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Carol E. Higbee, P.J.Ch.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

IN RE: ACCUTANE® LITIGATION

CASE NO. 271

CIVIL ACTION
ACCUTANE® LITIGATION

ORDER REGARDING STUDIES AND SCIENTIFIC PUBLICATION DISCLOSURES

THIS MATTER having been brought before the Court for the entry of an Order clarifying and setting forth the obligations of all parties with respect to certain scientific research activities and scientific publications, and for good cause having been shown:

IT IS on this 5th day of Sept, 2013,

ORDERED as follows:

General Provisions

1. The following definitions shall apply for purposes of this Order:

(a) Roche shall mean Hoffmann-La Roche Inc. and Roche Laboratories Inc. and any and all affiliates other than those described in paragraph 1(b).

(b) F.Hoffmann shall mean F.Hoffmann-La Roche Ltd and any and all affiliates, including Genentech Inc.

(c) Plaintiffs shall mean all plaintiffs that have filed complaints in In re: Accutane Litigation, No. 271.

(d) The Parties shall mean Plaintiffs, Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Roche"), and F.Hoffmann-La Roche Ltd ("F.Hoffmann").

2. The Orders dated December 16, 2009, December 23, 2009, January 4, 2013 and any other orders, either written or verbal, relating to scientific research activities/scientific publications and the disclosure obligations of the Parties (the "Prior Orders") are hereby superseded by this order.[1]

Research Activities

3. The Parties shall identify all scientific research, scientific investigation, and scientific study activities (including any manuscript commissioning, preparation, or review) concerning or relating to isotretinoin, any other retinoid, ulcerative colitis, Crohn's disease, or inflammatory bowel disease initiated from 2003 to present (exclusive of research activities relating to etrolizumab and any other research activities that the Court deems proprietary[2]) (collectively, "Research Activities") that the Parties have in any way authorized, suggested, guided, directed, approved, participated in, supported (e.g., through provision of in-kind or financial support, including but not limited to resources, data, personnel, drugs, monetary compensation, consulting payments, contractual terms, non-monetary compensation, parallel support, departmental or general grants, or other types of funding), regardless of whether such authorization, suggestion, guidance, direction, approval, participation, or in-kind/financial support has been direct or indirect, or employed the use of intermediaries.

[1] Since April 2, 2013, the parties have been negotiating the terms of this Order in good faith and made a good faith attempt to comply with a prior version of this Order in connection with the May 2, 2013 Disclosures.
[2] Roche has asserted that research related to etrolizumab is proprietary, but has agreed to disclose any direct or indirect in-kind and/or financial support as required by this Order for individuals and entities that have performed research activities relating to etrolizumab. Any request for further disclosure relating to etrolizumab other than that to which Roche has agreed shall be sought by separate motion. Disclosures regarding any research activities that the Court determines are proprietary shall be made in the manner determined by the Court.

4. For each such research activity identified pursuant to paragraph 3,[3] the Parties shall provide:

(a) a description of the research activity, including a detailed description of the role and involvement of the Party with the research activity and the dates of involvement;

(b) the full identity and affiliation of employees and agents of the Party who in any way participated in the research activity, together with the extent of their involvement;

(c) the identity and affiliation of any non-employees with whom the Party interacted in connection with the research activity, and the nature of their involvement;

(d) the identity of any intermediary that in any way participated in the research activity, and the nature of their involvement;

(e) the nature and quantum of any support, in-kind, financial or otherwise, direct or indirect, provided for such research activity; and

(f) copies of all documents concerning or reflecting items (a) through (e) or the Bates Numbers for any such documents that have previously been produced.

5. The Parties shall identify -- through the exercise of reasonable diligence -- all agents, independent contractors, consultants, third parties, firms, operatives, counsel, public affairs firms, lobbyist firms, government relations firms, litigation firms, and crisis management firms, compensated, contracted with, or retained by or on behalf of the Party to facilitate, oversee, plan, direct, review, or consult on any research activity, or that have been in any way involved with or reviewed such research activity, as defined in Paragraph 3.

[3] Resubmission of information disclosed prior to September 9, 2013 is not required. However, the Parties shall reasonably cooperate to confirm and consolidate any prior disclosures to the extent necessary.

