Representative Original Group I Claims	'933 Polypeptide Claims
	conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding the human erythropoietin amino acid sequence set out in FIG. 6 or a fragment thereof; and (b) isolating a glycosylated erythropoietin polypeptide therefrom. 5. A non-naturally occurring human erythropoietin glycoprotein possessing the *in vivo* biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells which is the product of the process comprising the steps of: (a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence comprising a sequence encoding the leader sequence of human erythropoietin set out in FIG. 6; and (b) isolating a glycosylated erythropoietin polypeptide therefrom. 6. A non-naturally occurring glycoprotein product of the expression in a non-human eucaryotic host of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin, said product possessing the *in vivo* biological property of causing human bone marrow

Representative Original Group I Claims	'933 Polypeptide Claims
	cells to increase production of reticulocytes and red blood cells and having an average carbohydrate composition which differs from that of naturally occurring erythropoietin. 7. The glycoprotein product according to claim 3, 4, 5 or 6 wherein the host cell is a non-human mammalian cell. 7. The glycoprotein product according to claim 3, 4, 5 or 6 wherein the host cell is a non-human mammalian cell. 8. The glycoprotein product according to claim 7 wherein the non-human mammalian cell is a CHO cell.

178. I may use the following table in my testimony in light of Dr. Lodish's expert report to explain how claims 9-14 of Dr. Lin's '933 patent relate to the original claims in Dr. Lin's '298 application that were assigned to restriction Group V:

Original Group V Claims	'933 Pharmaceutical Composition Claims
55. A pharmaceutical composition comprising an effective amount of a polypeptide according to claims 1, 16, 39, 40 or 41 and a pharmaceutically acceptable diluent, adjuvant or carrier.	9. A pharmaceutical composition comprising an effective amount a glycoprotein product effective for erythropoietin therapy according to claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.
56. A method for providing erythropoietin therapy to a mammal comprising administering an effective amount of a polypeptide according to claims 1, 16, 39, 40 or 41.	10. A method for providing erythropoietin therapy to a mammal comprising administering an effective amount of a pharmaceutical composition of claim 9.
57. A method according to claim 56 wherein the therapy comprises enhancing hematocrit levels.	11. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 9 in an amount effective to increase the hematocrit level of said patient.
	12. A pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy according to claim 7 and a pharmaceutically acceptable diluent, adjuvant or carrier.
	13. A method for providing erythropoietin therapy to a mammal comprising administering an effective amount of a pharmaceutical composition of claim 12.
	14. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 12 in an amount effective to increase the hematocrit

Original Group V Claims	'933 Pharmaceutical Composition Claims
	level of said product.

179. I may use the following table in my testimony in light of Dr. Lodish's expert report to explain how claims 1-3 and 7 of Dr. Lin's '080 patent relate to the original claims in Dr. Lin's '298 application that were assigned to restriction Group I:

Representative Original Group I Claims	'080 Polypeptide Claims
1. A purified and isolated polypeptide having part or all of the primary structural conformation and one or more of the biological properties of naturally-occurring erythropoietin and characterized by being the product of procaryotic or eucaryotic expression of an exogenous DNA sequence. 40. A glycoprotein product having a primary structural conformation sufficiently duplicative of that of a naturally-occurring erythropoietin to allow possession of one or more of the biological properties thereof and having an average carbohydrate composition which differs from that of naturally-occurring erythropoietin.	1. An isolated erythropoietin glycoprotein having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6 and has glycosylation which differs from that of human urinary erythropoietin. 2. An isolated erythropoietin glycoprotein having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6 and is not isolated from human urine. 3. A non-naturally occurring erythropoietin glycoprotein having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6. 7. An isolated polypeptide product characterized by being the product of the expression by a prokaryotic host cell of an exogenous DNA sequence encoding the mature erythropoietin amino acid sequence of FIG. 6.

180. I may use the following table in my testimony in light of Dr. Lodish's expert report to explain how claims 4-6 of Dr. Lin's '080 patent relate to the original claims in

Dr. Lin's '298 application that were assigned to restriction Group V:

Original Group V Claims	'080 Pharmaceutical Composition Claims
55. A pharmaceutical composition comprising an effective amount of a polypeptide according to claims 1, 16, 39, 40 or 41 and a pharmaceutically acceptable diluent, adjuvant or carrier.	4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3.
56. A method for providing erythropoietin therapy to a mammal comprising administering an effective amount of a polypeptide according to claims 1, 16, 39, 40 or 41.	5. A method for providing erythropoietin therapy to a mammal comprising administering an effective amount of a pharmaceutical composition of claim 4.
57. A method according to claim 56 wherein the therapy comprises enhaneing hematocrit levels.	6. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient.

