## IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ANACOR PHARMACEUTICALS, INC.,	)
Plaintiff,	)
V.	) Civil Action No. 18-202-IMK )
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)
Defendants.	)

# ANSWER TO COUNTERCLAIMS OF MYLAN PHARMACEUTICALS INC.

Plaintiff and Counterclaim Defendant Anacor Pharmaceuticals, Inc. ("Anacor"), by its attorneys, hereby answers the counterclaims of Defendant and Counterclaim Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), *see* D.I. 21, using the paragraph numbers of Mylan's Counterclaims, as follows:

#### **COUNTERCLAIMS**

In response to the unnumbered paragraph under the heading "COUNTERCLAIMS" on page 17 of Mylan's Answer to Plaintiff's Complaint and Counterclaims, Anacor admits that Mylan purports to assert counterclaims seeking a declaratory judgment that the claims of U.S. Patent Nos. 9,459,938 ("the '938 patent"), 9,566,289 ("the '289 patent"), 9,566,290 ("the '290 patent"), and 9,572,823 ("the '823 patent") (collectively, "the patents-in-suit") are invalid, but denies that Mylan is entitled to a declaratory judgment of invalidity, or to any other relief whatsoever.



#### **PARTIES**

- 1. In its Complaint, Anacor pleaded the allegations recited in Paragraph 1 based on information and belief. Mylan admitted the truth of those allegations in its Answer to Anacor's Complaint. Anacor therefore admits the allegations of Paragraph 1.
  - 2. Anacor admits the allegations of Paragraph 2.

#### **NATURE OF THE ACTION**

3. Anacor admits that Mylan purports to seek declaratory judgments that the claims of the patents-in-suit are invalid, but denies that Mylan is entitled to a declaratory judgment of invalidity, or to any other relief whatsoever.

#### **JURISDICTION AND VENUE**

- 4. The allegations of Paragraph 4 set forth legal conclusions to which no response is required.
- 5. The allegations of Paragraph 5 set forth legal conclusions to which no response is required.
- 6. The allegations of Paragraph 6 set forth legal conclusions to which no response is required.
- 7. The allegations of Paragraph 7 set forth legal conclusions to which no response is required.

#### **BACKGROUND**

- 8. Anacor admits the allegations of Paragraph 8.
- 9. Anacor admits the allegations of Paragraph 9.
- 10. Anacor admits the allegations of Paragraph 10.



- 11. Anacor admits that Mylan notified Anacor by letter dated September 17, 2018 ("Mylan's Notice Letter") that Mylan had submitted to the FDA ANDA No. 212065 ("Mylan's ANDA"), which purportedly seeks approval to engage in the commercial manufacture, use and/or sale of Mylan's generic tavaborole topical solution ("Mylan's ANDA Product"). Anacor lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 11.
- 12. Anacor admits that Mylan's Notice Letter informed Anacor, in writing, that Mylan's ANDA had been submitted to the FDA with certifications alleging that the patents-insuit are invalid, unenforceable, and/or will not be infringed by Mylan's ANDA Product. The remaining allegations of Paragraph 12 set forth legal conclusions to which no response is required. To the extent a response is required, Anacor denies those allegations.
- 13. Anacor admits that Mylan's Notice Letter included a statement of the purported factual and legal bases for Mylan's alleged certification that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by Mylan's ANDA Product. The remaining allegations of Paragraph 13 set forth legal conclusions to which no response is required. To the extent a response is required, Anacor denies those allegations.
  - 14. Anacor admits the allegations of Paragraph 14.

#### COUNT 1

#### Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,459,938

- 15. Anacor incorporates each of the preceding paragraphs 1–14 as if fully set forth herein.
  - 16. Anacor admits the allegations of Paragraph 16.



- 17. Anacor admits that Paragraph 17 purports to state Mylan's contentions with regard to the '938 patent, but denies those contentions and denies that Mylan is entitled to a judgment of noninfringement or invalidity of the '938 patent, or to any other relief whatsoever.
- 18. Anacor admits that it asserts that Mylan's ANDA Product will infringe the claims of the '938 patent, and that it is seeking a judgment that would prohibit Mylan from manufacturing, using, offering for sale, and selling Mylan's ANDA Product until after the expiration of the '938 patent. Anacor denies that by doing so, it is "interfer[ing]" with any legitimate business objective of Mylan. The remaining allegations of Paragraph 18 purport to state Mylan's subjective belief as to what will happen in the future "[u]nless Counterclaim Defendant is enjoined." Anacor lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 18.
  - 19. Anacor denies the allegations of Paragraph 19.
- 20. The allegations of Paragraph 20 state legal conclusions to which no response is required. To the extent a response is required, Anacor denies that the '938 patent is invalid and denies that Mylan is entitled to a declaratory judgment of invalidity, or to any other relief whatsoever.
  - 21. Anacor denies the allegations of Paragraph 21.

#### COUNT 2

#### Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,566,289

- 22. Anacor incorporates each of the preceding paragraphs 1–21 as if fully set forth herein.
  - 23. Anacor admits the allegations of Paragraph 23.



- 24. Anacor admits that Paragraph 24 purports to state Mylan's contentions with regard to the '289 patent, but denies those contentions and denies that Mylan is entitled to a judgment of noninfringement or invalidity of the '289 patent, or to any other relief whatsoever.
- 25. Anacor admits that it asserts that Mylan's ANDA Product will infringe the claims of the '289 patent, and that it is seeking a judgment that would prohibit Mylan from manufacturing, using, offering for sale, and selling Mylan's ANDA Product until after the expiration of the '289 patent. Anacor denies that by doing so, it is "interfer[ing]" with any legitimate business objective of Mylan. The remaining allegations of Paragraph 25 purport to state Mylan's subjective belief as to what will happen in the future "[u]nless Counterclaim Defendant is enjoined." Anacor lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 25.
  - 26. Anacor denies the allegations of Paragraph 26.
- 27. The allegations of Paragraph 27 state legal conclusions to which no response is required. To the extent a response is required, Anacor denies that the '289 patent is invalid and denies that Mylan is entitled to a declaratory judgment of invalidity, or to any other relief whatsoever.
  - 28. Anacor denies the allegations of Paragraph 28.

#### COUNT 3

#### Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,566,290

- 29. Anacor incorporates each of the preceding paragraphs 1–29 as if fully set forth herein.
  - 30. Anacor admits the allegations of Paragraph 30.



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