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

AMGEN'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NO OBVIOUSNESS-TYPE DOUBLE PATENTING

730791_2

TABLE OF CONTENTS

PAGE NO.

TABLE OF AUTHORITIES

PAGE NO.

Cases

Statutes and Rules

Other Authorities

I. INTRODUCTION

Amgen's motion raises three fundamental issues: (1) whether the § 121 safe harbor protects Lin's '933, '349, and '422 claims-in-suit from Roche's ODP attack based on Lin's '008 patent claims; (2) whether the two-way double patenting test applies for purposes of Roche's separate ODP attack based on Lai and Strickland's '016 patent; and (3) whether Lin's claims-in-suit are patentably distinct from '016 claim 10. Roche concedes that all three of these issues are questions of law. Nonetheless, Roche's opposition brief restates the same flawed arguments presented in its expert reports and debunked in Amgen's expert reports.

Recognizing that it cannot avoid summary judgment on the record developed during discovery, Roche has attempted to fill the holes in its case by submitting entirely new and different opinion "evidence" from its experts, Drs. Harlow and Lowe. But these opinions were never previously disclosed in Dr. Harlow's and Dr. Lowe's expert reports or depositions. In fact, Dr. Harlow's new opinions are inconsistent with his deposition testimony. The Court should grant Amgen's motion to strike this untimely expert testimony. (Docket Item ("D.I.") 612.)

Roche also attempts to avoid summary judgment by representing to the Court that Amgen's past statements are inconsistent with its current arguments regarding the '016 patent, and that the Court may therefore resolve these issues as a simple matter of judicial estoppel. Nothing could be further from the truth. As demonstrated in Amgen's prior briefing, many of these purported "admissions" — including the "different manifestations of the same invention" statement that Roche represents is a basis for judicial estoppel — have absolutely nothing to do with the '016 patent. (*See* D.I. 577, at 22-26.)

For the reasons explained below and in Amgen's prior briefing (D.I. 499, 576, 577), the Court should grant Amgen's motion for summary judgment of no obviousness-type double patenting (D.I. 498) and deny Roche's ODP motion based on '016 claim 10 (D.I. 490).

II. ARGUMENT

A. UNDER 35 U.S.C. § 121, LIN'S '933, '349, AND '422 PATENT CLAIMS ARE EXEMPT FROM OBVIOUSNESS-TYPE DOUBLE PATENTING OVER LIN'S '008 PATENT CLAIMS

Section 121 routinely protects patentees against ODP attacks where, as here, the Patent Office has imposed a restriction requirement that forced the applicant to prosecute its inventions in separate applications.[1] In its opening brief, Amgen demonstrated that 35 U.S.C. § 121 immunizes the claims of the '933, '349, and '422 patents from obviousness-type double patenting based on the '008 patent claims.[2] (D.I. 499, at 8-13.) The parties agree that the applicability of § 121 is a question of law, *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1348 n.1 (Fed. Cir. 2004), and that Amgen bears the burden of proof on this issue.[3] *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 2007 U.S. Dist. LEXIS 20190, at *215-16 (D.N.J. Mar. 20, 2007). The parties also agree that § 121 applies if: (1) the later issued patent arises from an application that was filed as a result of a restriction requirement; and (2) the claims in the later

[1] For example, in the case of tissue plasminogen activator ("tPA"), a human protein Roche cites as prior art to Lin's inventions, the Patent Office required Roche's subsidiary, Genentech, to prosecute separate applications for DNA encoding tPA and tPA products produced from cells transformed or transfected with that DNA. The original tPA patent application filed in 1982 claimed DNA encoding human tPA, tPA expression vectors, cells transformed with such vectors, tPA polypeptides, methods of treatment and pharmaceutical compositions. In April 1985, the PTO issued a restriction requirement requiring Genentech to elect between two groups of claims: "polypeptides, pharmaceutical compositions, and uses thereof" (Group I) or "DNA, cloning and expression vectors, transformed hosts, and protein production" (Group II). (7/9/07 Fishman Decl., Ex. A, at 2.) Genentech elected Group II, and prosecuted these claims to issuance in the '075 patent, which issued in 1988 and expired in 2005. (*Id.*, Ex. B.)

In February 1987, almost two years after the restriction requirement, Genentech began filing a series of divisional and continuation applications. Over the next 14 years, these applications gave rise to 11 more patents. Several of these later patents claim the tPA product inventions of non-elected Group I. For example, the '486 patent, which issued 10 years after the '075 patent, claims: "Human tissue plasminogen activator as produced by recombinant expression of DNA encoding said tissue plasminogen activator in transformed Chinese Hamster Ovary (CHO) cells." (*Id.*, Ex. C, at 30:13-16.) Although the '486 specification is nearly identical to the '075 specification, no terminal disclaimer over the '075 patent was required because the '486 patent does not claim any of the Group II inventions claimed in the '075 patent. The '486 patent expires in 2015 — 10 years after the '075 patent.

[2] Roche's assertion that "Amgen does not dispute that its earlier filed and now expired '008 patent claims render the asserted claims of the '349, '933, and '422 claims obvious," (D.I. 568, at 1), is baseless. Amgen's decision not to seek summary judgment on that issue in light of the applicability of § 121 does not waive its longstanding position that the claims-in-suit are patentably distinct from the '008 claims.

