UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM IN SUPPORT OF AMGEN INC.'S MOTION FOR SUMMARY JUDGMENT OF NO OBVIOUSNESS-TYPE DOUBLE PATENTING

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I. INTRODUCTION

Roche contends that every one of Amgen's claims-in-suit is invalid for obviousness-type double patenting ("ODP"). According to Roche, Dr. Lin's claims-in-suit would have been obvious over claims in Dr. Lin's first-issued '008 patent, and also over claims in a separate Amgen purification patent, the Lai/Strickland '016 patent. Amgen moves for summary judgment on these Roche defenses because Amgen's product claims (the '933 and '422 patents) and cell claims (the '349 patent) are statutorily protected under 35 U.S.C. § 121 from ODP based on Dr. Lin's '008 claims. In addition, Roche fails to apply the correct legal and evidentiary test for ODP involving the Lai/Strickland '016 claims.

ODP is a judge-made doctrine designed "to prevent an inventor from effectively extending the term of exclusivity by the subsequent patenting of variations that are not patentably distinct from the first-patented invention." *Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996). The party asserting the affirmative defense of ODP must prove by clear and convincing evidence that the two claims at issue are not patentably distinct. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580-81 (Fed. Cir. 1991). Unlike the obviousness analysis of 35 U.S.C. § 103, ODP analysis involves a comparison of two ***claims***, and it is impermissible to treat the patent specification underlying one claim as prior art against the other claim. *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1281 (Fed. Cir. 1992); *In re Longi*, 759 F.2d 887, 892 n.4 (Fed. Cir. 1985). ODP is a question of law. *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

To protect patentees from obviousness-type double patenting attacks, Congress enacted a safe harbor provision in 35 U.S.C. § 121 that applies where a restriction requirement imposed by the Patent Office during prosecution required an applicant to prosecute in two or more separate applications claims that were originally filed in one application. *See Applied Materials*, 98 F.3d

at 1568-69. The applicability of § 121 is a question of law. *Id.* at 1567.

Here, the claims of Dr. Lin's '933, '349, and '422 patents are exempt from ODP over Dr. Lin's '008 patent claims because the Patent Office required Dr. Lin to prosecute those claimed inventions separately from his '008 claims. As shown in Exhibit A,[1] Dr. Lin's '933, '349, '422 and '008 patents all descend from a common ancestor — Dr. Lin's '298 application. During prosecution, the Patent Office determined that the '298 application included claims to multiple, patentably distinct inventions, and required Dr. Lin to prosecute only one of these inventions in the '298 application, and to prosecute his remaining inventions in separate applications. Amgen complied. It restricted the claims prosecuted in Dr. Lin's '298 application to one invention (Lin's DNA claims), which ultimately issued as the '008 patent. It filed separate applications for the remaining inventions and prosecuted the claims to Dr. Lin's product and cell inventions in separate applications that ultimately issued as the '933 and '422 patents[2] and the '349 patent, respectively. Consequently, pursuant to the terms of 35 USC § 121, the product and cell claims of Dr. Lin's '933, '422 and '349 patents cannot be challenged for ODP over the '008 claims. It is simply false to suggest, as Roche does, that Amgen has enjoyed any protection for Dr. Lin's '008 claimed inventions longer than the law allows.[3]

As to the Lai/Strickland '016 patent, the PTO reviewed the very same ODP question that Roche raises now and concluded that Dr. Lin's product and process claims were patentably distinct from the '016 claims. The '016 patent application was filed ***after*** Dr. Lin's patents-in-

[1] All referenced exhibits are attached to the accompanying declaration of Mario Moore.

[2] Amgen disclaimed the term of Dr. Lin's '422 patent to the extent it would have extended beyond the expiration of his '933 patent.

[3] Dr. Lin's '868 and '698 patent claims also are patentably distinct from the '008 patent claims. During prosecution of the '868 and '698 patents, Amgen overcame an explicit rejection for ODP over the '008 claims. However, Amgen is not moving for summary judgment on this issue at this time.

suit and claims a specific process for the purification of EPO. The '016 inventions invoke ***use*** of Dr. Lin's earlier inventions, and disclose an improved process to purify EPO. Lai and Strickland's '016 inventions are therefore entirely different than Dr. Lin's pioneering inventions involving erythropoietin. Although '016 claim 10 requires the use of recombinant EPO as a starting material in the claimed purification process, it does not recite or describe any method for making the EPO starting material. Simply reciting recombinant EPO does not teach or otherwise render Dr. Lin's claims obvious.

