UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY **ORAL ARGUMENT REQUESTED**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT THE CLAIMS OF PATENTS-IN-SUIT ARE INVALID FOR DOUBLE PATENTING OVER AMGEN '016 PATENT

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I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") move for summary judgment that the claims-in-suit,[1] owned by Plaintiff Amgen Inc. ("Amgen"), are all invalid for obviousness-type double patenting over claim 10 of Amgen's earlier-issued and now-expired U.S. Patent No. 4,667,016 ("the '016 patent"). In support of this motion, Roche relies upon the accompanying Statement of Undisputed Material Facts ("S"), the Declarations of Edward Everett Harlow, Ph.D. ("Harlow Decl.") and Michael Sofocleous ("Sofocleous Decl."), and the exhibits attached to the Declaration of Kimberly J. Seluga ("Seluga Decl.").

II. SUMMARY OF THE ARGUMENT

At the very least, with the expiration of the '016 patent in 2005, Amgen's right to exclude competitors from selling recombinant erythropoietin ("rEPO") has come to an end. Amgen's early 1980s EPO Project resulted in the first expired '008 patent,[2] the now expired '016 patent and the patents-in-suit. The '016 patent's claim 10 renders the claims-in-suit obvious, as the accompanying declarations and exhibits demonstrate, and as Amgen's own admissions during prosecution of the patents-in-suit and in prior litigations also demonstrate. Thus, the doctrine of obviousness-type double patenting precludes Amgen from enforcing the claims-in-suit beyond the now-expired term of the '016 patent.

Briefly stated, the '016 patent claim 10 is directed to the harvesting of purified "recombinant erythropoietin from a mammalian cell culture supernatant fluid." S ¶ 4. That is

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[1] The claims-in-suit include claims 1 and 2 of U.S. Patent No. 5,441,868 ("the '868 patent"), 4-9 of U.S. Patent No. 5,618,698 ("the '698 patent"), 7 of U.S. Patent No. 5,756,349 ("the '349 patent"), 1 of U.S. Patent No. 5,955,422 ("the '422 patent"), and 3, 7, 8, 9, 11, 12 and 14 of U.S. Patent No. 5,547,933 ("the '933 patent"). S ¶ 1.

[2] Amgen's EPO Project also resulted in expired U.S. Patent No. 4,703,008 ("the '008 patent"), which is directed to the DNA-sequence and host cell aspects of its EPO project. S ¶ 3. While the '008 patent also provides a basis for invalidating the claims-in-suit for double patenting, the present brief lays out an entirely separate and independent basis why the claims-in-suit are invalid for obviousness-type double patenting from that of the '008 patent.

the product that is the subject of Amgen's patents-in-suit. Once available in purified form as taught by the '016 patent claim 10, rEPO could be used in a pharmaceutical composition to treat kidney dialysis patients by following conventional methods well known to those of skill in the art. Thus, as the Harlow Declaration and Amgen's own admissions demonstrate, it would have been obvious to one of skill in the art in December 1983 to use the mammalian cell culture to recover recombinant EPO (as claimed in the '016 patent) thereby producing glycosylated, biologically active EPO protein (as claimed in the '868, '698 and '933 patents) at levels exceeding "1000 U" (as claimed in the '349 patent) for use in a pharmaceutical composition (as claimed in the '422 and '933 patents) to treat kidney dialysis patients (as claimed in the '933 patent). Thus, the processes, proteins, compositions and use of rEPO in treatments described in the asserted claims are just a rewording or obvious variation of the process claims of the '016 patent.

The '016 patent gave Amgen a full term of exclusivity, which expired June 20, 2005, 20 years after its filing date. By filing additional applications after the '016 patent issued,[3] Amgen obtained the five patents-in-suit that, on their faces, would last up to 10 more years, until 2015. This Court should hold the claims-in-suit invalid for obviousness-type double patenting to prevent Amgen from obtaining a 10-year extension of patent protection for the subject matter of the expired '016 patent, in violation of the judicially created doctrine and the patent statute.

Obviousness-type double patenting specifically precludes applicants from, in effect, extending the patent term for a single invention by claiming obvious variants in later patents.

[3] Although the patents-in-suit claim priority going back to 1983-1984, Amgen waited until after the issuance of the '016 patent (on May 19, 1987) – sometimes as long as eight years after – to file the applications that issued as the patents-in-suit. The '179 application (which issued as the '868 patent) was filed October 23, 1987, the '197 application (which issued as the '422 patent) was filed August 2, 1993, the '774 application (which issued as the '933 patent) was filed June 7, 1995, and the '556, '369 and '381 applications (which respectively issued as the '080, '349 and '698 patents) were filed June 6, 1995. S ¶¶ 1-2.

Claims that are different from but not patentably distinct from claims in an earlier-issued, commonly owned patent are invalidated, unless a terminal disclaimer is filed to have the later-issued patent(s) expire no later than the earlier-issued patent. In the present case, the doctrine of obviousness-type double patenting requires that Amgen's right to exclude others from selling rEPO terminate with the expiration of the '016 patent.

This present case of obviousness-type double patenting presents no genuine issue of material fact. Under Amgen's claim constructions, the '933 and '422 patent claims encompass rEPO – the very same product that was recovered in the claimed '016 process – and its intended use in a pharmaceutical composition and for treating kidney dialysis patients. Likewise, according to Amgen, the '868, '698 and '349 patent claims encompass the production of rEPO through growth in mammalian host cells – the very same product that was isolated in the claimed '016 process. Amgen and its experts have made many admissions in prior proceedings that disprove any attempt to assert that there is a genuine issue of material fact. For purposes of this motion, the Court can take Amgen's assertions as true and accurate.

