

1 (All parties and counsel listed on Signature Page)

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3
4 UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
5 SAN FRANCISCO DIVISION

6 PAR PHARMACEUTICAL, INC., and
HANDA PHARMACEUTICALS, LLC.,

Case No. 5:13-cv-1927 LHK

7 Plaintiffs,

STIPULATED PROTECTIVE ORDER

8 v.

9 TAKEDA PHARMACEUTICAL CO., LTD.,
10 TAKEDA PHARMACEUTICALS NORTH
AMERICA, INC., TAKEDA
11 PHARMACEUTICALS AMERICA, INC.,
AND TAKEDA PHARMACEUTICALS
12 U.S.A., INC.,

Judge: Hon. Lucy H. Koh

13 Defendant.

14
15 1. PURPOSES AND LIMITATIONS

16 Disclosure and discovery activity in this action are likely to involve production of
17 confidential, proprietary, or private information for which special protection from public
18 disclosure and from use for any purpose other than prosecuting this litigation would be warranted.
19 Accordingly, the parties hereby stipulate to and petition the Court to enter the following
20 Stipulated Protective Order. The parties acknowledge that this Order does not confer blanket
21 protections on all disclosures or responses to discovery and that the protection it affords from
22 public disclosure and use extends only to the limited information or items that are entitled to
23 confidential treatment under the applicable legal principles. The parties further acknowledge, as
24 set forth in Section 14, below, that this Stipulated Protective Order does not entitle them to file
25 confidential information under seal; Civil Local Rule 79-5 sets forth the procedures that must be
26 followed and the standards that will be applied when a party seeks permission from the Court to
27 file material under seal. This Stipulated Protective Order is submitted and entered without
28 prejudice to Plaintiffs' position that the instant case should be related to the matter *Takeda*

STIPULATED PROTECTIVE ORDER
CASE NO. 5:13-CV-1927 LHK

1 *Pharmaceutical Co., Ltd. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*, No.
2 3:11-cv-840 (N.D. Cal.) and heard by Judge Spero. By stipulating to this Stipulated Protective
3 Order, Plaintiffs do not waive any right they otherwise would have with respect to this position or
4 its advancement.

5 2. DEFINITIONS

6 2.1 Challenging Party: a Party or Non-Party that challenges the designation of
7 information or items under this Order.

8 2.2 “CONFIDENTIAL” Information or Items: information (regardless of how
9 it is generated, stored or maintained) or tangible things that qualify for protection under Federal
10 Rule of Civil Procedure 26(c). “CONFIDENTIAL” information or items includes information or
11 tangible things produced in the matter *Takeda Pharmaceutical Co., Ltd. v. Handa*
12 *Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*, No. 3:11-cv-840 (N.D. Cal.) designated by
13 any Party as “CONFIDENTIAL” under the protective order issued in that case, [No. 3:11-cv-840
14 D.N. 121], which in the interest of avoiding repetitive discovery, are deemed produced in this
15 case, notwithstanding the provisions in the aforementioned protective order foreclosing the use of
16 such materials in other litigation (*see* [No. 3:11-cv-840, D.N. 121] ¶ 7.1) and subject to the
17 requirements of the Amended Stipulated Protective Order submitted for entry in that case on July
18 12, 2013 [No. 3:11-cv-840, D.N. 440].

19 2.3 Counsel (without qualifier): Outside Counsel of Record and House
20 Counsel (as well as their support staff).

21 2.4 Designated House Counsel: House Counsel who seek access to “HIGHLY
22 CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information in this matter.

23 2.5 Designating Party: a Party or Non-Party that designates information or
24 items that it produces in disclosures or in responses to discovery as “CONFIDENTIAL” or
25 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.”

26 2.6 Disclosure or Discovery Material: all items or information, regardless of
27 the medium or manner in which they are generated, stored, or maintained (including, among other
28

1 things, testimony, transcripts, and tangible things), that are produced or generated in disclosures
2 or responses to discovery in this matter.

3 2.7 Expert: a person who has been retained by a Party or its Counsel to serve
4 as an expert witness or as a consultant in this action, subject to the provisions of Paragraph 7.2(c)
5 below. The consent to designation of an individual as an “Expert” under this Order is without
6 prejudice to any objections a Party may have to that witness or his or her testimony.

