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20	IN THE UNITED STA	ATES DISTRICT COURT
21	IN AND FOR THE NORTHE	RN DISTRICT OF CALIFORNIA
22	DEPOMED, INC., a California Corporation,	No. 09-CV-05587 PJH
23	Plaintiff,	STIPULATED PROTECTIVE ORDER
24	V.	
25	LUPIN PHARMACEUTICALS, INC., a	
26	Virginia Corporation, and LUPIN LIMITED, an Indian Corporation,	
27	Defendants.	
28		

STIPULATED PROTECTIVE ORDER CASE NO. 09-CV-05587 PJH

1. PURPOSES AND LIMITATIONS

Disclosure and discovery activity in this action are likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the court to enter the following Stipulated Protective Order. The parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords extends only to the limited information or items that are entitled under the applicable legal principles to treatment as confidential. The parties further acknowledge, as set forth in Section 10, below, that this Stipulated Protective Order creates no entitlement to file confidential information under seal; Civil Local Rule 79-5 sets forth the procedures that must be followed and reflects the standards that will be applied when a party seeks permission from the court to file material under seal.

2. DEFINITIONS

- 2.1 <u>Party</u>: any party to this action, including all of its officers, directors, employees, consultants, retained experts, and outside counsel (and their support staff).
- 2.2 <u>Depomed</u>: Plaintiff Depomed, Inc., its directors, officers, employees, attorneys, accountants, consultants, representatives, agents, subsidiaries, divisions, successors in interest, any partnerships or joint ventures to which it is a party, and/or other persons acting on its behalf.
- 2.3 <u>Lupin</u>: Defendants Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Limited ("Lupin Limited"), individually or collectively, their directors, officers, employees, attorneys, accountants, consultants, representatives, agents, subsidiaries, divisions, successors in interest, any partnerships or joint ventures to which they are a party, and/or other persons acting on their behalf.
- 2.4 <u>Disclosure or Discovery Material</u>: all items or information, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced or generated in disclosures or responses to discovery in this matter.

- 2.5 <u>"Confidential" Information or Items</u>: information (regardless of how generated, stored or maintained) or tangible things that qualify for protection under standards developed under F.R.Civ.P. 26(c).
- 2.6 "Highly Confidential Attorneys' Eyes Only" Information or Items: is limited to information from (a) ongoing and future clinical trials and communications with regulatory authorities regarding such trials, (b) ongoing labeling negotiations for any therapeutic product pending but not yet approved for sale by a regulatory authority, (c) active and ongoing research and development of any therapeutic product for which no regulatory approval has been sought; (d) ongoing collaboration or licensing agreements, and negotiations thereto, including any associated financial information; and (e) any current patent prosecution.
- 2.7 <u>Receiving Party</u>: a Party that receives Disclosure or Discovery Material from a Producing Party.
- 2.8 <u>Producing Party</u>: a Party or non-party that produces Disclosure or Discovery Material in this action.
- 2.9 <u>Designating Party</u>: a Party or non-party that designates information or items that it produces in disclosures or in responses to discovery as "Confidential" or "Highly Confidential Attorneys' Eyes Only."
- 2.10 <u>Protected Material</u>: any Disclosure or Discovery Material that is designated as "Confidential" or as "Highly Confidential Attorneys' Eyes Only."
- 2.11 <u>Outside Counsel</u>: attorneys who are not employees of a Party but who are retained to represent or advise a Party in this action.
 - 2.12 <u>House Counsel</u>: attorneys who are employees of a Party.
- 2.13 <u>Counsel (without qualifier)</u>: Outside Counsel and House Counsel (as well as their support staffs).
- 2.14 <u>Expert</u>: a person with specialized knowledge or experience in a matter pertinent to the litigation who has been retained by a Party or its counsel to serve as an expert witness or as a consultant in this action and who is not a past or a current employee of a Party. This definition includes a professional jury or trial consultant retained in connection with this litigation.

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2.15 <u>Professional Vendors</u>: persons or entities that provide litigation support services (e.g., photocopying; videotaping; translating; interpreting; conducting trial studies or analysis, preparing exhibits or demonstrations; organizing, storing, retrieving data in any form or medium; etc.) and their employees and subcontractors, including in the case of jury consultants, mock jurors.