As the PTO acknowledged during prosecution, in situations such as this, where a claim to a follow-on invention (Lai/Strickland) is asserted as an ODP reference against an earlier-filed (but later-issued) claim to the fundamental invention (Lin), a "two-way" double patenting test applies, and there is no ODP unless ***both*** the claim of the later-issued patent (Lin) would have been obvious over the claim of the earlier-issued patent (Lai/Strickland) ***and vice versa***. *See generally Berg*, 140 F.3d at 1432-37. Roche has failed to come forward with any evidence, let alone clear and convincing evidence that would be required for a reasonable jury to find ODP under the two-way test.

Even under the one-way test, which Roche erroneously contends should apply to its '016 ODP allegations, there is no genuine issue of material fact precluding summary judgment in Amgen's favor. The only "evidence" that Dr. Lin's claims would have been obvious over '016 claim 10 is the opinion of Roche's expert, Dr. Harlow. But Dr. Harlow impermissibly goes beyond the subject matter ***claimed*** in '016 claim 10 (a process for purifying recombinant EPO) and erroneously relies on the underlying and unclaimed disclosure — including the earlier teachings of Dr. Lin's own patent applications (which teach the production of recombinant EPO) — as if it were prior art against Dr. Lin's claims-in-suit. Since it is forbidden to look beyond the claim itself and to use the teachings and disclosures of the patent specification as if it were prior

art, Dr. Harlow's opinions are simply irrelevant. Thus, under both the "two-way" and "one-way" double patenting tests, it is beyond genuine dispute that Dr. Lin's asserted claims are not invalid for ODP over the Lai/Strickland '016 claims.

II. STATEMENT OF FACTS[4]

A. PROSECUTION HISTORY OF DR. LIN'S PATENTS-IN-SUIT AND THE '008 PATENT

As shown in Exhibit A, each of Dr. Lin's patents-in-suit,[5] as well as Dr. Lin's earlier-issued U.S. Patent No. 4,703,008 ("the '008 patent") (Ex. B), claims priority from a series of four applications filed with the U.S. Patent and Trademark Office ("PTO") in 1983 and 1984. The last and most comprehensive of Dr. Lin's initial applications, No. 06/675,298 ("the '298 application") (Ex. H-1), was filed on November 30, 1984.

Amgen made repeated efforts to accelerate examination of the '298 application so that Dr. Lin could obtain a patent on his inventions as soon as possible. On April 24, 1986, Amgen filed a "Petition to Make Special," requesting that the Patent Office examine the '298 application ahead of other, earlier-filed applications. (Ex. H-5) The Patent Office granted this petition. (Ex. H-7) Amgen responded to the PTO's office actions within a shortened, three-month response period — in one instance submitting a lengthy response in less than five weeks. (Exs. H-12, H-15) In each response, Amgen requested "early notice" of allowance for the claims in Dr. Lin's '298 application. (Exs. H-6 at 7, H-12 at 39, H-15 at 28) Amgen also requested that the '298 application "be suitably 'tagged' upon allowance of the claims to allow for priority in printing." (Ex. H-15, at 28) Notwithstanding these efforts by Amgen, it took almost 3 years for a patent to

[4] The undisputed facts justifying granting this motion are set forth in Amgen Inc.'s Rule 56.1 Statement of Undisputed Material Facts Regarding No Obviousness-Type Double Patenting.

[5] The patents-in-suit are U.S. Patent Nos. 5,547,933 ("the '933 patent") (Ex. C), 5,756,349 ("the '349 patent") (Ex. D), 5,955,422 ("the '422 patent") (Ex. E), 5,441,868 ("the '868 patent") (Ex. F), and 5,618,698 ("the '698 patent") (Ex. G).

issue from Dr. Lin's '298 application.

On July 3, 1986, after an initial assessment of Dr. Lin's '298 application, the PTO determined that the '298 application included claims to six different categories or "groups" of patentably distinct inventions. For the convenience of the PTO and its examination, the examiner imposed a "restriction requirement" that required Amgen to select one of the six invention groups for examination in the '298 application, and to file separate applications for examination of the remaining, "non-elected" inventions:

> "Restriction to one of the following inventions is required under 35 U.S.C. 121:
>
> I. Claims 1-13, 16, 39-41, 47-54 and 59, drawn to polypeptide, classified in Class 260, subclass 112.
>
> II. Claims 14, 15, 17-36, 58 and 61-72, drawn to DNA, classified in Class 536, subclass 27.
>
> III. Claims 37-38, drawn to plasmid, classified in Class 435, subclass 240.
>
> IV. Claims 42-46, drawn to cells, classified in Class 435, subclass 240.
>
> V. Claims 55-57, drawn to pharmaceutical composition, classified in Class 435, subclass 177.
>
> VI. Claim 60, drawn to assay, classified in Class 435, subclass 6."[6]

