Restriction Group	Claim Language
	occurring erythropoietin, said process comprising: growing, under suitable nutrient conditions, prokaryotic or eukaryotic host cells transformed or transfected with a DNA vector according to claim 62, and isolating desired polypeptide products of the expression of DNA sequences in said vector. 70. A process for the production of a polypeptide having part or all of the primary structural conformation and one or more of the biological activities of naturally-occurring erythropoietin, said process comprising: growing, under suitable nutrient conditions, prokaryotic or eukaryotic host cells transformed or transfected with a DNA vector according to claim 63, and isolating desired polypeptide products of the expression of DNA sequences in said vector. 71. A process for the production of a polypeptide having part or all of the primary structural conformation and one or more of the biological activities of naturally-occurring erythropoietin, said process comprising: growing, under suitable nutrient conditions, prokaryotic or eukaryotic host cells transformed or transfected with a DNA vector according to claim 65, and isolating desired polypeptide products of the expression of DNA sequences in said vector. 72. A process for the production of a polypeptide having part or all of the primary structural conformation and one or more of the biological activities of naturally-occurring erythropoietin, said process comprising: growing, under suitable nutrient conditions, prokaryotic or eukaryotic host cells transformed or transfected with a DNA vector according to claim 67, and isolating desired polypeptide products of the expression of DNA sequences in said vector.
Group III: Plasmid	37. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to either of claims 14, 17, 34 or 35. 38. A prokaryotic or eukaryotic host cell stably transformed or transfected with a DNA vector according to claim 37.
Group IV: Cells	42. Vertebrate cells which can be propagated *in vitro* continuously and which upon growth in culture are capable of producing in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay. 43. Vertebrate cells according to claim 42 capable of producing in excess of 500 U erythropoietin per 10^6 cells in 48 hours. 44. Vertebrate cells according to claim 42 capable of producing in excess of 1,000 U erythropoietin per 10^6 cells in 48 hours. 45. Vertebrate cells according to claim 42 which are mammalian or avian cells. 46. Vertebrate cells according to claim 45 which are COS-1 cells or CHO cells.
Group V: Pharmaceutical Composition	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

Restriction Group	Claim Language
	or 41. 57. A method according to claim 56 wherein the therapy comprises enhancing hematocrit levels.
Group VI: Assay	60. An improvement in the method for detection of a specific single stranded polynucleotide of unknown sequence in a heterogeneous cellular or viral sample including multiple single-stranded polynucleotides wherein: (a) a mixture of labeled single-stranded polynucleotide probes is prepared having uniformly varying sequences of bases, each of said probes being potentially specifically complementary to a sequence of bases which is putatively unique to the polynucleotide to be detected; (b) the sample is fixed to a solid substrate; (c) the substrate having the sample fixed thereto is treated to diminish further binding of polynucleotides thereto except by way of hybridization to polynucleotides in said sample; (d) the treated substrate having the sample fixed thereto is transitorily contacted with said mixture of labeled probes under conditions facilitative of hybridization only between totally complementary polynucleotides; and (e) the specific polynucleotide is detected by monitoring for the presence of a hybridization reaction between it and a totally complementary probe within said mixture of labeled probes, as evidenced by the presence of a higher density of labeled material on the substrate at the locus of the specific polynucleotide in comparison to a background density of labeled material resulting from non-specific binding of labeled probes to the substrate, said improvement comprising using in excess of 32 mixed probes and performance of one or more of the following: (1) employing a nylon-based paper as said solid substrate; (2) treating with a protease in step (c); (3) employing individual labeled probe concentrations of approximately 0.025 picomoles; and (4) employing as one of the hybridization conditions in step (d) stringent temperatures approaching to with 4°C away from the lowest calculated Td of any of the probes employed.