3. SCOPE

The protections conferred by this Stipulation and Order cover not only Protected Material (as defined above), but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by parties or counsel to or in court or in other settings that might reveal Protected Material.

4. DURATION

Even after the termination of this litigation, the confidentiality obligations imposed by this Order shall remain in effect until a Designating Party agrees otherwise in writing or a court order otherwise directs.

5. DESIGNATING PROTECTED MATERIAL

5.1 Exercise of Restraint and Care in Designating Material for Protection. Each Party or non-party that designates information or items for protection under this Order must take care to limit any such designation to specific material that qualifies under the appropriate standards. A Designating Party must take care to designate for protection only those parts of material, documents, items, or oral or written communications that qualify – so that other portions of the material, documents, items, or communications for which protection is not warranted are not swept unjustifiably within the ambit of this Order.

Mass, indiscriminate, or routinized designations are prohibited. Designations that are shown to be clearly unjustified, or that have been made for an improper purpose (e.g., to unnecessarily encumber or retard the case development process, or to impose unnecessary expenses and burdens on other parties), expose the Designating Party to sanctions.

If it comes to a Party's or a non-party's attention that information or items that it designated for protection do not qualify for protection at all, or do not qualify for the level of

protection initially asserted, that Party or non-party must promptly notify all other parties that it is withdrawing the mistaken designation.

5.2 <u>Manner and Timing of Designations</u>. Except as otherwise provided in this Order (see, e.g., second paragraph of section 5.2(a), below), or as otherwise stipulated or ordered, material that qualifies for protection under this Order must be clearly so designated before the material is disclosed or produced.

Designation in conformity with this Order requires:

- (a) <u>for information in documentary form</u> (apart from transcripts of depositions or other pretrial or trial proceedings), that the Producing Party affix the legend "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY" at the top or bottom of each page that contains Protected Material. A Party or non-party that makes original documents or materials available for inspection need not designate them for protection until after the inspecting Party has indicated which material it would like copied and produced. During the inspection and before the designation, all of the material made available for inspection shall be deemed "HIGHLY CONFIDENTIAL –ATTORNEYS' EYES ONLY." After the inspecting Party has identified the documents it wants copied and produced, the Producing Party must determine which documents, or portions thereof, qualify for protection under this Order, then, before producing the specified documents, the Producing Party must affix the appropriate legend ("CONFIDENTIAL" or "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY") at the top or bottom of each page that contains Protected Material.
- (b) for testimony given in deposition or in other pretrial or trial proceedings, that deposition testimony and transcripts including exhibits attached thereto shall be treated as "CONFIDENTIAL" information, unless otherwise designated as "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY" information. Counsel may designate all or portions of the transcript and exhibits used therein as "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY" information at any time during the deposition and for a period of 30 days following receipt of the transcript by counsel for the deponent. Persons entitled to see CONFIDENTIAL information pursuant to § 7.2(b) shall not have access to such transcripts or exhibits until after the

expiration of said 30 business days and provided that the designation has not been changed to "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY."

- (c) <u>for information produced in some form other than documentary, and for any other tangible items,</u> that the Producing Party affix in a prominent place on the exterior of the container or containers in which the information or item is stored the legend "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY." If only portions of the information or item warrant protection, the Producing Party, to the extent practicable, shall identify the protected portions, specifying whether they qualify as "CONFIDENTIAL" or as "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY."
- 5.3 <u>Inadvertent Failures to Designate</u>. If timely corrected, an inadvertent failure to designate qualified information or items as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY" does not, standing alone, waive the Designating Party's right to secure protection under this Order for such material. If material is appropriately designated as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY" after the material was initially produced, the Receiving Party, on timely notification of the designation, must make reasonable efforts to assure that the material is treated in accordance with the provisions of this Order.

6. CHALLENGING CONFIDENTIALITY DESIGNATIONS

- 6.1 <u>Timing of Challenges</u>. Unless a prompt challenge to a Designating Party's confidentiality designation is necessary to avoid foreseeable substantial unfairness, unnecessary economic burdens, or a later significant disruption or delay of the litigation, a Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed.
- 6.2 <u>Meet and Confer.</u> A Party that elects to initiate a challenge to a Designating Party's confidentiality designation must do so in good faith and must begin the process by conferring directly (in voice to voice dialogue; other forms of communication are not sufficient) with counsel for the Designating Party. In conferring, the challenging Party must explain the basis for its belief that the confidentiality designation was not proper and must give the

Designating Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain the basis for the chosen designation. A challenging Party may proceed to the next stage of the challenge process only if it has engaged in this meet and confer process first.