2. Under 35 U.S.C. § 121, Dr. Lin's '008 Patent Claims Cannot Be Used as a Reference to Invalidate Dr. Lin's '933 and '080 Patent Claims

181. Having reviewed the file history for Dr. Lin's '933 and '080 patents, and based on my understanding of the subject matter of the claims assigned to the various restriction groups as informed by Dr. Lodish's expert report (Lodish ¶¶ 524-530), it is my opinion that the applications giving rise to Dr. Lin's '933 and '080 patents were filed after the Examiners' July 1986 restriction requirement in the '298 application and contained claims drawn to the non-elected inventions — specifically, the inventions of restriction Groups I and V — and not to the Group II invention elected and prosecuted to issuance in Dr. Lin's '008 patent. Therefore, it is my opinion that the applications giving rise to Dr. Lin's '933 and '080 patents satisfy the "filed

as a result of" requirement for § 121 protection. I note that Mr. Sofocleous does not contest this point in his report.

182. Mr. Sofocleous does, however, contest that the consonance requirement for § 121 protection is satisfied for Dr. Lin's '933 and '080 patents. Mr. Sofocleous opines that the claims of the '933 and '080 patents are not consonant with the July 1986 restriction requirement for two separate reasons (discussed below), and that, "[a]s a result, the safe harbor provisions of 35 U.S.C. § 121 do not apply, and the '008 patent claims are available for double-patenting purposes against the '933 and '080 patents." Sofocleous ¶¶ 465, 468. This opinion is flawed because Mr. Sofocleous does not apply the proper legal analysis in his assessment of consonance.

183. The first consonance violation alleged by Mr. Sofocleous regarding Dr. Lin's '933 and '080 patents is that, when certain '933 and '080 claims "were amended such that they could not be made from natural sources, and only from recombinant DNA and host cells, Applicant vitiated the Patent Office's rationale for its restriction requirement and broke the consonance requirement of § 121." Sofocleous ¶ 464. This argument is flawed because Mr. Sofocleous attempts to set the line of demarcation surrounding restriction Group II on a basis other than by looking to the actual restriction groupings (i.e., the substance of the claims in each restriction group), as the Federal Circuit has instructed. *See Texas Instruments*, 988 F.2d at 1179.

184. Specifically, Mr. Sofocleous focuses on the following statement made by the Examiner and speculates that "the Examiner separated the polypeptide claims [in Group I] from the recombinant DNA and host cell claims [in Group II], because she concluded that the [Group I] polypeptide claims could be made from an alternative source, such as natural tissue"

(Sofocleous ¶ 464):

> Inventions I and II are related as process of making and product made.
>
> The inventions are distinct if either (1) the process as claimed can be used to make another and materially different product, or (2) the product as claimed can be made by another and materially different process. MPEP 806.05(f).
>
> In this case, the product as claimed may be made by a materially different product, such as isolation from a naturally occurring source.

Sofocleous ¶ 459 (quoting '298 File History, Paper 8, 7/3/86 Office Action) (emphasis added by Mr. Sofocleous) (AM-ITC 00952500).

185. Having reviewed the substance of the claims assigned to restriction Groups I and II, and Dr. Lodish's analysis of them, I believe that Mr. Sofocleous is reading too much into the Examiners' remarks quoted above. As Dr. Lodish explains, while "some of the original Group I claims (e.g., claim 40) could be made by a materially different process than the process encompassed within restriction Group II," Mr. Sofocleous's interpretation of the Examiner's remarks "is inconsistent with the fact that Group I included claims that could ***not*** encompass products isolated from a naturally occurring source." Lodish ¶¶ 526-527. For example, Dr. Lodish explains in his report that original claim 1, which was assigned to Group I, was limited to polypeptides made from non-natural sources:

> 1. A purified and isolated polypeptide having part or all of the primary structural conformation and one or more of the biological properties of naturally-occurring erythropoietin and characterized by being the product of procaryotic or eucaryotic expression of an exogenous DNA sequence.

Lodish ¶ 526. For these reasons, I disagree with Mr. Sofocleous's premise that, in order to maintain consonance, the '933 and '080 claims must not be limited to polypeptides made from non-natural sources. Sofocleous ¶ 464.

