failure to adequately and appropriately mitigate the alleged damages.

TENTH DEFENSE

Plaintiffs' damages, if any, were proximately caused by unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of Sun. The actions and omissions of Sun, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

ELEVENTH DEFENSE

Sun's conduct was not the proximate or producing cause of Plaintiffs' alleged injuries, if any.

TWELFTH DEFENSE

The benefits of the product outweigh the risk of danger or harm, if any, inherent in the product.

THIRTEENTH DEFENSE

The product that is at issue in this lawsuit was not in an unreasonably dangerous condition.

FOURTEENTH DEFENSE

Sun's product was not defective in manufacture, design or construction and it conformed to all representations made by Sun, if any.

FIFTEENTH DEFENSE

Any and all warnings and information pertaining to the Docefrez product were, at all times relevant to the FAMLFC, in conformity with governmental requirements.

SIXTEENTH DEFENSE

Any communications and/or actions between any of the defendants and the United States Food and Drug Administration and/or any governmental agency or entity are constitutionally

protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

SEVENTEENTH DEFENSE

The product at issue in this lawsuit was sold in a reasonable and prudent manner based upon available medical and scientific knowledge and further were processed in accordance with and pursuant to all applicable regulations of the federal Food and Drug Administration.

EIGHTEENTH DEFENSE

Based on the state of scientific, medical, and technological knowledge at the time the product was marketed, the product at issue in this litigation was reasonably safe for its normal and foreseeable uses. In light of the existing reasonably available medical, scientific, and technological knowledge, the design characteristics, if any, that allegedly caused the damages Plaintiffs complains of, or the alleged risk of such characteristics, could not have been known.

NINETEENTH DEFENSE

If Plaintiffs suffered or sustained any injuries, loss, or damage as a result of the alleged incident referred to in Plaintiffs' FAMLFC, the same were a direct result of Plaintiffs' failure to follow the reasonable advice of her health care providers.

TWENTIETH DEFENSE

The injuries or damages sustained by Plaintiffs, if any, may be attributed to several causes and accordingly should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

TWENTY-FIRST DEFENSE

Sun at all times discharged its duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations consistent with the existing state of medical and scientific knowledge.

TWENTY-SECOND DEFENSE

Plaintiffs' claims based on inadequate warning are barred even if Sun failed to provide adequate warnings with respect to known or potential dangers or risks associated with the use of the product, which is denied, because physicians prescribing the product either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or which should be known to members of the profession.

TWENTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because there is no evidence that Plaintiffs' physician would have heeded a different warning.

TWENTY-FOURTH DEFENSE

If Plaintiffs sustained damages by reason of the matters alleged in the FAMLFC, which is denied, then said damages were caused solely by or contributed to by the acts or fault of third parties and were not caused or contributed to by any acts or fault of Sun, its officers, agents, contractors, servants, employees, or others for whom it was responsible.

TWENTY-FIFTH DEFENSE

Plaintiffs failed to exercise ordinary care under the circumstances in using the product and such failure was the substantial cause of the occurrence that caused injury or damage, if any, to Plaintiffs.

TWENTY-SIXTH DEFENSE

The injuries and damages claimed by Plaintiffs resulted from Plaintiffs' own conduct so that Plaintiffs' claims are barred, in whole or in part, by the comparative negligence, fault, or responsibility of causation attributed to Plaintiffs. Thus, Plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence. Plaintiffs' recovery of damages, if any exist, must be reduced by the comparative negligence and/or fault of Plaintiffs and other persons, including responsible non-parties.

TWENTY-SEVENTH DEFENSE

The injuries and damages claimed by Plaintiffs were caused, in whole or in part, by the acts or omissions of persons other than Sun, over whom Sun had no control. Therefore, any recovery by Plaintiffs should be apportioned in direct proportion to such fault in accordance with applicable law.

TWENTY-EIGHTH DEFENSE

Any injuries or damages sustained by Plaintiffs were directly and proximately caused by the failure of Plaintiffs and/or Plaintiffs' physician to heed warnings and instructions. Therefore, no recovery is available to Plaintiffs.

TWENTY-NINTH DEFENSE

All or part of the claims in this action are barred by the learned intermediary doctrine.

THIRTIETH DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by misuses, abuse, modification, alteration, acts, or omissions of Plaintiffs or third parties over whom Sandoz had no control or

authority, and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

THIRTY-FIRST DEFENSE

Plaintiffs' claims are barred to the extent the injuries alleged in the FAMLFC were caused or enhanced by pre-existing or unrelated medical, genetic, environmental, or psychiatric conditions, diseases or illnesses, by Plaintiffs' own idiosyncratic reactions, and/or by operation of nature.

THIRTY-SECOND DEFENSE

Plaintiffs' claims are barred on the grounds that Plaintiffs knew, or in the exercise of ordinary care should have known, of the risks of the injuries or damages alleged in the FAMLFC, if any, and nevertheless, did freely and voluntarily assume said risks, and in this undertaking proximately caused and contributed to the losses, injuries, or damage, if any, alleged by Plaintiffs.

THIRTY-THIRD DEFENSE

The claims asserted in the Complaint are barred, in whole or in part, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

THIRTY-FOURTH DEFENSE

Sun breached no warranties, either express or implied, which may have existed between it and Plaintiffs.

THIRTY-FIFTH DEFENSE

The express and implied warranties alleged to have been made were expressly disclaimed and excluded by the label; any and all statements made concerning the product referred to in the FAMLFC applied only when used as directed.

THIRTY-SIXTH DEFENSE

Plaintiffs' claims of breach of warranty fail because there was no privity between Plaintiffs and Sun.

