

PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN PRODUCTS AND
PHARMACEUTICAL COMPOSITIONS
CONTAINING RECOMBINANT
HUMAN ERYTHROPOETIN**

Investigation No. 337-TA-568

COMMISSION OPINION

This investigation was instituted on May 12, 2006, based on a complaint filed by Amgen Inc. (“Amgen”) of Thousand Oaks, California. 71 *Fed. Reg.* 27,742 (May 12, 2006). The complaint alleged a violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, sale for importation, or sale within the United States after importation of certain products and pharmaceutical compositions containing recombinant human erythropoietin by reason of infringement of various claims of six United States patents: U.S. Patent Nos. 5,441,868 (“the ’868 patent”); 5,547,933 (“the ’933 patent”); 5,618,698 (“the ’698 patent”); 5,621,080 (“the ’080 patent”); 5,756,349 (“the ’349 patent”); and 5,955,422 (“the ’422 patent”). The complaint 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.

After separate remands by the Court of Appeals for the Federal Circuit of this investigation and a parallel civil action involving many of the same patents, on December 18, 2009, the private parties executed a settlement agreement that allows Roche to begin selling accused products in the United States in mid-2014. Form 10-K, Amgen Inc., at 8 (Mar. 1, 2010);

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see also Settlement Agreement (Dec. 18, 2009). On December 21, 2009, Amgen and Roche submitted a proposed consent order to the district court in that parallel civil action, and on December 22, 2009, the district court entered judgment.

On December 22, 2009, Amgen moved to withdraw certain patent claims from this investigation that had not been asserted in the district court. Unopposed Compl't Amgen Inc.'s Mot. to Terminate Investigation as to Claims 4, 5 and 11 of the '933 Patent, Claims 4 and 6 of the '080 Patent, and Claims 4 and 5 of the '698 Patent (Dec. 22, 2009). The Commission granted that motion. *75 Fed. Reg.* 18,548 (Apr. 12, 2010).

Also on December 22, 2009, Amgen moved the Commission to terminate this investigation by entry of an exclusion order based on preclusion caused by the district court judgment. Addendum to August 24, 2009 Stipulation (Dec. 22, 2009). Two Amgen motions regarding claim 7 of the '349 patent followed. By notice on April 6, 2010, the Commission sought clarification from the parties about, among other things, the effect of the stipulated district court judgment on this investigation. *75 Fed. Reg.* 18,548 (Apr. 12, 2010).

On March 11, 2011, the Commission issued an order to show cause why the investigation should not be terminated in view of the parties' settlement. In relevant part, the order stated:

The Commission has a longstanding policy of not reaching the issue of violation in terminating investigations based on settlement agreements. . . . Amgen's request for an exclusion order, notwithstanding its settlement of its underlying patent dispute, appears to contravene this policy. In addition, the Commission rule for terminating investigations upon settlement, 19 C.F.R. § 210.21(b), (c), does not provide for the issuance of an exclusion order upon settlement of the underlying intellectual property dispute.

The private parties are each hereby ordered to show cause why the investigation should not be terminated by the Commission under 19 U.S.C. § 1337(c) in light of the settlement agreement. Given that a consent stipulation and proposed consent order are not pending, the parties

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may address whether the Commission could and should issue a consent order under the present circumstances where settlement was not contingent on the issuance of a consent order. If the respondent believes that a consent order provides appropriate relief, it shall submit an executed consent order stipulation and a proposed consent order in compliance with Commission rule 210.21(c)(3). The Commission expects that any proposed consent order will not deviate in form, substance, or scope from consent orders ordinarily issued by the Commission. Nothing in this order should be read to imply that Commission will necessarily issue a consent order.

Notwithstanding the foregoing, if any party believes that an exclusion order should issue, that party shall provide examples of instances where the Commission has reached the merits of a case despite settlement, shall provide good cause why the Commission should do so in this case, and shall explain how its proposed mechanism for terminating this investigation with an exclusion order is consistent with Commission rule 210.21.

Order at 2.

Amgen and Roche filed a joint response. They no longer seek an exclusion order, but instead seek a consent order. Their basis for a consent order is as follows:

Commission Rule 210.21(c) permits the Commission to terminate an investigation on the basis of a consent order. Moreover, the Commission routinely terminates investigations on the basis of an executed consent order stipulation. Indeed, the Commission has previously terminated investigations when there is both a settlement agreement and an executed consent order stipulation. [See Notices, *Certain Digital Multimeters and Products with Multimeter Functionality*, Inv. No. 337-TA-588 (May 31, 2007 and July 3, 2007).] As a result, it is consistent with Commission precedent to terminate this investigation on the basis of the private parties' executed consent order stipulation.

Joint Response of Complainant and Respondents to the Commission's Order to Show Cause and Request for Termination on the Basis of a Consent Order 2-3 (Apr. 21, 2011) (footnotes omitted) ("Joint Response").

Having examined the record of this investigation, including the responses to the Commission's March 2011, Order, the Commission has determined to terminate the

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investigation on the basis of the settlement agreement between Amgen and Roche. The Commission declines to exercise its discretion to issue a consent order. Under the unusual facts of this investigation, each of the following reasons would suffice for the Commission to determine not to issue a consent order.

