TUCKER ELLIS LLP Mollie F. Benedict SBN 187084 mollie.benedict@tuckerellis.com E. Todd Chayet SBN 217694 todd.chayet@tuckerellis.com Linda G. Ronan SBN 231003 linda.ronan@tuckerellis.com 515 South Flower Street Forty-Second Floor Los Angeles, CA 90071-2223 Telephone: 213.430.3400 Facsimile: 213.430.3409 Attorneys for Defendants ALZA CORPORATION and SANDOZ INC.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

CHARLES WETHERINGTON, SR. and KATHY LEE WETHERINGTON Plaintiffs,) Case No. CIV S-12-0349 KJM DAD)) STIPULATED PROTECTIVE ORDER)
v. ALZA CORPORATION, SANDOZ INC. and	
JOHN DOES 1 through 100 Defendants.)))
· ·	

WHEREAS, Plaintiffs Charles Wetherington, Sr. and Kathy Lee Wetherington, ("Plaintiffs") and/or any other party may seek the production of documents and information from Defendants ALZA Corporation and Sandoz Inc. (collectively, "Defendants");

WHEREAS, 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 and/or Sandoz Fentanyl

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Transdermal System specific information which Defendants deem confidential;

WHEREAS, 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 Defendants in that many years have been invested in researching, developing, manufacturing, and marketing the product at issue, and 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 may be 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 Defendants may be stamped "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 Defendants may be disclosed to any person, except as permitted in paragraphs 2 and 3 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

- 3. In addition, Protected Documents and/or any portion thereof deemed confidential may be disclosed to (a) persons noticed for depositions or designated as trial witnesses to the extent reasonably necessary in preparing to testify; and (b) to 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. Before any 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 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 Defendants' counsel, except that a copy of the Confidentiality Agreement signed by a person described in subsection (b) need not be served upon 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 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 fentanyl through the skin, and shall include any agent, employee, consultant, or other person currently similarly affiliated with such entity or person. Before disclosing any Document to any person listed in paragraph 3(a) or 3(b) who may also be a competitor of 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 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 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 upon Defendants' counsel. Defendants' counsel shall have seven (7) business days to object to 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 any party from seeking leave of court upon good cause shown to disclose Protected Documents to a Competitor of 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 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 contained in such reports.

6. **Documents at Depositions.**

a. A deponent who is not a current employee of Defendants may, during the deposition, be shown and examined about the Protected Documents as long as disclosure comports with

19

20

21

22

23

24

25

26

27

28

1

2

3

4

5

6

8

9

the provisions of paragraphs 3 and 4, although the deponent can comply with the requirements of paragraphs 3 and 4 via oral testimony on the record under oath during the deposition instead of actually signing the affidavits. Notwithstanding such, a former employee of Defendants may be shown a Protected Document if such former employee authored or has previously seen such document before. 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 Affidavits described in paragraphs 3 and 4.

- 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. 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. (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 CourtPursuant to the Status (Pretrial Scheduling) Order entered in this case, if any party intends to file Protected Documents or quote or reveal the information contained in Protected Documents, prior court approval shall be sought before a Protected Document or motion may be filed under seal or redacted. All requests to seal or redact shall be governed by Local Rules of the Eastern District of California, Rules 140 and 141. If

20

21

22

23

24

25

26

27

28

1

2

3

4

5

6

8

9

either party intends to make a filing of Protected Documents or a motion quoting or revealing the contents of such Protected Documents or information identified as confidential, the filing party shall provide sufficient notice in advance of filing to allow for the seeking of an order of sealing or redaction from the Court. A court order to seal or redact any motion quoting or revealing the contents of such Protected Documents or information identified as confidential shall be sought before any such motion is filed pursuant to the Status (Pretrial Scheduling) order entered in this case. 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 this paragraph. 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.

- Documents used at Trial. Defendants may move this Court for an order that the 8. evidence at trial be received in such a way as to prevent unnecessary disclosure consistent with applicable law. Absent such additional order of Court, all parties are entitled to use Protected Documents as evidence during trial without restriction.
- 9. **Declassification.** Any party may request from this Court a ruling that a Document or deposition transcript is not entitled to continued protection under this Protective Order.
- 10. Subpoena by Other Courts or Agencies. If another court or an administrative agency subpoenas or orders production of the Protected Documents which a party has obtained under the terms of this Protective Order, the party shall promptly notify Defendants' counsel of such subpoena or order. Protected Documents shall not be produced by the party until Defendants' counsel has been notified of such subpoena or order and has had a reasonable opportunity to protect Defendants' 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.

1

Cleveland ♦ Columbus ♦ Denver ♦ Los Angeles ♦ San Francisco

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

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" bate stamp prefix may be used in other Sandoz 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 LLP written notice of the documents it intends to use. Additionally, Defendants agree that it will not be a violation of any Protective Order for Heygood, Orr & Pearson to use such Protected Documents produced in other Sandoz Fentanyl Transdermal System cases against Defendants where Heygood, Orr & Pearson was or is lead counsel in the preparation and trial, appeal, or retrial of this action or any Sandoz Fentanyl Transdermal System cases against Defendants where Heygood, Orr & Pearson is lead counsel.

13. Non-Termination.

- Within thirty (30) days after final conclusion of all cases that Heygood, Orr & a. Pearson are handling involving Sandoz Fentanyl Transdermal System, the Protected Documents and all copies thereof (other than exhibits of record) shall be returned to counsel for Defendants or destroyed. Notes, summaries, memos, computer data bases, and other information compilations from the Documents shall be destroyed. All parties and their counsel shall certify compliance herewith and shall deliver the same to counsel for Defendants not more than forty-five (45) days after final termination of this litigation.
- b. Consultants and/or experts who are retained by counsel for Plaintiffs and continue to consult on active cases involving Sandoz Fentanyl Transdermal System are not required to return to Defendants' counsel and/or destroy the Protected Documents at the termination of the above-styled action. However, within thirty (30) days after final conclusion of all aspects of the active Sandoz Fentanyl Transdermal System cases for which the consultant and/or expert has been retained, the Protected Documents and all copies thereof (other than exhibits of record) shall be returned to counsel for Defendants, or at Defendants' option, destroyed. All parties and their counsel shall certify compliance herewith and shall deliver the same to counsel for Defendants not more than forty-five (45) days after final termination of all aspects of the active Sandoz Fentanyl Transdermal System cases for which the consultant and/or expert has been retained.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

14. **Previously Produced Documents.** Documents that have previously been produced to Heygood, Orr & Pearson in other related litigation with a DUR or WEST bates prefix shall be deemed to have been produced by Defendants in this case.

Defendants and Plaintiffs further stipulate that subsequent productions of Protected Documents identified by the bates prefix "DUR" or "WEST" produced by Defendants in this or other cases involving a Sandoz Fentanyl Transdermal System fentanyl patch in which Heygood, Orr & Pearson is lead trial counsel will also be deemed produced in this case on the condition that discovery is still open in this case on the date such Protected Documents are produced to Heygood, Orr & Pearson. This Stipulation shall have no bearing on the admissibility of the Protected Documents deemed produced herein. Furthermore, Defendants do not waive any objections regarding use of the Protected Documents before, during or after the trial of this matter.

- 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 Producing 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, "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 party – the other party shall provide the Producing Party with the name, address, and telephone number of such person(s) as well as the date of and reason for the transmission of the document.
- 16. 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

CONFIDENTIALITY AGREEMENT

846039.1

846039.1