## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

Civil Action No. 1:18-cv-12029-ADB

### [PROPOSED] STIPULATED PROTECTIVE ORDER

WHEREAS Plaintiffs Teva Pharmaceuticals International GmbH ("Teva GmbH") and Teva Pharmaceuticals USA, Inc. ("Teva USA" and together with Teva GmbH, "Plaintiffs" or "Teva") and Defendant Eli Lilly and Company ("Lilly" or "Defendant") (Teva and Lilly collectively, the "Parties") expect that discovery in the above-captioned action (the "Litigation") will entail the disclosure and production of documents, things, testimony, and information containing confidential, proprietary, personal, trade secret, and/or commercially sensitive information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure;

WHEREAS the Parties believe that such information must be protected by certain terms and conditions (the "Protective Order") to preserve the Parties' legitimate business interests;

WHEREAS the Parties have, through their undersigned counsel, stipulated to the entry of this Protective Order in order to expedite the flow of discovery material, facilitate the prompt resolution of any disputes over confidentiality, balance the Parties' need for information to conduct



this Litigation against their need to maintain the confidentiality of information entitled to be kept confidential; and

WHEREAS the Parties have established good cause for entry of this Protective Order;

IT IS HEREBY ORDERED that this Protective Order shall govern discovery in the Litigation.

- 1. <u>Definitions</u>. Words shall have their normally accepted meanings as employed in this Protective Order. The word "shall" is mandatory. The words "includes" and "including" are not limiting. The singular shall include the plural and vice versa. Additionally, the Parties hereby incorporate by reference the definitions set forth in Rule 26.5 of the Local Rules of the United States District Court for the District of Massachusetts ("Local Rules" or "L.R.") as if fully set forth herein. Certain definitions from the Local Rules have been reproduced below for clarity. In addition, as used herein, the following words shall have the following meanings:
- (a) As used herein, the term "Document" is defined to be synonymous in meaning and equal in scope to the usage of the term "documents or electronically stored information" in Fed. R. Civ. P. 34(a)(1)(A) and Local Rule 26.5(c)(2). A draft or non-identical copy is a separate document within the meaning of this term.
- (b) As used herein, the term "Information" includes information of any type, kind or character whether it be a document, information contained in a document, information revealed during a deposition, information revealed in an interrogatory or other discovery response, or otherwise.
- (c) As used herein, the term "Litigation Material" shall mean Documents and Information produced, disclosed (as outlined in Paragraph 7, below), or filed in the Litigation by a Party or non-party, whether produced pursuant to formal or informal discovery requests or



motion practice, by agreement or otherwise, and whether revealed in a document, deposition (including testimony and deposition exhibits), an interrogatory answer, a response to a request for production or for admission(s), a submission to the court or otherwise, and including all Documents and Information produced or disclosed by non-parties in this Litigation pursuant to subpoena and/or deposition notice.

- (d) As used herein, the term "Producing Party" shall mean any Party to the Litigation or any non-party or third party, including its counsel, retained experts, directors, officers, employees, business partners, or agents, who produces, discloses, or files any Litigation Material.
- (e) As used herein, the term "Receiving Party" shall mean any Party to the Litigation, including its counsel, retained experts, directors, officers, employees, business partners, or agents, who receives any Litigation Material.
- (f) As used herein, the term "Confidential Health Information" ("CHI") shall mean any patient health information protected by any state or federal law. CHI includes, without limitation, information relating to: the past, present, or future physical health, mental health, condition, or medical treatment of an individual which identifies or reasonably could be expected to identify the individual. It also includes, but is not limited to, medical bills, claims forms, charges sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanation of benefits, checks, notices, and requests, and includes all notes, summaries, compilations, extracts, abstracts or oral communications that are based on or derived from CHI, regardless of form or format. CHI does not include any document or information in which the Producing Party has redacted the identifiers listed and does not have actual knowledge that information could be used alone or in combination with other information to identify an individual who is subject of the information. A Producing Party may, but is not



required to, perform such redactions before producing documents that originally contained CHI so long as the redactions do not result in prejudice to another party.

- (g) As used herein, the term "Final Resolution of the Litigation" shall mean the date thirty (30) calendar days following:
  - (i) the Court's entry of a stipulated dismissal disposing of all claims and counterclaims in the Litigation,
  - (ii) the Court's entry of a voluntary dismissal disposing of all claims and counterclaims in the Litigation, or
  - (iii) the entry of a final, non-appealable order disposing of the case.
- (h) As used herein, the term "In-House Counsel" shall mean attorneys who are employees of a Party, licensed patent attorneys admitted to practice before a national or European patent office who are employees of a Party, or scientific litigation advisors who are employees of a Party working in the Party's legal department who are responsible for overseeing this Litigation for a Party and who do not and shall not have direct responsibility for prosecuting or filing any patent applications involving fremanezumab, galcanezumab, or any other anti-CGRP antagonist antibody, and do not and shall not have direct responsibility for submitting regulatory documents to FDA or for communications with FDA involving fremanezumab, galcanezumab, or any other anti-CGRP antagonist antibody, including without limitation any Citizen Petition, with the exception of the preparation of a notification under 42 U.S.C. § 262(1)(6)(C)(i).
- 2. <u>Scope of Protective Order</u>. This Protective Order includes within its scope any and all Litigation Material.
- 3. <u>Scope and Designation of Confidentiality</u>. "Protected Information" shall include Litigation Material designated either "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL—



OUTSIDE COUNSEL ONLY," as defined below. No information shall be regarded as Protected Information:

- (a) if it is in the public domain at the time of disclosure, as evidenced by a document, electronically stored information, or tangible thing;
- (b) if it becomes part of the public domain through no fault of the Receiving Party, as evidenced by a document, electronically stored information, or tangible thing;
- (c) if it was in the rightful and lawful possession of the Receiving Party prior to the time of the disclosure, without any applicable obligation of confidentiality, as evidenced by a document, electronically stored information, or tangible thing; or
- (d) if it is received lawfully by the Receiving Party at a later date from a third party without restriction as to disclosure, provided that such third party has the right to make such unrestricted disclosure to the Receiving Party.
- 4. <u>Designation as "CONFIDENTIAL"</u>. The designation "CONFIDENTIAL" shall mean information that the Producing Party in good faith believes is of a proprietary or commercially sensitive nature and/or information that is required to be treated as confidential pursuant to statute or common law, including applicable foreign data privacy laws, including, but not limited to, information that the Producing Party in good faith believes constitutes a trade secret in the possession of the Producing Party, including the trade secrets of the Producing Party's customers, vendors, accountants, underwriters, or other party, that the Producing Party in good faith believes constitutes other highly sensitive proprietary information that is entitled to additional protections, or that is not generally available in the public domain and for which Paragraphs 3(a)-(d) do not apply. Information designated "CONFIDENTIAL" may include, but is not limited to,



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