149. As the Examiners pointed out in this Office Action, by a Preliminary Amendment filed April 24, 1986, Amgen's counsel had selected the DNA-related inventions identified as Group II for continued examination in Dr. Lin's '298 application. Thus, the

Examiners withdrew the non-elected claims directed to the other inventions of Groups I and III-VI from further consideration in the '298 application. When an Examiner withdraws claims from further consideration, under USPTO practice and procedures, it means that those claims are not subject to examination in the present application. Therefore, after the Examiners withdrew the non-elected claims from further examination in the '298 application, Amgen's counsel's option for obtaining patents on Dr. Lin's other inventions claimed in Groups I and III-VI was to file additional applications to have those claims examined separately from the claims in the '298 application (which, as will be explained in more detail below, is exactly what Amgen's counsel did).

150. Dr. Lin's '298 application ultimately issued on October 27, 1987 as the '008 patent. Dr. Lodish has explained that, "consistent with Amgen's election to have the Group II claims examined in the '298 application, all of the '008 patent claims fall within the scope of restriction Group II." Lodish ¶ 531.

B. DR. LIN'S '349 CLAIMS ARE NOT INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER DR. LIN'S '008 CLAIMS

1. Examination History of Dr. Lin's '349 Patent

151. My discussion of Dr. Lin's '349 patent begins with U.S. Patent Application No. 06/113,179 ("the '179 application"). 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. The '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 — for examination in Dr. Lin's '179 application.

152. On June 6, 1995, Amgen's counsel advanced the examination leading to the '349 patent by filing U.S. Patent Application No. 08/468,369 ("the '369 application"). Like the '179 application, Dr. Lin's '369 application was filed under 37 C.F.R. § 1.60, which permitted Amgen's counsel to file the '369 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 Dr. Lin's '179 application, Amgen's counsel, consistent with the Examiners' 1986 restriction requirement, canceled all claims that belonged to restriction Group II and selected claims from the other, non-elected groups for examination in Dr. Lin's '369 application. Specifically, Amgen's counsel selected original claims 42-44, and 46 — which belonged to restriction Group IV — for further examination in Dr. Lin's '369 application.[10] Dr. Lin's '179 application provided continuity for Dr. Lin's '369 application to permit the '369 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120.

153. As often happens during the course of examination of a patent application, on May 16, 1997, Amgen's counsel chose to cancel the claims then pending in Dr. Lin's '369 application and to replace them with new claims to advance the examination of the application.

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[10] During examination, Amgen pointed out to the Examiner that claims 42-44 and 46 were "substantially identical" to claims 42-46 in the '298 application that were assigned to restriction Group IV, "drawn to cells." (*See* '349 File History, Tab 8, 12/24/96 Second Preliminary Amendment (AM-ITC 00942695)). Amgen also pointed out to the Examiner that claim 61 (the predecessor of '349 claim 7), although not an original '298 claim, was "directed to a method for using the novel vertebrate cells of claims 42-44 and 46 for the production of erythropoietin," which the '298 specification taught as the intended use of the cells claimed in the Group IV claims. *Id.*

These new claims, numbered 66-72, were ultimately allowed by the Examiner on September 9, 1997, and they issued as claims 1-7 of Dr. Lin's '349 patent on May 26, 1998.

154. I may use the following table in my testimony in light of Dr. Lodish's expert report to explain how the claims in Dr. Lin's '349 patent relate to the original claims in Dr. Lin's '298 application that were assigned to restriction Group IV:

Original Group IV Claims	'349 Cell Claims
42. Vertebrate cells which can be propagated *in vitro* continuously and which upon growth in culture are capable of producing in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay.	1. Vertebrate cells which can be propagated in vitro and which are capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay, said cells comprising non-human DNA sequences which control transcription of DNA encoding human erythropoietin.
43. Vertebrate cells according to claim 42 capable of producing in excess of 500 U erythropoietin per 10^6 cells in 48 hours.	2. Vertebrate cells according to claim 1 capable of producing in excess of 500 U erythropoietin per 10^6 cells in 48 hours.
44. Vertebrate cells according to claim 42 capable of producing in excess of 1,000 U erythropoietin per 10^6 cells in 48 hours.	3. Vertebrate cells according to claim 1 capable of producing in excess of 1000 U erythropoietin per 10^6 cells in 48 hours.
45. Vertebrate cells according to claim 42 which are mammalian or avian cells.	4. Vertebrate cells which can be propagated *in vitro* which comprise transcription control DNA sequences, other than human erythropoietin transcription control sequences, for production of human erythropoietin, and which upon growth in culture are capable of producing in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by
46. Vertebrate cells according to claim 45 which are COS-1 cells or CHO cells.	