7 2.8 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY”
8 Information or Items: extremely sensitive “Confidential Information or Items,” disclosure of
9 which to another Party or Non-Party would create a substantial risk of serious harm that could not
10 be avoided by less restrictive means. “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES
11 ONLY” information or items includes information or tangible things produced in the matter
12 *Takeda Pharmaceutical Co., Ltd. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*,
13 No. 3:11-cv-840 (N.D. Cal.) designated by any Party as “HIGHLY CONFIDENTIAL –
14 ATTORNEYS’ EYES ONLY” under the protective order issued in that case, [No. 3:11-cv-840
15 D.N. 121], which in the interest of avoiding repetitive discovery, are deemed produced in this
16 case, notwithstanding the provisions in the aforementioned protective order foreclosing the use of
17 such materials in other litigation (*see* [No. 3:11-cv-840, D.N. 121] ¶ 7.1) and subject to the
18 requirements of the Amended Stipulated Protective Order submitted for entry in that case on July
19 12, 2013 [No. 3:11-cv-840, D.N. 440].

20 2.9 House Counsel: attorneys or intellectual property professionals¹ who are
21 employees of a party to this action. House Counsel does not include Outside Counsel of Record
22 or any other outside counsel.

23 2.10 Non-Party: any natural person, partnership, corporation, association, or
24 other legal entity not named as a Party to this action.

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26 _____
27 ¹ “Intellectual property professionals” shall refer to Japanese intellectual property professionals trained in intellectual
28 property whose primary responsibilities include tasks typically performed by lawyers in the United States, including, e.g., litigation management, prosecution, and licensing.

1 2.11 Outside Counsel of Record: attorneys who are not employees of a Party to
2 this action but are retained to represent or advise a Party to this action and have appeared in this
3 action on behalf of that Party or are affiliated with a law firm which has appeared on behalf of
4 that Party.

5 2.12 Party: any party to this action, including all of its officers, directors,
6 employees, consultants, retained experts, and Outside Counsel of Record (and their support
7 staffs).

8 2.13 Producing Party: a Party or Non-Party that produces Disclosure or
9 Discovery Material in this action.

10 2.14 Professional Vendors: persons or entities that provide litigation support
11 services (e.g., photocopying, videotaping, translating, preparing exhibits, graphics, or
12 demonstrations, and organizing, storing, retrieving data in any form or medium, and so on) and
13 their employees and subcontractors.

14 2.15 Protected Material: any Disclosure or Discovery Material that is
15 designated as “CONFIDENTIAL,” or as “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES
16 ONLY.” “Protected Material” includes information or tangible things produced in the matter
17 *Takeda Pharmaceutical Co., Ltd. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*,
18 No. 3:11-cv-840 (N.D. Cal.) constituting “Protected Material” under the protective order issued in
19 that case, [No. 3:11-cv-840 D.N. 121], which in the interest of avoiding repetitive discovery, are
20 deemed produced in this case, notwithstanding the provisions in the aforementioned protective
21 order foreclosing the use of such materials in other litigation (*see* [No. 3:11-cv-840, D.N. 121] ¶
22 7.1) and subject to the requirements of the Amended Stipulated Protective Order submitted for
23 entry in that case on July 12, 2013 [No. 3:11-cv-840, D.N. 440].

24 2.16 Receiving Party: a Party that receives Disclosure or Discovery Material
25 from a Producing Party.

26 3. SCOPE

27 The protections conferred by this Stipulated Protective Order cover not only Protected
28 Material (as defined above), but also (1) any information copied or extracted from Protected

1 Material; (2) all copies, excerpts, summaries, or compilations of Protected Material; and (3) any
2 testimony, conversations, or presentations by Parties or their Counsel that might reveal Protected
3 Material.

4 However, the protections conferred by this Stipulated Protective Order do not cover the
5 following information: (a) any information that is in the public domain at the time of disclosure
6 to a Receiving Party or becomes part of the public domain after its disclosure to a Receiving Party
7 as a result of publication not involving a violation of this Order, including becoming part of the
8 public record through trial or otherwise; and (b) any information known to the Receiving Party
9 prior to the disclosure or obtained by the Receiving Party after the disclosure from a source who
10 obtained the information lawfully and under no obligation of confidentiality to the Designating
11 Party. Any use of Protected Material at trial shall be governed by a separate agreement or order.

12 4. DURATION

13 Even after final disposition of this litigation, the confidentiality obligations imposed by
14 this Order shall remain in effect until a Designating Party agrees otherwise in writing or a court
15 order otherwise directs. Final disposition shall be deemed to be the later of (1) dismissal of all
16 claims and defenses in this action, with or without prejudice; and (2) final judgment herein after
17 the completion and exhaustion of all appeals, rehearings, remands, trials, or reviews of this action,
18 including the time limits for filing any motions or applications for extension of time pursuant to
19 applicable law.

