

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

_____)	
IN RE: ARMODAFINIL PATENT LITIGATION)	MDL Docket No.: 1:10-md-2200-GMS
_____)	
CEPHALON INC. and)	
CEPHALON FRANCE,)	
)	
Plaintiffs,)	Civil Action No. 1:09-cv-918-GMS
)	
v.)	
)	
TEVA PHARMACEUTICALS USA INC. et al.,)	
)	
Defendants.)	
_____)	

STIPULATION AND ORDER DISMISSING ACTION

This stipulation is made by and between (i) Cephalon, Inc. and Cephalon France (collectively “Cephalon”); and (ii) Actavis Group (“Actavis Group”), Actavis Pharma Manufacturing PVT. Ltd. (“Actavis Pharma”), and Actavis Inc. (“Actavis Inc.”) (collectively “Actavis”).

WHEREAS, Cephalon originally brought suit against Actavis, designated Civil Action No. 09-cv-940 GMS (“Actavis Action”), now consolidated under the above-captioned dockets;

WHEREAS, the Actavis Action was brought pursuant to the Hatch-Waxman Act by Cephalon for, *inter alia*, infringement of United States Patent No. 7,132,570 (“the ’570 Patent”) and premised upon Actavis’s filing of ANDA No. 200-168, through which Actavis originally sought FDA approval to market a generic version of Cephalon’s Nuvigil® (armodafinil) drug products prior to the expiration of the ’570 patent;

WHEREAS, Actavis has elected not to seek to market and will not market any generic version of Cephalon's Nuvigil[®] (armodafinil) drug products prior to the expiration of the '570 patent and any associated regulatory exclusivities;

WHEREAS, Actavis and Cephalon wish to discontinue and end the Actavis Action;

NOW THEREFORE, pursuant to Fed. R. Civ. P. 41(a), Cephalon and Actavis, by and through their respective undersigned counsel in the Action, and subject to the approval of the Court, stipulate and agree as follows:

1. Actavis, including its officers, directors, employees, agents, successors, affiliates and assigns and all persons and entities acting in concert or participation therewith, shall not engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of any generic version of Cephalon's Nuvigil[®] (armodafinil) drug products until after the expiration of the '570 patent and any regulatory exclusivities attaching thereto.

2. Actavis shall not seek final approval of its ANDA No. 200-168 before the expiration of the '570 patent and any associated regulatory exclusivities for Cephalon's Nuvigil[®] products, and any such final approval of Actavis's ANDA shall be deemed to have an effective date that is no earlier than the date upon which the '570 patent and any associated regulatory exclusivities for Cephalon's Nuvigil[®] products expire. For the avoidance of doubt, expiration of the '570 patent for purposes of Paragraphs 1 and 2 includes the entry of a final nonappealable judgment rendering the claims of the '570 patent invalid and/or unenforceable.

3. Cephalon hereby dismisses its Complaint filed against Actavis in the Actavis Action (D.I. 1, C.A. No. 09-940-GMS) without prejudice.

4. Actavis hereby dismisses its counterclaims for non-infringement and invalidity of the '570 patent (D.I. 17, C.A. No. 09-940-GMS) with prejudice, and shall not contest the enforceability of the '570 patent.

5. With respect to Paragraph 4 above, Cephalon acknowledges that Actavis's dismissal of its counterclaims for non-infringement and invalidity of the '570 patent (D.I. 17, C.A. No. 09-940-GMS) and agreement to not contest the enforceability of the '570 patent are with prejudice, except:

(I) this dismissal will not have res judicata or collateral estoppel effect in any future suit against Actavis alleging infringement of the '570 patent that relates to an Actavis ANDA product for which approval is sought from the Food and Drug Administration pursuant to 21 U.S.C. §355(j) that does not reference Cephalon's New Drug Application No. 021-875; and

(II) if Cephalon, or an authorized Cephalon licensee of the '570 patent, commercially launches in the United States an armodafinil dosage form not currently approved under Cephalon's New Drug Application No. 021-875 ("new dosage form") or product in which armodafinil is combined with another active ingredient ("combination product"), this dismissal will not have res judicata or collateral estoppel effect in any future suit against Actavis alleging infringement of the '570 patent that relates to an Actavis ANDA for which approval is sought from the Food and Drug Administration pursuant to 21 U.S.C. §355(j) for the new dosage form or combination product.

6. The Actavis Action designated as C.A. No. 09-940-GMS is hereby dismissed and closed, including being dismissed from the consolidated actions MDL Docket No. 1:10-md-2200-GMS and Civil Action No. 1:09-cv-918-GMS.

7. The terms of this Stipulation and Order are made without prejudice to the position of Cephalon in the remaining actions consolidated under the above-captioned cases.

8. This Stipulation and Order do not act as an adjudication on the merits of any issue, claim, counterclaim, or defense raised in this action or any of the consolidated actions.

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Dated March 16, 2011

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Dated March 15, 2011

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ACTAVIS INC.*

It is SO ORDERED.

Date: _____, 2011 By: _____
Chief Judge Gregory M. Sleet