Amgen complied with the PTO's restriction requirement by selecting claims to the DNA inventions in Group II for continued examination in the '298 application, and prosecuting claims to the other, non-elected inventions in separate applications. (Ex. H-8, at 3) On October 27, 1987, Dr. Lin's '298 application issued as the '008 patent. (Ex. B) Consistent with Amgen's election to have Group II claims examined in the '298 application, all of the '008 patent claims

[6] Ex. H-8. The language of the claims assigned to each of these restriction groups is set forth in Exhibit H-1, at 97-105 and Exhibit H-6, at 2-4. Although DNA and process claims were both assigned to restriction Group II, during subsequent prosecution of the process claims in the '868 and '698 patents, Amgen overcame an explicit rejection for ODP based on the DNA claims in the '008 patent. Thus, the process claims are patentably distinct from the DNA claims.

fall within the scope of restriction Group II.[7]

Shortly before issuance of the '008 patent, on October 23, 1987, Amgen filed two new applications — Nos. 07/113,178 ("the '178 application") (Ex. I) and 07/113,179 ("the '179 application") (Ex. J) — that contained claims to non-elected inventions that the PTO had required be examined separately from the '298 application. The '178 application as filed contained original claims 1-13, 16, 39-41, 47-49, and 55-57, which the PTO had assigned to restriction Groups I and V. (*See* Exs. I; H-8, at 2) The '179 application as filed contained original claim 1, which the PTO had assigned to restriction Group I. (*See* Exs. J; H-8, at 2)

As shown in Exhibit A, the '178 and '179 applications were the first applications giving rise to the patents-in-suit filed after the PTO's 1986 restriction requirement, and all of Dr. Lin's patents-in-suit arise from one of these two applications. For example, the '933 patent arises from the '178 application, and the '422 and '349 patents arise from the '179 application.

During prosecution of the '178, '179, and subsequent applications leading to the patents-in-suit, Amgen canceled claims, amended claims, and added new claims. As a result, the issued claims in the patents-in-suit are not identical to the original claims filed in the '178 and '179 applications. But consistent with the claims originally filed in the '178 and '179 applications, all claims of the '933, '349, and '422 patents fall within the scope of the non-elected restriction groups, and none of these claims fall within the scope of restriction Group II, which was prosecuted to issuance in the '008 patent. (Lodish Decl. ¶¶ 26-34)

B. PROSECUTION HISTORY OF THE LAI/STRICKLAND '016 PATENT

On June 20, 1985, approximately six months after Dr. Lin's '298 application, two other Amgen researchers, Drs. Lai and Strickland, filed U.S. Patent Application No. 06/747,119 ("the

[7] *See* Declaration of Harvey F. Lodish, Ph.D. in Support of Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting ("Lodish Decl.") ¶ 25.

'119 application") (Ex. K) for their inventions relating to a specific method of purifying EPO. The '119 application was much shorter than Dr. Lin's '298 application, contained far fewer claims, and focused narrowly on protein purification, which was a relatively mature and developed field. Only 23 months after filing, on May 19, 1987, the '119 application issued as U.S. Patent No. 4,667,016 ("the '016 patent") (Ex. L).

The inventions claimed in the '016 patent build on the teachings in Dr. Lin's earlier-filed '298 application. The Lai/Strickland '016 inventions had not been conceived or reduced to practice as of the November 30, 1984 filing date of Dr. Lin's '298 application and consequently could not have been filed as part of that application.[8] The specification of the '016 patent expressly references the earlier teachings in Dr. Lin's '298 application as a means to obtain recombinant EPO for use in the '016 EPO purification process. (Ex. L, at 2:64-3:6 and 4:34-38) Even so, the '016 patent issued approximately five months before Dr. Lin's first patent, the '008 patent.

The PTO has determined on multiple occasions that the claims of Dr. Lin's patents-in-suit are patentably distinct from the claims of the Lai/Strickland '016 patent. (*See* Exs. M-5, at 2; N-3, at 2) Unlike Dr. Lin's patent claims, the '016 patent claims do not claim a process for ***producing*** recombinant EPO — instead, they claim a process for ***purifying*** recombinant EPO that has already been produced in some manner not specified in the '016 claims. (Ex. L) The suggestion that '016 claim 10 rendered Dr. Lin's EPO claims obvious is akin to placing the cart before the horse. As explained during prosecution of Dr. Lin's patents: "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." (Ex. M-4, at 4)

[8] *See* Declaration of Thomas W. Strickland, Ph.D. in Support of Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting ("Strickland Decl.") ¶¶ 11-16.

III. ARGUMENT

A. STANDARD FOR SUMMARY JUDGMENT

Summary judgment should be granted where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). If the moving party demonstrates an absence of material fact, the nonmoving party "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 587 (quoting Fed. R. Civ. P. 56(e)).

