1 JENNIFER RANDLETT MADDEN (Bar No. 184905) MEGHAN M. BAKER (Bar No. 243765) 2 DOWNEY BRAND LLP 621 Capitol Mall, 18<sup>th</sup> Floor 3 Sacramento, CA 95814 Telephone: (916) 444-1000 4 Facsimile: (916) 444-2100 5 jmadden@downeybrand.com mbaker@downeybrand.com 6 Admitted Pro Hac Vice: 7 CLEM C. TRISCHLER (Pa. Bar No.: 52957) JASON M. REEFER (Pa. Bar No.: 208514) 8 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP 9 One Oxford Centre, 38<sup>th</sup> Floor 10 Pittsburgh, PA 15219 Telephone: (412) 263-2000 11 Facsimile: (412) 263-2001 cct@pietragallo.com 12 jmr@pietragallo.com 13 Attorneys for Defendants 14 Mylan Inc.; Mylan Pharmaceuticals Inc; Mylan Technologies Inc. 15 16 UNITED STATES DISTRICT COURT 17 EASTERN DISTRICT OF CALIFORNIA 18 MISTY SHAW, JAMES SHAW, and Case No.: 2:11-cv-00189-JAM-CMK 19 LUCILLE SHAW, 20 STIPULATED PROTECTIVE ORDER Plaintiffs, 21 v. 22 Judge: Honorable John A. Mendez MYLAN, INC., MYLAN 23 PHARMACEUTICALS, INC., MYLAN TECHNOLOGIES, INC., ALZA 24 CORPORATION, JANSSEN PHARMACEUTICALS, and DOES 1-100 25 Defendants. 26 27 28

WHEREAS, Plaintiffs and/or any other party may seek the production of documents and information from Defendants, Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Technologies Inc., (collectively, "Mylan"), and Janssen Pharmaceuticals, Inc. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and improperly sued as Janssen Pharmaceuticals) ("Janssen") (Mylan and Janssen collectively referred to herein as "Product Defendants");

WHEREAS, Product Defendants allege such documents contain competitive sales, marketing, or product information including, but not limited to: (1) descriptions, identifications, changes, and modifications of any sort made to equipment used in the manufacturing process; (2) operations involved in the entire manufacturing process; (3) manufacturing practices and procedures and specific records illustrating same; (4) formulations and specifications relating to the product at issue; (5) practices, procedures and protocols relating to quality control and quality assurance; (6) other scientific marketing and/or research and development information; and/or (7) corporate financial Janssen-specific information and/or Mylan-specific information which Product Defendants deem confidential.

WHEREAS, Product Defendants deem that knowledge of any of the foregoing categories of information to the public and specifically to any competitor would cause a severe competitive injury to Product Defendants in that many years have been invested in researching, developing, manufacturing, and marketing the products at issue, and Product Defendants currently rely on such expertise;

WHEREAS, it has been agreed by and among the parties in the above-styled action, through their counsel, that such documents may include trade secrets that are protected under applicable state and federal law;

WHEREAS, it has been agreed by and among the parties in the above-styled action, through their counsel, that a Protective Order preserving the confidentiality of certain documents and information should be entered by the Court; and

WHEREAS, the Court has reviewed the terms and conditions of this Protective Order submitted and stipulated to by the parties, and has found that the confidentiality provisions of this Protective Order are proper.