[3] Roche characterizes Amgen's burden as a "heavy" one. (D.I. 568, at 2.) Amgen's burden is to prove by a preponderance of the evidence that § 121 applies. That burden must not be confused with Roche's far heavier burden of proving, by clear and convincing evidence, that the claims-in-suit are invalid for ODP.

patent are consonant with that restriction requirement. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 687-88 (Fed. Cir. 1990). Roche failed to rebut Amgen's proof on both of these elements.

1. The '178 and '179 Applications That Gave Rise to the '933, '349, and '422 Patents Were Filed As a Result of the PTO's 1986 Restriction Requirement

As shown in Amgen's opening brief, the '933, '349, and '422 patents all satisfy the "filed as a result of a restriction requirement" element for § 121 protection. The first applications filed after the 1986 restriction requirement (the '178 and '179 applications) that give rise to these patents contain claims drawn only to the non-elected inventions, and contain no claims drawn to the Group II inventions elected for examination in the parent '298 application and prosecuted to issuance in the '008 patent. (D.I. 499, at 10-12.)

Roche concedes, as it must, that the '178 and '179 applications "eventually matured into all of the patents-in-suit." (D.I. 568, at 4.)[4] In its Rule 56.1 response, Roche also admits that the '178 and '179 applications as filed contained claims only to the non-elected groups of the 1986 restriction requirement, and did not contain any claims belonging to Group II. (*Compare* D.I. 500, ¶¶ 4-5 *with* D.I. 573, ¶¶ 4-5.) While Roche argues that the '933, '349, and '422 patents were not filed as a result of the 1986 restriction requirement, Roche's arguments have no merit.

First, contrary to its earlier admissions, Roche contends that the '178 and '179 applications as filed contained ***all*** of the original claims from the '298 application, including the Group II claims. (D.I. 568, at 4, 13.) This is unequivocally false. As explained in Amgen's opening brief and ignored in Roche's opposition brief, the '178 and '179 applications were filed under 37 C.F.R. § 1.60 (also referred to as "Rule 60"). This is stated on the cover form of each application. (D.I. 501, Ex. I, at AM-ITC 00941076; Ex. J, at AM-ITC 00454000.) Section 1.60

[4] *See generally* D.I. 501, Ex. A (providing a visual overview of the prosecution history of Dr. Lin's patents).

and the associated PTO procedures permitted Amgen to file the '178 and '179 applications by submitting a copy of the prior '298 application (as originally filed), and then canceling certain of the original '298 claims so that only subsets of those claims were included in the '178 and '179 applications as filed. MPEP § 201.06(a) (D.I. 501, Ex. P-1).[5] The cover forms for the '178 and '179 applications show that Amgen cancelled a number of claims, including all Group II claims. (D.I. 501, Ex. I, at AM-ITC 00941077; Ex. J, at AM-ITC 00454001.)

The cancellation of these claims is corroborated in the filing fee section of the '178 and '179 applications. At the time, the filing fee for § 1.60 applications was calculated based on the number of claims in the new application (*i.e.*, the non-canceled claims), and not on the number of claims originally filed in the parent application. MPEP § 201.06(a) (D.I. 501, Ex. P-1). The filing fee calculation in the '178 and '179 applications makes clear that the canceled claims were not part of the '178 and '179 applications as filed. (*See* D.I. 501, Ex. I, at AM-ITC 00941076 (fee based on 29 [sic 23] claims; Ex. J, at AM-ITC 00454000 (fee based on 1 claim)) Thus, the '178 and '179 applications themselves — the only evidence Roche cites — disprove Roche's assertion that the '178 and '179 applications as filed contained ***all*** of the original '298 claims.[6] Because the '178 and '179 applications did not begin "a new proceeding in which all of the original claims . . . were once again presented for examination," Roche's citation to *Bristol-Myers* is inapposite. (*See* D.I. 568, at 11 (quoting *Bristol-Myers*, 361 F.3d at 1348))

Second, Roche argues that the '933, '349, and '422 patents were not "filed as a result of" the 1986 restriction requirement because 35 U.S.C. § 121 only applies to divisional applications.

[5] MPEP § 201.06(a) provides: "Although a copy of all original claims in the prior application must appear in the 37 CFR 1.60 application, some of the claims may be cancelled by request in the 37 CFR 1.60 application in order to reduce the filing fee, however, one original claim must remain at the time of granting the filing date . . . ."

[6] While Roche opted not to include the claim cancellation and fee calculation sections of the '178 and '179 applications in its exhibits (*See* D.I. 572, Exs. W, X), even the first pages of Roche's incomplete exhibits show that the '178 and '179 applications as filed did not contain all 60 claims from the '298 application. *See id.* (listing "total claims" of 23 and 1 in the "as filed" rows for the '178 and '179 applications, respectively).