THIRTY-SEVENTH DEFENSE

To the extent Plaintiffs seek exemplary or punitive damages, the FAMLFC fails to allege facts sufficient to entitle Plaintiffs to an award of exemplary or punitive damages.

THIRTY-EIGHTH DEFENSE

Plaintiffs' claim for punitive damages cannot be sustained if punitive damages are awarded absent evidence that Sun has engaged in intentionally malicious conduct and had actual knowledge of malicious conduct. Absent such evidence, an award of punitive damages would violate Sun's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and Article I, Section 2 of the Constitution of the State of Louisiana, or any similar provision under any other state's law deemed to apply to the individual Plaintiffs' claims. Plaintiffs' claim for punitive damage cannot be sustained if there is an award of punitive damages by a jury that (1) is not provided standards of sufficient clarity determining the appropriateness and the appropriate size of the punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by applicable standards of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Sun; (4) is permitted to award punitive damages under the standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; or (5) is

not subject to trial-court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards. Accordingly, each of the aforementioned conditions would violate Sun's due process and equal protection rights guaranteed by the Fourteenth Amendment to the United States Constitution and the due process and equal protection provisions of the Constitution of the State of Louisiana, or any similar provisions under any other state's law deemed to apply to the individual Plaintiffs' claims, and would be improper under applicable common law and public policies.

THIRTY-NINTH DEFENSE

As to Plaintiffs' claims for punitive or aggravated damages, Sun specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 123 S. Ct. 1513, 1519, 1521 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007).

FORTIETH DEFENSE

To the extent that the claims stated in the FAMLFC have been settled, compromised, or otherwise discharged, a set off is due.

FORTY-FIRST DEFENSE

Plaintiffs' claims, if any, are barred, reduced and/or limited pursuant to any other applicable limitations of awards, caps on recovery, and setoffs permitted by law, including, but not limited to Louisiana law regarding non-economic loss or injury, and applicable Louisiana law related to amounts paid or provided by collateral sources.

FORTY-SECOND DEFENSE

Sun adopts and relies upon all provisions and defenses afforded it under the United States Constitution and the Louisiana Constitutions.

FORTY-THIRD DEFENSE

Sun affirmatively states that Docefrez is a safe and effective product, that it was reasonable for Sun to place it on the market and that the Docefrez did not cause any injury to the Plaintiffs.

FORTY-FOURTH DEFENSE

Plaintiffs' claims are barred, reduced, and/or limited pursuant to applicable statutory and common laws regarding limitation of awards, caps on recovery, and setoffs. Further, Plaintiffs are not entitled to collect an award of punitive damages because such an award would violate the due process, equal protection, and excessive fines clauses of the Louisiana and United States Constitutions and any similar provisions under any other state's law deemed to apply to the individual Plaintiffs' claims.

FORTY-FIFTH DEFENSE

Sun expressly invokes the procedural provisions authorized by the Louisiana Code of Civil Procedure Chapter 5, and any similar provisions under any applicable state law deemed to apply to the individual Plaintiffs' claims.

FORTY-SIXTH DEFENSE

Sun affirmatively states that any Docefrez sold by Sun was appropriately designed and manufactured, was accompanied by appropriate warnings, was not defective or unreasonably

dangerous, was not negligently designed or manufactured, and Sun did not breach any warranties.

FORTY-SEVENTH DEFENSE

Plaintiffs' claims of fraud are not sufficiently pled as required by Fed.R.Civ.P.9(b).

FORTY-EIGHTH DEFENSE

With respect to each and every purported cause of action, the acts of Sun were at all times done in good faith and without malice.

FORTY-NINTH DEFENSE

Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs did not detrimentally rely upon any statement made by Sun in determining to use Sun's product.

FIFTIETH DEFENSE

Docefrez is a drug listed in the United States Pharmacopoeia and is manufactured, packaged, labeled and/or distributed as prescribed therein and/or in accordance with the Federal Food, Drug and Cosmetic Act and, accordingly, all or part of Plaintiffs' claims are barred.

FIFTY-FIRST DEFENSE

Sun incorporates the defenses of all others who are or may become parties to this action as though more fully set forth herein.

FIFTY-SECOND DEFENSE

Sun reserves the right to amend this answer to raise any and all defenses, affirmative or otherwise, which may become available during the course of this action.

WHEREFORE, defendant, Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd., by counsel, demands:

1. That any and all claims against it in the FAMLFC, be dismissed with prejudice;

2. Its costs herein expended; and
3. Any and all other relief to which it may be entitled.

Dated this 16th day of October, 2017.

Respectfully submitted,

/s/ Geoffrey M. Coan

Geoffrey M. Coan (Bar No. 641998)
Kathleen E. Kelly (Bar No. 637394)
HINSHAW & CULBERTSON LLP
28 State Street, Floor 24
Boston, MA 02109
Telephone: 617-213-7000
Facsimile: 617-213-7001
gcoan@hinshawlaw.com
kekelly@hinshawlaw.com

/s/ Stanton E. Shuler, Jr.

Stanton E. Shuler, Jr. (T.A.) #19152
Cristin F. Bordelon - #29863
E-mail: sshuler@leakeandersson.com
cbordelon@leakeandersson.com

Leake & Andersson, L.L.P.

1100 Poydras Street, Suite 1700
New Orleans, LA 70163-1701
Tel: 504/585-7500
Fax: 504/585-7775

**Counsel for Sun Pharmaceutical Industries, Inc.
f/k/a Caraco Pharmaceutical Laboratories, Ltd.**

CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2017, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification of such filing to all counsel of record.

/s/ Stanton E. Shuler, Jr.