When deciding a motion for summary judgment, the Court "must view the evidence presented through the prism of the substantive evidentiary burden." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986). As with other affirmative defenses of invalidity, the defendant bears the burden of proving obviousness-type double patenting by clear and convincing evidence, "a heavy and unshifting burden." *Symbol*, 935 F.2d at 1580. Thus, "a patentee is entitled to summary judgment with respect to the patent's validity where a reasonable jury could not find clear and convincing evidence of the patent's invalidity." *Diomed, Inc. v. AngioDynamics, Inc.*, 450 F. Supp. 2d 130, 138 (D. Mass. 2006).

B. AS A MATTER OF LAW, UNDER 35 U.S.C. § 121, THE '933, '349, AND '422 PATENT CLAIMS ARE EXEMPT FROM OBVIOUSNESS-TYPE DOUBLE PATENTING OVER THE '008 PATENT CLAIMS

1. The Section 121 Safe Harbor

Congress enacted a safe harbor provision in 35 U.S.C. § 121 to protect patentees from obviousness-type double patenting attacks involving two claims that could not have issued together in a single patent because of a "restriction requirement" imposed by the Patent Office

during prosecution. *See Applied Materials*, 98 F.3d at 1568-69. Section § 121 states in pertinent part:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. 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. . . .

Section 121 "effects a form of estoppel that shields the [patentee] from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent." *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 361 (Fed. Cir. 1986) (Newman, J., concurring). In so doing, § 121 "assures that the technicalities of restriction practice are not elevated from their purpose of examination convenience to a potential taint on the validity of the ensuing patents." *Applied Materials*, 98 F.3d at 1568.

Section 121 immunizes an issued patent from an obviousness-type double patenting attack if two fundamental requirements are met: (1) the patent arises from an application that was filed as a result of a restriction requirement; and (2) the claims in the patent are consonant with that restriction requirement. *See, e.g., Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 687-88 (Fed. Cir. 1990). Although the heavy burden of proving obviousness-type double patenting remains with the party challenging the validity of the patent at all times (i.e., it never shifts to the patentee), the patentee bears the burden of proving, by a preponderance of the evidence, that the safe harbor provision of § 121 applies. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, No. 04-cv-754, 2007 U.S. Dist. LEXIS 20190, at *215-16 (D.N.J. Mar. 20, 2007).

Whether § 121 applies is a question of law. *Bristol-Myers Squibb Co. v. Pharmachemie*

B.V., 361 F.3d 1343, 1348 n.1 (Fed. Cir. 2004); *Applied Materials*, 98 F.3d at 1567. Thus, the § 121 issue is frequently decided on summary judgment. *See, e.g.*, *Gerber*, 916 F.2d at 685; *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, No. 01-cv-3751, 2002 U.S. Dist. LEXIS 27230 (D.N.J. July 25, 2002); *Union Carbide Corp. v. Dow Chem. Co.*, 619 F. Supp. 1036, 1055-60 (D. Del. 1985).

2. The '933, '349 and '422 Patents Arise from Applications Filed As a Result of the PTO's 1986 Restriction Requirement

There is no genuine issue of material fact that the '933, '349, and '422 patents all satisfy the first requirement for § 121 protection: "filed as a result of a restriction requirement." As applied in the case law, this element is satisfied if the first application giving rise to the patent-in-suit filed after the restriction requirement contains 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). *See, e.g.*, *Gerber*, 916 F.2d at 687-88.[9]

As shown in Exhibit A, each of the '933, '349, and '422 patents arises from one of two applications filed on October 23, 1987 — after the PTO's 1986 restriction requirement in the '298 application and before issuance of the '008 patent. The '933 patent arises from the '178

[9] Several cases have indicated that § 121 applies to applications that are not formally designated as "divisional" applications. *See, e.g.*, *Gerber*, 916 F.2d at 684, 686-89 (applying § 121 to continuation-in-part application and finding lack of consonance); *Studiengesellschaft Kohle*, 784 F.2d at 353, 355-56 (stating in dicta that § 121 would have applied to application, which was a continuation-in-part); *id.* at 357-61 (Newman, J., concurring) (agreeing that § 121 applied to application, which was a continuation-in-part, and arguing that case should be decided on § 121 grounds); *Pfizer*, 2007 U.S. Dist. LEXIS 20190 at *234 n.58 (stating in dicta that "[t]he Federal Circuit has applied § 121 to continuation-in-part applications on several occasions"); *cf. Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994) ("[T]he expressions 'continuation,' 'divisional,' and 'continuation-in-part' are merely terms used for administrative convenience.").

application, and the '349 and '422 patents arise from the '179 application.[10] The '178 and '179 applications are both "divisional" applications under the PTO's definition because they are "later application[s]" (than the '298 application), "carved out of a pending application" (the '298 application), containing claims to "a distinct and independent invention" (Groups I and V, not Group II), and "disclosing and claiming only subject matter disclosed in the earlier or parent application" (as 37 CFR § 1.60 applications, the disclosure and claim language is identical to that in the parent '298 application). *See* MPEP § 201.6 (Exs. P-1 and P-2). The '178 and '179 applications were the first applications giving rise to the patents-in-suit filed after the PTO's 1986 restriction requirement.

