Similarly, and as noted in the preceding section A, claim 7 of the '349 patent was first introduced as a new claim on December 24, 1996, when Amgen noted that it was "not included in the original claims of Serial No. 06/675,298." ('369 File History, 12/24/96 Second Preliminary Amendment at 9). Accordingly, the PTO was not responsible for the fact that claim 7 of the '349 patent issued after the 5/19/87 issuance of the Lai '016 patent.

Claims 4-9 of the '698 patent were not filed until 1995. Moreover, claims 4-9 of the '698 patent are similar to the process claims that were voluntarily cancelled from the '298 prosecution and reasserted in application '179, after the '016 Lai patent had issued. Accordingly, the PTO was not responsible for the fact that claims 4-9 of the '698 patent issued after the 5/19/87 issuance of the Lai '016 patent.

Claims 1 and 2 of the '868 patent are process claims originally included in the Group II claims elected for prosecution in the '298 application. In a break with the Examiner's restriction requirement, Amgen voluntarily cancelled those process claims and reasserted them in application '179, after the '016 Lai patent had issued. Accordingly, the PTO was not responsible for the fact that claims 1-2 of the '868 patent issued after the 5/19/87 issuance of the Lai '016 patent.

The file histories that set forth double-patenting rejections based on the Lai '016 patent (see Section V), include the following excerpt:

> While the instantly claimed method is an obvious variation of the process of Lai et al. it is considered that applicant is not responsible for the delay in the prosecution of the instant application which resulted in the prior patenting of a later filed application to an invention derived from the instant invention. (see Ex parte Nesbit, 25 USPQ2d 1817 (1992)). Accordingly, the two-way test for obviousness double patent has been applied (see In re Braat 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991))). In support to this conclusion the examiner notes that the instant application, and its immediate parent, 06/675,298 have been subjected to

> extensive interparty interference and court proceedings which have delayed prosecution."

('179 File History, Paper 34, 2/15/94 Office Action at 2). The Examiner found that the '179 claims were obvious in light of the Lai '016 patent but withdrew the obviousness-type double patenting rejection solely on the basis that the two way test applied.

The Examiner apparently found that the two-way test applied on the ground that interference proceedings were responsible for the delay in prosecution. This finding is erroneous because it failed to apply the proper analysis. First, the Examiner appears to have overlooked the first, necessary prong of the analysis entirely: whether the applications could have been filed together. Second, the Examiner failed to consider factors that prove it was Amgen's prosecution strategy—and not administrative delay at the PTO—that resulted in the prosecution delay of the claims-in-suit. For example, the Examiner failed to consider the fact that the claims at issue—the Group II process claims—had been voluntarily withdrawn from earlier consideration, and could have avoided the interference prior to issuance had they been prosecuted along with the related Group II claims that issued in the '008 patent. Similarly, the Examiner failed to take into account that during the co-pendency period of the Lai '016 patent and the patents-in-suit (and before any interference was declared) Amgen requested and received five extensions of time. For at least these reasons, the Examiner's finding that the two-way test applied was in error.

The one-way test is also the appropriate test for analyzing obviousness-type double patenting of the '080 and '933 claims over the Lai '016 claims. As stated above, Amgen could have filed the patents-in-suit together with the claims of the Lai '016 patent. Therefore, the first necessary condition for applying the two-way test fails.

Both the '080 and the '933 patents stem from the '178 application, which was filed after the Lai '016 patent issued. For that reason alone, the PTO could not have been responsible for the fact that any of the claims-in-suit of these patents issued after the Lai '016 patent.

Furthermore, as noted below, numerous limitations were not introduced until years after the Lai '016 patent issued, even though they were supported by the '298 disclosure. For that reason as well, the PTO could not have been responsible for the fact that those claims issued after the Lai '016 patent.

For example, limitations specifying use for the treatment of kidney dialysis patients that appear in the asserted claims of both the '080 and the '933 patents was not introduced until prosecution claim 98 was entered on 2/22/1995. ('874 File History, 2/22/1995 Amendment after Final Office Action, at 5).