Original Group IV Claims	'349 Cell Claims
	radioimmunoassay. 5. Vertebrate cells according to claim 4 capable of producing in excess of 500 U erythropoietin per 10^6 cells in 48 hours. 6. Vertebrate cells according to claim 4 capable of producing in excess of 1000 U erythropoietin per 10^6 cells in 48 hours 7. A process for producing erythropoietin comprising the step of culturing, under suitable nutrient conditions, vertebrate cells according to claim 1, 2, 3, 4, 5 or 6.

2. Under 35 U.S.C. § 121, Dr. Lin's '008 Patent Claims Cannot Be Used as a Reference to Invalidate Dr. Lin's '349 Patent Claims

155. In his report, Mr. Sofocleous appears to suggest that the safe harbor provisions of 35 U.S.C. § 121 do not prevent use of Dr. Lin's '008 patent claims for purposes of double-patenting against Dr. Lin's '349 patent because the applications giving rise to Dr. Lin's '349 patent did not expressly state that the claims in those applications were being filed as a result of the restriction requirement in Dr. Lin's '298 application:

> In addition, Applicant made no mention in the continuation '381 application that he was filing the claims which issued as the '349 in response to the restriction requirement in the '298 application, let alone that he was filing each of the claims as a result of that restriction.

Sofocleous ¶ 456.

156. As an initial matter, Dr. Lin's '381 application, which issued as Dr. Lin's '698 patent, is irrelevant to determining whether § 121 protection applies to the '349 patent. But

even assuming that Mr. Sofocleous intended to refer to Dr. Lin's '179 or '369 applications, which led to Dr. Lin's '349 patent, I disagree with any suggestion that an applicant must recite the words "in response to the restriction requirement" or "as a result of the restriction requirement," or any other such phrase, in order to gain the protections of § 121. Mr. Sofocleous does not cite any legal support for this proposition. Nor am I aware of any such legal requirement. Rather, as explained above, the § 121 requirement that the application be filed "as a result of a restriction requirement" is satisfied if the first application giving rise to the patent-in-suit filed after the restriction requirement contained claims drawn only to the non-elected invention or inventions (and not to the invention elected in response to the restriction requirement for examination in the parent application).

157. Having reviewed the file history for Dr. Lin's '349 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 '349 patent were filed after the Examiners' July 1986 restriction requirement in the '298 application and contained claims drawn to the non-elected invention or 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 '349 patent satisfy the "filed as a result of" requirement for § 121 protection even though they are not technically labeled as divisional applications.

158. Elsewhere in his report, Mr. Sofocleous opines that claim 7 of the '349 patent "broke consonance with the July 1986 restriction requirement that required all process claims to be prosecuted together in restriction Group II," 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 '349 patent." Sofocleous ¶ 457. This opinion is flawed because it relies on the premise that there was a requirement that all process claims be prosecuted together in restriction Group II. As Dr. Lodish explains, the focal point of Group II was not "process claims" *per se*, but rather the DNA. Lodish ¶ 524.

159. I have carefully reviewed the July 3, 1986 Office Action in which Examiners Wiseman and Giesser issued a restriction requirement for the claims in Dr. Lin's '298 application. Nowhere in the restriction requirement do the Examiners state that "all process claims [must] be prosecuted together in restriction Group II." Rather, as quoted above, the Examiners described Group II as "Claims 14, 15, 17-36, 58 and 61-72, drawn to DNA, classified in Class 536, subclass 27."

160. The Examiners' description of Group II in terms of the claims assigned to Group II reflects the principle that the line of demarcation is drawn around a restriction group based on the subject matter of the claims assigned to that group, rather than any label that the Examiner may use to refer to the group. The language of the claims in Dr. Lin's '298 application that the Examiners assigned to Group II is set forth in ¶ 148, above.