Further, the '178 and '179 applications as filed contained claims drawn only to inventions that were not elected for examination in the parent '298 application. They did not initially contain any claims drawn to the Group II invention that was elected in the '298 application and prosecuted to issuance in the '008 patent. The '178 and '179 applications were filed under 37 C.F.R. § 1.60. That provision, 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. *See* MPEP § 201.06(a) (Ex. P-1).[11] In keeping with the 1986 restriction requirement and the election of Group II in the '298

[10] The fact that the '933, '349, and '422 patents issued from applications that were themselves continued from the '178 and '179 applications does not take away § 121 protection. *See, e.g., Symbol*, 935 F.2d at 1579-80 (Section 121 applied to patent that issued from continuation of earlier application filed as a result of the restriction requirement).

[11] The filing fee for applications filed under 37 C.F.R. § 160 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) (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* Ex. I, at AM-ITC 00941076; Ex. J, at AM-ITC 00454000).

application, Amgen canceled all claims belonging to Group II, and selected only claims belonging to the non-elected restriction groups for filing in the '178 and '179 applications. The '178 application as filed contained original claims 1-13, 16, 39-41, 47-49, and 55-57, which the PTO had assigned to restriction Groups I and V. (*See* Exs. I and H-8, at 2) The '179 application as filed contained original claim 1, which the PTO had assigned to restriction Group I. (*See* Exs. J and H-8, at 2) Thus, there is no genuine issue of material fact that the '178 and '179 applications that gave rise to the '933, '349, and '422 patents were filed as a result of the 1986 restriction requirement in the '298 application.

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

There is no genuine issue of material fact that all claims in the '933, '349, and '422 patents satisfy the second requirement for § 121 protection: "consonance." The consonance requirement is satisfied if all claims in the patent fall within the scope of the non-elected restriction groups and "do not cross the line of demarcation drawn around the invention elected in the restriction requirement." *Symbol*, 935 F.2d at 1579. New or amended claims in the patent (i.e., claims not originally present in the application filed as a result of the restriction requirement) also are entitled to the protection of § 121, provided all claims in the patent satisfy the consonance requirement. *Id.* When assessing whether claims are consonant with a restriction requirement, the proper point of reference is the actual restriction groupings (i.e., the substance of the claims in each restriction group), not the examiner's written descriptions thereof. *See Texas Instruments Inc. v. ITC*, 988 F.2d 1165, 1179 (Fed. Cir. 1993).

As explained in detail in Dr. Lodish's accompanying declaration, Dr. Lodish compared the substance of the '933, '349, and '422 patent claims to that of the original claims assigned to each of the 1986 restriction groups, and concluded that all the '933, '349, and '422 claims fall within the scope of the non-elected restriction groups, and that none of these claims cross the line

of demarcation drawn around the Group II invention elected in the '298 application and prosecuted to issuance in the '008 patent. (Lodish Decl. ¶¶ 26-34) Applying the perspective of the ordinarily skilled artisan, Dr. Lodish determined that: '933 claims 1-8 (EPO glycoproteins and glycoprotein products) fall within the scope of Group I, drawn to "polypeptide;" '933 claims 9-14 and '422 claims 1-2 (pharmaceutical compositions and methods of using same) fall within the scope of Group V, drawn to "pharmaceutical composition;" and '349 claims 1-7 (vertebrate cells for producing EPO and processes for using same) fall within the scope of Group IV, drawn to "cells." (*Id.*) Thus, there is affirmative evidence, from a technical expert skilled in the relevant art, demonstrating that all claims in the '933, '349, and '422 patents are consonant with the PTO's 1986 restriction requirement. *Cf. Symbol*, 935 F.2d at 1580 (affirming determination of consonance and § 121 protection based on declaration of technical expert).

For the reasons discussed above and in Dr. Lodish's supporting declaration, 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 in those patents are exempt from an obviousness-type double patenting attack based on the claims of the '008 patent.