20 5. DESIGNATING PROTECTED MATERIAL

21 5.1 Exercise of Restraint and Care in Designating Material for Protection.

22 Each Party or Non-Party that designates information or items for protection under this Order must
23 take care to limit any such designation to specific material that qualifies under the appropriate
24 standards. To the extent it is practical to do so, the Designating Party must designate for
25 protection only those parts of material, documents, items, or oral or written communications that
26 qualify — so that other portions of the material, documents, items, or communications for which
27 protection is not warranted are not swept unjustifiably within the ambit of this Order.
28

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

5 If it comes to a Designating Party's attention that information or items that it designated
6 for protection do not qualify for protection at all or do not qualify for the level of protection
7 initially asserted, that Designating Party must promptly provide written notice to all other parties
8 that it is withdrawing the mistaken designation.

9 5.2 Manner and Timing of Designations. Except as otherwise provided in this
10 Order (*see, e.g.*, second paragraph of Section 5.2(a), below), or as otherwise stipulated or ordered,
11 Disclosure or Discovery Material that qualifies for protection under this Order must be clearly so
12 designated before the material is disclosed or produced.

13 Designation in conformity with this Order requires:

14 (a) for information in documentary form (e.g., paper or electronic documents,
15 but excluding transcripts of depositions or other pretrial or trial proceedings), that the Producing
16 Party affix the legend "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – ATTORNEYS'
17 EYES ONLY" to each page that contains protected material. If only a portion or portions of the
18 material on a page qualifies for protection, the Producing Party also must clearly identify the
19 protected portion(s) (e.g., by making appropriate markings in the margins) and must specify, for
20 each portion, the level of protection being asserted.

21 A Party or Non-Party that makes original documents or materials available for inspection
22 need not designate them for protection until after the inspecting Party has indicated which
23 material it would like copied and produced. During the inspection and before the designation, all
24 of the material made available for inspection shall be deemed "HIGHLY CONFIDENTIAL –
25 ATTORNEYS' EYES ONLY." After the inspecting Party has identified the documents it wants
26 copied and produced, the Producing Party must determine which documents, or portions thereof,
27 qualify for protection under this Order. Then, before producing the specified documents, the
28 Producing Party must affix the appropriate legend ("CONFIDENTIAL" or "HIGHLY

1 CONFIDENTIAL – ATTORNEYS’ EYES ONLY”) to each page that contains Protected
2 Material. If only a portion or portions of the material on a page qualifies for protection, the
3 Producing Party also must clearly identify the protected portion(s) (e.g., by making appropriate
4 markings in the margins) and must specify, for each portion, the level of protection being asserted
5 (either “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY”).

6 (b) for testimony given in deposition or in other pretrial or trial proceedings,
7 that the Designating Party identify on the record, before the close of the deposition, hearing, or
8 other proceeding, all protected testimony, and further specify the portions of the testimony that
9 qualify as “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.” When it is
10 impractical to identify separately each portion of testimony that is entitled to protection and it
11 appears that substantial portions of the testimony may qualify for protection, the Designating
12 Party may invoke on the record (before the deposition, hearing, or other proceeding is
13 concluded) a right to have up to 21 days to identify the specific portions of the testimony as to
14 which protection is sought and to specify the level of protection being asserted. Only those
15 portions of the testimony that are appropriately designated for protection within the 21 days
16 shall be covered by the provisions of this Stipulated Protective Order.

17 The use of a document as an exhibit at a deposition shall not in any way affect its
18 designation as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES
19 ONLY.”

20 Deposition transcripts containing Protected Material must be separately bound by the
21 court reporter, who must affix to the front of the transcript the legend “CONFIDENTIAL” or
22 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” as instructed by the Party
23 offering or sponsoring the testimony. Any transcript that is prepared before the expiration of a
24 21-day period for designation shall be treated during that period as if it had been designated
25 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” in its entirety unless otherwise
26 agreed. After the expiration of that period, the transcript shall be treated only as actually
27 designated.

28 (c) for information produced in some form other than documentary and for

1 any other tangible items, that the Producing Party affix in a prominent place on the exterior of
2 the container or containers in which the information or item is stored the legend
3 “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.” If only
4 a portion or portions of the information or item warrant protection, the Producing Party, to the
5 extent practicable, shall identify the protected portion(s) and specify the level of protection
6 being asserted.