186. Dr. Lodish has explained that the focal point of the Group II claims is DNA:

> The Examiner described Group II as "drawn to DNA." Based on the subject matter of the claims assigned to Group II, I agree with this characterization. The claims assigned to Group II included both process and non-process claims. The common feature of claims 14, 15, 17-36, 58, and 61-72 is that each claim requires a specific, purified, and isolated DNA sequence, encoding either human or monkey erythropoietin or an analog polypeptide related to erythropoietin in both structure and function. While some of these claims are directed to host cells containing or processes using such purified and isolated DNAs, none are directed to erythropoietin polypeptides or erythropoietin pharmaceutical compositions. Nor do any of these claims relate to host cells or processes for use defined by structures other than the introduction of purified and isolated DNA encoding the desired polypeptide. Additionally, these claims do not relate to cells or processes defined by a required production level for any polypeptide. Therefore, based on the subject matter of the claims assigned to Group II, it is my opinion that the focal point of Group II was the recited DNA.

Lodish ¶ 524. Based on Dr. Lodish's opinion that the focal point of the Group II claims is DNA, and not isolation from non-natural sources, it is my opinion that the mere fact that some '933 and '080 claims were amended to recite "non-naturally occurring" glycoprotein products is irrelevant to determining whether those claims are consonant with the Examiners' restriction requirement.

187. Dr. Lodish examined the substance of the '933 and '080 claims from a technical perspective and concluded that none of these claims "fall within the scope of restriction Group II, 'drawn to DNA.'" Lodish ¶¶ 533, 539. Dr. Lodish explained why his opinion was not inconsistent with the fact that some of the '933 and '080 claims recite the term "DNA":

> Some of the original claims assigned to Group I (e.g. original claims) as well as '933 claims 1-8 make reference to use of an exogenous DNA sequence to produce EPO erythropoietin polypeptides. But like the original claims assigned to Group I, none of '933 claims 1-8 is directed to DNA or a host cell transfected with DNA. Thus, it is my opinion that an ordinarily skilled artisan would recognize and understand that there are no

> material differences between original claims 1-13 of the '298 application and '933 claims 1-8 which thus would fall within the scope of the Group I category of claims and would not fall within the scope of the Group II category of claims.
>
> . . . .
>
> Unlike the claims of the '933 patent, each of the '080 claims is limited by the Fig. 6 ***polypeptide*** sequence. While there were no original claims reciting the Fig. 6 erythropoietin amino acid sequence, this narrowing limitation in no way crosses the line of demarcation drawn around the DNA cell subject matter of restriction Group II. Moreover, as described above, is clear that the Examiner made no distinction in the restriction requirement between an EPO "polypeptide" and an EPO "glycoprotein," given the inclusion of original claim 40 directed to "a glycoprotein product" in restriction Group I. Like the original claims assigned to Group I, none of '080 claims 1-3 or 7 is directed to DNA or a host cell transfected with DNA. In fact, like original claim 40, none of '080 claims 1-3 or 7 makes any reference to EPO DNA sequences whatsoever. Thus, it is my opinion that an ordinarily skilled artisan would recognized and understand that '080 claims 1-3 and 7 fall within the scope of restriction Group I, and do not fall within the scope of restriction Group II.

Lodish ¶¶ 535, 541. For the reasons explained in Dr. Lodish's report, it is my opinion that none of the claims of Dr. Lin's '933 and '080 patents cross the line of demarcation drawn around the invention elected by Amgen following the Examiners' restriction requirement in the '298 application.

188. Equally important, Dr. Lodish examined the substance of the '933 and '080 claims as compared to that of the original claims in Dr. Lin's '298 application and concluded that all the '933 and '080 claims fall within the scope of either Group I or Group V — two of the restriction groups not elected for examination in the '298 application. Lodish ¶¶ 533, 539. Specifically, Dr. Lodish opined that '933 claims 1-8 and '080 claims 1-3, and 7 fall within the scope of Group I, and that '933 claims 9-14 and '080 claims 4-6 fall within the scope of Group V. Lodish ¶¶ 534, 536, 540, 542. I note that Mr. Sofocleous agrees that '933 claims 9-14

and '080 claims 4-5 "fall within restricted Group V" (and, therefore, do not cross the line of demarcation drawn around restriction Group II). Sofocleous ¶ 466. For the reasons explained in Dr. Lodish's report, it is my opinion that all the claims of Dr. Lin's '933 and '080 patents are consonant with the claims in Dr. Lin's '298 application that the Examiners assigned to restriction Groups I and V.

189. The second consonance violation alleged by Mr. Sofocleous regarding the '933 and '080 patents is that these patents broke consonance "by issuing with claims from multiple restricted Groups," specifically Groups I and V. Sofocleous ¶¶ 466, 468. This argument is flawed because it has no basis in the law.

