UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SANOFI-AVENTIS DEUTSCHLAND GMBH, Plaintiff and Counterclaim-Defendant, v. GENENTECH, INC. AND BIOGEN IDEC INC., Defendants and Counterclaimants.	CASE NO. 08-cv-04909-SI (BZ) CASE NO. 09-cv-04919-SI [PROPOSED] ORDER APPOINTING SPECIAL MASTER

[~~PROPOSED~~] ORDER

In its Tenth Discovery Order, the Court ordered that, pursuant to Federal Rule of Civil Procedure 53 and subject to its agreement to undertake the appointment, BioReliance be appointed special master to test the DNA used to produce Avastin® for the presence of an HCMV enhancer. (D.N. 100.) This Order is to be read in a manner consistent with the Tenth Discovery Order.

I. SCOPE OF THE SPECIAL MASTER'S APPOINTMENT

1. BioReliance will act as a neutral expert to test the genomic material used to produce Avastin® for the presence of HCMV enhancer DNA.

2. BioReliance is directed to proceed with all reasonable diligence in performing its duties in accordance with this Order.

3. BioReliance shall:

   a. extract DNA from the cells used to produce Avastin®, which will be provided by Genentech;

   b. establish a protocol for a validated, quantitative TaqMan PCR assay, including appropriate controls, and conduct experiment(s) thereunder to determine: (1) whether HCMV enhancer DNA is present in the DNA from the cells used to produce Avastin® and (2) the copy number of any detected HCMV enhancer DNA per cell; and

   c. communicate its findings in a report in accordance with paragraph 11.

4. If BioReliance detects HCMV enhancer DNA at a frequency of (within experimental error) one copy per cell or greater, BioReliance shall:

   a. after receiving further suggestions by the parties as provided for in paragraph 5;

   b. establish a protocol for determining the sequence of genomic DNA upstream and downstream of the HCMV enhancer DNA sequence sufficient to identify at least the nearest promoter and protein coding sequence and conduct testing pursuant to that protocol.

5. In developing the protocol contemplated in paragraph 3(b), BioReliance will consider recommendations by the parties within three (3) days of BioReliance's communicating to the

Court that it agrees to serve as special master. In developing a protocol contemplated in paragraph 4, BioReliance will consider recommendations by the parties within three (3) days of BioReliance's communicating its findings in accordance with paragraph 3(c).

6. BioReliance shall follow appropriate procedures for ensuring that its test methods adhere to Good Laboratory Practices.

7. In validating its assays, BioReliance shall establish procedures for ensuring the accuracy, sensitivity, specificity, and reproducibility of any test methods that it employs and should determine the false-positive rate, false-negative rate, and limit of detection of the assays unless not scientifically feasible. Cost is not a basis on which to determine that procedure is not scientifically feasible. Genentech maintains that these procedures are scientifically feasible.

8. BioReliance shall establish a quality control/quality assurance plan to be carried out on an ongoing basis to ensure that all that it conducts assays to perform within the specifications outlined in paragraph (7).

9. Each employee of BioReliance engaged in any activity pursuant to this Order shall sign an undertaking pursuant to the August 6, 2009 Protective Order.

10. Thirty (30) days after BioReliance has submitted a testing report to the Court with copies to Sanofi and Genentech, unless otherwise ordered by the Court, BioReliance will destroy all Genentech genomic or other Genentech biological material in its possession and product obtained or derived from such material and will certify the destruction to Genentech.

11. The testing report referenced in paragraph 3 of the Tenth Discovery Order shall include the following:

a. a description of materials used in testing;

b. a list of personnel involved in testing;

c. a description of the chain of custody of the materials tested and the extraction or handling of the materials tested;

d. a description of all protocols adopted and used by BioReliance;

e. a description of the procedures used to validate its tests as well as the validation data;

f. data generated from the testing; and

g. a discussion of the testing results, including a determination of whether HCMV enhancer DNA was present in the DNA used to produce Avastin® and a listing and description of all sequence data generated.

12. The tests will be conducted "blind," in other words, those conducting the tests will not be informed whether they are testing the DNA used to produce Avastin® or a control.

II. EX PARTE COMMUNICATIONS

The parties may not have *ex parte* communications with any BioReliance representative regarding the protocol of the tests that it is conducting or the manner in which the testing is conducted. The parties may have *ex parte* communications with a BioReliance representative regarding the progress and expected completion of (1) the testing and (2) the preparation of BioReliance's report. In all other respects, there will be no communications with BioReliance without prior notice to opposing counsel.

No party may attend or observe any testing conducted by BioReliance unless otherwise agreed in writing by the parties.

III. NATURE OF MATERIALS TO BE PRESERVED AND FILED

BioReliance will file the testing report discussed in paragraph 3 of the Tenth Discovery Order and as further described in the instant Order.

IV. PROCEDURES AND STANDARDS OF REVIEW

The testing report shall be completed and filed as specified in the Tenth Discovery Order. Genentech contends that, pursuant to the Court's Tenth Discovery Order, Sanofi has waived the right to contest or object to the findings of BioReliance. Per the Tenth Discovery Order: "As stipulated by Sanofi in open court, if the test fails to disclose the presence of the HCMV enhancer in the tested material, Sanofi will dismiss its claims against Avastin® with prejudice." Sanofi contends that its objection to findings of fact made or recommended by BioReliance should be decided de novo.

The Court will determine which party's position is correct.

Genentech's objections to findings of fact made or recommended by BioReliance will be decided de novo.

V. FEES AND COSTS OF SPECIAL MASTER

BioReliance shall send invoices related to the testing performed under this order to Sanofi's counsel. BioReliance shall provide a cost estimate to Sanofi as soon as possible.

To complete the appointment, the Parties' counsel will assist BioReliance in the preparation of the affidavit contemplated by Federal Rule of Civil Procedure 53(b)(3). By November 12, 2010, BioReliance will provide the Parties with the executed affidavit, which Sanofi will file with the Court by November 15, 2010.

IT IS SO ORDERED.

November 5, 2010

The Honorable Bernard Zimmerman
UNITED STATED MAGISTRATE JUDGE