(D.I. 568, at 10-11.) This argument is a red herring because Roche does not dispute that the '178 and '179 applications are both "divisional" applications under the PTO's definition, even though they are not formally designated as such. (*See* D.I. 499, at 11 (applying MPEP § 201.6).) Roche itself characterized these applications as "divisional applications" in its summary judgment memorandum: "After the 1983 filing for the now-expired '008 Lin patent (and after issuance of the '016 patent [in May 1987]), Amgen pursued 'a progeny of ***divisional applications***, continuation applications, and patents that rivals the Habsburg legacy." (D.I. 491 at 7, emphasis added.) Moreover, Roche's argument is based on general statutory interpretation principles from cases concerning statutes other than 35 U.S.C. § 121 and ignores Amgen's cited cases regarding § 121 that demonstrate that § 121 applies even to applications that are not formally designated as divisional applications. (*See* D.I. 499, at 10 n.9)

Third, Roche suggests in its brief that the '933, '349, and '422 patents were not "filed as a result of" the 1986 restriction requirement because these patents issued from applications that were continued from the '178 and '179 applications and filed several years after the 1986 restriction requirement. (D.I. 568, at 11.) Roche fails to provide any case law support for this attorney argument and for good reason.

As Amgen noted in its opening brief, the Federal Circuit has applied § 121 to patents that issued from continuations of earlier applications filed as a result of a restriction requirement. (*See* D.I. 499, at 11 n.10.) For example, in *Symbol Techs. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991), the Federal Circuit affirmed § 121 protection for a patent that issued from an application that was a continuation of an earlier application filed as a result of the restriction requirement. *Id.* at 1579-80. The filing date information for the patents in *Symbol* indicates that this continuation application was filed approximately three years after the restriction requirement. Similarly, in *Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 98

F.3d 1563 (Fed. Cir. 1996), the Federal Circuit affirmed § 121 protection for a patent that issued from an application that was one in a series of continuations of an earlier application filed as a result of the restriction requirement. *Id.* at 1567-69. The Court even noted that "the history of these patents shows several refilings, amendments, and continuations-in-part . . . ." *Id.* at 1567. The filing date information for the patents in *Applied Materials* indicates that the continuation application from which the challenged patent issued was filed approximately ten years after the restriction requirement. Thus, Roche's contention that the '933, '349, and '422 patents must be stripped of § 121 protection because they issued from continuations of the '178 and '179 applications is wrong as a matter of law.

2. The '933, '349, and '422 Patent Claims Are Consonant with the PTO's 1986 Restriction Requirement

As shown in Amgen's opening brief, the '933, '349, and '422 patents also satisfy the "consonance" requirement for § 121 protection. None of the claims cross the line of demarcation drawn around the Group II inventions elected in response to the 1986 restriction requirement and prosecuted to issuance in the '008 patent. (*See* D.I. 499 at 12-13 and D.I. 502 Ex. C (depicting all claims in each restriction group)). Roche does not dispute that the 1986 restriction requirement is "documented by the PTO in enough clarity and detail" to assess consonance. *Geneva Pharms., Inc. v. GlaxoSmithKline, PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003). Roche, however, contends that the '933, '349, and '422 claims broke consonance with Amgen's election to prosecute Group II claims in the application culminating in the '008 patent.

First, Roche argues that the '933 patent breaks consonance by having claims from both Group I and Group V. (D.I. 568, at 2, 8-9, 13; D.I. 573, ¶ 6.) Roche does not and cannot cite any legal authority to support this argument, however, because consonance is not violated if a patent contains claims from multiple, ***non-elected*** restriction groups. Consonance is maintained so long as the claims are drawn to the non-elected inventions, and "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); *see also 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). This makes sense because a patent, such as the '933 patent, that contains claims drawn only to the non-elected inventions, and not to the inventions elected for examination in the earlier patent, does not extend the term of patent protection for the previously elected inventions. Consistent with this principle, the Examiners raised no objection to the inclusion of claims from both Groups I and V in the '178, '874, and '774 applications leading to Lin's '933 patent. Because the '933 claims do not transgress the line demarcating Group II claims, they are entitled to the protection of Section 121.

Based on the Examiner's statement that "the [Group I] product as claimed ***may*** be made by a materially different [process than the Group II process], ***such as isolation from a naturally occurring source***," (D.I. 501, Ex. H-8, at 2) (emphasis added), Roche also contends that Group I claims require polypeptides isolated from a naturally occurring source. Because the '933 claims encompass "non-naturally occurring" polypeptides, Roche contends they are not consonant with the 1986 restriction requirement. (D.I. 568, at 7-8, 2, 12.) Roche's argument is demonstrably false.

As an initial matter, Roche's argument distorts the Examiner's statement, which characterized "isolation from a naturally occurring source" as one of many possible ***examples*** by which the polypeptides of Group I could be obtained, not a requirement of every Group I claim. More importantly, Roche's argument ignores the set of claims identified by the Examiner as characterizing the inventions of Group I. For example, original claim 1, which was assigned to restriction 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***.[7]

The Federal Circuit has held that consonance must be assessed based on the actual restriction groupings imposed by the Examiner (*i.e.*, the substance of the claims in each restriction group), and not on the Examiner's written description thereof. *Texas Instruments Inc. v. ITC*, 988 F.2d 1165, 1179 (Fed. Cir. 1993); *see also Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 1994 U.S. Dist. LEXIS 7810, at *28-34 (N.D. Cal. Apr. 26, 1994) ("[T]he line of demarcation and its attendant consonance requirement are controlled by the actual claim groupings made by the Examiner, [not] by the Examiner's subsequent explanatory comments."), *aff'd*, 98 F.3d 1563 (Fed. Cir. 1996). Here, some of the claims assigned to restriction Group I by the Examiner encompassed products isolated from a naturally occurring source and some did not. Roche's argument that the '933 claims must encompass polypeptides isolated from a naturally occurring source to maintain consonance is inconsistent with the actual restriction groupings imposed by the Examiner.[8]

