

2. All parties agree that the claim term “lyophilized pharmaceutical composition” in the ‘190 patent should be construed to mean “a freeze-dried composition that is made under conditions such that it is suitable for administration to humans upon reconstitution.”

3. All parties agree that the claim term “pharmaceutical composition that has been reconstituted” in the ‘270 patent should be construed to mean “pharmaceutical composition that has been dissolved in a solvent and that is suitable for medical administration.”

4. All parties except InnoPharma agree that the claim term “stable lyophilized preparation” in the ‘863 patent should be construed to mean “solid material obtained by freeze-drying having sufficient stability to have utility as a pharmaceutical product,” with the understanding that this claim term covers only solid material.¹

5. All parties except InnoPharma agree that the claim term “lyophilized preparation” / “lyophilized composition” in the ‘270 patent should be construed to mean “freeze-dried preparation” / “freeze-dried composition,” with the understanding that this claim term covers only solid material.²

¹ InnoPharma contends that this claim term means “the solid product of lyophilization that has a detectable amount of TBA or an amount of TBA that materially alters the solubility of bendamustine in water, having sufficient stability to have utility as a pharmaceutical product.”

² InnoPharma contends that this claim term means “the solid product of lyophilization, and not the reconstituted product or the pre-lyophilization product, having an alcohol added that materially alters the solubility of bendamustine.”

SO AGREED AND STIPULATED:

SHAW KELLER LLP

/s/ John W. Shaw
John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
300 Delaware Ave., Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

OF COUNSEL:

David M. Hashmall
Calvin E. Wingfield Jr.
Jonathan A. Auerbach
Timothy J. Rousseau
Joshua A. Whitehill
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Paul F. Ware
Daryl L. Wiesen
Emily L. Rapalino
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1000

*Counsel for Plaintiff Cephalon, Inc. in C.A.
Nos. 13-2046-GMS; 13-2082-GMS; 13-2094-
GMS; 14-122-GMS; 14-334-GMS; 14-335-
GMS; 14-568-GMS, 14-671-GMS, 14-1116-
GMS, 14-1241-GMS, 14-1242-GMS, and 14-
1332*

BAYARD, P.A.

/s/ Stephen B. Brauerman
Stephen B. Brauerman (No. 4952)
Vanessa R. Tiradentes (No. 5398)
Sara E. Bussiere (No. 5725)
222 Delaware Avenue, Suite 900
Wilmington, DE 19801
(302) 655-5000
sbrauerman@bayardlaw.com
vtiradentes@bayardlaw.com
sbussiere@bayardlaw.com

OF COUNSEL:

David M. Hashmall
Calvin E. Wingfield Jr.
Jonathan A. Auerbach
Timothy J. Rousseau
Joshua A. Whitehill
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Paul F. Ware
Daryl L. Wiesen
Emily L. Rapalino
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, MA 02109
(617) 570-1000

*Counsel for Plaintiff Cephalon, Inc. in C.A.
Nos. 13-2080-GMS; 13-2081-GMS; 13-2095-
GMS; 13-2104-GMS; 14-590-GMS, 14-1045-
GMS, 14-1237-GMS, 14-1238-GMS, and 14-
1239-GMS*

SMITH KATZENSTEIN & JENKINS LLP

/s/ Neal C. Belgam

Neal C. Belgam (No. 2721)
800 Delaware Avenue, Suite 1000
P.O. Box 410
Wilmington, DE 19899
(302) 504-1688
nbelgam@skjlaw.com

OF COUNSEL:

Michael R. Dzwonczyk
Sughrue Mion, PLLC
2100 Pennsylvania Ave., N. W.
Washington, DC 20037
mdzwonczyk@sughrue.com

Counsel for Accord Healthcare Inc.

ROSS ARONSTAM & MORITZ LLP

/s/ Benjamin J. Schladweiler

Benjamin J. Schladweiler (No. 4601)
100 S. West Street, Suite 400
Wilmington, DE 19801
(302) 576-1600
bschladweiler@ramllp.com

OF COUNSEL:

Anthony J. Fitzpatrick
Vincent L. Capuano
Laura A. Vogel
Carolyn A. Alenci
Duane Morris LLP
100 High Street, Suite 2400
Boston, MA 02110-1724
ajfitzpatrick@duanemorris.com
vcapuano@duanemorris.com
lavogel@duanemorris.com
caalenci@duanemorris.com

Counsel for Actavis LLC

MORRIS JAMES LLP

/s/ Mary B. Matterer

Mary B. Matterer (No. 2696)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
mmatterer@morrisjames.com

OF COUNSEL:

Nicole Stafford
Anna Phillips
Wilson, Sonsini, Goodrich & Rosati
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Austin, TX 78746
nstafford@wsgr.com
anphillips@wsgr.com

Joshua Mack
Wilson, Sonsini, Goodrich & Rosati
12235 El Camino Real, Suite 200
San Diego, CA 92130
(858)350-2300
jmack@wsgr.com

*Counsel for Agila Specialties Inc., Onco
Therapies Limited*

PINCKNEY, WEIDINGER, URBAN &
JOYCE LLC

/s/ Gregory T. Donilon

Elizabeth Wilburn Joyce (No. 3666)
Gregory T. Donilon (No. 4244)
1220 N. Market Street, Suite 950
Wilmington, DE 19801
(302) 504-1497
ewilburnjoyce@pwujlaw.com

OF COUNSEL:

Louis H. Weinstein
James P. Barabas
BUDD LARNER, P.C.
50 John F. Kennedy Parkway
Short Hills, NJ 07078
(973) 379-4800
lweinstein@buddlerner.com
jbarabas@buddlerner.com

*Counsel for Dr. Reddy's Laboratories Ltd. and
Dr. Reddy's Laboratories Inc.*

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