7 5.3 Inadvertent Failures to Designate. If timely corrected, an inadvertent
8 failure to designate qualified information or items does not, standing alone, waive the Designating
9 Party’s right to secure protection under this Order for such material. Upon timely correction of a
10 designation, the Receiving Party must make reasonable efforts to assure that the material is
11 treated in accordance with the provisions of this Order. Any disclosure of such information that
12 is not otherwise in violation of this Stipulated Protective Order and that was made prior to the
13 correction of the designation is not a breach of this Order.

14 6. CHALLENGING CONFIDENTIALITY DESIGNATIONS

15 6.1 Timing of Challenges. Any Party or Non-Party may challenge a
16 designation of confidentiality at any time. Unless a prompt challenge to a Designating Party’s
17 confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary
18 economic burdens, or a significant disruption or delay of the litigation, a Party does not waive its
19 right to challenge a confidentiality designation by electing not to mount a challenge promptly
20 after the original designation is disclosed.

21 6.2 Meet and Confer. The Challenging Party shall initiate the dispute
22 resolution process by providing written notice of each designation it is challenging and describing
23 the basis for each challenge. To avoid ambiguity as to whether a challenge has been made, the
24 written notice must recite that the challenge to confidentiality is being made in accordance with
25 this specific paragraph of the Protective Order. The parties shall attempt to resolve each
26 challenge in good faith and must begin the process by conferring directly (in voice-to-voice
27 dialogue; other forms of communication are not sufficient) within 14 days of the date of service
28 of notice. In conferring, the Challenging Party must explain the basis for its belief that the

1 confidentiality designation was not proper and must give the Designating Party an opportunity to
2 review the designated material, to reconsider the circumstances, and, if no change in designation
3 is offered, to explain the basis for the chosen designation. A Challenging Party may proceed to
4 the next stage of the challenge process only if it has engaged in this meet-and-confer process first
5 or establishes that the Designating Party is unwilling to participate in the meet-and-confer process
6 in a timely manner.

7 6.3 Judicial Intervention. If the Parties cannot resolve a challenge without
8 court intervention, the Designating Party shall file and serve a motion to retain confidentiality
9 under Civil Local Rule 7 (and in compliance with Civil Local Rule 79-5, if applicable) within 21
10 days of the initial notice of challenge or within 14 days of the parties agreeing that the meet-and-
11 confer process will not resolve their dispute, whichever is earlier. Each such motion must be
12 accompanied by a competent declaration affirming that the movant has complied with the meet-
13 and-confer requirements imposed in the preceding paragraph. Failure by the Designating Party to
14 make such a motion including the required declaration within 21 days (or 14 days, if applicable)
15 shall automatically waive the confidentiality designation for each challenged designation. In
16 addition, the Challenging Party may file a motion challenging a confidentiality designation at any
17 time if there is good cause for doing so, including a challenge to the designation of a deposition
18 transcript or any portions thereof. Any motion brought pursuant to this provision must be
19 accompanied by a competent declaration affirming that the movant has complied with the meet-
20 and-confer requirements imposed by the preceding paragraph.

21 The burden of persuasion in any such challenge proceeding shall be on the Designating
22 Party. Frivolous challenges and those made for an improper purpose (e.g., to harass or impose
23 unnecessary expenses and burdens on other parties) may expose the Challenging Party to
24 sanctions. Unless the Designating Party has waived the confidentiality designation by failing to
25 file a motion to retain confidentiality as described above, all parties shall continue to afford the
26 material in question the level of protection to which it is entitled under the Producing Party's
27 designation until the court rules on the challenge.

28 7. ACCESS TO AND USE OF PROTECTED MATERIAL

1 7.1 Basic Principles. A Receiving Party may use Protected Material that is
2 disclosed or produced by another Party or by a Non-Party in connection with this case only for
3 prosecuting, defending, or attempting to settle this litigation. Such Protected Material shall not be
4 used for any business, commercial, regulatory, competitive, personal, or other purpose. In
5 particular, Protected Material disclosed in this litigation shall not be submitted to or used to
6 prepare submissions to any foreign or domestic regulatory agency, including but not limited to
7 citizen petitions to the United States Food and Drug Administration (“FDA”), and/or any
8 submission to the United States Pharmacopeia, British Pharmacopeia, or European Pharmacopeia.
9 Furthermore, any Protected Material disclosed in this litigation shall not be used in any other
10 litigation, including lawsuits against the FDA. Any summary, compilation, notes, memoranda,
11 analysis, or copy containing Confidential Information or Highly Confidential Information and any
12 electronic image or database containing “CONFIDENTIAL” OR “HIGHLY CONFIDENTIAL –
13 ATTORNEYS’ EYES ONLY” Information shall be subject to the terms of this Protective Order
14 to the same extent as the material or information from which such summary, compilation, notes,
15 copy, memoranda, analysis, electronic image, or database is derived.