Next, Roche argues that the '349 patent breaks consonance because '349 claim 7 is a process claim and, under Roche's flawed theory, that characteristic alone brings it within the scope of Group II.[9] (*See* D.I. 568, at 2, 4-6, 12.) But there was no requirement that all process claims be prosecuted together in restriction Group II. The claims assigned to Group II by the Examiner require a DNA sequence encoding human EPO, cells transformed or transfected with a

---

[7] D.I. 501, Ex. H-1 (emphasis added). Original claim 59 in Group I was also limited to polypeptides made from non-natural sources. *See id.*

[8] Contrary to the impression Roche attempts to create in its brief (*see* D.I. 568, at 8), at no time has Amgen represented to the PTO that the '933 claims fall within the scope of restriction Group II.

[9] Roche does not dispute that claims 1-6 of the '349 patent fall within the scope of Group IV, and not Group II, of the 1986 restriction requirement. (*Compare* D.I. 500, ¶ 7 *with* D.I. 573, ¶ 7.)

DNA sequence encoding human EPO, or processes of producing EPO using cells that have been transformed or transfected with such a DNA. (D.I. 502, ¶ 21.) By way of contrast, none of the Group IV claims, and none of the '349 claims, requires cells transformed or transfected with a DNA sequence encoding human EPO. (*Id.*, ¶¶ 23, 30.) That only 4 of the 35 claims assigned to Group II were process claims (*see id.*, Ex. C.), further demonstrates that "process claims" is not a defining characteristic of Group II.

In response to Amgen's evidence that the '349 claims, including claim 7, fall outside the scope of restriction Group II (D.I. 502, ¶¶ 29-30), Roche offers only an untimely declaration from Dr. Lowe, who offers opinions never previously disclosed regarding the 1986 restriction requirement and consonance. Amgen has filed a motion to strike these untimely opinions. (D.I. 612.) But even if Dr. Lowe's opinions had been disclosed during discovery, they would be insufficient to avoid summary judgment because Dr. Lowe applied the wrong legal framework in his consonance analysis. The consonance of an issued claim is properly determined by comparing the claim to the original restriction groupings (*i.e.*, the original claims assigned to each restriction group by the PTO). *Texas Instruments*, 988 F.2d at 1179. Instead of comparing '349 claim 7 to the original claims in the 1986 restriction requirement, however, Dr. Lowe assessed consonance by comparing '349 claim 7 with claim 4 of the '698 patent, which issued in 1997.[10] (D.I. 571, ¶¶ 20-21.) Roche repeated this error in its brief. (D.I. 568, at 5-6, 12.)

It is not surprising that Roche avoids any comparison of '349 claim 7 to the original claims in the 1986 restriction requirement, because '349 claim 7 is significantly different from the original Group II claims. Unlike the Group II claims, all of which require either a DNA sequence encoding EPO or cells transformed or transfected with a DNA sequence encoding EPO, the original Group IV claims and '349 Claim 7 impose no such requirement. Instead, the

Group IV claims require vertebrate cells that, when propagated *in vitro*, are capable of producing recited levels of erythropoietin. There is no requirement that the cells encompassed within Group IV be transformed or transfected with a DNA encoding EPO. The Group IV invention resides in the use of vertebrate cells capable of producing certain recited levels of EPO, however made, not in the insertion of a DNA sequence encoding EPO. Just like the original Group IV claims, the '349 patent claims vertebrate cells capable upon growth in culture of producing certain levels of EPO over time. Nothing in '349 claim 7 (or any other '349 claim) requires cells that are transformed or transfected with a DNA encoding EPO. (*See* D.I. 502, Ex. C.) *Cf. Symbol Techs.*, 935 F.2d at 1580 (rejecting defendant's argument that consonance was destroyed by the addition of "apparatus" claims where the corresponding restriction group contained "method" claims and was described as a "method" in the restriction requirement).

Because of the significant difference between the original Group IV claims and the original Group II claims, Roche's assertion that the 1986 restriction requirement "specifically separated these vertebrate cell claims (Group IV) from the process of using ***these*** [*i.e.*, the Group IV] cells to make erythropoietin (Group II)" is plainly incorrect. (D.I. 568, at 5 (emphasis added).) Similarly, Roche's statement that '349 claim 7 and the Group II process claims both claim "the same subject matter of the process of producing recombinant human erythropoietin by growing vertebrate cells and using non-human promoters" is also false. (*Id.* at 2.)

Finally, Roche argues that the '422 patent breaks consonance because it issued with claims from multiple restriction groups of a later ***1992*** restriction requirement in the '741 application. (D.I. 568, at 2, 9-10, 13.) This is nothing more than a red herring.