## IT IS HEREBY ORDERED THAT:

- 1. **Non-Disclosure of Documents.** Documents produced by Product Defendants may be stamped "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" and/or "Protected Document. Document Subject to Protective Order" (hereinafter "Protected Documents") to signify that the documents are subject to protection by this Order. Interrogatory answers, responses to Requests for Admission, deposition transcripts and exhibits, pleadings, motions, affidavits, briefs, summaries, notes, computer-generated material, computer discs or retrievable data, other means of storage or duplication, and oral statements or communications that quote, summarize, or contain information from the Protected Documents are also subject to protection by this Order. No Protected Document or any portion of any Protected Document produced by Product Defendants may be disclosed to any person, except as permitted in paragraphs 2, 3 and 4 below.
- 2. Protected Documents and/or any portion thereof deemed confidential may be disclosed to (a) counsel of record who are actively engaged in the conduct of this litigation; (b) the partners, associates, secretaries, paralegals, and employees of such counsel to the extent reasonably necessary to render professional services in the above-styled action; and (c) any party to this litigation, including current employees or representatives of Product Defendants, subject to the restrictions set forth in paragraphs 3 and 4.
- 3. In addition, Protected Documents and/or any portion thereof deemed confidential may be disclosed to (a) employees of the producing party noticed for depositions or designated as trial witnesses; and (b) outside consultants or experts retained by any party or their counsel for the purpose of assisting counsel in the litigation or to testify at trial, provided, however, that such experts or consultants are not presently employed by, nor have any present intention to be employed by, any party or a competitor of any party. Before any Protected Document may be disclosed to any person described in (a) and/or (b) of this paragraph, however, the person so described must sign the attached Confidentiality Agreement. The Confidentiality Agreement reflects that the signatory has read this Protective Order, understands that anything other than the inadvertent disclosure of Protected Documents constitutes contempt of court, and consents to the exercise of personal jurisdiction by this Court. The original of each signed Confidentiality Agreement shall be retained by counsel and a copy

thereof served upon Product Defendants' counsel, except that a copy of the Confidentiality Agreement signed by a person described in subsection (b) need not be served upon Product Defendants' counsel until such person is disclosed as a witness.

4. Protected Documents subject to this Protective Order shall not be disclosed to any Competitor of Product Defendants. For purposes of this Order, "Competitor" shall be defined as any entity or person currently engaged in the commercial discovery and/or commercial development and/or commercialization of transdermal or patch technology designed to deliver pharmaceuticals through the skin, and shall include any agent, employee, consultant, or other person currently similarly affiliated with such entity or person. For purposes of this Order, Mylan and Janssen and their agents, employees, consultants or other persons similarly affiliated with Mylan and Janssen respectively, are deemed to be Competitors. For purposes of the captioned matter, Competitor shall not refer to those individuals identified in paragraph 2(a) & (b). Before disclosing any Protected Document to any person listed in paragraph 2(c), 3(a) or 3(b), who may also be a Competitor of Product Defendants, the procedures in this paragraph shall be followed to assure that no confidential information is disclosed to any Competitor.

Entry of this Protective Order by the Court imposes a duty upon any person who may be a Competitor of Product Defendants to whom any Protected Documents are to be disclosed to make a good faith determination as to whether he or she is a Competitor.

- a. If the person determines himself or herself to be a Competitor, neither the Protected Documents nor the contents thereof shall be discussed with or disclosed to such person.
- b. If the person determines himself or herself not to be a Competitor, that person and counsel who intends to disclose Protected Documents to that person shall execute Affidavit "A" and Affidavit "B" respectively in addition to the Confidentiality Agreement attached hereto. Except as otherwise provided in paragraph 3, the original Affidavits and Confidentiality Agreement shall be retained by counsel and a copy thereof served upon Product Defendants' counsel seven (7) business days prior to the disclosure of any Protected Documents and/or the contents thereof.

c. If the person is unable to determine whether he or she is a Competitor, counsel for the disclosing party shall prepare a written statement identifying the potential Competitor, including the name and current residence of the potential Competitor, his or her job title and employer's name and address for the previous five (5) years. The original of such statement shall be retained by counsel and a copy thereof served in accordance with applicable rules of Civil Procedure upon Product Defendants' counsel. Product Defendants' counsel shall have seven (7) business days to object to the disclosure of Protected Documents to the potential Competitor. If no objection is made, the Affidavits and Confidentiality Agreement shall be executed and served as described in subsection (b).