190. Mr. Sofocleous fails to identify any legal support for his theory that consonance is violated when a patent issues with claims drawn to inventions assigned to two different restriction groups, neither of which was elected for examination in the parent application. Nor am I aware of any legal support for Mr. Sofocleous's theory. In my opinion, the rule proposed by Mr. Sofocleous moves away from the fundamental purpose of the double patenting doctrine, because a later patent that contains claims drawn only to the non-elected inventions, and not to the subject matter that was elected for examination in the earlier patent, does not extend the term of that earlier patent.

191. As the Federal Circuit has made clear, the consonance requirement is satisfied as long as the claims in the issued patent "do not cross the line of demarcation drawn around ***the invention elected in the restriction requirement***." *Symbol Techs.*, 935 F.2d at 1579 (emphasis added). To my knowledge, the Federal Circuit has never held that an application filed as a result of a restriction requirement (or a patent issuing therefrom) cannot contain claims drawn to inventions from multiple restriction groups not elected for examination in the parent

application. If anything, the language in *Gerber Garment*, one of the Federal Circuit's key cases regarding consonance, suggests just the opposite. *See Gerber*, 916 F.2d at 688 ("To gain the benefits of Section 121 . . . Gerber must have brought its case within the purview of the statute, i.e., it must have limited the claims in its divisional application to the non-elected invention ***or inventions***.") (emphasis added).

192. Additionally, Mr. Sofocleous's theory that the '933 and '080 patents are not consonant because they include claims from Groups I and V ignores that restriction practice is discretionary, *see* 35 U.S.C. § 121; MPEP § 803, and that the Examiners in this case exercised their discretion to allow Amgen's counsel to prosecute claims from Groups I and V together in the '178, '874, '774, and '556 applications leading to Dr. Lin's '933 and '080 patents. For all these reasons, it is my opinion that Dr. Lin's '933 and '080 patents do not violate the consonance requirement by including claims from both Group I and Group V.

193. In my view, the relevant consideration in assessing consonance for Dr. Lin's '933 and '080 patents is whether the claims in those patents are consonant with the Group I and Group V claims pending in Dr. Lin's '298 application at the time of the 1986 restriction requirement — claims which the Examiners deemed patentably distinct from the Group II claims that were elected and prosecuted to issuance in Dr. Lin's '008 patent. As noted above, Dr. Lodish has examined the claims from a technical perspective and opined that '933 claims 1-8 and '080 claims 1-3, and 7 fall within the scope of Group I, and that '933 claims 9-14 and '080 claims 4-6 fall within the scope of Group V. Lodish ¶¶ 534, 536, 540, 542. Therefore, it is my opinion that Dr. Lin's '933 and '080 patents satisfy the consonance requirement for § 121 protection.

194. For the reasons discussed above, it is my opinion that the safe harbor

provisions of 35 U.S.C. § 121 apply to Dr. Lin's '933 and '080 patents, and that Dr. Lin's '008 patent claims cannot be used for double-patenting purposes to invalidate Dr. Lin's '933 and '080 patent claims. In connection with my testimony regarding this opinion, I may use certain graphics or demonstratives, such as those included in Exhibit 4 to my report.

3. Dr. Lin's '933 and '080 Patent Claims Are Patentably Distinct from Dr. Lin's '008 Patent Claims

195. Mr. Sofocleous does not state in his report that the '933 and '080 patent claims are ***not*** patentably distinct from the '008 patent claims. Nor does Mr. Sofocleous state that Amgen's counsel has improperly extended the term of Dr. Lin's '008 patent by failing to terminally disclaim Dr. Lin's '933 and '080 patents. However, Exhibit C of Mr. Sofocleous's report includes an unnumbered demonstrative, titled "Term of Amgen EPO Patents," which graphically depicts that Dr. Lin's '933 and '080 patents represent an "improper extension of monopoly." Even if § 121 did not prohibit use of Dr. Lin's '008 claims for double patenting purposes against Dr. Lin's '933 and '080 claims (which it does, for the reasons explained above), it is my opinion that the conclusion expressed in Mr. Sofocleous' demonstrative is unsupported because it depends on the unstated assumption that the claims of the '933 and '080 patents are not patentably distinct from the claims in the '008 patent — an issue that Mr. Sofocleous did not address anywhere in his report.

196. Moreover, based on the expert report of Dr. Lodish, it is my opinion that, in addition to being unsupported, Mr. Sofocleous's demonstrative is wrong. I have been informed that '933 claims 3, 7-9, and 11-14 are the only claims of Dr. Lin's '933 patent asserted in this case, and the only '933 claims which Roche contends are invalid for double patenting over the '008 patent claims. As Dr. Lodish explains in detail in his expert report, '933 claims 3, 7-9, and 11-14 are patentably distinct from the claims of the '008 patent. Lodish ¶¶ 417-420.

