

Gregory S. Gewirtz
LERNER DAVID LLP
20 Commerce Drive
Cranford, NJ 07016
Tel: 908.518.6343
Email: ggewirtz@lernerdavid.com

Attorneys for Defendant Ascent Pharmaceuticals, Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

[illegible]

**DEFENDANT ASCENT PHARMACEUTICALS’
ANSWER TO AMENDED COMPLAINT**

Defendant Ascent Pharmaceuticals Inc. (“Ascent”) hereby provides the following Answer to the corresponding numbered paragraphs set forth in the Amended Complaint of Plaintiff Jazz Pharmaceuticals, Research UK Limited, (collectively “Jazz” or “Plaintiffs”).

For convenience and clarity, this Answer, in some instances, uses language from the headings in the Amended Complaint. Ascent does not admit any allegations contained in such headings.

Ascent denies each and every allegation of the Amended Complaint that is not specifically admitted or qualified below.

RESPONSE TO NATURE OF THE ACTION

1. Ascent admits that this purports to be an action for patent infringement relating to Ascent's ANDA No. 217944, seeking FDA approval to market a certain generic pharmaceutical product before expiration of certain patents identified in that ANDA. Ascent denies infringement. Ascent avers that the remaining allegations of the paragraph are directed to other parties and do not require a response from Ascent; to the extent a response is required Ascent lacks information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

RESPONSE TO NATURE OF THE PARTIES

2. Ascent admits that Epidolex (cannabidiol) is approved by the FDA for certain indications. Ascent lacks information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them

3. Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

4. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

5. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent

lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

6. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

7. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

8. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

9. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

10. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

11. Admitted.

12. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

13. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

14. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

15. The allegations in this paragraph are directed to defendants other than Ascent and do not require a response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

RESPONSE TO PATENTS-IN-SUIT

16. Ascent admits that a copy of the '330 Patent is attached as an Exhibit to the Complaint and avers that the patent speaks for itself in terms of its title, named inventors, and date of issue. Ascent lacks information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

17. Ascent admits that a copy of the '441 Patent is attached as an Exhibit to the Complaint and avers that the patent speaks for itself in terms of its title, named inventors, and date of issue. Ascent lacks information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

18. Ascent admits that a copy of the '102 Patent is attached as an Exhibit to the Complaint and avers that the patent speaks for itself in terms of its title, named inventors, and date of issue. Ascent lacks information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

The Epidiolex® Drug Product

19. Ascent lacks information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

20. Ascent admits that the '330, '411, and '102 patents are listed in the Orange Book with respect to Epidiolex and denies any remaining allegations in this paragraph.

RESPONSE TO JURISDICTION AND VENUE AS TO APOTEX

21-29. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO JURISDICTION AND VENUE
AS TO INVAGEN, CIPLA AND API PHARMA**

30-74. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

RESPONSE TO JURISDICTION AND VENUE AS TO LUPIN

75-83. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

RESPONSE TO JURISDICTION AND VENUE AS TO TARO

84-94. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

RESPONSE TO JURISDICTION AND VENUE AS TO ASCENT

95. Ascent admits that this Court has subject matter jurisdiction over this action against Ascent and denies any remaining allegation in this paragraph.

96. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

97. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

98. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

99. The allegations in this paragraph are directed to future events and cannot be admitted or denied and therefore require no response; to the extent a response is required, they are denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

100. Admitted.

101. Ascent avers that its allegations in other litigations speak for themselves and have no bearing on this case and denies the allegations in this paragraph. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

102. Admitted.

103. Denied. Nevertheless, Ascent does not contest venue for the purpose of this action only.

**RESPONSE TO JURISDICTION AND VENUE AS TO
MSN PHARMACEUTICALS AND MSN LABS**

104-121. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO JURISDICTION AND
VENUE AS TO BIOPHORE AND ZENARA**

122-137. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO ACTS GIVING RISE TO
COUNTS I AND II AGAINST APOTEX**

138-141. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO ACTS GIVING RISE TO COUNTS III, IV, AND V
AGAINST INVAGEN, CIPLA, AND API PHARMA**

142-148. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO ACTS GIVING RISE TO
COUNTS VI AND VII AGAINST LUPIN**

149-153. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO ACTS GIVING RISE TO
COUNTS VIII, IX, AND X AGAINST TARO**

154-159. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO ACTS GIVING RISE TO
COUNTS XI, XII, AND XIII AGAINST ASCENT**

160. Ascent admits that it submitted ANDA 217944 to the FDA, avers that its ANDA speaks for itself, and denies any remaining allegation in this paragraph.

161. Ascent admits that it sent a Notice Letter on or about December 6, 2022, avers that the Notice Letter speaks for itself, and denies the remaining allegations in this paragraph.

162. Ascent admits that it provided a Paragraph IV certification with regard to certain Orange Book patents in connection with its ANDA, avers that the ANDA speaks for itself, and denies the remaining allegations in this paragraph.

163. The allegations in this paragraph are directed to future events and cannot be admitted or denied; to the extent a response is required at this time, they are denied.