Notably, Roche does not contend, nor can it, that any '422 claim breaks consonance with

[10] Moreover, Amgen has never conceded that '698 claim 4 belongs to restriction Group II.

the 1986 restriction requirement.[11] Because the issue is whether § 121 prevents the use of Lin's ***'008 patent claims*** for double-patenting purposes against his '422 claims, the relevant restriction requirement is the one that first forced Amgen to prosecute the '422 patent claims in a separate application from the claims that were prosecuted to issuance in the '008 patent. *Cf. Geneva*, 349 F.3d at 1378 ("Thus, if the [later] patents and the [earlier] patent trace their lineage back to a common parent which was subject to a restriction requirement, then § 121 intervenes to prevent a non-statutory double patenting rejection.") Whether Lin's '422 claims broke consonance with a subsequent restriction requirement in a different application is simply irrelevant to the relief Amgen seeks in this motion.[12]

Roche relies on *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343 (Fed. Cir. 2004) ("*BMS*") for its theory that the 1992 restriction requirement governs the consonance analysis for the '422 patent. (D.I. 568, at 13 n.8.) But the facts of that case are materially different. The district court in *BMS* had mistakenly held that § 121 applied because the claims of the attacked patent were consonant with a restriction requirement imposed during prosecution of an ***abandoned*** patent application from which no patent ever issued (the '989 application). The Federal Circuit vacated this holding because another restriction requirement had been imposed during prosecution of the patent asserted as the ODP reference (the '955 application/'707 patent), and that subsequent restriction requirement was different from, and inconsistent with, the earlier restriction requirement. *Id.* at 1349.[13] Here, because the '008 patent is asserted as the ODP reference, the 1986 restriction requirement in the '008 prosecution is the appropriate requirement

[11] It is undisputed that all of the '422 patent claims fall within the scope of Group V, and not Group II, of the 1986 restriction requirement. (*Compare* D.I. 500, ¶ 8 *with* D.I. 573, ¶ 8.)

[12] Notably, the two claims that allegedly broke consonance by issuing in the same '422 patent are necessarily subject to the same expiration date and therefore cannot extend the life of Lin's patent protection vis-à-vis one another.

[13] The Federal Circuit did not reach the question of whether the attacked patent was consonant with this second restriction requirement.

for the Court's ODP analysis.

For the reasons discussed above and in Amgen's opening brief (*see* D.I. 499, at 8-12), the Court should hold as a matter of law that the safe harbor provision of 35 U.S.C. § 121 applies to Dr. Lin's '933, '349, and '422 patents, and that the claims of those patents are exempt from obviousness-type double patenting over the claims of Lin's '008 patent.

B. NONE OF LIN'S CLAIMS-IN-SUIT IS INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER THE LAI/STRICKLAND '016 PATENT CLAIMS

In its opening brief, Amgen demonstrated that each of the claims-in-suit is patentably distinct from the claims of the '016 patent. (D.I. 499, at 13-20.) Amgen also provided a more detailed explanation of these issues in its opposition to Roche's motion for summary judgment of ODP based on '016 claim 10. (D.I. 576.) Roche does not dispute that the claims-in-suit are patentably distinct over claims 1-9 and 11 of the '016 patent. Roche only contends that the claims-in-suit are invalid for ODP over '016 claim 10. (D.I. 568, at 17-20.)

The parties agree that obviousness-type double patenting is an issue of law for the Court. *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992). It is also beyond dispute that Roche bears the heavy burden of proving obviousness-type double patenting by clear and convincing evidence. *Symbol*, 935 F.2d at 1580; *see also* D.I. 576, at 10.

1. The Two-Way Double Patenting Test Applies for Purposes of Obviousness-Type Double Patenting Based On the '016 Claims

Roche failed to develop an ODP defense under the two-way double patenting test. Thus, Roche went to great lengths to disparage the two-way test. Roche called it a "disfavored" test, and a "rare exception," and even tried to imply that it is not good law for applications filed after the Patent Law Amendments Act of 1984. (D.I. 568, at 14 and n.9; D.I. 491, at 13, 16-17.) But the Federal Circuit's opinion in *Berg* (a case involving applications filed after 1984) makes clear that the two-way test still applies in certain circumstances. *In re Berg*, 140 F.3d 1428, 1432-37

(Fed. Cir. 1998). Thus, Roche's disparagement does not eliminate the need for a proper legal analysis.

The parties agree that the determination of whether a two-way or one-way ODP test applies is a question of law. *Berg*, 140 F.3d at 1432. As stated in Amgen's opening brief, the two-way test must be used if: (1) the applicant could not have filed both claims together in the earlier-filed application;[14] and (2) the applicant did not cause the later-filed claim to issue first by delaying examination of the earlier-filed claim during the period when both applications were pending before the PTO (the "co-pendency period").[15]

Regarding the first requirement, it is beyond genuine dispute that Lin's '298 application from which all of the patents-in-suit claim priority is the "earlier-filed application" as compared to the '119 application from which the '016 patent claims priority. Lin's '298 application was filed on November 30, 1984, whereas the '119 application was filed on June 20, 1985. (D.I. 501, Exs. C-G, L.) Roche admitted in its Rule 56.1 statement that "the applications that matured into the patents-in-suit are considered the earlier filed applications compared to the '016 patent filed on June 20, 1985." (D.I. 492, ¶ 42.)[16] It is also beyond genuine dispute that the '016 patent claims could not have been filed as part of the earlier-filed '298 application on November 30, 1984, because the inventions claimed in the '016 patent were not conceived as of that date. (*Compare* D.I. 500, ¶ 11 *with* D.I. 573, ¶ 11.) Thus, there is no genuine dispute that the first requirement for application of the two-way test is satisfied.