One of the distinctions Dr. Lodish discusses in his expert report is that "each of the asserted claims recite a ***positive requirement*** for the products' *in vivo* biological activity (or therapeutic effect), as compared to the '008 claims, which do not." Lodish ¶ 418. Other distinctions between the '933 and '008 patent claims also are explained in Dr. Lodish's expert report. Lodish Ex. G.

197. I have been informed that '080 claims 3, 4, and 6 are the only claims of Dr. Lin's '080 patent asserted in this case, and the only '080 claims which Roche contends are invalid for double patenting over the '008 patent claims. As Dr. Lodish explains in detail in his report, '080 claims 3, 4, and 6 are patentably distinct from the claims of Dr. Lin's '008 patent. Lodish ¶¶ 417-420. One of the distinctions Dr. Lodish discusses in his report is that, "each of the asserted claims recite a ***positive requirement*** for the products' *in vivo* biological activity (or therapeutic effect), as compared to the '008 claims, which do not." Lodish ¶ 418. Other distinctions between the '080 and '008 patent claims also are explained in Dr. Lodish's expert report. Lodish Ex. G.

198. As noted earlier, the obviousness-type double patenting doctrine is designed to prevent improper timewise extension of the patent right by prohibiting claims in a later patent which are not patentably distinct from claims in a commonly-owned earlier patent from enjoying a longer patent term. Because, for the reasons discussed in Dr. Lodish's expert report, the claims in Dr. Lin's '933 and '080 patents ***are*** patentably distinct from the claims in Dr. Lin's '008 patent, the '933 and '080 patent claims do not extend the term of patent protection for the '008 patent.

D. DR. LIN'S '422 PATENT CLAIMS ARE NOT INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER DR. LIN'S '008 PATENT CLAIMS

1. Examination history of Dr. Lin's '422 Patent

199. My discussion of Dr. Lin's '422 patent begins with the '179 application. As mentioned above, Dr. Lin's '179 application was filed on October 23, 1987, after the restriction requirement that was entered during examination of Dr. Lin's '298 application. Dr. Lin's '179 application was filed under 37 C.F.R. § 1.60, which permitted Amgen's counsel to file the '179 application by submitting a true copy of the prior '298 application, including a copy of the oath or declaration originally filed in Dr. Lin's '298 application. In keeping with the earlier restriction requirement, Amgen's counsel cancelled all claims that belonged to restriction Group II (which were being examined in Dr. Lin's '298 application), and selected original claim 1 — which belonged to restriction Group I of the '298 application — for examination in the '179 application.

200. On November 6, 1990, with examination of Dr. Lin's '179 application delayed pending the outcome of the '097 interference proceeding, discussed above, Amgen's counsel advanced the examination leading to the '422 patent by filing U.S. Patent Application No. 07/609,741 ("the '741 application"). Like the '179 application, Dr. Lin's '741 application was filed under 37 C.F.R. § 1.60, which permitted Amgen's counsel to file the '741 application by submitting a true copy of the prior '179 application, including a copy of the oath or declaration originally filed in Dr. Lin's '179 application. And, as it had done when filing the '179 application, Amgen's counsel, consistent with the Examiners' 1986 restriction requirement in the '298 application, canceled all claims that belonged to restriction Group II, and selected a claim from the other, non-elected groups for examination in the '741 application. Amgen's counsel then added three new claims, numbered 61-63, to the '741 application. The '179 application provided continuity for Dr. Lin's '741 application to permit the '741 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120.

201. On April 6, 1992, Examiner Nolan issued a restriction requirement for Dr. Lin's '741 application. The restriction requirement identified seven separate invention groups and required that Amgen's counsel select claims from only one of these seven groups for further examination in the '741 application. '741 File History, Tab 4, 4/6/92 Office Action (AM-ITC 00943131). In response to this restriction requirement, Amgen's counsel selected pending claims 61-63, which the Examiner had assigned to Group VII, for further examination in the '741 application.

202. On October 6, 1992, Amgen advanced the examination leading to the '422 patent by filing U.S. Patent Application No. 07/957,073 ("the '073 application"). Dr. Lin's '073 application utilized the "file wrapper continuation" procedure under 37 C.F.R. § 1.62, which is discussed above. As a result, the prior '741 application was abandoned, and its specification, claims and drawings, including all amendments, were carried forward and "continued" (i.e., physically included) in Dr. Lin's '073 application. The '741 and '179 applications provided continuity for Dr. Lin's '073 application to permit the '073 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120.