**RESPONSE TO ACTS GIVING RISE TO
COUNTS XIV AND XV AGAINST MSN**

164-169. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO ACTS GIVING RISE TO COUNTS XVI,
XVII, AND XVIII AGAINST BIOPHORE AND ZENARA**

170-175. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT I: INFRINGEMENT
OF THE '330 PATENT BY APOTEX**

176-183. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT II: INFRINGEMENT
OF THE '102 PATENT BY APOTEX**

184-191. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT III: INFRINGEMENT OF
THE '330 PATENT BY INVAGEN, CIPLA AND API PHARMA**

192-199. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT IV: INFRINGEMENT OF
THE '411 PATENT BY INVAGEN, CIPLA AND API PHARMA**

200-207. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT V: INFRINGEMENT OF
THE '102 PATENT BY INVAGEN, CIPLA AND API PHARMA**

208-215. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT VI: INFRINGEMENT
OF THE '330 PATENT BY LUPIN**

216-223. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT VII: INFRINGEMENT
OF THE '102 PATENT BY LUPIN**

224-231. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT VIII: INFRINGEMENT
OF THE '330 PATENT BY TARO**

232-239. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT IX: INFRINGEMENT
OF THE '411 PATENT BY TARO**

240-247. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT X: INFRINGEMENT
OF THE '102 PATENT BY TARO**

248-255. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT XI: INFRINGEMENT OF
THE '330 PATENT BY ASCENT**

256. In response to this paragraph, Ascent repeats and realleges the preceding paragraphs of this Answer as if fully set forth herein.

257. Denied.

258. Admitted.

259. Denied.

260. Denied.

261. Denied.

262. Denied.

263. Denied.

**RESPONSE TO COUNT XII: INFRINGEMENT OF
THE '411 PATENT BY ASCENT**

264. In response to this paragraph, Ascent repeats and realleges the preceding paragraphs of this Answer as if fully set forth herein.

265. Denied.

266. Admitted.

267. Denied.

268. Denied.

269. Denied.

270. Denied.

271. Denied.

**RESPONSE TO COUNT XIII: INFRINGEMENT OF
THE '102 PATENT BY ASCENT**

272. In response to this paragraph, Ascent repeats and realleges the preceding paragraphs of this Answer as if fully set forth herein.

273. Denied.

274. Admitted.

275. Denied.

276. Denied.

277. Denied.

278. Denied.

279. Denied.

**RESPONSE TO COUNT XIV: INFRINGEMENT OF
THE '330 PATENT BY MSN**

280-287. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT XV: INFRINGEMENT OF
THE '102 PATENT BY MSN**

288-295. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT XVI: INFRINGEMENT OF
THE '330 PATENT BY BIOPHORE AND ZENARA**

296-303. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT XVII: INFRINGEMENT OF
THE '411 PATENT BY BIOPHORE AND ZENARA**

304-311. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

**RESPONSE TO COUNT XVIII: INFRINGEMENT OF
THE '102 PATENT BY BIOPHORE AND ZENARA**

312-319. The allegations in these paragraphs are directed to other defendants and require no response from Ascent; to the extent a response is required, Ascent lacks information sufficient to form a belief as to their truth and therefore denies them.

RESPONSE TO “PRAYER FOR RELIEF”

Ascent denies that Plaintiff is entitled to any relief requested in the Amended Complaint or to any other relief whatsoever.

FIRST AFFIRMATIVE DEFENSE

Ascent has not, and will not, infringe directly, by contribution or by inducement, literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit.

SECOND AFFIRMATIVE DEFENSE

One or more claims of the patents-in-suit are invalid and/or unenforceable for failure to comply with one or more statutory or judicial requirements, including but not limited to the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

One or more counts of the Amended Complaint is subject for dismissal for failure to state a claim.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to injunctive relief, at least because any alleged injury to Plaintiff is not immediate or irreparable, because Plaintiff has an adequate remedy at law, and because public policy concerns weigh against any injunctive relief.

FIFTH AFFIRMATIVE DEFENSE

Ascent reserves all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws, and any additional defenses that discovery may reveal, including that Plaintiff has failed to aver any factors supporting the conclusion that this is an exceptional case or that an award of attorney's fees under 35 U.S.C. § 285 is warranted.

PRAYER FOR RELIEF

WHEREFORE, Defendant Ascent Pharmaceuticals Inc. respectfully prays for judgment as follows:

- a) Dismissing the Amended Complaint with prejudice; denying Plaintiff the relief requested in the Complaint and any relief whatsoever.
- b) Awarding Ascent its reasonable attorney's fees under 35 U.S.C. § 285.
- c) Awarding Ascent its costs; and
- d) Awarding Ascent such other and further relief as the Court deems just and equitable.

Respectfully submitted,

Dated: August 14, 2024

By: s/ Gregory S. Gewirtz

Gregory S. Gewirtz
LERNER DAVID LLP
20 Commerce Drive
Cranford, NJ 07016
Tel: 908.654.5000
ggewirtz@lernerdavid.com
litigation@lernerdavid.com

OF COUNSEL
Sri K. Sankaran (*pro hac vice pending*)
Padmanabhan & Dawson, PLLC
9800 Shelard Parkway, Suite 120
Minneapolis, MN 55441
Tel: 612.444.3768
sri@paddalawgroup.com

*Attorneys for Defendant
Ascent Pharmaceuticals, Inc.*