18239

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,)
Plaintiffs,)
)
V.)
AMGEN INC.,)
Defendant.)

C.A. No.: 18-924-CFC

FIRST AMENDED STIPULATED PROTECTIVE ORDER

WHEREAS, Plaintiffs Genentech, Inc. ("Genentech") and City of Hope and Defendant Amgen Inc. ("Amgen") expect discovery requests made in this action (the "Litigation") to encompass certain information which may constitute trade secrets and/or other confidential research, development, or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G) for which special protection from public disclosure and from use for any purpose other than in this Litigation is warranted, the Parties, by and through their respective Outside Counsel, HEREBY STIPULATE to the entry of this First Amended Protective Order regarding discovery in this Litigation.

DEFINITIONS

1. "Affiliate" means any Third Party that directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a Party to this Litigation.

2. "CONFIDENTIAL" means information that constitutes, contains, reveals, or reflects trade secrets or other confidential research, development, business, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G), including but not limited to:

scientific and technical information; product information; financial, budgeting and/or accounting information; information about existing and potential customers; marketing and other business strategies, decisions, or negotiations; and personnel compensation, evaluations, and other employment information; information received from a Third Party pursuant to a confidentiality, non-disclosure or similar agreement; and includes such confidential and proprietary information about a Third Party, including parents, subsidiaries, and/or other Affiliates. Confidential information also includes Protected Health Information, which means any information that a party believes in good faith to be subject to the Health Insurance Portability and Accountability Act and the regulations thereunder, 45 CFR Part 160 and Subparts A and E of Part 164. Protected Health Information includes, but is not limited to, health information, including demographic information, relating to either, (a) the past, present or future physical or mental condition of an individual, (b) the provision of care to an individual, or (c) the payment for care provided to an individual, which identifies the individual or which reasonably could be expected to identify the individual. Provisions of this Protective Order relating to CONFIDENTIAL information shall be understood to encompass any information derived from, as well as testimony and oral conversation related to, CONFIDENTIAL information, and all copies, excerpts, and summaries thereof.

3. "CONFIDENTIAL Discovery Material" means Discovery Material a Producing Party designates as CONFIDENTIAL pursuant to the terms of this Protective Order, as well as information provided by a Party pursuant to 42 U.S.C. § 262(l)(1) and 42 U.S.C. § 262(l)(2).

4. "Designated Inside Counsel" means an Inside Counsel who is designated during this Litigation pursuant to Paragraph 28(b) of this Protective Order.

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5. "Discovery Material" means all documents, testimony, pleadings, exhibits, and all other material or information produced or disclosed in this Litigation, including responses to requests for production of documents and/or things, answers to interrogatories, responses to requests for admissions, documents and things made available for inspection, deposition testimony, expert testimony and reports, and all other discovery taken pursuant to the Federal Rules of Civil Procedure, including Third Party discovery pursuant to Fed. R. Civ. P. 45, matters in evidence and any other information hereafter furnished, directly or indirectly, by or on behalf of any Party, Third Party, or witness in connection with this Litigation. This Protective Order and protections herein shall apply to all Discovery Material.

6. "Expert" means a person with specialized knowledge or experience in a matter pertinent to this Litigation who has been retained by a Party or its Inside or Outside Counsel to serve as an expert witness or as a consultant in this Litigation who, at the time of retention, is not an officer, director, or employee of a Party or an Affiliate and is not anticipated to become an officer, director, or employee of a Party or an Affiliate. Nothing in this Protective Order purports to alter in any way the requirements for offering testimony under Fed. R. Evid. 703, or to define the term "expert" for purposes other than those addressed in this Protective Order.

7. "Inside Counsel" means any United States attorney who works in the legal department of a Party and who is admitted to practice in the United States.

8. "Outside Counsel" means any attorney from a law firm that has at least one attorney who has made a formal appearance as counsel of record for a Party in this Litigation and who is not an employee of a Party or of an Affiliate as of the date of entry of this Order.

9. "Party" means a party to this Litigation.

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10. "Producing Party" means any Party or any Third Party who produces or otherwise discloses, whether through formal or informal means, Discovery Material in this Litigation.

11. "Professional Vendor(s)" means persons or entities that provide litigation support services (e.g., photocopying, audio or video recording, translating, preparing exhibits or demonstrations, and organizing, storing, or retrieving data in any form or medium; jury consulting, mock trial coordination) and their employees and subcontractors.

12. "Prosecution" means directly, indirectly, or otherwise participating in (a) the drafting of, amending of, or advising on any patent or patent application anywhere in the world, including the drafting of, amending of, advising on, or otherwise affecting the scope or maintenance of patent claims, and (b) the amendment or addition of claims in any proceeding (*e.g.*, an *inter partes* review proceeding, post-grant review proceeding, reexamination, reissue, covered business method review proceeding, or any similar proceeding.)

13. "Prosecution Bar Patent or Application" means any patent or application (a) to which any of the patents-in-suit in this Litigation assert priority, or which asserts priority to any of the patents-in-suit, or which asserts priority to an application or patent to which any of the patents-in-suit assert priority; (b) is a foreign counterpart of any patent or application defined in (a) of this Paragraph; (c) that concerns in whole or in part trastuzumab, including without limitation developing, making, purifying, manufacturing, formulating, using or administering any product, formulation or composition that contains trastuzumab, including without limitation methods of treating any disease or medical condition; or (d) that concerns in whole or in part subject matter related to the patents identified on Genentech's list under 42 U.S.C. § 262(l)(3)(A), including without limitation as supplemented pursuant to 42 U.S.C. § 262(l)(7).

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14. "Protective Order" means this Stipulated Protective Order.

15. "Receiving Party" means any Party that receives information produced or otherwise disclosed by any Producing Party.

16. "Related Litigation" means any additional litigation or adversarial proceeding (including without limitation reexaminations, *inter partes* reexaminations, reissues, covered business method review proceedings, *inter partes* review proceedings, and post grant review proceedings, in the United States or any similar proceedings in any foreign country), including any appeals, between any of the Parties that involves the infringement, validity or enforceability of the patents-in-suit or a Prosecution Bar Patent or Application.

17. "Third Party" means a person or entity that is not a Party.

DESIGNATION

18. Any Producing Party may designate Discovery Material as CONFIDENTIAL in accordance with this Protective Order if such Party in good faith believes that such Discovery Material contains CONFIDENTIAL information as defined above.

19. Discovery Material may, as appropriate, be marked by the Producing Party with the legend "CONFIDENTIAL" in conjunction with the identity of the Producing Party, or another suitable legend, and the Producing Party must use reasonable efforts to ensure that such legend appears on each page of each document or file as the format permits. In the case of computer media, the designation shall be placed on the medium and its label and/or cover. In the case of files produced in native format, the designation shall be included in the accompanying metadata and/or in the file's name.

20. Information revealed by inspection of things and premises under Fed. R. Civ. P. 34 shall be treated as though it were designated CONFIDENTIAL provided that prior to, or at any time up to, thirty days (as calculated by Fed. R. Civ. P. 6) after the inspection, the Party permitting

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