203. On August 2, 1993, Amgen's counsel advanced the examination leading to the '422 patent by filing U.S. Patent Application No. 08/100,197 ("the '197 application"). Like the '073 application before it, Dr. Lin's '197 application utilized the "file wrapper continuation" procedure under 37 C.F.R. § 1.62. As a result, the prior '073 application was abandoned, and its specification, claims and drawings, including all amendments, were carried forward and "continued" (i.e., physically included) in Dr. Lin's '197 application. The '073, '741, and '179 applications provided continuity for Dr. Lin's '197 application to permit the '197 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120.

204. As often happens during the course of examination of a patent application, on April 28, 1999, Amgen's counsel chose to cancel pending claims 61-63 and to replace them with new claims to advance the examination of the '197 application. These new claims, numbered 64 and 65, were ultimately allowed by the Examiner on May 28, 1999, and they issued as claims 1 and 2 of Dr. Lin's '422 patent on September 21, 1999.

205. Because the '197 application contained claims drawn to the inventions of Group V of the 1986 restriction requirement in the '298 application, Amgen's counsel filed terminal disclaimers to ensure that the end of the term of the '422 patent coincided with the end of the term of the '933 and '080 patents, which, as explained above, also contained claims that fell within the scope of 1986 restriction Group V. (*See* '422 File History, Tabs 37 and 39, 4/26/99 Terminal Disclaimers (AM-ITC 00943727; AM-ITC 00943736)).

206. I may use the following table in my testimony in light of Dr. Lodish's expert report to explain how the claims of Dr. Lin's '422 patent relate to the original claims in Dr. Lin's '298 application that were assigned to restriction Group V:

Original Group V Claims	'422 Pharmaceutical Composition Claims
55. A pharmaceutical composition comprising an effective amount of a polypeptide according to claims 1, 16, 39, 40 or 41 and a pharmaceutically acceptable diluent, adjuvant or carrier. 56. A method for providing erythropoietin therapy to a mammal comprising administering an effective amount of a polypeptide according to claims 1, 16, 39, 40 or 41. 57. A method according to claim 56 wherein the therapy comprises enhancing hematocrit levels.	1. A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture. 2. A pharmaceutically-acceptable preparation containing a therapeutically effective amount of erythropoietin wherein human serum albumin is mixed with said erythropoietin.

2. Under 35 U.S.C. § 121, Dr. Lin's '008 Patent Claims Cannot Be Used as a Reference to Invalidate Dr. Lin's '422 Patent Claims

207. Having reviewed the file history for Dr. Lin's '422 patent, and based on my understanding of the subject matter of the claims assigned to the various restriction groups as informed by Dr. Lodish's expert report (Lodish ¶¶ 524-530), it is my opinion that the applications giving rise to Dr. Lin's '422 patent were filed after the Examiners' July 1986 restriction requirement in the '298 application and contained claims drawn to the non-elected inventions and not to the Group II invention elected and prosecuted to issuance in Dr. Lin's '008 patent. Therefore, it is my opinion that the applications giving rise to Dr. Lin's '422 patent satisfy the "filed as a result of" requirement for § 121 protection. I note that Mr. Sofocleous does not contest this point in his report.

208. Mr. Sofocleous does, however, contest that the consonance requirement

for § 121 protection is satisfied for Dr. Lin's '422 patent. Specifically, Mr. Sofocleous contends that the '422 patent broke consonance by issuing with claims from both Group V and Group VII of the 1992 restriction requirement. Sofocleous ¶¶ 471-74. This opinion is flawed because Mr. Sofocleous does not apply the proper legal analysis in his assessment of consonance.

209. Mr. Sofocleous's consonance opinion relies on the premise that the 1992 restriction requirement set forth in the '741 application ***always*** "supersedes the earlier July 1986 restriction requirement set forth in the '298 application for the applications leading to the '422 patent" — even for purposes of assessing whether § 121 prohibits use of the ***'008 patent claims*** for double patenting purposes against the '422 patent claims. Sofocleous ¶ 470. Mr. Sofocleous fails to identify any legal support for this assertion. This is not surprising, because Mr. Sofocleous's theory is inconsistent with both the purpose and the text of the § 121 safe harbor.

210. As explained above, § 121 is designed to protect applicants from allegations of double patenting in instances where the USPTO has determined that an application contains claims to multiple independent and distinct inventions, and has issued a restriction requirement forcing the applicant to divide out and prosecute claims to these inventions in separate applications. Section 121 provides in pertinent part:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

Therefore, when obviousness-type double patenting is raised in the litigation context (i.e., when a claim of a commonly-owned, earlier patent is asserted for double patenting purposes against a claim of a patent-in-suit), the relevant restriction requirement is the one that first forced the

Applicant to prosecute the claims of the patent-in-suit in a separate application from the claims that were prosecuted to issuance in the patent being asserted for double patenting purposes. In other words, the relevant restriction requirement is the one that caused the initial "fork in the road" leading to two separate patents.