6. For each such individual/entity identified pursuant to paragraph 5, the Parties shall provide:

(a) a description of the research activity in which the individual/entity was involved, including a detailed description of the role and involvement of the individual/entity with the research activity and the dates of involvement;

(b) the full identity of all affiliates of the individual/entity;

(c) a description of the nature of involvement by the Party in the research activity;

(d) the full identity and affiliation of employees and agents of the Party who in any way participated in the research activity, together with the extent of their involvement;

(e) the identity and affiliation of any non-employees with whom the Party interacted in connection with the research activity, and the nature of their involvement;

(f) the identity of any intermediary that in any way participated in the research activity, and the nature of their involvement;

(g) the nature and quantum of any support, financial or otherwise, direct or indirect, provided for such research activity;

(h) the compensation paid to such individual/entity for each such service provided; and

(i) copies of all documents concerning or reflecting items (a) through (h) or the Bates Numbers for any such documents that have previously been produced.

7. With respect to Research Activities previously disclosed by F.Hoffmann, this Order shall require that the bates-numbers of documents previously produced be provided, but F. Hoffmann shall not be required to re-produce already produced documents.

8. The Parties must continue to exercise reasonable diligence in identifying Research Activities on a periodic basis. If additional research activities are identified, the identifying Party must provide an updated written disclosure to all other Parties according to the following schedule and protocol:

(a) September 9, 2013, November 1, 2013, and quarterly thereafter on the first business day of the applicable month;

(b) If after exercising reasonable diligence, a Party has no new information to disclose for the quarter, the Party is not required to take any affirmative actions;

(c) For Plaintiffs, updated disclosures shall be provided directly to counsel for Roche with a copy to Plaintiffs' liaison counsel. All Plaintiffs' counsel of record are individually responsible for complying with this Order. For those Plaintiffs' counsel of record who did not previously provide an affirmative disclosure, those counsel shall make an initial affirmative disclosure no later than November 1, 2013, in the manner set forth in this Order; and

(d) In the event of a scheduled trial, the Parties may agree to modify the schedule set forth in paragraph 8(a) to require more frequent updated disclosures and/or affirmative action verifying after reasonable diligence, no new, responsive information has been identified.

9. It is hereby acknowledged that Roche provided to Plaintiffs on August 15, 2011, the attached Declaration of Ulf-W. Wiegand, Ph.D., dated July 25, 2011 and a supplemental Declaration of Dr. Wiegand on May 4, 2013, attached, with respect to Research Activities involving F.Hoffmann. Roche shall further supplement the disclosure for Dr. Wiegand on the timetable and in accordance with paragraph 9 by providing a supplemental declaration of Dr. Wiegand in the event there is new information to be supplied. No disclosure is required with respect to this paragraph in the absence of new information.

New Scientific Publications - Generally

10. In accordance with the schedule set forth in paragraph 8 above, all Parties must notify the Court and all other parties of the publication of any clinical or epidemiological study (other than those listed below), whether in abstract, poster, or full article form, concerning or relating to (i) isotretinoin, any other retinoid, and/or any other posited cause or trigger of ulcerative colitis, Crohn's disease, or inflammatory bowel disease, **and** (ii) ulcerative colitis, Crohn's disease, or inflammatory bowel disease ("New Studies"). The definition of "New Studies" also shall include the following previously published studies and abstracts[4]: Charles N. Bernstein, et al., Isotretinoin Is Not Associated With Inflammatory Bowel Disease: A Population-Based Case Control Study, 104 Am. J. Gastroenterology 2774, 2777 (2009); Seth D. Crockett et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case-Control Study, 105 Am. J. Gastroenterology 1986 (2010); A. Racine et al., Abstract, Isotretinoin Use and Risk of Inflammatory Bowel Disease: A Case-Control Study from the French National Health Insurance System, 6 J. Crohn's & Colitis S176-S177 (Supp. 1) (2012); Mahyar Etminan & Joseph A. Delaney, Study Report, 2012, http://www.broadmedical.org/asset/1406-finalprogressreport-etminan2.pdf (last visited July 31, 2012); Raed O. Alhusayen et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Population-Based Cohort Study, J. Investigative Dermatology (2012); H.C. Lin et al., Abstract, Acne Drug Therapy and the Development of Comorbid Inflammatory Bowel Disease in the United States, 15 Value in Health A635 (2012); Sarah Fenerty et al., Abstract, Impact of Acne Treatment on Inflammatory Bowel Disease, 68 J. Am. Acad. Dermatology AB5 (Supp. 1) (Apr. 2013); and Mahyar Etminan

[4] Resubmission of information disclosed prior to September 9, 2013, is not required. However, the Parties shall reasonably cooperate to confirm and consolidate any prior disclosures to the extent necessary.

et al., Isotretinoin and Risk for Inflammatory Bowel Disease: A Nested Case-Control Study and Meta-Analysis of Published and Unpublished Data, 149 JAMA Dermatology 216 (Feb. 2013).[5]

11. The Party must provide a copy of the publication to the Court and all other Parties at the time of such disclosure, and further disclose whether or not that the publication is the result of a Research Activity as defined in Paragraph 3.