If there is an uncertainty or a dispute as to whether the person is a Competitor, any party may seek a ruling from this Court regarding the same. Pending a ruling by the Court on that dispute, no Protected Documents shall be disclosed to the potential Competitor. Nothing herein shall prevent Plaintiffs from seeking leave of court upon good cause shown to disclose Protected Documents to a Competitor of Product Defendants.

5. Certain documents prepared in compliance with the regulations of the United States Food and Drug Administration contain material that is privileged and confidential under the patient-physician privilege or specific federal regulations governing clinical trials and adverse drug experience reporting. To protect these privileges, all such documents produced by Product Defendants in response to a discovery request shall have the name and address of the patient and physician redacted as well as all identifying information regarding the reporter, but such redaction shall not be done in such a manner as to redact material data in such reports.

## 6. **Documents at Depositions.**

a. A deponent who is not a current employee of Product Defendants may, during the deposition, be shown and examined about the Protected Documents as long as disclosure comports with the provisions of the preceding paragraphs, although the deponent can comply with the requirements of the preceding paragraphs via oral testimony on the record under oath during the deposition instead of actually signing the affidavits. Notwithstanding such, a former employee of Product Defendants may be shown a Protected Document if such former

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employee authored or has previously seen such document. A deponent shall not retain or copy portions of the transcript of his or her deposition containing confidential information not provided by the deponent or the entities whom he or she represents unless he or she signs the Confidentiality Agreement as well as the applicable Affidavit described above.

- b. Any party and any deponent may, within thirty (30) days after receiving a deposition transcript, designate the transcript as protected pursuant to this Protective Order by written notice to all counsel of the designation and by having the cover page of the transcript marked as follows: "PROTECTED DOCUMENT – SUBJECT TO PROTECTIVE ORDER," "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER," and/or "Protected Document. Document Subject to Protective Order." During the initial thirty (30) day period, the entire deposition will be treated as subject to protection against disclosure under this Protective Order, but if no party or deponent timely designates the transcript as protected, then the transcript shall not thereafter be subject to this Protective Order. However, deposition exhibits that are protected documents pursuant to this Protective Order will continue to be protected without further designation being required. The continued protection of such documents will not be dependent upon the transcript being designated as protected. If there is uncertainty or any dispute as to whether a transcript has been properly designated as protected, any party may seek a ruling from this Court. Pending a ruling by the Court, the entire deposition will be treated as subject to protection against disclosure under this Protective Order. Deposition transcripts designated as protected may be filed with the Court only under seal, consistent with the provisions of Paragraph 7.
- 7. **Filing.** The Protected Documents are not to be filed with this Court except when required in connection with motions or other matters pending before this Court. If any party intends to file Protected Documents, such party shall adhere to the provisions for sealing a record under the applicable rules of civil procedure and local rules. Any motion quoting or revealing the contents of such Protected Documents or information shall also be filed under seal and a redacted public version may be filed without quoting or revealing the contents of any confidential information. If any party notifies another party that they intend or need to file one or more of the Protected Documents in

response to a motion previously filed, the party who filed such motion specifically agrees to provide whatever extension or continuance is necessary to file such response to allow for compliance with paragraph 7. Specifically, upon request, the parties agree to provide an extension or continuance for the filing of any response to any motion to provide appropriate time to comply with the applicable law regarding filing such documents under seal.

- 8. **Documents used at Trial**. All trials are open to the public. Absent order of the Court, there will be no restrictions on the use of any document that may be introduced by any party during the trial. If a party intends to present at trial Protected Documents or information derived therefrom, such party shall provide advance notice to the other parties at least five (5) days before the commencement of trial by identifying the documents or information at issue as specifically as possible (i.e., by Bates number, page range, deposition transcript lines, etc.). The Court may thereafter make such orders as are necessary to govern the use of such documents or information at trial.
- 9. **Declassification.** Any "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" or "Protected Document. Document Subject to Protective Order" designation is subject to challenge by any party or nonparty with standing to object (hereafter "party"). Before filing any motions or objections to a confidentiality designation with the Court, the objecting party shall have an obligation to meet and confer in a good faith effort to resolve the objection by agreement. If agreement is reached confirming or waiving the "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" or "Protected Document. Document Subject to Protective Order" designation as to any documents subject to the objection, the designating party shall serve on all parties a notice specifying the documents and the nature of the agreement. If agreement is not reached, the objecting party may request from this Court a ruling that a Document or deposition transcript is not entitled to continued protection under this Protective Order.
- subpoenas or orders production of Protected Documents which a party has obtained under the terms of this Protective Order, the party shall promptly notify the producing party's counsel of such subpoena or order. Protected Documents shall not be produced by the party until the producing party's counsel has been notified of such subpoena or order and has had a reasonable opportunity to