---

[14] *See, e.g.*, *Berg*, 140 F.3d at 1434-37; MPEP § 804(II)(B)(1)(a) (D.I. 495, Ex. O, at 14).

[15] *See, e.g.*, *In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997); *Engineered Prods. Co. v. Donaldson Co.*, 225 F. Supp. 2d 1069, 1111 (N.D. Iowa 2002), *vacated in part on other grounds*, 147 Fed. Appx. 979 (Fed. Cir. 2005).

[16] In is opposition brief, Roche tries to confuse the issue by referring to the '298 application as "the '008 patent application," and arguing that the '016 patent application (filed in 1985) is the earlier-filed application because it predates the '178 and '179 applications (filed in 1987). (D.I. 568, at 15.) This interpretation is preposterous. All of the patents-in-suit claim priority to the '298 application (and earlier applications), and the fact that the '298 application issued as the '008 patent does not deprive the patents-in-suit of the benefit of the priority date of that application. *See* 35 U.S.C. §§ 121, 120.

Roche contends that the correct inquiry is whether the claims-in-suit and '016 claim 10 could have been filed together "in the earlier-filed or later-filed application." (D.I. 568, at 15 (emphasis in original).) But this overly-broad statement of the test is contrary to the very authorities Roche cites in its brief. For example, MPEP § 804 states the requirement as follows: "that applicant could not have filed the conflicting claims in a single ***(i.e., the earlier filed)*** application." MPEP § 804 (D.I. 495, Ex. O, at 14) (emphasis added). This is consistent with the Federal Circuit's opinion in *Berg*, where the Court stated that the first requirement for application of the two-way test is satisfied if "an applicant could not have filed both sets of claims in one application — for example, ***because the second application claimed an invention that was not adequately disclosed in the first application*** . . . ." *Berg*, 140 F.3d at 1437 (emphasis added); *see also id.* at 1434 n.5.

In re Emert does not hold otherwise. The appeal in *Emert* concerned the second two-way test requirement — *i.e.*, whether applicant caused the later-filed claim to issue first by delaying examination of the earlier-filed claim during the co-pendency period. *See Emert*, 140 F.3d at 1460 ("Specifically, Emert faults the Board's finding that his delays slowed prosecution of his application and caused the '624 patent to issue ahead of the '887 application."). The Federal Circuit's holding that the one-way test applied was clearly based on Emert's failure to satisfy this second two-way test requirement. *Id*. at 1461 ("Because Emert orchestrated the rate of prosecution for the two applications, this court applies a one-way analysis."). Moreover, the dicta cited by Roche is consistent with *Berg* and MPEP § 804 because the two applications in *Emert* were so similar that the claims in the later-filed application could have been filed as part of the earlier-filed application. *See, e.g., id.* at 1462 ("The Board treated the chemical mixtures B and B[1] as if they were equivalent or identical. Indeed, Emert . . . effectively conced[es] that the differences between B and B[1] are not material and would have been obvious to a person

having ordinary skill in the art."). Thus, there is absolutely no legal basis for Roche's assertion that the one-way test must be used if the '016 claims and Dr. Lin's claims could have been filed together in a subsequent application filed ***after*** Lin's earlier-filed '298 application.

Regarding the second requirement for application of the two-way test, Roche concedes that the relevant inquiry is whether Amgen caused the '016 patent to issue before the patents-in-suit by delaying examination of Dr. Lin's '298 application during the co-pendency period. (*See, e.g.*, D.I. 568, at 14, 16-17; D.I. 491, at 17, 19; D.I. 492, ¶¶ 42, 51.) Roche also admits that Amgen accelerated prosecution of the '298 application during the co-pendency period. (D.I. 568, at 16.) Nonetheless, Roche argues that Amgen caused the later-filed '016 patent to issue first by failing to file the '178 and '179 applications immediately after the 1986 restriction requirement. (D.I. 568, at 16-17.) Roche's suggestion that the patents-in-suit would have issued before the '016 patent if the '178 and '179 applications had been filed after the July 1986 restriction requirement and before the May 1987 issuance of the '016 patent (instead of in October 1987) is implausible and contrary to the evidence. The fact that Dr. Lin's '008 patent, which issued directly from the pending '298 application, did not issue until 5 months ***after*** the '016 patent,[17] demonstrates that even if the '178 and '179 applications had been filed shortly after July 1986, they would not have issued before May 1987. Moreover, once the '178 and '179 applications were filed, their examination was delayed by ***3-4 years*** due to interference proceedings**.** (*See* D.I. 501, Ex. A.) Thus, it is beyond genuine dispute that Amgen did not ***cause*** the '016 patent to issue before the patents-in-suit by delaying examination of Dr. Lin's

[17] Roche's assertion that Amgen "feigned interest in the process claims" and "completely stalled prosecution of [the non-DNA] claims during the pendency of the '016 patent," is ridiculous. (D.I. 568, at 16.) As is evident from the file history, Amgen tried desperately to secure issuance of its process claims in the '008 patent, but was forced to cancel those claims because of the PTO's improper *In re Durden* rejection. (*See* D.I. 577, at 43.) As a result, even after issuance of the '008 patent, Amgen was left with no protection against foreign manufacturers who might have sought to import a recombinant erythropoietin product for commercial sale. *See Amgen v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1538 (Fed. Cir. 1990).

