UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Broward Division

HOECHST MARION ROUSSEL, INC. And CARDERM CAPITAL, L.P.,	
Plaintiffs and Counterclaim Defendants	
v.	
ANDRX PHARMACEUTICALS, INC.	96-06121-Civ-Roettger
Defendant and Counterclaim Plaintiff	Magistrate Judge Seltzer
v.	
HOECHST AG,	
Third Party Counterclaim Defendant	

Stipulation

This matter having come before the Court on the pleadings of record, and it being represented that the above-entitled action has been settled on the following bases, the parties hereto stipulate, agree, and represent

1. On September 22, 1995, Andrx filed Abbreviated New Drug Application ("ANDA") 74-752 with the U.S. Food and Drug Administration ("FDA") seeking FDA approval

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to manufacture and sell a generic form of Cardizem® CD, a cardiovascular drug manufactured and sold by HMRI.

2. On December 30, 1995, Andrx certified to HMRI that the product reflected in ANDA 74-752 did not infringe patents owned or controlled by HMRI or its affiliates as anticipated by 21 U.S.C. Section 355(j)(2)(A)(vii)(IV).

3. On January 31, 1996, HMRI filed this action against Andrx alleging Andrx's infringement with United States Patent No. 5,470,584 ("the '584 patent").

4. HMRI and Andrx have diligently prosecuted and defended this action;

5. HMRI believes and continues to assert that the formulation of the Andrx product identified in the complaint in this action did and continues to infringe the relevant HMRI patent, and Andrx believes and continues to assert that it does not or that such patent is invalid;

6. On September 11, 1998, Andrx filed a Supplement to ANDA 74-752 (the "Supplement") with the FDA reflecting a reformulation of the product that Andrx intends to sell, ("the Reformulated Product"), which the parties hereto agree is an authorized supplementation of ANDA 74-752 and which, among other things, provided for a modification in formulation and the dissolution specification for one of the intermediates for the product — diltiazem hydrochloride extended-release SR2 pellets.

7. On February 3, 1999, Andrx certified to HMRI that the Reformulated Product reflected in the Supplement does not infringe patents owned or controlled by HMRI or its affiliates as anticipated by 21 U.S.C. Section 355(j)(2)(A)(vii)(IV).

8. Without waiving or compromising to any extent its defenses in this action or otherwise and without to any extent conceding that any patent in suit is valid or that any Andrx

product violates any said patent, Andrx, having received or believing it is about to receive FDA approval for the Reformulated Product, intends to commence marketing of the Reformulated Product following receipt of such approval and in such event (unless Andrx has obtained a license from HMRJ to market a Cardizem CD product prior to that time ("Prior Licensing")) shall not market in the United States its earlier version of said product, inventories of which shall have been or shall be destroyed except as may otherwise be required by law.

9. In light of the representations and agreements of the parties as recited herein, the parties believe that they can avoid further litigation over the Reformulated Product and promote the prompt commencement of marketing by Andrx of the Reformulated Product pursuant to ANDA 74-752 as more fully described herein.

10. Andrx stipulates and agrees that, upon approval by the FDA of the Reformulated Product (unless Prior Licensing has occurred), Andrx presently intends to manufacture and sell in the United States a Reformulated Product that incorporates SR2 pellets having dissolution values substantially the same as the values set forth in the data sheets which accompanied Andrx's letter to HMRJ dated October 7, 1998. For the purpose of this Stipulation, SR2 pellets shall be deemed to have substantially the same values as set forth in said data sheets if the average dissolution of a single batch of SR2 pellets at 18 hours is not less than 68% (the "Applicable Dissolution Values").

11. HMRJ stipulates and agrees that, irrespective of the dismissal of this action, neither it nor its affiliates shall initiate or prosecute any action, claim or proceeding directly or indirectly alleging patent infringement with respect to the Reformulated Product or seek to enjoin Andrx from manufacturing or marketing the Reformulated Product or seek any damages or other

terminate as of June 1, 1999, and the period for taking a license under Paragraph 6(A)(i) shall

remedy on account of such manufacturing or marketing, whether in a new action or in this action provided that the Applicable Dissolution Values are met or exceeded. The parties agree that Andrx is free to amend, modify, or supplement the Supplement, in which event nothing in this Stipulation precludes HMRI from asserting that the change constituting the amendment, modification, or supplementation infringes its patents, except that HMRI shall be precluded from asserting that any said product infringes based on the dissolution values of the SR2 pellets if said product meets or exceeds the Applicable Dissolution Values.

12. Without to any extent limiting the foregoing, before HMRI initiates any action, claim, or proceeding against Andrx, including without limitation on the grounds that the SR2 pellets contained in the Reformulated Product do not meet or exceed the Applicable Dissolution Values, HMRI shall provide Andrx with at least 30 days prior express written notice of said alleged breach together with full particulars of the alleged grounds of the breach and the bases on which HMRI believes that breach has occurred. To the extent that Andrx cures the alleged breach within 30 days of receiving such notice (or such other longer period as HMRI in writing expressly consents), such cure shall be deemed full compliance (retroactive to the date of the first asserted default).

13. The parties further stipulate and agree that this action, together with all claims and counterclaims set forth in the pleadings herein, are hereby dismissed. Approval by the FDA of the Reformulated Product shall constitute Final Judgment under the Stipulation and Agreement between the parties dated September 24, 1997 provided however that the periods for calculating payments pursuant to Paragraphs 3(B) and 4(A) of said Stipulation and Agreement shall terminate as of June 1, 1999, and the period for taking a license under Paragraph 6(A)(i) shall

commence immediately and shall end on the date 30 days after receipt by Andrx of said approval. Any license fee paid by Andrx pursuant to a license taken under Paragraph 6(A)(iii) shall be refunded in the event that FDA approval of the Reformulated Product occurs prior to January 9, 2000. The parties further agree that any obligations arising under Paragraph 7(B) of the September 24, 1997 Stipulation shall be deemed fully satisfied without any further or other payments by either party to the other.

14. The signatories hereto are fully authorized to execute this Stipulation and Agreement, and this Stipulation and Agreement is and shall be binding and effective immediately as between the parties hereto and upon their affiliates, successors and any prior or

subsequent assigns without further order of this Court or otherwise, and shall be in addition to any other rights or understandings of the parties unless expressly stated to the contrary herein.

AGREED TO AND ACCEPTED BY.

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