16 Protected Material may be disclosed only to the categories of persons and under the
17 conditions described in this Order. When the litigation has been terminated, a Receiving Party
18 must comply with the provisions of Section 15 below (FINAL DISPOSITION).

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

21 7.2 Disclosure of “CONFIDENTIAL” Information or Items. Unless otherwise
22 ordered by the Court or permitted in writing by the Designating Party, a Receiving Party may
23 disclose any information or item designated “CONFIDENTIAL” only to:

24 (a) the Receiving Party’s Outside Counsel of Record in this action, as well as
25 employees of said Outside Counsel of Record to whom it is reasonably necessary to disclose the
26 information for this litigation;

27 (b) the officers, directors, and employees (including House Counsel) of the
28 Receiving Party to whom disclosure is reasonably necessary for this litigation;

1 (c) Experts of the Receiving Party (1) to whom disclosure is reasonably
2 necessary for this litigation, (2) who have signed the “Acknowledgment and Agreement to Be
3 Bound” (Exhibit A), and (3) as to whom the procedures set forth in Section 7.4(a)(3), below,
4 have been followed;

5 (d) the Court and its personnel;

6 (e) court reporters and their staff and Professional Vendors to whom
7 disclosure is reasonably necessary for this litigation;

8 (f) during their depositions, witnesses in the action to whom disclosure is
9 reasonably necessary and who have signed the “Acknowledgment and Agreement to Be Bound”
10 (Exhibit A), unless otherwise agreed by the Designating Party or ordered by the Court. Pages of
11 transcribed deposition testimony or exhibits to depositions that reveal Protected Material must
12 be separately bound by the court reporter and may not be disclosed to anyone except as
13 permitted under this Stipulated Protective Order.

14 (g) the author or recipient of a document containing the information or a
15 custodian or other person who otherwise possessed or knew the information.

16 7.3 Disclosure of “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES
17 ONLY” Information or Items. Unless otherwise ordered by the Court or permitted in writing by
18 the Designating Party, a Receiving Party may disclose any information or item designated
19 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” only to:

20 (a) the Receiving Party’s Outside Counsel of Record in this action, as well as
21 employees of said Outside Counsel of Record to whom it is reasonably necessary to disclose the
22 information for this litigation;

23 (b) Designated House Counsel of the Receiving Party, as set forth below,
24 provided that (i) prior to accessing any information or item designated “HIGHLY
25 CONFIDENTIAL – ATTORNEYS’ EYES ONLY” the Designated House Counsel shall sign
26 the “Acknowledgment and Agreement to Be Bound” that is attached hereto as Exhibit A, as well
27 as a declaration affirming their: (1) non-involvement in the preparation or prosecution of any
28 U.S. or foreign patent application relating to proton pump inhibitors, including dexlansoprazole;

1 (2) non-involvement in advising on decisions about pricing or design made in light of similar or
2 corresponding information about a competitor regarding proton pump inhibitors, including
3 dexlansoprazole; and (3) non-involvement in the preparation or submission of U.S. Food and
4 Drug Administration documents (including but not limited to citizen petitions), or any similar
5 documents in any foreign country, regarding approval requirements relating to proton pump
6 inhibitors, including dexlansoprazole, except where such correspondence is regarding the
7 Receiving Party's own pending drug approval application and (ii) the procedures set forth in
8 Section 7.4 below have been followed.

9 (c) Notwithstanding the provisions of Paragraph 7.3(b), the parties agree that
10 Ken Greisman, Vice President and Chief Legal Counsel for Litigation for Takeda
11 Pharmaceuticals North America, Inc., and Eiji Nara, Director of Intellectual Property for Takeda
12 Pharmaceutical Company, Inc., may obtain advice on the progress of the litigation from their
13 Outside Counsel of Record and may review pleadings, briefs, and other papers, including drafts,
14 filed or served in this matter, provided, however, that Mr. Greisman and Dr. Nara may not
15 receive any Bates-numbered documents produced by Defendants. Mr. Greisman and Dr. Nara
16 shall sign the "Acknowledgment and Agreement to Be Bound" that is attached hereto as Exhibit
17 A.

