

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIRE LLC et al.,	:	
	:	
Plaintiffs	:	
	:	C.A. No. 2:11-cv-03781-SRC-CLW
v.	:	(CONSOLIDATED)
	:	
AMNEAL PHARMACEUTICALS LLC et al.,	:	
	:	
Defendants.	:	

~~[PROPOSED]~~ ORDER FOR
FINAL JUDGMENT UNDER FED. R. CIV. P. 54(B)
AND STAY OF FURTHER PROCEEDINGS PENDING APPEAL

This is an action for patent infringement having been brought by Plaintiffs Shire LLC and Shire Development LLC ("Plaintiffs") against Defendants Actavis LLC and Actavis Elizabeth LLC (collectively "Actavis"), Amneal Pharmaceuticals, LLC ("Amneal"), Johnson Matthey Pharmaceutical Materials and Johnson Matthey Inc. (collectively "JM"), Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively "Mylan"), Roxane Laboratories Inc. ("Roxane"), and Sandoz Inc. ("Sandoz") (all of the defendants are collectively "Defendants," and collectively with Plaintiffs, the "Parties").

On June 23, 2014 the Court issued its Opinion and Order, finding that all of the asserted claims of U.S. Patent Nos. 7,655,630 ("the '630 patent"), 7,659,253 ("the '253 patent"), and 7,662,787 ("the '787 patent"), and one of the asserted claims (claim 4) of U.S. Patent No. 7,105,486 ("the '486 patent") were infringed and not invalid (ECF Nos. 698, 699), which adjudicated all of the claims, counterclaims, and affirmative defenses asserted by the Parties concerning such patent claims.

AND THE PARTIES' HAVING
AGREED THAT CERTIFICATION OF THE COURT'S GRANT OF
SUMMARY JUDGMENT IS APPROPRIATE FOR CERTIFICATION AS
FINAL UNDER FRCP 54(b), AND THE PARTIES' HAVING FAILED
TO AGREE AS TO THE APPROPRIATE FORM OF ORDER, AND THE
COURT HAVING CONSIDERED THE PARTIES' SUBMISSIONS,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED:

1. This Court has jurisdiction over the Parties and subject matter of this action.
2. This Court, having considered the concerns of judicial economy, for the reasons stated herein and in the Court's June 23, 2014 Opinion and Order (ECF Nos. 698, 699), finds that said Opinion and Order is effectively a final adjudication of Plaintiffs' claims of patent infringement against each Defendant as to all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and one of the asserted claims (claim 4) of the '486 patent, and of each Defendant's affirmative defenses and/or counterclaims as to such claims, and that pursuant to Federal Rule of Civil Procedure 54(b) there is no just reason for delay in entering a final judgment that allows for an appeal of this ruling.
3. JUDGMENT is hereby entered under Federal Rule of Civil Procedure 54(b) in favor of Plaintiffs and against each Defendant as to all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and one of the asserted claims (claim 4) of the '486 patent.
4. All further proceedings in this Court, pending the outcome on appeal, are STAYED without waiver or prejudice. The Parties will be allowed to assert their claims, counterclaims, and affirmative defenses if this matter is remanded for further consideration to the extent applicable following remand.
5. ORDERED that pursuant to 35 U.S.C. section 271(e)(4)(A) the effective date of any approval of Actavis's Abbreviated New Drug Application ("ANDA") No. 202802 be a date which is not earlier than the date of the expiration, including any

extensions by FDA, of the later of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.

~~6. ORDERED that pursuant to 35 U.S.C. section 271(e)(4) Actavis shall be enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the drug in ANDA No. 202802 until the earlier of either (i) the date on which the United States Court of Appeals for the Federal Circuit decides that all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are invalid or not infringed, or (ii) the date of the expiration of the later of said patents.~~

7. ORDERED that pursuant to 35 U.S.C. section 271(e)(4)(A) the effective date of any approval of Amneal's ANDA No. 202830 be a date which is not earlier than the later of the date of the expiration, including any extensions by FDA, of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.

