

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

WARNER CHILCOTT COMPANY, LLC and	)	
HOFFMANN-LA ROCHE INC.,	)	
<i>Plaintiffs,</i>	)	C.A. No. 08-627-LPS
v.	)	
SUN PHARMA GLOBAL FZE,	)	(Member Case C.A. No. 10-1085-LPS)
<i>Defendant.</i>	)	
	)	

**SUN PHARMA GLOBAL FZE ANSWER AND AFFIRMATIVE DEFENSES TO  
AMENDED COMPLAINT**

Defendant, Sun Pharma Global FZE (“Sun”) hereby responds to the allegations of the Amended Complaint as follows:

To the extent that the “Nature of the Action” constitutes allegations requiring a response, Sun admits the first sentence and the last sentence, admits that this action relates to ANDA No. 90-886, but denies the remaining allegations.

To the extent that the “Related Actions” constitute allegations requiring a response, Sun admits that the actions listed are related to this action, admits this action was previously consolidated with the listed actions, but otherwise denies the remaining allegations.

1. Sun is without sufficient knowledge or information to form a belief about the truth of this allegation, and thus denies the same.
2. Sun is without sufficient knowledge or information to form a belief about the truth of this allegation, and thus denies the same.
3. Admitted.
4. Sun admits that this Court has subject matter jurisdiction over Plaintiffs’ patent infringement claims under 28 U.S.C. §§ 1331, and 1338(a). Sun denies that this Court has

subject matter jurisdiction under 28 U.S.C. §1400(b), which is a venue statute. Sun denies that this Court has subject matter jurisdiction under 28 U.S.C. §§ 2201 and 2202.

5. Sun consents to personal jurisdiction in this jurisdiction for purposes of this lawsuit only, but otherwise denies the remainder of the allegations in this paragraph.

6. Sun admits that it is now the owner of ANDA No. 90-886. Sun consents to personal jurisdiction for purposes of this lawsuit only, but otherwise denies that its ownership and/or filing of ANDA No. 90-886 or alleged harm to Plaintiffs constitute grounds for this court to exercise personal jurisdiction over Sun.

7. Sun consents to venue in this district for purposes of this lawsuit only, but otherwise denies the remainder of the allegations of this paragraph.

8. Sun is without knowledge sufficient to form a belief as to the first sentence of this paragraph and denies the same. Sun admits the second sentence.

9. Sun is without knowledge sufficient to form a belief as to the allegations of this paragraph and denies the same.

10. Sun is without sufficient knowledge or information to form a belief about the ownership of the '634 patent, and denies those allegations. Sun admits that a copy of what purports to be the '634 patent is attached to the Amended Complaint as Exhibit A. Sun denies that the '634 patent was duly and legally issued and denies that the claims of the '634 patent are valid and enforceable. To the extent, if any, that Sun has not responded to all of the allegations in this paragraph, any remaining allegations are denied.

11. Sun is without sufficient knowledge or information to form a belief about the ownership or licensing of the '634 patent, and denies those allegations.

12. Sun admits that its predecessor in interest in ANDA No. 90-886 sent a letter to Proctor & Gamble and Roche dated December 12, 2008, which provided notice that Sun Pharma Global, Inc. had submitted ANDA No. 90-886 to the FDA under 21 U.S.C. § 355(j) with a Paragraph IV certification. Sun admits that it intends to market the product defined by ANDA No. 90-886 upon final FDA approval. Sun denies the remaining allegations of this paragraph.

13. Sun admits that by filing ANDA No. 90-886, Sun submitted to FDA any required bioavailability and/or bioequivalence data. Sun denies any remaining allegations of this paragraph.

14. Sun admits that in the Notice letter, Sun notified Proctor & Gamble and Roche that ANDA No. 90-886 was submitted under 21 U.S.C. § 355(j)(1) and (2)(A) with Paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of risedronate sodium tablets before the expiration of the '634 patent, which is alleged to be invalid and/or not infringed. Sun denies any remaining allegations of this paragraph.

15. Admitted.

16. Sun incorporates its responses to paragraphs 1-15 as if fully set forth.

17. Denied.

18. Denied.

19. Denied.

### **AFFIRMATIVE DEFENSES**

#### **FIRST AFFIRMATIVE DEFENSE**

The claims of the '634 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

**Prayer for Relief**

WHEREFORE, Sun prays for relief as follows:

- (a) A judgment that the claims of the '634 Patent are invalid and thus will not be infringed by the product for which approval is sought in ANDA No. 90-886;
- (b) Reasonable costs of suit incurred by Sun in this action; and
- (c) Such further and other relief as this Court deems proper and just.

Dated: August 10, 2011

PHILLIPS, GOLDMAN & SPENCE, P.A.

/s/ John C. Phillips, Jr.

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