C. THERE IN NO GENUINE ISSUE OF MATERIAL FACT THAT THE CLAIMS-IN-SUIT ARE NOT INVALID FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER THE LAI/STRICKLAND '016 PATENT CLAIMS

Roche's ODP arguments based on the Lai/Strickland '016 patent are ripe for resolution on summary judgment because the only evidence Roche has adduced fails to apply the correct legal test and impermissibly relies on the disclosures underlying the '016 claims rather than the claims only. Additionally, Roche applies only the one-way test, whereas the proper test for ODP in these circumstances is the two-way test, precisely as the PTO determined.

1. The One-Way and Two-Way Double Patenting Tests

If a claim is not exempt from a particular allegation of obviousness-type double patenting

under 35 U.S.C. § 121, the next step in the double patenting analysis is to determine whether the claim is "patentably distinct" from the claim being asserted as a double patenting reference.[12] If the two claims are patentably distinct, there is no obviousness-type double patenting violation.

In determining whether or not two claims are patentably distinct, courts (and the PTO) have applied an analysis that parallels the obviousness analysis applied in the context of 35 U.S.C. § 103. *See Longi*, 759 F.2d at 892 n.4; MPEP § 804(II)(B)(1). One important difference, however, is that the double-patenting analysis involves a comparison of two ***claims***, and it is impermissible to treat the patent specification underlying one claim as prior art against the other claim. *See Gen. Foods*, 972 F.2d at 1281; *Longi*, 759 F.2d at 892 n.4; *In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986).

The "one-way" and "two-way" double patenting tests are related legal tests for determining whether two claims are patentably distinct. Under the "one-way" test, ODP exists if a claim in a later-issued patent is "obvious over" a claim in a commonly-owned earlier patent. Under the "two-way" test, ODP exists only if the claim of the later-issued patent is obvious over the claim of the earlier-issued patent ***and vice versa***. *Berg*, 140 F.3d at 1432. The two-way test guards against the possibility that a claim to an improvement or follow-on invention that issues first might be used to invalidate an earlier-filed (but later-issued) claim to the fundamental invention on which the improvement invention builds. In so doing, the two-way test ensures that "an applicant (or applicants), who files applications for basic and improvement patents [is not] penalized by the rate of progress of the applications through the USPTO, a matter over which the applicant does not have complete control." *In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991). Under both the one-way and two-way tests, the defendant must prove obviousness-type double

[12] Section 121 does not shield the claims-in-suit from ODP over the '016 patent claims because these claims were not prosecuted separately as a result of a restriction requirement.

patenting by clear and convincing evidence. *Symbol*, 935 F.2d at 1580. ODP is a question of law. *Berg*, 140 F.3d at 1432.

2. The Two-Way Test Applies for Purposes of Obviousness-Type Double Patenting Over the '016 Patent Claims

The determination of whether the one-way or the two-way test applies also is a question of law. *Berg*, 140 F.3d at 1432. The two-way test must be used if two requirements are met:

1. The applicant could not have filed both claims together in the earlier-filed application;[13] 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").[14]

There is no genuine issue of material fact that the two-way test applies for purposes of Roche's defense that the claims-in-suit are invalid for ODP over the Lai/Strickland '016 claims.

The first two-way test requirement is satisfied because it was impossible — both as a practical matter and as a legal matter under 35 U.S.C. §112 — for Amgen to have filed the '016 claims as part of the earlier-filed applications that gave rise to Dr. Lin's patents-in-suit. Dr.

[13] *See, e.g.*, *Berg*, 140 F.3d at 1434-37; MPEP § 804(II)(B)(1). Although not binding in federal court, the MPEP requirement — "that applicant could not have filed the conflicting claims in a single ***(i.e., the earlier filed)*** application" (emphasis added) — is consistent with the Federal Circuit's opinion in *Berg*, where the Court stated that the first requirement for two-way test eligibility 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.

[14] *See, e.g.*, *Emert*, 124 F.3d at 1461; *Engineered Prods. Co. v. Donaldson Co., Inc.*, 225 F. Supp. 2d 1069, 1111 (N.D. Iowa 2002), *vacated in part on other grounds*, 147 Fed. Appx. 979 (Fed. Cir. 2005). The fundamental purpose of the second requirement for two-way test eligibility is to ensure that the applicant did not cause the second-filed patent to issue first. *See Berg*, 140 F.3d at 1437. Any delay by an applicant ***after*** the co-pendency period (i.e., after the second-filed patent has in fact issued first) is irrelevant because it does not affect the order of issuance of the two patents.