~~8. ORDERED that pursuant to 35 U.S.C. section 271(e)(4) Amneal shall be enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the drug in ANDA No. 202830 until the earlier of either (i) the date on which the United States Court of Appeals for the Federal Circuit decides that all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are invalid or not infringed, or (ii) the date of the expiration of the later of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.~~

9. ORDERED that pursuant to 35 U.S.C. section 271(e)(4)(A) the effective date of any approval of Mylan's ANDA No. 202835 be a date which is not earlier than

the date of the later of the expiration, including any extensions by FDA, of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.

~~10. ORDERED that pursuant to 35 U.S.C. section 271(e)(4) Mylan shall be enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the drug in ANDA No. 202835 until the earlier of either (i) the date on which the United States Court of Appeals for the Federal Circuit decides that all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are invalid or not infringed, or (ii) the date of the expiration of the later of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.~~

11. ORDERED that pursuant to 35 U.S.C. section 271(e)(4)(A) the effective date of any approval of Roxane's ANDA No. 202827 be a date which is not earlier than the date of the later of the expiration, including any extensions by FDA, of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.

~~12. ORDERED that pursuant to 35 U.S.C. section 271(e)(4) Roxane shall be enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the drug in ANDA No. 202827 until the earlier of either (i) the date on which the United States Court of Appeals for the Federal Circuit decides that all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are invalid or not infringed, or (ii) the date of the expiration of the later of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.~~

13. ORDERED that pursuant to 35 U.S.C. section 271(e)(4)(A) the effective date of any approval of Sandoz's ANDA No. 202836 be a date which is not earlier than the date of the later of the expiration, including any extensions by FDA, of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.

~~14. ORDERED that pursuant to 35 U.S.C. section 271(e)(4) Sandoz shall be enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the drug in ANDA No. 202836 until the earlier of either (i) the date on which the United States Court of Appeals for the Federal Circuit decides that all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are invalid or not infringed, or (ii) the date of the expiration of the later of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.~~

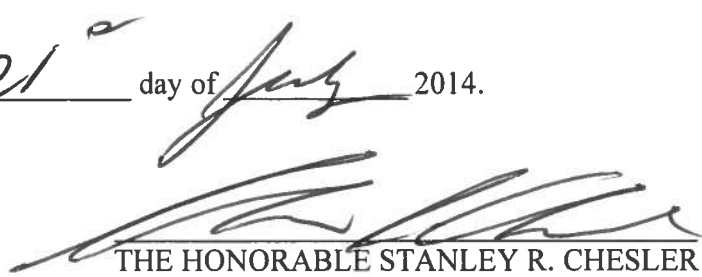
~~15. ORDERED that JM shall be enjoined from commercially making, using, offering to sell, or selling into the United States the active pharmaceutical ingredient ("API") in JM's DMF No. 22442 in support of the drugs in Actavis's, Amneal's, Mylan's, Roxane's, and Sandoz's ANDAs until the earlier of either (i) the date on which the United States Court of Appeals for the Federal Circuit decides that all of the asserted claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are invalid or not infringed, or (ii) the date of the expiration of the later of the '630 patent, the '253 patent, the '787 patent, and the '486 patent.~~

~~16. ORDERED that Actavis, Amneal, Mylan, Roxane, and Sandoz each promptly inform the FDA of the Court's summary judgment Opinion and Order and that, for their respective ANDAs, a final judgment has been entered that all of the asserted~~

~~claims of the '630 patent, the '253 patent, and the '787 patent, and claim 4 of the '486 patent are infringed and not invalid, and provide confirmation of such communication to Plaintiffs within seven days thereof.~~

17. This Court shall retain jurisdiction of these actions and over the Parties for purposes of enforcement of the provisions of this Judgment and Order, and for all remaining asserted claims, defenses, and counterclaims in these actions.

IT IS SO ORDERED this 21st day of July 2014.


THE HONORABLE STANLEY R. CHESLER
UNITED STATES DISTRICT JUDGE