18 (d) Experts of the Receiving Party (1) to whom disclosure is reasonably
19 necessary for this litigation, (2) who have signed the "Acknowledgment and Agreement to Be
20 Bound" (Exhibit A), and (3) as to whom the procedures set forth in Section 7.4(a)(3), below,
21 have been followed;

22 (e) the Court and its personnel;

23 (f) court reporters and their staff and Professional Vendors to whom
24 disclosure is reasonably necessary for this litigation and who have signed the "Acknowledgment
25 and Agreement to Be Bound" (Exhibit A); and

26 (g) the author or recipient of a document containing the information or a
27 custodian or other person who otherwise possessed or knew the information.

28 (h) The list of persons to whom information or items that has been designated

1 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may be disclosed may be
2 expanded or modified by mutual agreement in writing by Counsel for the Designating Party and
3 the Receiving Party without necessity of modifying this Order.

4 7.4 Procedures for Approving or Objecting to Disclosure of Information or
5 Items to Designated House Counsel or Experts.

6 (a)(1) Unless otherwise ordered by the Court or agreed to in writing by the Designating
7 Party, a Party that seeks to disclose materials that have been designated “HIGHLY
8 CONFIDENTIAL – ATTORNEYS’ EYES ONLY” to Designated House Counsel first must
9 make a written request to the Designating Party that (1) sets forth the full name of the Designated
10 House Counsel and the city and state of his or her residence, and (2) describes the Designated
11 House Counsel’s current and reasonably foreseeable future primary job duties and responsibilities
12 in sufficient detail to determine if House Counsel is involved, or may become involved, in any
13 competitive decision-making.

14 (a)(2) Designated House Counsel who receive “HIGHLY CONFIDENTIAL –
15 ATTORNEYS’ EYES ONLY” information pursuant to this Order must disclose any relevant
16 changes in job duties or responsibilities prior to final disposition of the litigation to allow the
17 Designating Party to evaluate any later-arising competitive decision-making responsibilities.

18 (a)(3) Unless otherwise ordered by the Court or agreed to in writing by the Designating
19 Party, a Party that seeks to disclose to an Expert (as defined in this Order) any information or item
20 that has been designated “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’
21 EYES ONLY” pursuant to Sections 7.2(c) or 7.3(d), respectively, first must make a written
22 request to the Designating Party that (1) sets forth the full name of the Expert and the city and
23 state of his or her primary residence, (2) attaches a copy of the Expert’s current resume,
24 (3) identifies the Expert’s current employer(s), and (4) identifies (by name and number of the case
25 and location of court) any litigation in connection with which the Expert has offered expert
26 testimony, including through a declaration, report, or testimony at a deposition or trial, during the
27 preceding five years.

28 (b) A Party that makes a request and provides the information specified in the

1 preceding respective paragraphs may disclose the subject Protected Material to the identified
2 Designated House Counsel or Expert unless, within 7 calendar days of delivering the request,
3 the Party receives a written objection from the Designating Party. Any such objection must set
4 forth in detail the grounds on which it is based.

5 (c) A Party that receives a timely written objection must meet and confer
6 with the Designating Party (through direct voice-to-voice dialogue) to try to resolve the matter
7 by agreement within 7 calendar days of the written objection. If no agreement is reached, the
8 Party seeking to make the disclosure to Designated House Counsel or the Expert may file a
9 motion as provided in Civil Local Rule 7 (and in compliance with Civil Local Rule 79-5, if
10 applicable) seeking permission from the Court to do so. Any such motion must describe the
11 circumstances with specificity, set forth in detail the reasons why the disclosure to Designated
12 House Counsel or the Expert is reasonably necessary, assess the risk of harm that the disclosure
13 would entail, and suggest any additional means that could be used to reduce that risk. In
14 addition, any such motion must be accompanied by a competent declaration describing the
15 parties' efforts to resolve the matter by agreement (i.e., the extent and the content of the meet-
16 and-confer discussions) and setting forth the reasons advanced by the Designating Party for its
17 refusal to approve the disclosure.