211. In this instance, since Amgen's counsel is invoking the § 121 safe harbor to prevent using the ***'008 patent claims*** for double-patenting purposes against the '422 claims, the relevant restriction requirement is the one that caused the initial "fork in the road" leading to the '008 patent in one direction and the '422 patent in the other. Thus, the relevant point of reference is the ***1986*** restriction requirement in the '298 application, in which the Examiners forced Amgen to prosecute its non-elected claims separately from its Group II claims that were prosecuted to issuance in Dr. Lin's '008 patent.

212. Mr. Sofocleous's assertion that the 1992 restriction requirement set forth in the '741 application "supersedes the earlier July 1986 restriction requirement set forth in the '298 application for the applications leading to the '422 patent" is flawed because it is overbroad and incorrect when applied to the issue of whether § 121 precludes use of the ***'008 patent claims*** for double patenting purposes against the '422 patent claims. The 1992 restriction requirement set forth in the '741 application might be relevant if Amgen were invoking § 121 to prevent Roche from using another patent that issued from the '741 application, or another patent that issued from a different application filed as a result of the 1992 restriction requirement, for double-patenting purposes against the '422 patent. But no such argument can be made in this case, because Dr. Lin's '422 patent is the only patent that issued from the '741 application and subsequent related applications.

213. Applying the correct legal analysis, Dr. Lodish examined the claims of the

'422 patent as compared to the original claims subject to the 1986 restriction requirement in the '298 application, and opined that the '422 patent claims fall within the scope of Group V of the 1986 restriction requirement — one of the restriction groups not elected for examination in the earlier '298 application — and do not fall within the scope of Group II. Lodish ¶¶ 548-552. Dr. Lodish provided the following explanation in his expert report:

> Consistent with the original claims assigned to restriction Group V ("drawn to pharmaceutical composition"), '422 claim 1 is drawn to a pharmaceutical composition comprising human EPO. '422 claim 1 does not include any limitation concerning or invoking the purified or isolated EPO DNA of restriction Group II. This is confirmed by the Federal Circuit's holding that '422 claim 1 is infringed by a pharmaceutical composition comprised of human EPO produced by a process using "gene activated" EPO DNA, wherein the EPO DNA was never purified or isolated. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F3d. 1313, 1348-49 (Fed. Cir. 2003). The limitation "purified from mammalian cells grown in culture" was not present in the original claims assigned to restriction Group V in the '298 application. This subject matter, however, bears no relationship to the EPO DNA and transfected host cell subject matter of restriction Group II.
>
> '422 claim 2 is also drawn to a pharmaceutical composition comprising human EPO consistent with the original claims assigned to restriction Group V, "drawn to pharmaceutical composition." The limitation "wherein human serum albumin is mixed with said erythropoietin" was not present in the original claims assigned to restriction Group V in the '298 application. This subject matter, however, bears no relationship to the EPO DNA and transfected host cell subject matter of restriction Group II.
>
> Thus, it is my opinion that an ordinarily skilled artisan in 1984 would have recognized and understood that the '422 claims fall within the scope of restriction Group V and do not fall within the scope of restriction Group II.

Lodish ¶¶ 550-552. For the reasons explained in Dr. Lodish's expert report, it is my opinion that Dr. Lin's '422 patent satisfies the consonance requirement for § 121 protection.

214. For the reasons discussed above, it is my opinion that the safe harbor

provisions of 35 U.S.C. § 121 apply to Dr. Lin's '422 patent, and that the '008 patent claims cannot be used for double-patenting purposes to invalidate the '422 patent claims. In connection with my testimony regarding this opinion, I may use certain graphics or demonstratives, such as those included in Exhibit 4 to my report.

3. Dr. Lin's '422 Patent Claims Are Patentably Distinct from Dr. Lin's '008 Patent Claims

215. Mr. Sofocleous does not state in his report that the '422 patent claims are ***not*** patentably distinct from the '008 patent claims. Nor does Mr. Sofocleous state that Amgen has improperly extended the term of Dr. Lin's '008 patent by failing to terminally disclaim Dr. Lin's '422 patent. However, Exhibit C of Mr. Sofocleous's report includes an unnumbered demonstrative, titled "Term of Amgen EPO Patents," which graphically depicts that the '422 patent represents an "improper extension of monopoly." Even if § 121 did not prohibit use of Dr. Lin's '008 claims for double patenting purposes against Dr. Lin's '422 claims (which it does, for the reasons explained above), it is my opinion that the conclusion expressed in Mr. Sofocleous's demonstrative is unsupported because it depends on the unstated assumption that the claims of Dr. Lin's '422 patent are not patentably distinct from the claims in Dr. Lin's '008 patent — an issue that Mr. Sofocleous did not address anywhere in his report.