161. Having reviewed each of the claims in Dr. Lin's '298 application that the Examiners assigned to Group II, and Dr. Lodish's analysis of them, I note that these claims included both process and non-process claims. In fact, only 4 of the 35 claims assigned to Group II were process claims. Therefore, I disagree with Mr. Sofocleous's suggestion that the focal point of Group II is "process claims."

162. As Dr. Lodish explained in his expert report, 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 process claims (as opposed to non-process claims), it is my opinion that the mere fact that '349 claim 7 is a process claim is irrelevant to determining whether that claim is consonant with the Examiners' restriction requirement. For this same reason, the fact that '349 claim 7 appears to Mr. Sofocleous (a non-technical expert) to be "very similar" to other process claims that were filed (and later cancelled) in Dr. Lin's '381 application (Sofocleous ¶ 454) also is irrelevant to determining whether '349 claim 7 is consonant with the Examiners' restriction requirement.

163. Elsewhere in his report, Mr. Sofocleous asserts that "Claim 7 of the '349 application recites a 'process for producing a polypeptide' similar to the restricted Group II claims 69-72 of the '298 application [which] recite 'a process for the production of a polypeptide ... comprising ... host cells.'" Sofocleous ¶ 453. There are a number of problems with this argument. First, Mr. Sofocleous mischaracterizes the text of '349 claim 7. As is plain from the text of the claim, which is set forth in ¶ 154, above, '349 claim 7 does not recite the words "process for producing a polypeptide." Nor do any of the other claims of Dr. Lin's '349 patent,

Second, for the reasons described above, it is irrelevant to the consonance determination that '349 claim 7 and claims 69-72 of Dr. Lin's '298 application are all process claims. Finally, because all limitations in a claim are relevant to defining the scope of the claim, it also is irrelevant to the consonance determination that, by using ellipses to omit the bulk of the claim language (including some of the very limitations which differentiate these claims), Mr. Sofocleous can create the misimpression that '349 claim 7 is substantively similar to claims 69-72 of Dr. Lin's '298 application.

164. Dr. Lodish examined the substance of Dr. Lin's '349 claims from a technical perspective and concluded that "[n]one of the claims of the '349 patent 'cross the line of demarcation' drawn around restriction Group II, 'drawn to DNA.'" Lodish ¶ 545. Dr. Lodish explained why his opinion was not inconsistent with the fact that some of Dr. Lin's '349 claims recite the term "DNA":

> Although '349 claims 1-3 recite "DNA encoding human erythropoietin" they do not cross the line of demarcation drawn around the EPO DNA inventions of restriction Group II because the '349 claims do require that the EPO DNA in the vertebrate cells be isolated or purified at any time. Rather, the DNA encoding human EPO in these vertebrate cells merely needs to be transcriptionally controlled by "non-human DNA sequences." This interpretation is confirmed by the Federal Circuit's holding that '349 claims 1-7 are infringed by a process using "gene activated" EPO DNA, wherein the EPO DNA was never purified or isolated. *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 457 F.3d 1293, 1317 (Fed. Cir. 2006).

Lodish ¶ 547. For the reasons explained in Dr. Lodish's expert report, it is my opinion that none of the claims of Dr. Lin's '349 patent cross the line of demarcation drawn around the Group II invention elected by Amgen's counsel following the Examiners' 1986 restriction requirement.

165. Equally important, Dr. Lodish examined the substance of Dr. Lin's '349 claims as compared to that of the original claims in Dr. Lin's '298 application and concluded that

all the '349 claims, including claim 7, fall within the scope of Group IV, one of the restriction groups not elected for examination in the earlier '298 application. Lodish ¶¶ 544-547. As Dr. Lodish explained in his report:

> The cell claims of Dr. Lin's '349 patent are very similar to the Dr. Lin's original cell claims that were assigned to restriction Group IV in the '298 application. Both sets of claims cover the same types of cells (vertebrate cells), and require the same EPO production capabilities. The difference between the '349 cell claims and the original cell claims assigned to restriction Group IV is that original cell claims (numbered 42-46) did not include any structural limitation regarding the contents of the cells. . . . Therefore, it is clear that the '349 claims fall within the scope of restriction Group IV and do not fall within the scope of restriction Group II.