6.3 <u>Judicial Intervention</u>. A Party that elects to press a challenge to a confidentiality designation after considering the justification offered by the Designating Party may file and serve a motion under Civil Local Rule 7 (and in compliance with Civil Local Rule 79-5, if applicable) that identifies the challenged material and sets forth in detail the basis for the challenge. Each such motion must be accompanied by a competent declaration that affirms that the movant has complied with the meet and confer requirements imposed in the preceding paragraph and that sets forth with specificity the justification for the confidentiality designation that was given by the Designating Party in the meet and confer dialogue.

The burden of persuasion in any such challenge proceeding shall be on the Designating Party. Until the court rules on the challenge, all parties shall continue to afford the material in question the level of protection to which it is entitled under the Producing Party's designation.

7. ACCESS TO AND USE OF PROTECTED MATERIAL

7.1 <u>Basic Principles.</u> A Receiving Party may use Protected Material that is disclosed or produced by another Party or by a non-party in connection with this case only for prosecuting, defending, or attempting to settle this litigation. Such Protected Material may be disclosed only to the categories of persons and under the conditions described in this Order, and shall not be used for any purposes other than this lawsuit, including but not limited to for purposes related to prosecution of applications before the United States Patent and Trademark Office and to any submission before the Food and Drug Administration, including but not limited to any Citizens Petitions, and/or any submissions to the United States Pharmacopeia, British Pharmacopeia or European Pharmacopeia. When the litigation has been terminated, a Receiving Party must comply with the provisions of section 11, below (FINAL DISPOSITION).

Protected Material must be stored and maintained by a Receiving Party at a location and in a secure manner that ensures that access is limited to the persons authorized under this Order.

1	(f) during and in preparation for their depositions, witnesses in the action to
2	whom disclosure is reasonably necessary and who have signed the "Agreement to Be Bound by
3	Protective Order" (Exhibit A). Pages of transcribed deposition testimony or exhibits to
4	depositions that reveal Protected Material must be separately bound by the court reporter and may
5	not be disclosed to anyone except as permitted under this Stipulated Protective Order; and
6	(g) the author of the document or the original source of the information.
7	7.3 <u>Disclosure of "HIGHLY CONFIDENTIAL – ATTORNEYS" EYES ONLY"</u>
8	<u>Information or Items</u> . Unless otherwise ordered by the court or permitted in writing by the
9	Designating Party, a Receiving Party may disclose any information or item designated "HIGHLY
10	CONFIDENTIAL – ATTORNEYS' EYES ONLY" only to:
11	(a) the Receiving Party's Outside Counsel of record in this action, as well as
12	employees of said Counsel to whom it is reasonably necessary to disclose the information for this
13	litigation and who have signed the "Agreement to Be Bound by Protective Order" that is attached
14	hereto as Exhibit A;
15	(b) the following specified officers, directors, or representatives of the Parties
16	who have signed the "Agreement to Be Bound by Protective Order" (Exhibit A), provided that
17	they do not, during this litigation or for two years thereafter, have direct responsibility for the
18	following activities, advise someone regarding those activities, or otherwise be involved in the
19	day-to-day activities, direction or prosecution of the following activities:
20	(i) prosecution of patent applications claiming formulations containing
21	metformin hydrochloride or processes for making formulations containing metformin hydrochloride;
22	(ii) making or preparing submissions to the FDA regarding any
23	metformin product using GLUMETZA® as a reference listed drug,
24	including Citizen Petitions or related submissions, regarding metformin hydrochloride; and/or
25	(iii) making or preparing any submissions to the U.S. Pharmacopeia or
26	any foreign pharmacopeia regarding formulations containing metformin hydrochloride:
27	nydroemoride.
28	