Lin's '298 application was filed on November 30, 1984.[15] (Ex. H-1) As of that date, the subject matter claimed in the '016 patent was not conceived or reduced to practice. (Strickland Decl. ¶¶ 11-16) The application that gave rise to the '016 patent was not filed until June 20, 1985. (Ex. K) Because the inventions claimed in the '016 patent were not conceived as of the November 30, 1984 filing date of Dr. Lin's '298 application, the '016 claimed inventions were not, and could not have been, described or enabled in Dr. Lin's '298 application.[16]

The second two-way test requirement is satisfied also, because Amgen did not cause the later-filed '016 patent to issue before Dr. Lin's patents-in-suit by delaying examination of Dr. Lin's earlier-filed '298 application during the co-pendency period. Dr. Lin's '298 application was filed on November 30, 1984, and the patents-in-suit issued between 1995 and 1999. (*See* Exs. H-1 and C-G) The '119 application which led to the Lai/Strickland '016 patent was filed on June 20, 1985, and the '016 patent issued on May 19, 1987. (Ex. K) Thus, the relevant "co-pendency" period is from June 20, 1985 to May 19, 1987.

During the co-pendency period, Amgen did not request or receive any extensions of time to prosecute Dr. Lin's '298 application, nor did it delay examination of the '298 application in any other manner to cause the '016 patent to issue first. Instead, Amgen made repeated efforts to ***accelerate*** examination of the '298 application.[17] Amgen filed a "Petition to Make Special," which the PTO granted. As a result, the '298 application advanced through the examination process on an accelerated schedule and was examined ahead of other, earlier-filed applications.

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[15] The '298 application was a continuation-in-part of three earlier applications. *See generally, Amgen Inc. v. Chugai Pharm. Co. Ltd.*, 13 U.S.P.Q.2d 1737, 1746-49 (D. Mass. 1989).

[16] *See also* Declaration of Ralph A. Bradshaw, Ph.D. in Support of Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting ("Bradshaw Decl.") ¶¶ 32-34 (explaining how the '016 claims "are directed to a new and non-obvious combination"); Lodish Decl. ¶¶ 59-61 (similar).

[17] *See supra* p.4 (citing relevant exhibits).

Amgen repeatedly requested "early notice" of allowance for the claims pending in the '298 application, and also requested that the '298 application "be suitably 'tagged' upon allowance of the claims to allow for priority in printing." The fact that Amgen did not delay examination of the '298 application during the co-pendency period, combined with the fact that the '008 patent — the very first patent to issue from Dr. Lin's applications — nonetheless issued ***after*** the Lai/Strickland '016 patent, indicates that there was nothing Amgen reasonably could have done to secure issuance of Dr. Lin's claims-in-suit before the '016 patent issued on May 19, 1987.

For the foregoing reasons, the Court should hold, as a matter of law, that the two-way double patenting test applies, and that there can be no ODP violation based on the Lai/Strickland '016 claims unless (1) Dr. Lin's claims-in-suit are obvious over the '016 claims ***and*** (2) the '016 claims are obvious over Dr. Lin's claims-in-suit.

This same issue was considered during examination of the '349, '868, and '698 patents-in-suit, and the PTO determined that the "two-way" test properly governed its analysis, and that Dr. Lin's then-pending claims were patentably distinct from the '016 claims under the two-way test. (*See* Ex. N-3, at 2) Since the PTO previously rejected Roche's ODP argument based on the '016 patent claims, Roche bears an even heavier burden in proving ODP over the '016 patent claims. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 105 (D. Mass. 2001) (Where the asserted grounds for invalidity were reviewed by the PTO, "the challenger has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job.") (internal quotation omitted).

3. Roche Failed To 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

Roche bears the heavy burden of proving obviousness-type double patenting. However, nowhere in its pleadings, answers to interrogatories, or admissions does Roche contend that the

claims-in-suit are invalid for ODP over the '016 patent claims under the two-way test. Nor do any of Roche's dozens of expert reports assert ODP under the two-way test, even though Amgen previously had stated in its interrogatory responses that the two-way test applies. (*See, e.g.*, Amgen's 4/2/07 Response to Roche's Interrog. No. 40 (Ex. O); *see also* Bradshaw Decl. ¶¶ 32-34 (explaining no ODP under two-way test); Lodish Decl. ¶¶ 59-61 (same)) In short, Roche has failed to come forward with any evidence during discovery, let alone the type of clear and convincing evidence that would be required for a reasonable jury to find in Roche's favor.[18] Therefore, the Court should grant summary judgment that the claims-in-suit are not invalid for ODP over the claims of '016 patent. *See, e.g.*, *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. 04-cv-29, 2007 U.S. Dist. LEXIS 36425 at *44-45 (D. Or. May 17, 2007) (granting summary judgment of no ODP because defendant failed "to give the court some evidence--some factual presentation--as to why the differences between claims are not 'patentably distinct,'" and instead "relie[d] solely on argument").