Lodish ¶ 547. The language of the claims in Dr. Lin's '298 application that the Examiners assigned to Group IV is set forth in ¶ 148, above.

166. Mr. Sofocleous appears to suggest that because '349 claim 7 is a process claim and not a product claim, it is not consonant with the original Group IV claims in Dr. Lin's '298 application. Sofocleous ¶ 455. Having reviewed each of the claims in Dr. Lin's '298 application that the Examiners assigned to Groups I-VI, I note that other restriction groups, such as Group III, also contained product claims. For this reason, I do not agree that the focal point of the Group IV claims is "product claims" (as opposed to process claims).

167. Moreover, Dr. Lodish has explained that the focal point of the Group IV claims is cells:

> The common feature of claims 42-46 is that each claim requires a vertebrate cell that produces the large quantities of erythropoietin polypeptide required for the practical use of the protein. Moreover, the cells in Group IV are distinct from the cells in Group II because the Group IV cells do not require that they be transfected or transformed with exogenous EPO DNA. Therefore, based on the subject matter of the claims assigned to Group IV, it is my opinion that the focal point of Group IV was the recited cells.

Lodish ¶ 529. Thus, for the reasons explained in Dr. Lodish's expert report, it is my opinion that all the claims of Dr. Lin's '349 patent, including '349 claim 7, are consonant with the claims in Dr. Lin's '298 application that the Examiners assigned to restriction Group IV, and that none of the '349 claims cross the line of demarcation drawn around the Group II invention elected by Amgen's counsel following the Examiners' 1986 restriction requirement.

168. For the reasons discussed above, it is my opinion that safe harbor provisions of 35 U.S.C. § 121 apply to Dr. Lin's '349 patent, and that Dr. Lin's '008 patent claims cannot be used for double-patenting purposes to invalidate Dr. Lin's '349 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 '349 Patent Claims Are Patentably Distinct from Dr. Lin's '008 Patent Claims

169. In his report, Mr. Sofocleous concludes that "the '349 patent has not been terminally disclaimed over the '008 patent, thereby improperly extending patent protection approximately 10 ½ years beyond the expiration of the '008 patent." Sofocleous ¶ 458. Mr. Sofocleous also includes in Exhibit C of his report two unnumbered demonstratives, both titled "Term of Amgen EPO Patents," which graphically depict his conclusion that Dr. Lin's '349 patent improperly extends the term of patent protection for Dr. Lin's '008 patent. Even if § 121 did not prohibit use of Dr. Lin's '008 claims for double patenting purposes against Dr. Lin's '349 claims (which it does, for the reasons explained above), it is my opinion that Mr. Sofocleous's conclusion in ¶ 458 and related demonstratives is unsupported because it depends on the unstated assumption that the claims of Dr. Lin's '349 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.

170. Moreover, based on the expert report of Dr. Lodish, it is my opinion that, in addition to being unsupported, Mr. Sofocleous's conclusion in ¶ 458 and related demonstratives is wrong. I have been informed that '349 claim 7 is the only claim of Dr. Lin's '349 patent asserted in this case, and the only '349 claim which Roche contends in invalid for double patenting over Dr. Lin's '008 patent claims. As Dr. Lodish explains in detail in his expert report, '349 claim 7 is patentably distinct from the claims of Dr. Lin's '008 patent. Lodish ¶¶ 425-432. One of the distinctions Dr. Lodish discusses in his expert report is that "'349 claim 7 does not require transfected EPO (or EPO analog) DNA, the key element of the '008 claims." Lodish ¶ 429. Other distinctions between the '349 and '008 patent claims also are explained in Dr. Lodish's expert report. Lodish ¶¶ 430-431.

171. 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 '349 patent *are* patentably distinct from the claims in Dr. Lin's '008 patent, the '349 patent claims do not extend the term of patent protection for the '008 patent.