- For Depomed: Matthew Gosling, Vice President and General Counsel, Depomed Inc.
- For Lupin: Sofia Mumtaz
- (c) Experts (as defined in this Order) (1) to whom disclosure is reasonably necessary for this litigation, (2) who have signed the "Agreement to Be Bound by Protective Order" (Exhibit A), and (3) as to whom the procedures set forth in paragraph 7.4, below, have been followed;
 - (d) the Court and its personnel;
- (e) court reporters, their staffs, and professional vendors to whom disclosure is reasonably necessary for this litigation and who have signed the "Agreement to Be Bound by Protective Order" (Exhibit A); and
 - (f) the author of the document or the original source of the information.
- 7.4 <u>Procedures for Approving Disclosure of "HIGHLY CONFIDENTIAL –</u>
 ATTORNEYS' EYES ONLY" Information or Items to "Experts"
- (a) Unless otherwise ordered by the court or agreed in writing by the Designating Party, a Party that seeks to disclose to an "Expert" (as defined in this Order) any information or item that has been designated "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY" first must make a written request to the Designating Party that (1) sets forth the full name of the Expert and the city and state of his or her primary residence, (2) attaches a copy of the Expert's current resume, (3) identifies the Expert's current employer(s), (4) identifies each person or entity from whom the Expert has received compensation for work in his or her areas of expertise or to whom the expert has provided professional services at any time during the preceding five years, and (5) identifies (by name and number of the case, filing date, and location of court) any litigation in connection with which the Expert has provided any professional services during the preceding five years.
- (b) A Party that makes a request and provides the information specified in the preceding paragraph may disclose the subject Protected Material to the identified Expert unless,

within seven court days of delivering the request, the Party receives a written objection from the Designating Party. Any such objection must set forth in detail the grounds on which it is based.

(c) A Party that receives a timely written objection must meet and confer with the Designating Party (through direct voice to voice dialogue) to try to resolve the matter by agreement. If no agreement is reached, the Party seeking to make the disclosure to the Expert may file a motion as provided in Civil Local Rule 7 (and in compliance with Civil Local Rule 79-5, if applicable) seeking permission from the court to do so. Any such motion must describe the circumstances with specificity, set forth in detail the reasons for which the disclosure to the Expert is reasonably necessary, assess the risk of harm that the disclosure would entail and suggest any additional means that might be used to reduce that risk. In addition, any such motion must be accompanied by a competent declaration in which the movant describes the parties' efforts to resolve the matter by agreement (i.e., the extent and the content of the meet and confer discussions) and sets forth the reasons advanced by the Designating Party for its refusal to approve the disclosure.

In any such proceeding, the Party opposing disclosure to the Expert shall bear the burden of proving that the risk of harm that the disclosure would entail (under the safeguards proposed) outweighs the Receiving Party's need to disclose the Protected Material to its Expert.

8. <u>PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN OTHER LITIGATION.</u>

If a Receiving Party is served with a subpoena or an order issued in other litigation that would compel disclosure of any information or items designated in this action as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY," the Receiving Party must so notify the Designating Party, in writing (by fax, if possible) immediately and in no event more than three court days after receiving the subpoena or order. Such notification must include a copy of the subpoena or court order.

The Receiving Party also must immediately inform in writing the Party who caused the subpoena or order to issue in the other litigation that some or all the material covered by the subpoena or order is the subject of this Protective Order. In addition, the Receiving Party must

deliver a copy of this Stipulated Protective Order promptly to the Party in the other action that caused the subpoena or order to issue.

The purpose of imposing these duties is to alert the interested parties to the existence of this Protective Order and to afford the Designating Party in this case an opportunity to try to protect its confidentiality interests in the court from which the subpoena or order issued. The Designating Party shall bear the burdens and the expenses of seeking protection in that court of its confidential material – and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court.

9. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL

If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Protected Material to any person or in any circumstance not authorized under this Stipulated Protective Order, the Receiving Party must immediately (a) notify in writing the Designating Party of the unauthorized disclosures, (b) use its best efforts to retrieve all copies of the Protected Material, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons to execute the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit A.