'298 application during the co-pendency period. For all of these reasons, the Court should hold as a matter of law that the two-way ODP test applies.

2. Roche Failed To Timely Offer Any Evidence That the Claims-In-Suit Are Invalid for Obviousness-Type Double Patenting Over the '016 Patent Claims Under the Two-Way Test

Nowhere in its pleadings, answers to interrogatories, or admissions does Roche contend that the claims-in-suit are invalid for ODP over '016 claim 10 under the two-way test. Nor do any of Roche's expert reports assert ODP under the two-way test. The only Roche expert who addressed Roche's '016 ODP allegations, Dr. Harlow, admitted during deposition that he had no opinion regarding ODP under the two-way test. (D.I. 579, Ex. C, at 97:11-24.) Therefore, the Court should grant summary judgment that the claims-in-suit are not invalid for ODP over the claims of the '016 patent.

In a desperate attempt to avoid summary judgment, Roche belatedly filed a declaration from Dr. Harlow who, contrary to his sworn testimony only nine days earlier, now states an opinion that '016 claim 10 would have been obvious in light of the claims-in-suit. This is the only evidence that Roche cites in support of its new position of ODP under the two-way test. (D.I. 568, at 20.) Amgen has filed a motion to strike this untimely "evidence." (D.I. 612.) In any event, Dr. Harlow's new opinion would be inadequate to preclude summary judgment because Dr. Harlow did not perform the separate claim-by-claim analyses required to demonstrate that '016 claim 10 would have been obvious in light of each of the claims-in-suit.

3. Roche's One-Way Double Patenting Argument Based on '016 Claim 10 Is Legally Flawed Because It Confuses That Which Is Named In '016 Claim 10 for That Which Is Claimed, and Seeks To Use the Teachings of Dr. Lin's Patents — Which Are Not Prior Art — To Render Obvious Dr. Lin's Claims

As explained in Amgen's opening brief and in its opposition to Roche's summary judgment motion (D.I. 576), Roche's one-way test argument that the claims-in-suit would have

been obvious over claim 10 of the '016 patent in 1983 is legally unsound because it confuses the reference to "recombinant erythropoietin" in '016 claim 10 for what is actually claimed, and seeks to use the teachings of Dr. Lin's own patent specification as prior art.

These legal errors are manifest throughout Roche's briefing. For example, Roche and its experts repeatedly suggest that "recombinant erythropoietin" is claimed in '016 claim 10.[18] This is wrong as a matter of law. (*See* D.I. 576, at 16-20.) ODP analysis is not concerned with "what one skilled in the art would be aware from reading the claims but with what inventions the claims define." *In re Sarett*, 327 F.2d 1005, 1013 (C.C.P.A. 1964). Contrary to the suggestions in Roche's briefing, during the term of the '016 patent, one could make, use, sell, offer for sale, and import into the United States "recombinant erythropoietin" without infringing '016 claim 10. Roche improperly focuses on what the disclosures of the '016 specification, including the words in '016 claim 10, purportedly would have taught one of ordinary skill in the art, rather than the legally relevant question of what is claimed by '016 claim 10. (*See*, *e.g.*, D.I. 568, at 13.) Even the title of Roche's summary judgment motion demonstrates Roche's improper focus on the disclosure of the '016 patent: "Defendants' Motion for Summary Judgment That the Claims of the Patents-In-Suit Are Invalid for Double Patenting Over Amgen's '016 ***Patent***."

Roche cannot escape the simple truth that a method of purifying recombinant EPO cannot be modified to produce recombinant EPO any more than a method of washing a car can be modified to make a car. Roche and its experts try to obfuscate the significance of the car wash analogy by suggesting that the '016 claim 10 process is like a special method for washing a particular make and model of car, and that this car cannot be driven if it is dirty. (D.I. 568, at 19 n.11; D.I. 569, ¶ 6.) This entirely avoids the point. Whether rEPO is a dirty or a clean car, a

[18] *See*, *e.g.*, D.I. 568, at 17 ("the rEPO claimed in '016 claim 10"); D.I. 492, ¶ 6 ("rEPO, such as claimed in claim 10 of the '016 patent"); *id.* at ¶ 12 (same); D.I. 491, at 3 ("Amgen's right to exclude others from selling rEPO terminate[d] with the expiration of the '016 patent"); *see also id.* at 1, 4-5, 9; D.I. 494, ¶ 85; D.I. 569, ¶ 7.

Beetle or a Hummer, Roche does not and cannot genuinely dispute that a claim to a method for washing a car does not teach one how to build the car. To make rEPO in 1983-84, the ordinarily skilled artisan would have needed the blueprints provided in Dr. Lin's patent application. However, Lin's blueprints were not publicly available at the time. (*See* D.I. 576, at 19-20.)