Amgen and Roche point to, and only to, the 588 investigation, where two respondents (Parts Express and Velleman) were each terminated on the basis of a combined settlement agreement and consent order stipulation. Joint Response at 3 n.3. The settlement agreements and consent order stipulations for those two respondents, however, were bound up together as part of a single negotiation between the parties, and the issuance of a consent order may have facilitated the settlement.¹ There is no such nexus here, where the parties' December 18, 2009, settlement agreement – which also resolved concurrent district court litigation – makes no mention of the proposed consent order.² Indeed, Roche, at Amgen's apparent urging, withdrew

¹ Settlement Agreement [between Fluke and Parts Express] § A (May 24, 2007) (Public Version) (EDIS Doc. ID No. 319290-275236) (“NOW THEREFORE, in consideration of the Consent Order Stipulation executed by the Parties and filed in the Action, it is hereby agreed between them as follows”); *id.* § E at 3 (“As recited in the Consent Order Stipulation attached as Exhibit B, Respondent Parts Express has already ceased, and agrees to forever desist”); *id.* § G ¶ 16 (“The parties further agree to submit themselves to the jurisdiction of the U.S. International Trade Commission regarding matters of enforcement of this Settlement and Release Agreement through a Consent Order Stipulation, attached hereto as Exhibit B”); Settlement Agreement [between Fluke and Velleman] § 7 ¶ 15 (Apr. 17, 2007) (Public Version) (EDIS Doc. No. 315903-273287) (“The Parties agree that the U.S. International Trade Commission shall retain jurisdiction of this Settlement Agreement The Parties further agree to submit themselves to the jurisdiction of the U.S. International Trade Commission regarding matters of enforcement of this Settlement Agreement through a Consent Order Stipulation, as attached hereto as Exhibit B”).

² The most appropriate circumstance for the issuance of a consent order in connection with settlement is when that order is a condition precedent to settlement. The Commission, however, undoubtedly has the authority to issue consent orders more broadly, such as in the 588 investigation. The Commission may in the future revisit situations such as those of the 588 investigation, especially if it is believed that the issuance of a consent order would impose an

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its earlier motion for a consent order prior to the parties' settlement. That Amgen hoped to receive an exclusion order is of no moment. That request for relief is no longer pursued, and the Commission declines to substitute an order not sought by the parties at the time of settlement.

In addition, as quoted in footnote 1 above, in the 588 investigation, the parties' settlement agreements vested the Commission with jurisdiction to oversee disputes, whereas the Amgen-Roche settlement agreement provides such jurisdiction [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]³ [REDACTED]. The Federal Circuit has construed similar provisions to divest parties from the ability to pursue relief at the Commission. *General Protecht Group, Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1357-58, 1365-66 (Fed. Cir. 2011) (ITC complaint withdrawn because of exclusive jurisdiction by the District of New Mexico); *Texas Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1328-32 (Fed. Cir. 2000) (enjoining participating in an ITC investigation because of exclusive jurisdiction in the California district courts). Accordingly, the Commission would appear to lack jurisdiction to enforce a consent order insofar as such enforcement would involve a dispute concerning the settlement agreement. In this investigation, enforcement could well involve a dispute involving the settlement agreement, because the proposed consent order carves out importations, offers for

inappropriate enforcement burden on the Commission. In any event, for the reasons set forth in the text, the facts of this investigation present a question of first impression and are readily distinguishable from the 588 investigation.

³ [REDACTED]

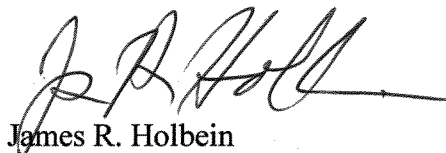
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sale, and sales that are licensed. Proposed Consent Order ¶¶ 5-6. These facts weigh strongly against the issuance of the proposed consent order.

Finally, the Commission observes that its order to show cause stated: “The Commission expects that any proposed consent order will not deviate in form, substance, or scope from consent orders ordinarily issued by the Commission.” Order at 2. Notwithstanding that admonition, Amgen and Roche chose to include language not routinely seen in consent orders, but seen instead in cease and desist orders.⁴ Whether such provisions might be appropriate in consent orders in other investigations is not an issue presented here, where the Commission provided express guidance regarding the appropriate form and scope of the consent order.

Against these reasons, Amgen and Roche have offered no basis, in law or policy, to support the Commission’s issuance of a consent order under the unusual facts of this investigation. Nor is the Commission itself aware of any such basis. Accordingly, the Commission terminates this investigation on the basis of the settlement agreement between the private parties. 19 U.S.C. § 1337(c); 19 C.F.R. §§ 210.21(b), 210.41.

By order of the Commission.



James R. Holbein
Secretary to the Commission

Issued: November 9, 2011

⁴ See Corrected Office of Unfair Import Investigations Response to Mot. to Terminate the Investigation on the Basis of a Consent Order 6 (May 6, 2011).

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337-TA-568

CERTIFICATE OF SERVICE

I, James R. Holbein, hereby certify that the attached has been served by hand upon the Commission Investigative Attorney, Anne Goalwin, Esq., and the following parties as indicated, on November 9, 2011.



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