EXHIBIT D

CONTAINS RESTRICTED ACCESS CONFIDENTIAL MATERIAL
PURSUANT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

DEFENDANTS' FIFTH SUPPLEMENTAL RESPONSES AND OBJECTIONS TO PLAINTIFF AMGEN INC.'S FIRST SET OF INTERROGATORIES TO DEFENDANTS (NOS. 9-11)

Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") make the following further supplemental objections and responses to Plaintiff Amgen Inc.'s ("Amgen") First Set of Interrogatories (Nos. 1-15).

GENERAL OBJECTIONS

Defendants' incorporate by reference its General and Specific Objections set forth in Roche's Third Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15) as if fully set forth herein.

Moreover, Roche specifically reserves its right to supplement its responses to interrogatories that deal with the obviousness of the asserted claims of the patents-in-suit. As Amgen is aware, the Supreme Court just yesterday issued its opinion in *KSR International Co. v. Teleflex Inc.*, 550 U.S. __ (2007), where the Court eliminated the requirement of a specific "teaching, suggestion, or motivation" within the prior art for purposes of finding obviousness

INTERROGATORY NO. 9

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend in your Fifth and Sixth Affirmative Defenses or Tenth Counterclaim is invalid, identify:

(a) on a limitation-by-limitation basis, the legal and factual grounds on which you contend that such claim is invalid;

(b) the level of skill of a person having ordinary skill in the art to which the subject matter of the patents-in-suit pertains at the time of the claimed inventions;

(c) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention(s), every test, experiment, and/or data upon which you rely in support of each contention that a claim is invalid;

(d) each person, other than counsel, who furnished information or was consulted regarding Roche's response to this interrogatory including the nature and substance of each such person's knowledge or information; and

(c) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

SUPPLEMENTAL RESPONSE:

In addition to all prior responses and subject to and without waiver of Roche's previously propounded Specific Objections and General Objections set forth above all of which are incorporated herein by reference, Defendants respond as follows.

Roche hereby incorporates by reference the Expert Report of Dr. Carolyn Bertozzi, dated 4/6/07, and supporting material; the Expert Report of Dr. Guenter Blobel, dated 4/6/07, and supporting material; the Expert Report of Dr. James W. Fisher, dated 4/6/07, and supporting material; the Expert Reports of Dr. Richard Flavell, dated 4/6/97 and 5/1/07, and supporting material; the Expert Report of Dr. Michael E. Fromm, dated 4/6/07, and supporting material; the Expert Report of Dr. Franklin Gaylis, dated 4/6/07, and supporting material; the Expert Report of Dr. Edward Everett Harlow, dated 4/6/07, and supporting material; the Expert Reports of Dr. Thomas Kadesch, dated 4/6/07 and 5/1/07, and supporting material, the Expert Report of Dr. Rodney E. Kellems, dated 4/6/07, and supporting material; the Expert Report of Dr. Robert Langer, dated 4/6/07, and supporting material, the Expert Reports of Dr. John Lowe, dated 4/6/07 and 5/1/07, and supporting material; the Expert Report of Jack Nunberg, dated 4/6/07, and supporting material; the Expert Report of Dr. Daniel Shouval, dated 4/6/07, and supporting material; the Expert Reports of Michael Sofocleus, dated 4/6/07 and 5/1/07, and supporting material, the Expert Reports of Dr. Bruce Spinowitz, dated 4/6/07 and 5/1/07, and supporting material; the Expert Report of Dr. Charles Zaroulis, dated 4/6/07.

Roche also incorporates by reference its defenses and counterclaims described in its pleadings, including Roche's First Amended Answer and Counterclaim, dated March 30, 2007.

9. Obviousness-Type Double Patenting

a. The Lai '016 patent

U.S. Patent 4,667,016 ("the Lai '016 patent"), entitled "Erythropoietin Purification," names Amgen employees Por-Hsiung Lai and Thomas Strickland as inventors and Kirin-Amgen, Inc. as assignee. The patent was filed as Ser. No. 747,119 ("the '119 application") on June 20,

1985 and issued on May 19, 1987. It expired in 2004. The obviousness-type double patenting analysis generally applies a one-way test. Under the one-way test, a later issued claim will be invalidated for obviousness-type double patenting where it is found to be obvious in light of an earlier claim in a co-owned patent. Under the two way test, a later issued claim will be invalidated for obviousness-type double patenting only where the later claim is obvious in light of the earlier claim, *and* the earlier claim is obvious in light of the later claim. (*See* MPEP §804 (8th ed. Rev.5, Aug. 2006)).