Similarly, in the prosecution of the '080 patent, the limitation directed to "non-naturally occurring" erythropoietin was not introduced until the entry of prosecution claim 68 on 12/24/1996. ('556 File History, 12/24/96 Second Preliminary Amendment at 7). Limitations specifying the in vivo biological activity of erythropoietin ("to increase production of reticulocytes and red blood cells") also were not introduced until 12/24/1996. ('556 File History, 12/24/96 Third Preliminary Amendment at 7-8).

Over the course of the prosecution of the patents-in-suit, Amgen sought thirteen extensions of time totaling over fifteen months. Furthermore, in many instances, Amgen waited until the last possible day to respond to correspondence from the PTO.

Interference proceedings do not account for the delay in issuance of the patents-in-suit. As noted above, the Group II process claims could have issued in the '008 patent before becoming embroiled in interferences but for Amgen's decision to cancel those claims from

prosecution alongside related product claims that issued in '008. Furthermore, the '334 Interference was not initiated until 1990, and after the interference was resolved and numerous claims were allowed, Applicant filed two additional continuation applications before the '933 and '080 patents finally issued. Finally, none of the interferences included counts relating to the '349 or '422 patent claims and, thus, do not account for any delay.

The initial '024 application was filed on 12/13/1983, and the last patent-in-suit issued on 9/21/1999. Fewer than three of these almost-sixteen years were attributable to the delay caused by interference proceedings. In my view, the prosecution strategy reflected in the preceding paragraphs—and not administrative delay on the part of the PTO—was responsible for the protracted prosecution of the claims-in-suit.

For all of the reasons stated above, even if Amgen had been required to file the Lai '016 application separately from the patents-in-suit, it cannot be said that the PTO was solely responsible for the delay in prosecution of any of the patents-in-suit. Accordingly, Amgen is not entitled to a two-way test for obviousness with respect to any of the claims-in-suit, and the Examiner's finding that the two-way test applied with respect to certain claims introduced in the '179 application was in error.

b. '868 and '698 Patents

For all the reasons set forth in Roche's prior supplemental response to this interrogatory regarding obviousness-type double patenting based on the earlier issued '008 patent, the asserted claims of the '933 patent, '080 patent, '349 patent, and '422 patent are either invalid for obviousness type double patenting based on the earlier issued claims of the '868 and '698 patent or should be deemed to expire on 8/15/12, the expiration date of the '868 and '698 patents. The claims of the '868 and '698 patents are directed to the process of making recombinant

erythropoietin by expressing DNA encoding the erythropoietin gene in vertebrate and mammalian host cells to make an in vivo biologically active glycoprotein. The various asserted claims of the '933, '080, '349, and '422 patents cover such glycoprotein products, pharmaceutical compositions containing such products, methods of treatment using these pharmaceutical compositions, and the process for using vertebrate cells to produce certain levels of erythropoietin. As a result, these latter claims would have been obvious over the earlier issued process claims of the '868 and '698 patents.

INTERROGATORY NO. 11

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend is invalid under 35 U.S.C. § 103 or for double patenting, identify and describe for each claim and for each asserted defense:

(k) where, on a limitation-by-limitation basis, you contend each claim limitation is found or disclosed in the prior art or earlier Lin patent claims;

(l) why the claim would have been obvious, including where the motivation to combine prior art disclosures or earlier Lin patent claims may be found;

(m) why 35 U.S.C. § 121 does not bar the application of the doctrine of obviousness-type double patenting;

(n) 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 or data upon which you rely to support your contention(s);

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

(p) 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.

RESPONSE:

See Objections and Response To Interrogatory No. 9 above.

DATED: May 1, 2007

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CERTIFICATE OF SERVICE

I hereby certify that a copy of this document was served upon the attorneys of record for the plaintiff of the law firms listed below via email on the above date.

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