- 10. <u>FILING PROTECTED MATERIAL</u>. Without written permission from the Designating Party or a court order secured after appropriate notice to all interested persons, a Party may not file in the public record in this action any Protected Material. A Party that seeks to file under seal any Protected Material must comply with Civil Local Rule 79-5.
- Party, within sixty days after the final termination of this action, each Receiving Party must return or destroy all Protected Material to the Producing Party. As used in this subdivision, "all Protected Material" includes all copies, abstracts, compilations, summaries or any other form of reproducing or capturing any of the Protected Material. Whether the Protected Material is returned or destroyed, the Receiving Party must submit a written certification to the Producing Party (and, if not the same person or entity, to the Designating Party) by the sixty day deadline that identifies (by category, where appropriate) all the Protected Material that was returned or

destroyed and that affirms that the Receiving Party has not retained any copies, abstracts, compilations, summaries or other forms of reproducing or capturing any of the Protected Material. Notwithstanding this provision, Counsel are entitled to retain an archival copy of all pleadings, motion papers, transcripts, legal memoranda, correspondence or attorney work product, even if such materials contain Protected Material. Further, all notes, summaries, or other documents prepared by attorneys, or outside experts/consultants designated as provided in Section 7.3, derived from or containing Confidential Material, shall after the conclusion of the action, be kept within the files of trial counsel for the party creating such work product, or be destroyed. Any such archival copies that contain or constitute Protected Material remain subject to this Protective Order as set forth in Section 4 (DURATION), above.

12. MISCELLANEOUS

- 12.1 <u>Right to Further Relief.</u> Nothing in this Order abridges the right of any person to seek its modification by the Court in the future.
- 12.2 <u>Right to Assert Other Objections</u>. By stipulating to the entry of this Protective Order no Party waives any right it otherwise would have to object to disclosing or producing any information or item on any ground not addressed in this Stipulated Protective Order. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order.
- drafts of expert reports and working notes in connection with the preparation of expert reports are not discoverable and need not be retained or produced; and (b) communications between an expert for a Party and that Party's attorneys are not discoverable, except to the extent that the expert relied upon any such communications as a basis or grounds for any opinion to be expressed by the expert in any direct or rebuttal testimony. In all other respects, the Parties and their experts shall fully comply with the disclosure requirements of Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure.

1	IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.	
2	Dated: August 4, 2010 MCDERMOTT WILL & EMERY LLP	
3		
4	By: <u>/s/ William G. Gaede</u> William G. Gaede	
5	Attorney for Depomed, Inc.	
6		
7	RAKOCZY MOLINO MAZZOCHI SIWIK LLP	
8		
9	By: <u>/s/ Paul J. Molino</u> Paul J. Molino	
10		
11	DURIE TANGRI LLP	
12	By: /s/ Daralyn Durie	
13	Daralyn Durie	
14	Attorneys for Lupin Pharmaceuticals, Inc. and Lupin Ltd.	
15	CICNATUDE ATTECTATION	
16	SIGNATURE ATTESTATION	
17	Pursuant to General Order 45.X(B), I hereby attest that concurrence has been obtained	
18	from Paul J. Molino and from Daralyn Durie indicated by a "conformed" signature (/s/) within this e-filed document.	
19		
20	<u>/s/ William G. Gaede, III</u> William G. Gaede, III	
21	-oOo-	
2223		
23	PURSUANT TO STIPULATION, IT IS SO ORDERED.	
25	STATU ACTO	
26	DATED: August 6, 2010	
27	Honorable United States Judge Phyllis J. Hamilton Dec	
28	Juage	
	STIPULATED PROTECTIVE ORDER	

CASE NO. 09-CV-05587 PJH

1 EXHIBIT A 2 ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND 3 I, full [print name], of or type 4 [print or type full address], declare under penalty of perjury that I have 5 read in its entirety and understand the Stipulated Protective Order that was issued by the United 6 States District Court for the Northern District of California on [date] in the case of **Depomed v.** 7 Lupin Pharmaceuticals, Inc., et al., Case no. 09-CV-05587 PJH. I agree to comply with and 8 to be bound by all the terms of this Stipulated Protective Order and I understand and acknowledge 9 that failure to so comply could expose me to sanctions and punishment in the nature of contempt. 10 I solemnly promise that I will not disclose in any manner any information or item that is subject 11 to this Stipulated Protective Order to any person or entity except in strict compliance with the 12 provisions of this Order. 13 I further agree to submit to the jurisdiction of the United States District Court for the 14 Northern District of California for the purpose of enforcing the terms of this Stipulated Protective 15 Order, even if such enforcement proceedings occur after termination of this action. 16 I hereby appoint [print or type full name] of 17 [print or type full address and telephone number] 18 as my California agent for service of process in connection with this action or any proceedings 19 related to enforcement of this Stipulated Protective Order. 20 21 Date: 22 City and State where sworn and signed: 23 Printed name: [printed name] 24 Signature: 25 [signature]

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