protect the producing party's interest by objecting to the subpoena or order.

- 11. **Client Consultation.** Nothing in this Protective Order shall prevent or otherwise restrict counsel from rendering advice to, or consulting with, their clients. All parties and their counsel, however, are bound by the terms of this Protective Order.
- 12. Use. Protected Documents and any information contained therein may be used for the preparation and trial, appeal, or retrial of the above-styled action. In addition, Protected Documents with a "DUR" Bates stamp prefix may be used in other Duragesic® Fentanyl Transdermal System cases in which Heygood, Orr & Pearson is lead trial counsel so long as this Protective Order or similar Stipulated Protective Order is entered in those cases and Heygood, Orr & Pearson gives Tucker, Ellis & West LLP written notice of the documents it intends to use. Additionally, Janssen agrees that it will not be a violation of any Protective Order for Heygood, Orr & Pearson to use such Protected Documents produced in other Duragesic® Fentanyl Transdermal System cases against ALZA and/or Janssen Defendants where Heygood, Orr & Pearson was or is lead counsel in the preparation and trial, appeal, or retrial of this action or any other Duragesic® Fentanyl Transdermal System cases against ALZA and/or Janssen Defendants where Heygood, Orr & Pearson is lead counsel.

Further, Protected Documents produced pursuant to the Global Discovery Agreement between Heygood, Orr & Pearson and Mylan with a "MYLAN" Bates stamp prefix may be used in other Mylan Fentanyl Transdermal System® cases in which Heygood, Orr & Pearson is lead trial counsel, pursuant to the Global Discovery Agreement between Mylan and Heygood, Orr & Pearson, with the exception of documents that are expressly produced for single cases only, so long as this Protective Order or similar Stipulated Protective Order is entered in those cases and Heygood, Orr & Pearson gives counsel for Mylan written notice of the documents it intends to use. Additionally, Mylan agrees that it will not be a violation of any Protective Order for Heygood, Orr & Pearson to use such Protected Documents produced in other Mylan Fentanyl Transdermal System® cases against Mylan Defendants where Heygood, Orr & Pearson was or is lead counsel in the preparation and trial, appeal, or retrial of this action or any other Mylan Fentanyl Transdermal System® cases against Mylan Defendants where Heygood, Orr & Pearson is lead counsel.

