Document 57-11 Filed 04/25/2006

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EXHIBIT J

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK,

Plaintiff,

v.

ROCHE DIAGNOSTICS GmbH,
formerly known as
BOEHRINGER MANNHEIM, GmbH

Defendant.

Civil Action No. 93-11512-NG



ANSWER TO SECOND AMENDED COMPLAINT

Defendant Roche Diagnostics GmbH ("Roche") responds to the correspondingly numbered paragraphs of the Second Amended Complaint for Patent Infringement as follows:

- 1. Roche admits that plaintiff, The Trustees of Columbia University in the City of New York ("Columbia") is a corporation organized and existing under the laws of the State of New York, having its principal offices at Broadway and West 116th Street, New York, New York 10027.
- 2. Roche admits that it is a corporation organized and existing under the laws of the Federal Republic of Germany, having its principal place of business at Sandhofer Strasse 116, D-68298 Mannheim, Germany, and has transacted and/or is transacting business in the district, but denies that it has committed and/or is committing tortious acts in this district.
- 3. Roche admits that this Court has jurisdiction over this action for patent infringement consistent with the Court's statutory authority to hear actions for infringement of United States patents under applicable United States laws. Roche admits that venue appears to be proper for this Court to hear the present action for infringement of United States patents under United States law.

Roche denies that there can be infringement of U.S. Patent No. 5,179,017 ("the '017 patent") since Roche has conducted no activity alleged to infringe subsequent to the issuance of the '017 patent.

- 4. Roche is without information sufficient to admit or deny the allegations of the first sentence of Paragraph 4 and therefore denies the same. Roche denies the allegations of the second sentence of Paragraph 4 and specifically denies that the patents were duly legally issued and are valid and subsisting.
 - 5. Roche denies the allegations of Paragraph 5.
 - 6. Roche denies the allegations of Paragraph 6.
- 7. Roche denies the allegations of Paragraph 7, inter alia, GI has an implied license from Columbia for the patents in suit.
- 8. Roche is without information sufficient to admit or deny the allegations as stated in Paragraph 8 and therefore denies the same.
 - 9. Roche denies the allegations of Paragraph 9.
 - Roche denies the allegations of Paragraph 10.
 - 11. Roche denies the allegations of Paragraph 11.
 - 12. Roche denies the allegations of Paragraph 12.
- 13. Roche denies the allegations of Paragraph 13 and states that Columbia is not entitled to any of the relief sought.

FIRST AFFIRMATIVE DEFENSE

Plaintiff is estopped from asserting the claims of U.S. Patent No. 4,399,216 ("the '216 patent"), U.S. Patent No. 4,634,665 ("the '665 patent"), and the '017 patent against Roche.

SECOND AFFIRMATIVE DEFENSE

The '216, '665 and '017 patents are invalid and void under the provisions of 35 U.S.C. § 102.

THIRD AFFIRMATIVE DEFENSE

The '216, '665 and '017 patents are invalid and void under the provisions of 35 U.S.C. § 103.

FOURTH AFFIRMATIVE DEFENSE

The '216, '665 and '017 patents are invalid and void under the provisions of 35 U.S.C. § 112.

FIFTH AFFIRMATIVE DEFENSE

The '216, '665 and '017 patents are invalid and void under the provisions of 35 U.S.C. § 116.

SIXTH AFFIRMATIVE DEFENSE

The '216, '665 and '017 patents are unenforceable as a result of applicants' inequitable conduct before the United States Patent and Trademark Office.

SEVENTH AFFIRMATIVE DEFENSE

The '216, '665 and '017 patents are unforceable as a result of applicants' fraud on the United States Patent and Trademark Office.

EIGHTH AFFIRMATIVE DEFENSE

The plaintiff's claims are barred by the doctrine of laches.

NINTH AFFIRMATIVE DEFENSE

The plaintiff's claims are barred by the doctrine of unclean hands.

TENTH AFFIRMATIVE DEFENSE

The plaintiff's claims are barred by an implied license granted to Genetics Institute (GI).

ELEVENTH AFFIRMATIVE DEFENSE

The plaintiff's claims are barred by an implied license granted to Roche.

TWELFTH AFFIRMATIVE DEFENSE

The claims of the '216, '665 and '017 patents are unforceable as a result of plaintiff's misuse of the patents.

THIRTEENTH AFFIRMATIVE DEFENSE

Roche has not infringed the claims of the patents in issue.

FOURTEENTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

FIFTEENTH AFFIRMATIVE DEFENSE

Regarding the '017 patent, the complaint fails to state a claim upon which relief can be granted because any and all acts alleged to infringe occurred prior to issuance of the '017 patent

WHEREFORE, Roche prays that:

- The Complaint be dismissed with prejudice; . 1.
 - 2. All relief prayed for in the Complaint be denied;
- An order be entered adjudging and decreeing that Roche has not infringed the '216, 3. '665 and '017 patents;
- An order be entered adjudging and decreeing that the '216, '665 and '017 patents are 4. invalid and/or unenforceable;
 - Roche be awarded its costs for this action;

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- Roche be awarded its attorneys fees; and 6.
- Roche be granted such other and further relief as the Court deems just and proper. 7.

Dated: May 7, 2001

ROCHE DIAGNOSTICS GmbH

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