

v.

PAR PHARMACEUTICAL COMPANIES, INC.,  
and PAR PHARMACEUTICAL, INC.,

Defendants

**DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND  
PAR PHARMACEUTICAL, INC.'S ANSWER AND SEPARATE DEFENSES**

Defendants Par Pharmaceutical, Inc. (“Par Pharmaceutical”) and Par Pharmaceutical Companies, Inc. (“Par Companies”)<sup>1</sup> (collectively, “Par.”), by and through their attorneys, for their Answer to the Complaint of Plaintiff Takeda Pharmaceuticals U.S.A., Inc. (“Takeda” or “Plaintiff”), hereby respond as follows:

**NATURE OF THE ACTION**

1. Par admits that the Complaint purports to be an action for patent infringement arising under the Food and Drug and Patent Laws of the United States, U.S.C. Titles 21 and 35 respectively, arising from Par Pharmaceutical’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”), seeking approval to sell commercially a generic version of the drug product COLCRYS® (colchicine, USP) prior to the expiration of United States Patent Nos. 7,906,519, 7,935,731, 8,093,298,

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<sup>1</sup> Par states that the definitions of Par Pharma and Par Pharma, Inc. in the Plaintiff’s Complaint are confusing. Par will use the terms “Par Companies” and “Par Pharmaceutical” instead of, respectively, “Par Pharma” and “Par Pharma, Inc.”

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2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business of Takeda. Par is also without knowledge and information sufficient to form a belief as to whether Takeda owns the entire right, title, and interest in each patent asserted in this action. Par thus denies all allegations of Paragraph 2.

3. Par avers that Par Companies is a Delaware corporation and is in the business of, *inter alia*, making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Par avers that Par Companies has its principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

4. Par avers that Par Pharmaceutical is a Delaware corporation and is in the business of, *inter alia*, making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. Par avers that Par Pharmaceutical has its principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Par admits that Par Pharmaceutical is a wholly-owned subsidiary of Par Companies. Par denies the remaining allegations of Paragraph 5.

6. Par denies the allegations of Paragraph 6.

JURISDICTION AND VENUE

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Par states that for this action only Par Pharmaceuticals does not dispute that this Court has jurisdiction over the subject matter of this action with respect to Par

Par Companies.

8. Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Companies is a Delaware corporation, that it regularly does business in this district by selling generic pharmaceutical products. Par admits that Par Companies has previously consented to the personal jurisdiction in this District and has asserted counterclaims in other actions initiated in this jurisdiction. Par Companies denies the remaining allegations of Paragraph 8.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that Par Pharmaceutical is a Delaware corporation, and regularly does business in this district by selling generic pharmaceutical products. Par admits that Par Pharmaceutical has previously consented to personal jurisdiction in this District, and has asserted counterclaims in other actions initiated in this District. Par Pharmaceutical further admits that for the limited purposes of this action only, Par Pharmaceutical does not contest personal jurisdiction of this Court. Par Pharmaceutical denies the remaining allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, for the limited purpose of this action only, Par Pharmaceutical does not contest venue in this judicial district. Par denies that venue is proper in this District as to Par Companies.

12. Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Par admits the allegations of Paragraph 12.

13. Paragraph 13 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 13.

14. Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the FDA approved COLCRYS® for marketing in the United States.

#### **THE COLCRYS® PATENTS**

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Par is without knowledge and information sufficient to form a belief as to whether Takeda is the lawful owner of all right, title, and interest in the following patents, including the right to sue and to recover for infringement thereof, and whether said patents contain one or more claims covering methods of use of COLCRYS®. Par thus denies all allegations of Paragraph 15.

A. Par admits a document which appears to be the '519 patent is attached to the complaint as Exhibit A; that the '519 patent, on its face, is titled "METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT," states the date of issue as March 15, 2011, and names Matthew Davis as the inventor. Par denies that the '519 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 15(A).

ANTIBIOTICS,” and names Matthew Davis as the inventor. Par denies that the ’731 patent was duly and legally issued on May 11, 2011. Par denies any remaining allegations of Paragraph 15(B).

C. Par admits that a document which appears to be the ’298 patent is attached to the Complaint as Exhibit C; that the ’298 patent, on its face, states the date of issue as January 10, 2012, and names Matthew Davis as the inventor. Par denies that the ’298 patent is entitled “METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A MACROLIDE ANTIGIOTICS,” and that it was duly and legally issued. Par denies any remaining allegations of Paragraph 15(C).

D. Par admits that a document which appears to be the ’648 patent is attached to the Complaint as Exhibit D; that the ’648 patent, on its face, is titled “METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT,” states the date of issue as June 21, 2011, and names Matthew Davis as the inventor. Par denies that the ’648 patent was duly and legally issued. Par denies any remaining allegations of Paragraph 15(D).

E. Par admits that a document which appears to be the ’297 patent is attached to the Complaint as Exhibit E; that the ’297 patent, on its face, is entitled “METHODS FOR CONCOMITANT ADMINISTRATION OF COLCHICINE AND A SECOND ACTIVE AGENT,” states the date of issue as January 10, 2012, and names Matthew Davis as the inventor.

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