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

22 8. REGULATORY AND PROSECUTION BAR

23 (a) Absent written consent from the Producing Party, any individual who
24 receives access to "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" information
25 shall not be involved in the prosecution of patents or patent applications relating to any proton
26 pump inhibitor, including without limitation the patents asserted in this action and any patent or
27 application claiming priority to or otherwise related to the patents asserted in this action, before
28 any foreign or domestic agency, including the United States Patent and Trademark Office ("the

1 Patent Office”). For purposes of this paragraph, “prosecution” includes directly or indirectly
2 drafting, amending, advising, or otherwise affecting the scope or maintenance of patent claims.²
3 To avoid any doubt, “prosecution” as used in this paragraph does not include representing a party
4 challenging a patent before a domestic or foreign agency (including, but not limited to, a reissue
5 protest, ex parte reexamination or inter partes reexamination). This Prosecution Bar shall begin
6 when access to “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information is
7 first received by the affected individual and shall end two (2) years after final termination of this
8 action.

9 (b) Absent written consent from the Producing Party, any individual who
10 receives access to “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information
11 shall not be involved in the preparation or submission of any FDA documents (including but not
12 limited to citizen petitions), or any similar documents in any foreign country, regarding approval
13 requirements relating to any proton pump inhibitors, including dexlansoprazole, except where
14 such correspondence is regarding the Receiving Party’s own pending drug approval application.

15 9. PROTECTED MATERIAL SUBPOENAED OR ORDERED PRODUCED IN
16 OTHER LITIGATION

17 If a Party is served with a subpoena or a court order issued in other litigation that compels
18 disclosure of any information or items designated in this action as “CONFIDENTIAL” or
19 “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” that Party must:

20 (a) promptly notify in writing the Designating Party (by FAX or e-mail, if
21 possible). Such notification shall include a copy of the subpoena or court order;

22 (b) promptly notify in writing the party who caused the subpoena or order to
23 issue in the other litigation that some or all of the material covered by the subpoena or order is
24 subject to this Protective Order. Such notification shall include a copy of this Stipulated
25 Protective Order; and

26 (c) cooperate with respect to all reasonable procedures sought to be pursued
27 _____

28 ² Prosecution includes, for example, original prosecution, reissue and reexamination proceedings.

1 by the Designating Party whose Protected Material may be affected.

2 If the Designating Party timely seeks a protective order, the Party served with the
3 subpoena or court order shall not produce any information designated in this action as
4 “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” before a
5 determination by the court from which the subpoena or order issued, unless the Party has obtained
6 the Designating Party’s permission. The Designating Party shall bear the burden and expense of
7 seeking protection in that court of its confidential material — and nothing in these provisions
8 should be construed as authorizing or encouraging a Receiving Party in this action to disobey a
9 lawful directive from another court.

10 10. A NON-PARTY’S PROTECTED MATERIAL SOUGHT TO BE PRODUCED
11 IN THIS LITIGATION

12 (a) The terms of this Order are applicable to information produced by a Non-
13 Party in this action and designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL –
14 ATTORNEYS’ EYES ONLY.” Such information produced by Non-Parties in connection with
15 this litigation is protected by the remedies and relief provided by this Order. Nothing in these
16 provisions should be construed as prohibiting a Non-Party from seeking additional protections.

17 (b) In the event that a Party is required, by a valid discovery request, to
18 produce a Non-Party’s confidential information in its possession, and the Party is subject to an
19 agreement with the Non-Party not to produce the Non-Party’s confidential information, then the
20 Party shall:

21 1. promptly notify in writing the Requesting Party and the Non-Party
22 that some or all of the information requested is subject to a confidentiality agreement with a Non-
23 Party;

24 2. promptly provide the Non-Party with a copy of the Stipulated
25 Protective Order in this litigation, the relevant discovery request(s), and a reasonably specific
26 description of the information requested; and

27 3. make the information requested available for inspection by the
28 Non-Party.

1 (c) If the Non-Party fails to object or seek a protective order from this Court
2 within 14 days of receiving the notice and accompanying information, the Receiving Party may
3 produce the Non-Party's confidential information responsive to the discovery request. If the
4 Non-Party timely seeks a protective order, the Receiving Party shall not produce any
5 information in its possession or control that is subject to the confidentiality agreement with the
6 Non-Party before a determination by the Court. Absent a court order to the contrary, the Non-
7 Party shall bear the burden and expense of seeking protection in this Court of its Protected
8 Material.

