

Ex. D

5,618,698, claims 4 and 6 of U.S. Patent No. 5,621,080, claim 7 of U.S. Patent No. 5,756,349, and claim 1 of U.S. Patent No. 5,955,422. The notice of investigation named Roche Holding Ltd. of Basel, Switzerland, F. Hoffman-La Roche, Ltd. of Basel, Switzerland, Roche Diagnostics GmbH of Mannheim, Germany, and Hoffman La Roche, Inc. of Nutley, New Jersey (collectively, "Roche") as respondents.

On May 19, 2006, Roche moved for summary determination of no violation of section 337, stating that its activities fell within the safe harbor created by 35 U.S.C. § 271(e)(1) which provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." Amgen opposed the motion. The Commission investigative attorney ("IA") supported the motion. On July 7, 2006, the ALJ issued an ID (Order No. 6) granting Roche's motion. Amgen filed a petition for review of the ID. Respondents and the IA filed oppositions to the petition for review. Amgen also filed a motion for leave to reply to the oppositions to its petition for review.

Having considered the petition for review, the oppositions thereto, and the relevant portions of the record, the Commission has determined not to review the ID and to deny Amgen's motion for leave.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and section 210.42(h) of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.42(h).

By order of the Commission.



Marilyn R. Abbott
Secretary to the Commission

Issued: August 31, 2006