The one-way test applies in all circumstances, including where the later issued claim was filed before the earlier issued claim, except where both of two conditions are satisfied: 1) the applicant could not have filed the earlier and later claims together, and 2) the PTO is solely responsible for the delay that caused the earlier-filed claims to issue after the later-filed claims. Only in those narrow circumstances should the two-way test apply.

The criteria for applying the two-way test are not met in this case. It is therefore my view that in determining whether any of the claims asserted by Amgen in this litigation is invalid for obviousness-type double patenting over the Lai '016 patent, the traditional one-way test should apply.

The Lai '016 patent and the patents-in-suit are all directed to recombinant erythropoietin, and they describe and claim how Amgen made the EPO glycoprotein. The inventions embodied in the Lai '016 patent and the patents-in-suit are therefore closely related.

In fact, the specification of the Lai '016 patent incorporates by reference the '298 disclosure:

> The disclosures of co-owned, co-pending U.S. patent application Ser. No. 675,298, entitled "Production of Erythropoietin", filed Nov. 30, 1984, by Fu Kuen Lin (corresponding to PCT No. US84/02021, filed Dec. 11, 1984, scheduled for publication June

> 20, 1985 as No. WO85/02610) are specifically incorporated by reference herein for the purpose of relating the background of the present invention, especially with respect to the state of the art regarding recombinant methodologies applied to large scale production of mammalian erythropoietin.
> (Lai '016 patent, col. 2:64-3:6).

The Lai '016 patent also makes explicit reference to Example 10 of the '298 Application:

> Practice of the present invention is believed to be suitably illustrated by the following examples practiced on pooled CHO cell supernatants prepared in the manner described in Example 10 of the aforementioned U.S. patent application Ser. No. 675,298. More specifically, the treated supernatants were derived from cell strain CHO pDSVL-gHuEPO "amplified" by means of MTX and grown in roller bottles in serum-free medium as described at page 62 of the application.

(Lai '016 patent, col. 4:33-42). At the time the Lai '016 patent and the '298 application were filed, the named inventors on those patents were working together on Amgen's EPO project.

There was no legal impediment to filing the Lai '016 patent and the '298 application together, particularly in view of the Patent Law Amendments Act of 1984, which took effect before either of those applications was filed. The 1984 Act provides that "[i]nventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent." 35 U.S.C. §116.

Given PTO rules and applicable patent laws, Amgen could have filed a continuation-in-part application combining the Lin '298 and Lai '016 disclosures and named all of Lin, Lai and Strickland as co-inventors. Alternatively, Amgen could have added the Lin disclosure to the Lai application and included Lin as a co-inventor. (MPEP §201.08 (5th ed. Aug. 1983); MPEP §201.01 (8th ed. Rev. 6, Aug. 2006) ("A joint continuation application may derive from an earlier

sole application."). In either case, neither Lin nor Lai would have lost his asserted effective filing date because each claim in a CIP application may have different priority dates.

For at least the reasons stated above, it cannot be said that Amgen was required to file the Lai '016 claims separately from the claims-in-suit. Therefore, the first required condition for applying the two-way test fails, and even if the second required condition were met, *i.e.*, even if the PTO were solely responsible for the delay in issuance of the later claims, the one-way test would still apply.

Amgen, and not the PTO, was responsible for the later issuance of the claims-in-suit. All six of the patents-in-suit are based on applications filed after the '016 patent issued on May 19, 1987. Although the patents-in-suit claim priority going back to 1983-1984, Amgen waited until after the issuance of the '016 patent to file the applications in which it pursued the claims-in-suit to issuance. Therefore, the PTO could not have been responsible for the fact that any of the claims-in-suit issued after the Lai '016 patent.

In addition, as noted below and in the preceding section A, many of the claims-in-suit were not even introduced until years after the Lai '016 patent issued. For this reason as well, the PTO could not have been responsible for the fact that any of the claims-in-suit issued after the Lai '016 patent.

In the prosecution of the '422 patent, Amgen did not introduce prosecution claim 64, which ultimately issued as claim 1 of the '422 patent, until 4/22/1999. At that time, Amgen referred to prosecution claim 64 as a "[n]ewly added" claim. ('197 File History, Paper 33, 4/28/99 Amendment at 4). Accordingly, the PTO was not responsible for the fact that claim 1 of the '422 patent issued after the 5/19/87 issuance of the Lai '016 patent.