New Scientific Publications - Disclosures of Contacts with Authors of Any New Study

12. In accordance with the schedule and obligations set forth in paragraph 8 above, all Parties must disclose whether or not the Party or any individual at the direction of the Party or with the knowledge of the Party has had any communications (written or verbal) with any author or authors of the New Studies - - prior to publication of the New Study - - concerning or relating to the New Study. [6]

13. As to all communications subject to disclosure under Paragraphs 12, if the communication is in writing or electronic form, subject to the provisions of paragraphs 18 and 19, the parties shall provide each other with copies of any such communications. If the communication is oral, the date of the communication, length of time of communication, and a brief summary of the content shall be provided.

New Scientific Publications - Contracts with and/or Payments to Authors of Any New Study

14. Subject to the provisions of paragraphs 18 and 19, all Parties must also disclose the following information in writing: any contracts with or payments that any Party, or any

[5] This list of previously published New Studies may be supplemented to the extent necessary to encompass earlier published studies that the parties agree, or the Court determines, are relevant to the claims or defenses in the litigation.

[6] Resubmission of information disclosed prior to September 9, 2013, is not required. However, the Parties shall reasonably cooperate to confirm and consolidate any prior disclosures to the extent necessary.

individual at the direction of or with the knowledge of a Party, has made to the authors of New Studies and affiliated institutions, including dates of any contracts, payments, and amounts.

15. The Parties must provide updates in accordance with this Order pursuant to the schedule set forth in Paragraph 8.

Protocol for Information/Documents Where a Claim for Privilege/Proprietary Information Is Made

16. To the extent any documents are produced in accordance with this Order and a document is withheld or a redaction is made by the producing party on the basis of a claim of privilege or that discovery not be had because the information at issue should be protected as proprietary, the withheld document or redacted material shall be clearly identified and disclosed in a log in accordance with R. 4:10-2(e) that shall accompany the production.

17. If a party contends that the mere identification of information or documents on a log in accordance with R. 4:10-2(e) would itself abrogate its claim of privilege and/or necessary protection of proprietary information, as soon as practicable, but no later than the due date of any required disclosure or production:

(a) the Party shall serve notice to all other Parties and the Court that it is withholding information and/or documents as privileged and/or proprietary and that identification of such information/documents in accordance with R. 4:10-2(e) on a log could constitute a waiver of the privilege claim and/or divulge proprietary information.

(b) the Party shall provide to the Court, in camera, a copy of the document(s) being withheld and the basis on which the Party contends the subject documents/information are privileged and/or proprietary and appropriately protected from production, and the specific basis

on which the Party contends the subject documents/information cannot be identified on a log and produced to receiving parties in accordance with R. 4:10-2(e).

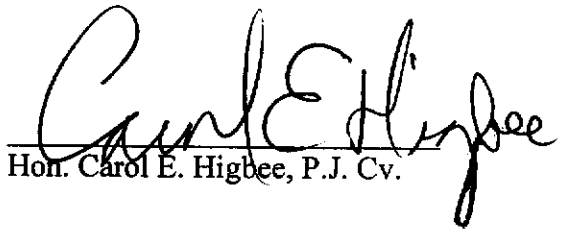
(c) following receipt of the Party's submission pursuant to paragraph (b), the Court shall direct a procedure for prompt resolution of the matter.

Other Provisions

18. For purposes of this Order, the knowledge of counsel for a Party shall be deemed knowledge of the Party.

19. To the extent that any Party is aware of information concerning the direct or indirect involvement of any other manufacturer or marketer of isotretinoin in any Research Activity, as described in paragraph 3, contacts with authors, as described in paragraph 13, or contracts or payments with authors, as described in paragraph 16, the Party shall provide the extent of the Party's knowledge in its disclosures under this Order.

20. A copy of this Order shall be served upon all parties by counsel for Roche within 7 days from the date of entry.



Hon. Carol E. Higbee, P.J. Cv.