216. Moreover, based on the expert report of Dr. Lodish, it is my opinion that, in addition to being unsupported, Mr. Sofocleous's demonstrative is wrong. I have been informed that '422 claim 1 is the only claim of Dr. Lin's '422 patent asserted in this case, and the only '422 claim which Roche contends is invalid for double patenting over Dr. Lin's '008 patent claims. As Dr. Lodish explains in detail in his expert report, '422 claim 1 is patentably distinct from the claims of the '008 patent. Lodish ¶¶ 417-420. One of the distinctions Dr. Lodish discusses in his expert report is that "each of the asserted claims recites a ***positive requirement***

for the products' *in vivo* biological activity (or therapeutic effect), as compared to the '008 claims, which do not." Lodish ¶ 418. Other distinctions between the '422 and '008 patent claims also are explained in Dr. Lodish's expert report. Lodish Ex. G.

217. As noted earlier, the obviousness-type double patenting doctrine is designed to prevent improper timewise extension of the patent right by prohibiting claims in a later patent which are not patentably distinct from claims in a commonly-owned earlier patent from enjoying a longer patent term. Because, for the reasons discussed in Dr. Lodish's expert report, the claims in Dr. Lin's '422 patent *are* patentably distinct from the claims in Dr. Lin's '008 patent, the '422 patent claims do not extend the term of patent protection for the '008 patent.

E. DR. LIN'S '868 AND '698 PATENT CLAIMS ARE NOT INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER DR. LIN'S '008 PATENT CLAIMS

218. In his report, Mr. Sofocleous concludes that, "by failing to properly disclaim the '868 patent term, Amgen extended its patent protection for nearly 8 years beyond the 2004 expiration of the '008 patent." Sofocleous ¶ 447. Similarly, with respect to the '698 patent, Mr. Sofocleous concludes that, "[b]y failing to properly disclaim the '698 patent term, Amgen extended its patent protection for nearly 8 years beyond the 2004 expiration of the '008 patent." Sofocleous ¶ 451. Mr. Sofocleous also includes in Exhibit C of his report two unnumbered demonstratives, both titled "Term of Amgen EPO Patents," which graphically depict his conclusions that the '868 and '698 patents improperly extend the term of patent protection for the '008 patent. In my opinion, these conclusions and the related demonstratives are unsupported because they depend on the unstated assumption that the claims of Dr. Lin's '868 and '698 patents are not patentably distinct from the claims in Dr. Lin's '008 patent — an issue that Mr. Sofocleous did not address anywhere in his report.

219. Moreover, based on the expert report of Dr. Lodish, it is my opinion that, in addition to being unsupported, Mr. Sofocleous's conclusions in ¶¶ 447 and 451 and related demonstratives are wrong. I have been informed that '868 claims 1-2 and '698 claims 4-9 are the only claims of the '868 and '698 patents asserted in this case, and the only '868 and '698 claims which Roche contends are invalid for double patenting over the '008 patent claims. As Dr. Lodish explains in detail in his expert report, '868 claims 1-2 and '698 claims 4-9 are patentably distinct from the claims of the '008 patent. Lodish ¶¶ 421-424. One of the distinctions Dr. Lodish discusses in his expert report is that "each of the asserted '868 and '698 claims recites a ***positive requirement*** for the product of the claimed process to ***have*** the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells," whereas "the '008 claims lack this critical requirement." Lodish ¶ 422. Other distinctions between the '868 and '698 patent claims and the '008 patent claims also are explained in Dr. Lodish's expert report. Lodish Ex. G.

220. As noted earlier, the obviousness-type double patenting doctrine is designed to prevent improper timewise extension of the patent right by prohibiting claims in a later patent which are not patentably distinct from claims in a commonly-owned earlier patent from enjoying a longer patent term. Because, for the reasons discussed in Dr. Lodish's expert report, the claims in Dr. Lin's '868 and '698 patents ***are*** patentably distinct from the claims in Dr. Lin's '008 patent, the '868 and '698 patent claims do not extend the term of patent protection for the '008 patent.

F. THE CLAIMS OF DR. LIN'S PATENTS-IN-SUIT ARE NOT INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CLAIM 10 OF THE LAI '016 PATENT

1. The USPTO Was Correct to Apply the "Two-Way" Double-Patenting Test