4. Even Under the One-Way Test, There Is No Genuine Issue of Material Fact that the Claims-In-Suit Are Patentably Distinct from the '016 Patent Claims

Even under the one-way test, the Court should grant summary judgment that the claims-in-suit are not invalid for ODP over the claims of the Lai/Strickland '016 patent. The only evidence offered by Roche during discovery regarding ODP based on the '016 claims is the analysis of Dr. Harlow, who contends that the claims-in-suit are obvious over claim 10 of the '016 patent under the one-way test. (Ex. Q, at ¶¶ 56-111) But Dr. Harlow's analysis is legally flawed because it reaches beyond what is ***claimed*** in '016 claim 10 and impermissibly exploits the underlying (and unclaimed) disclosure — including the teachings of Dr. Lin's own patents —

[18] Having failed to present any evidence on the two-way test during discovery, Roche should be barred from offering any such evidence in response to this motion.

as if it were prior art against Dr. Lin's claims-in-suit. The simple mention of "recombinant erythropoietin" in '016 claim 10 does not and could not render obvious Dr. Lin's claims at the time of Dr. Lin's inventions. Under the proper legal analysis, there is no question that the claims-in-suit were not obvious over '016 claim 10. (*See* Lodish Decl. ¶¶ 35-58)

Claim 10 of the Lai/Strickland '016 patent recites a specific, multi-step process "for the efficient recovery of recombinant erythropoietin from a mammalian cell culture supernatant fluid." (Ex. L) Importantly, '016 claim 10 does not claim (or even disclose) a process for ***producing*** recombinant EPO. Instead, it claims a process for ***purifying*** recombinant EPO. In other words, the '016 claim 10 process requires "recombinant erythropoietin" as a starting material, but the claim does not teach or describe how to obtain that "recombinant erythropoietin." (*See* Ex. L) During prosecution of the '933 patent, Amgen explained this key distinction using the following analogy: "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." (Ex. M-4, at 4) Neither method teaches how to make the necessary starting material, whether EPO polypeptide or cars. Rather, both methods presume that someone else has already invented what is needed to practice the method. The PTO agreed with this analysis and withdrew its obviousness-type double patenting rejection over the '016 claims. (Ex. M-5, at 2)

Roche's expert, Dr. Harlow, argues that the claims-in-suit are obvious over '016 claim 10 because one of ordinary skill in the art reading the words "recombinant erythropoietin" in '016 claim 10 would have understood how to obtain the recombinant erythropoietin described in Dr. Lin's '298 application and claimed in the patents-in-suit. (*See, e.g.*, Ex. Q, at ¶¶ 58, 66) But the words "recombinant erythropoietin" in '016 claim 10 merely name a thing. Those words alone would not teach an artisan how to obtain "recombinant erythropoietin," and they certainly do not describe a workable process for producing "recombinant erythropoietin." Nor do the words in

'016 claim 10, by themselves, provide any reasonable expectation of success in obtaining the recited "recombinant erythropoietin." As Dr. Lodish explains, without the teachings of Dr. Lin's patents, the words "recombinant erythropoietin" convey nothing more than a hope or wish, like the words "drug which cures all forms of cancer" and "car that gets 200 miles per gallon." (Lodish Decl. ¶ 49)

Roche's expert contends that the words "recombinant erythropoietin" in '016 claim 10 would have provided all the information required by one of ordinary skill in the art to obtain recombinant EPO for use in the claimed purification method, because the ***specification*** of the Lai/Strickland '016 patent expressly references the earlier teachings in Dr. Lin's '298 application as a means to obtain recombinant EPO. (Ex. Q, at ¶ 58, citing '016 patent at 4:33-39) In effect, Roche seeks to incorporate all of the teachings of Dr. Lin's patents into the words "recombinant erythropoietin" in '016 claim 10. Roche's argument must be rejected, as a matter of law, because it exploits the specification underlying claim 10 of the '016 patent — which in turn relies on the teachings of Dr. Lin's own patents-in-suit — as prior art against Dr. Lin's claims. This form of analysis is expressly forbidden by the Federal Circuit. *Gen. Foods*, 972 F.2d at 1281; *Longi*, 759 F.2d at 892 n.4; *Kaplan*, 789 F.2d at 1580. The disclosure in the '298 application and the patents-in-suit is Dr. Lin's — it is not in the prior art and therefore cannot be used as prior art in the ODP analysis. *Gerber*, 916 F.2d at 687. Thus, even under the one-way test, the Court should grant summary judgment that the claims-in-suit are not invalid for obviousness-type double patenting over the claims of Lai/Strickland '016 patent.

IV. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court grant Amgen's motion for summary judgment of no obviousness-type double patenting.

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Respectfully Submitted,
AMGEN INC.,
By its attorneys,

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSEN
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried
D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO# 542156)
PATRICIA R. RICH (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-9200
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 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

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 on the above date.

/s/ Michael R. Gottfried
Michael R. Gottfried