9 11. UNAUTHORIZED DISCLOSURE OF PROTECTED MATERIAL

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

17 12. INADVERTENT PRODUCTION OF PRIVILEGED OR OTHERWISE
18 PROTECTED MATERIAL

19 The Parties will comply with the requirements of Federal Rule of Civil Procedure
20 26(b)(5)(B) in the event of inadvertent production of material subject to a claim of attorney-client
21 privilege, work product immunity, or any other applicable privilege or immunity. Such
22 inadvertent production shall not constitute a waiver of, nor prejudice to, any claim that such or
23 related material is privileged or protected.

24 13. MISCELLANEOUS

25 13.1 Right to Further Relief. Nothing in this Order abridges the right of any
26 person to seek its modification by the Court in the future.

27 13.2 Right to Assert Other Objections. By stipulating to the entry of this
28 Protective Order no Party waives any right it otherwise would have to object to disclosing or

1 producing any information or item on any ground not addressed in this Stipulated Protective
2 Order. Similarly, no Party waives any right to object on any ground to use in evidence of any of
3 the material covered by this Protective Order.

4 14. FILING PROTECTED MATERIAL.

5 Without written permission from the Designating Party or a court order secured after
6 appropriate notice to all interested persons, a Party may not file in the public record in this action
7 any Protected Material. A Party that seeks to file under seal any Protected Material must comply
8 with Civil Local Rule 79-5.

9 15. FINAL DISPOSITION

10 Unless otherwise ordered or agreed to in writing by the Producing Party, within 60 days
11 after the final disposition of this action, as defined in paragraph 4, each Receiving Party must
12 return all Protected Material to the Producing Party or destroy such material. As used in this
13 subdivision, "all Protected Material" includes all copies, abstracts, compilations, summaries, or
14 any other format reproducing or capturing any of the Protected Material. Whether the Protected
15 Material is returned or destroyed, the Receiving Party must submit a written certification to the
16 Producing Party (and, if not the same person or entity, to the Designating Party) by the 60-day
17 deadline that (1) identifies (by category, where appropriate) all the Protected Material that was
18 returned or destroyed and (2) affirms that the Receiving Party has not retained any copies,
19 abstracts, compilations, summaries or any other format reproducing or capturing any of the
20 Protected Material. Notwithstanding this provision, Counsel are entitled to retain an archival
21 copy of all pleadings, motion papers, trial, deposition, and hearing transcripts, legal memoranda,
22 correspondence, deposition and trial exhibits, expert reports, attorney work product, and
23 consultant and expert work product, even if such materials contain Protected Material. Any such
24 archival copies that contain or constitute Protected Material remain subject to this Protective
25 Order as set forth in Section 4 (DURATION).

26 DATED: July 12, 2013
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HANDA PHARMACEUTICALS, LLC

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TAKEDA PHARMACEUTICALS NORTH
AMERICA, INC., TAKEDA
PHARMACEUTICALS AMERICA, INC., AND
TAKEDA PHARMACEUTICALS U.S.A., INC.,

By: /s/ Tina W. Arroyo

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PURSUANT TO STIPULATION, IT IS SO ORDERED.

DATED: July 15, 2013


Paul S. Grewal
UNITED STATES MAGISTRATE JUDGE

Filer's Attestation

I, Tina W. Arroyo, am the ECF user whose identification and password are being used to file this **STIPULATED PROTECTIVE ORDER**. In compliance with General Order 45.X.B., I hereby attest that the above-named signatories concur in this filing.

DATED: July 12, 2013

/s/ Tina W. Arroyo
Tina W. Arroyo

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EXHIBIT A

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

I, _____ [print or type full name], of _____
[print or type full address], declare under penalty of perjury that I have read in its entirety and understand the Stipulated Protective Order that was issued by the United States District Court for the Northern District of California on [date] in the case of *Par Pharmaceutical, Inc. and Handa Pharamaceuticals, LLC.*, Case No. 5:13-cv-1927 LHK. I agree to comply with and to be bound by all the terms of this Stipulated Protective Order and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to this Stipulated Protective Order to any person or entity except in strict compliance with the provisions of this Order.

I further agree to submit to the jurisdiction of the United States District Court for the Northern District of California for the purpose of enforcing the terms of this Stipulated Protective Order, even if such enforcement proceedings occur after termination of this action.

I hereby appoint _____ [print or type full name] of _____ [print or type full address and telephone number] as my California agent for service of process in connection with this action or any proceedings related to enforcement of this Stipulated Protective Order.

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Date: _____

1 City and State where sworn and signed: _____

2

3 Printed name: _____
4 [printed name]

5 Signature: _____
6 [signature]

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