- 13. **Non-Termination.** Within 45 days after final conclusion of all aspects of all cases that Heygood, Orr & Pearson are handling against Mylan and/or Janssen, the Protected Documents and all copies of same (other than exhibits of record) shall be returned to counsel for Mylan and/or Janssen or be destroyed. This includes Protected Documents produced by Product Defendants that were provided to and/or reviewed by any consultants and/or experts retained by any party. Notes, summaries, memos, computer data bases, and other information compilations from the Protected Documents shall also be destroyed. All counsel of record shall make certification of compliance herewith and shall deliver the same to counsel for Mylan and/or Janssen not more than 60 days after final termination of this litigation.
- 14. **Continuing Jurisdiction.** The provisions of this Protective Order shall remain in full force and effect and each person subject to this Order shall continue to be subject to the jurisdiction of this Court, for the purposes of this Order, in perpetuity, and the Court shall not be divested of jurisdiction of any person or of the subject matter of this Order by the occurrence of conclusion of this case, or by the filing of a notice of appeal, or other pleading which would have the effect of divesting this Court of jurisdiction of this matter generally.
- 15. **Inadvertent Disclosure.** Any inadvertent disclosure of confidential, proprietary, or privileged material will not be construed as a waiver, in whole or in part, of (1) the Producing Party's claims of confidentiality or privilege either as to the specific information inadvertently or unintentionally disclosed or more generally as to the subject matter of the information disclosed, or (2) the party's right to designate the material as confidential pursuant to this Order. A written representation by counsel for the Producing Party that the disclosure was inadvertent shall be deemed prima facie evidence of that fact. The Producing Party shall promptly notify the other party of an inadvertent disclosure following discovery of the inadvertent production, and that other party (i) shall in the case of a privileged document, return the inadvertently disclosed document forthwith, as well as any and all copies; or (ii) in the case of a confidential, proprietary document, shall mark it and all copies, "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER," and/or "Protected Document. Document Subject to Protective Order." In the event that the other party cannot comply with these requirements because, for example, the inadvertently produced document has been given to a third

1	party – the other party shall provide the Producing Party with the name, address, and telephone					
2	number of such person(s) as well as the date of and reason for the transmission of the document.					
3		DREYER BABICH BUCCOLA WOOD, LLP				
4	Date: September 27, 2011	DRETER BABICII BUCCOLA WOOD, LEF				
5						
6		By: /s/ Craig Sheffer (as authorized on 9/27/11) Craig C. Sheffer, Esq.				
7		Robert A. Buccola, Esq. Steven Campora, Esq.				
8		Attorneys for Plaintiffs MISTY SHAW, JAMES SHAW, and LUCILLE SHAW				
10	Date: September 27, 2011	HEYGOOD, ORR & PEARSON				
11						
12		By: /s/ Michael Heygood (as authorized on 9/27/11)				
13		Michael Heygood, Esq. James Craig Orr, Jr., Esq.				
14		Charles W. Miller, Esq. Eric Pearson, Esq.				
15		Attorneys for Plaintiffs MISTY SHAW, JAMES SHAW, and LUCILLE SHAW				
16	Date: September 27, 2011	TUCKER ELLIS & WEST LLP				
17						
18						
19		By: /s/ William H. Dance(as authorized on 9/27/11)				
20		William H. Dance, Esq. Attorney for Defendant JANSSEN				
21 22		PHARMACEUTICALS, INC.				
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	10 STIPULATED PROTECTIVE ORDER					
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1	Date: September 27, 2011	DOWNEY BRAND LLP
2	Date. September 27, 2011	DOWNET BRAND LLF
3		
4		By: <u>/s/ Meghan M. Baker</u> Meghan M. Baker, Esq.
5		Jennifer Randlett Madden, Esq. Attorneys for Defendants MYLAN
6		INC., MYLAN
7		PHARMACEUTICALS INC. and MYLAN TECHNOLOGIES INC.
8		PIETRAGALLO GORDON ALFANO BOSICK
9	Date: September 27, 2011	& RASPANTI, LLP
10		
11		
12		By: <u>/s/ Clem C. Trischler (as authorized on 9/27/11)</u> Clem C. Trischler, Esq.
13		Attorney for Defendants MYLAN INC., MYLAN
14		PHARMACEUTICALS INC. and
15		MYLAN TECHNOLOGIES INC.
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		11 STIPULATED PROTECTIVE ORDER