C. DR. LIN'S '933 AND '080 PATENT CLAIMS ARE NOT INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER DR. LIN'S '008 PATENT CLAIMS

1. Examination History of Dr. Lin's '933 and '080 Patents

172. My discussion of the examination histories of Dr. Lin's '933 and '080 patents begins with U.S. Patent Application No. 06/113,178 ("the '178 application"). Dr. Lin's '178 application was filed on October 23, 1987, after the restriction requirement that was entered during examination of Dr. Lin's '298 application. The '178 application was filed under 37

C.F.R. § 1.60, which permitted Amgen's counsel to file the '178 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 claims 1-13, 16, 39-41, 47-49, and 55-57 — which belonged to restriction Groups I and V — for examination in Dr. Lin's '178 application.

173. On February 28, 1994, Amgen's counsel advanced the examination leading to the '933 and '080 patents by filing U.S. Patent Application No. 08/202,874 ("the '874 application"). Dr. Lin's '874 application was filed under 37 C.F.R. § 1.62 and utilized what was known as the "file wrapper continuing" procedure. As a result of filing the '874 application under 37 C.F.R. § 1.62, the prior '178 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 '874 application. Dr. Lin's '178 application provided continuity for the '874 application to permit the '874 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120.

174. On June 6, 1995, Amgen's counsel advanced the examination leading to the '080 patent by filing U.S. Patent Application No. 08/468,556 ("the '556 application"). The '556 application was filed under 37 C.F.R. § 1.60, a provision of the USPTO Rules of Practice which permitted Amgen's counsel to file Dr. Lin's '556 application by submitting a true copy of the prior '874 application, including a copy of the oath or declaration originally filed in Dr. Lin's '874 application. Because Dr. Lin's '556 application was filed under 37 C.F.R. § 1.60 and not under 37 C.F.R. § 1.62, filing of the '556 application did not automatically result in abandonment of the prior '874 application. The '874 and '179 applications provided continuity for Dr. Lin's

'556 application to permit the '556 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120. Claims 69-75 of the '556 application were ultimately allowed by the Examiner on January 6, 1997, and they issued as claims 1-7 of Dr. Lin's '080 patent on April 15, 1997.

175. On June 7, 1995, Amgen's counsel advanced the examination leading to the '933 patent by filing U.S. Patent Application No. 08/487,774 ("the '774 application"). Like the earlier '874 application, Dr. Lin's '774 application utilized the "file wrapper continuation" procedure under 37 C.F.R. § 1.62. As a result, the '874 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 '774 application. The '874 and '178 applications provided continuity for Dr. Lin's '774 application to permit the '774 application to claim the benefit of the filing date of Dr. Lin's '298 application under 35 U.S.C. § 120. Claims 100-113 of the '774 application were ultimately allowed by the Examiner on March 14, 1996, and they issued as claims 1-14 of Dr. Lin's '933 patent on August 20, 1996.

176. Because Dr. Lin's '774 and '556 applications both contained claims drawn to the inventions of Groups I and V of the restriction requirement in the '298 application, Amgen's counsel voluntarily filed a terminal disclaimer to ensure that the end of the term of the '080 patent coincided with the end of the term of the '933 patent. (*See* '080 File History, Tab 5, 12/20/96 Terminal Disclaimer (AM-ITC 00941986)). Examiner Martinell stated in the file history that he was "favorably impressed" by Amgen's voluntary decision to file a terminal disclaimer. (*See* '080 File History, Tab 4, 12/11/96 Interview Summary (AM-ITC 00941982)).

177. I may use the following table in my testimony in light of Dr. Lodish's expert report to explain how claims 1-8 of Dr. Lin's '933 patent relate to the original claims in

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

Representative Original Group I Claims	'933 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. A non-naturally occurring erythropoietin glycoprotein product having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells and having glycosylation which differs from that of human urinary erythropoietin. 2. The non-naturally occurring EPO glycoprotein product according to claim 1 wherein said product has a higher molecular weight than human urinary EPO as measured by SDS-PAGE. 3. A non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin said product possessing the *in vivo* biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells. 4. 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