Roche urges the Court, as a matter of claim construction, to read all of the limitations of Dr. Lin's 16 different asserted claims into the words "recombinant erythropoietin" in '016 claim 10. (D.I. 568, at 18.) But the '016 patent specification does not operate to define the claim term "recombinant erythropoietin" in '016 claim 10 as having all the characteristics and uses claimed in Lin's patents. There is no lexicography. Moreover, it is undisputed that Lin's specification and his disclosure of the EPO DNA sequence were not publicly available to persons of ordinary skill in the art as of 1983-84. (*See* D.I. 576, at 19-20.) Without the benefit of Dr. Lin's patent applications, the ordinarily skilled artisan could not have made "recombinant erythropoietin,"[19] let alone the inventions claimed by Lin.

Roche attempts to circumvent the prohibition against the use of a patent's disclosure as prior art in an ODP analysis, by citing *Amgen/TKT* for the proposition that even unclaimed subject matter in a prior art patent is presumed enabling. (D.I. 491, at 4 n.4; D.I. 568, at 17.) But *Amgen/TKT* was not an ODP case, and no court has ever held that unclaimed (or claimed) disclosure may be presumed enabled in an ODP analysis. Extension of the *Amgen/TKT* enablement presumption into the ODP context would be contrary to numerous Federal Circuit ODP cases that have held that "the disclosure of a patent cited in support of a double patenting

[19] Roche's cite to *Geneva* is entirely inapposite. That case considered whether a claim to a compound having a single use rendered obvious a later method claim to that use. *Geneva*, 349 F.3d at 1385. Here, Roche asks the Court to hold that a claim to a process of purifying recombinant EPO rendered obvious the recombinant EPO starting material at a time when that recombinant EPO starting material was not known to the ordinarily skilled artisan. The *Perricone* case is not pertinent either. There, the independent claims at issue were both method claims and shared a species-genus relationship. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1373-74 (Fed. Cir. 2005). Here, '016 claim 10 and the claims-in-suit are not related as species and genus. *Research Corp. Techs., Inc. v. Gensia Labs., Inc.*, 10 Fed. Appx. 856 (Fed. Cir. 2001), is an ***unpublished*** opinion. It is neither controlling nor persuasive.

rejection cannot be used as though it were prior art, even where the disclosure is found in the claims." *Gen. Foods*, 972 F.2d at 1281. Unlike the Sugimoto patent in *TKT*, which was asserted as ***§ 102(a) prior art***, the '016 patent and Lin's application incorporated therein are not prior art to Lin's claims-in-suit. Moreover, the policy underlying the *Amgen/TKT* presumption — to avoid the need for courts "to conduct a mini-trial on the proper claim construction of a prior art patent every time an allegedly anticipating patent is challenged for lack of enablement," *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 n.21 (Fed. Cir. 2003) — is entirely inapplicable in the ODP context. "Double patenting is altogether a matter of what is claimed," *Gen. Foods*, 972 F.2d at 1277, and construction of both claims at issue generally is the first step in an ODP analysis. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

Enablement and ODP are different legal issues that must not be conflated. In assessing whether a patent claim satisfies the enablement requirement of 35 U.S.C. § 112, it is entirely appropriate, and indeed necessary, to consult the disclosures of the patent specification. But in an ODP analysis, it is improper to do so, except for the limited purpose of construing the claims at issue. *Gen. Foods*, 972 F.2d at 1281.

Elsewhere in its brief, Roche urges the Court to decide the ODP issue as a matter of judicial estoppel. (D.I. 568, at 19.) Roche would have the Court believe that Amgen and its experts have admitted that the claims-in-suit are patentably indistinct from the '016 claims. (*Id.*) Nothing could be further from the truth. As Amgen demonstrated in its response to Roche's Rule 56.1 statement, most of the statements Roche depicts as "admissions" have absolutely nothing to do with the '016 patent and, when read in context, many have the exact opposite meaning as that which Roche ascribes to them. (*See* D.I. 577, at 8-11, 21-37.) For example, the "different manifestations" statement that Roche mischaracterizes in its brief was made in the context of a priority argument during an interference proceeding, and had nothing whatsoever to

do with the '016 patent or the purification process of '016 claim 10. (*See id.* at 22-27.)

Finally, Roche suggests that there must be double patenting because the public cannot practice the '016 claim 10 process without infringing Dr. Lin's asserted claims. This argument is symptomatic of Roche's failure to distinguish between that which is merely named in '016 claim 10 and that which is claimed. The ODP doctrine prevents a patentee from ***claiming*** the same invention (or an obvious variation thereof) in multiple patents without a terminal disclaimer. It does not prevent the subsequent patenting of an invention that is merely referenced in an earlier-issued patent, even when that reference is found in the earlier claim itself. Because "recombinant erythropoietin" is not ***claimed*** in '016 claim 10, this case presents nothing more than "the not unusual situation in which, when a patent expires, something disclosed in it happens to be covered by the claims of another patent in common ownership." *Sarett*, 327 F.2d at 1011.

III. CONCLUSION

Because no genuine issue of material of fact exists, the Court should grant Amgen's motion for summary judgment of no obviousness-type double patenting (D.I. 498) and deny Roche's ODP motion based on '016 claim 10 (D.I. 490).

Dated: July 9, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Patricia R. Rich
D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
Christopher S. Kroon (BBO# 660286)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4204
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (*pro hac vice*)
DAY CASEBEER, MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede, III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants.

/s/ Patricia R. Rich
Patricia R. Rich