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1		<u>ORDER</u>	
2	IT IS SO ORDERED.		
3	9/28/2011	/S/ JOHN A. MENDEZ	
4	DATE	UNITED STATES DISTRICT JUDGE	
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1	UNITED STATES DISTRICT COURT			
2	EASTERN DISTRICT OF CALIFORNIA			
3	MISTY SHAW, JAMES SHAW, and	Case No.: 2:11-cv-00189-JAM-CMK		
4	LUCILLE SHAW,			
5	Plaintiffs,	CONFIDENTIALITY AGREEMENT		
6	v.			
7	MYLAN, INC., MYLAN	Judge: Honorable John A. Mendez		
8	PHARMACEUTICALS, INC., MYLAN TECHNOLOGIES, INC., ALZA			
9	CORPORATION, JANSSEN PHARMACEUTICALS, and DOES 1-100			
10	Defendants.			
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12		l		
13	The undersigned, having read and understood the Stipulated Protective Order governing the			
14	restricted use of Protected Documents of Product Defendants identified and marked as			
15	"CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER" and/or "Protected Document.			
16	Document Subject to Protective Order," and any information derived therefrom, hereby agrees to be			
17	bound by the terms thereof; understands the	hat any disclosure of the Protected Documents or any		
18	information derived therefrom constitutes co	ontempt of Court; and agrees to submit to the personal		
19	jurisdiction of this Court to enforce the Prote	ctive Order against the undersigned.		
20	Date:	By:		
21		Name:		
22		Title:		
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affiliated with a Competitor of Janssen, and/or Mylan. I understand that I may be receiving confidential information as described in the Stipulated Protective Order. By execution of this Affidavit, I agree to be bound by all provisions of the Order. I agree not to disclose confidential information as described in the Stipulated Protective Order to any person not entitled to receive it and agree not to use such information except in connection with this litigation. 7. I am informed and understand, and therefore acknowledge, that I may be subject to contempt of court or any other penalties authorized by law or statute if I fail to comply with each of the provisions of the Order. 8. I consent to and accept, generally and unconditionally, the jurisdiction of the United States District Court for the Eastern District of California for the enforcement of the provisions of the Order. I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this Affidavit was executed on the \_\_\_\_ day of \_\_\_\_\_, at (Signature) 443.

1	UNITED STATES DISTRICT COURT			
2	EASTERN DISTRICT OF CALIFORNIA			
3	MISTY SHAW, JAMES SHAW, and	Case No.: 2:11-cv-00189-JAM-CMK		
4	LUCILLE SHAW,	AFFIDAVIT OF COUNSEL		
5	Plaintiffs,	AFFIDAVII OF COUNSEL		
6	V.	Judge: Honorable John A. Mendez		
7	MYLAN, INC., MYLAN PHARMACEUTICALS, INC., MYLAN	Judge. Honorable John A. Mendez		
8	TECHNOLOGIES, INC., ALZA CORPORATION, JANSSEN			
9	PHARMACEUTICALS, and DOES 1-100			
10	Defendants.			
11				
12	1 1	colour and state the fallowing.		
13	I,, declare and state the following:			
14	1. I am over eighteen (18) years of age and am in all respects competent to execute thi			
15	Affidavit. The facts stated hereunder are true, known to me of my own personal knowledge, and i			
16	called as a witness, I could and would competently testify thereto.			
17	2. I am counsel of record for Plaintiffs Misty Shaw, James Shaw, and Lucille Shaw in			
18	lawsuit currently pending against Janssen P	harmaceuticals, Inc. ("Janssen") and Mylan Inc., Mylar		
19	Pharmaceuticals Inc., and Mylan Technological	ogies Inc. (collectively "Mylan") and/or certain other		
20	persons, firms, corporations or entities, invo	lving the product(s) known as Duragesic® and/or Mylar		
21	Fentanyl Transdermal System®.			
22	3. Pursuant to Paragraph 4 of the	e Stipulated Protective Order, after reasonable inquiry and		
23	consultation with, it	is my opinion that he/she is not presently engaged as a		
24	Competitor (as defined in paragraph 4 of the	Stipulated Protective Order) of and/or an agent,		
25	employee, consultant or person otherwise act	tively affiliated with a Competitor of Janssen, and/or		
26	Mylan.			
27				
28	1190			
	443.	A EIEID A VIIIE D		
1		AFFIDAVIT B		

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this Affidavit was executed on the \_\_\_\_\_ day of \_\_\_\_\_\_, at (Signature) 

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