III. STATEMENT OF FACTS

A. The Claims-in-Suit Contain At Most Only Obvious Additional Limitations in Light of Claim 10 of the '016 Patent

As is more fully set forth in the accompanying Harlow Declaration and Statement of Undisputed Material Facts (which provide claim charts), the limitations of the claims-in-suit not explicitly taught by claim 10 of the '016 patent all constitute obvious matter, well-known in the art at the time, none of which can provide a patentable distinction. Claim 10 of the '016 patent provides a process for harvesting purified "recombinant erythropoietin from a mammalian cell culture supernatant fluid," in substance, the end product of Amgen's EPO Project, which applied known techniques to clone the gene encoding that protein, i.e., EPO, and then produced rEPO. S

¶¶ 4-5. Claim 10 of the '016 patent puts one in possession of the rEPO,[4] which can then be converted, by conventional and well-known means, into pharmaceutical compositions for treatment of kidney dialysis patients. S ¶¶ 6 and 12-14.

(1) '933 Patent, Claims 3, 7-9, 11-12, 14

The '933 patent, claim 3, calls for EPO that is the product of "expression in a mammalian host cell," and that has "the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells." "Non-naturally occurring erythropoietin glycoprotein" of claim 3 is not patentably distinct from "recombinant erythropoietin" in claim 10 of the '016 patent. Claim 7 of the '933 patent calls for "a non-human mammalian [host] cell," and claim 8 specifies "a CHO cell." As noted above, claim 10 of the '016 patent explicitly requires "a mammalian cell culture," which was well-known to produce recombinant proteins. S ¶¶ 5, 8-12, 27-28, 30 and 35-36. CHO cells were also well-known to those of skill in the art as a preferred mammalian host cell culture for recombinant procedures in which biological activity was sought. S ¶¶ 8, 10, 27-28, 30 and 36. Indeed, Amgen itself has admitted in prior litigation that these additional limitations of the '933 patent, claims 3, 7 and 8, were well-known to those of skill in the art. *See* §IIIB below.

Similarly, the added limitations of the '933 patent, claims 9 and 12, directed to a pharmaceutical composition, were well-known. One of ordinary skill in the art in 1983 would

[4] The reference to "recombinant erythropoietin" in claim 10 need not be enabling on its face to render obvious the claims-in-suit. Claims are not intended to be enabled standing on their own. 35 U.S.C. § 112, ¶¶ 1 and 2. Claims are enabled by their specifications. In this case, the '016 specification explicitly incorporates by reference the entirety of the specification of the patents-in-suit. *See* Seluga Decl., Ex. F, '016 patent, col. 2, ln. 64 to col. 3, ln. 6 (identifying specification of '008 patent, which is identical to specification of all five patents-in-suit). For purposes of this motion the Court may assume that the claims of the Lin Patents are enabled, without Roche so conceding. Indeed, there is **no disclosure whatsoever in 'the 016 patent that its process could even work with <u>inactive</u> rEPO**. The only examples in the '016 patent provide *in vivo* biologically active rEPO. Furthermore, the '016 patent is presumed to be enabling. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 65 U.S.P.Q.2d 1385 (Fed. Cir. 2003). Likewise, it is not necessary for claim 10 to disclose the utility of the rEPO, and the fact that some claims-in-suit do so cannot constitute a patentable distinction. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003).

have understood that claim 10 of the '016 patent purified rEPO was intended for pharmaceutical use, and it would be absolutely routine to combine the rEPO with a diluent, adjuvant or carrier. S ¶¶ 5-6 and 12. Claims 11 and 14 of the '933 patent fare no better in specifying that the EPO be used for treating kidney dialysis patients to increase a patient's hematocrit level, uses of EPO well-known in the art in 1983. S ¶¶ 5-6 and 13. Once one has the purified rEPO of '016 claim 10, such uses are routine, obvious and non-inventive.

(2) '422 Patent, Claim 1

Claim 1 of the '422 patent reads:

> A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.

One of ordinary skill in 1983 would understand that the purified recombinant erythropoietin of the '016 patent was intended for use in a *pharmaceutical composition* and it would have been obvious to use an amount sufficient to be *therapeutically effective*, and that such use would include *a pharmaceutically acceptable diluent, adjuvant or carrier.* Claim 1 of the '422 patent echoes claim 10 of the '016 patent in specifying that *erythropoietin is purified from mammalian cells grown in culture.* Hence claim 1 of the '422 patent would have been obvious over the '016 patent claim 10. S ¶¶ 5-6 and 14.

(3) '698 Patent, Claims 4-9

Under Amgen's construction, process claim 4 of the '698 patent provides no patentable distinction over claim 10 of the '016 patent. The rEPO of claim 10 is "a glycosylated erythropoietin polypeptide" which inherently has as its utility "*in vivo* biological" activity, namely, "increas[ing] production of reticulocytes and red blood cells." The "suitable nutrient conditions" and "vertebrate cells" of claim 4 are inherent in claim 10's mammalian cell culture

of rEPO. The "promoter DNA other than human erythropoietin promoter DNA" of claim 4 was routinely used in recombinant protein synthesis in 1983. Further, "DNA encoding the mature erythropoietin amino acid sequence of FIG. 6" is inherent in claim 10's recombinant erythropoietin. Claim 4's step of "isolating said glycosylated erythropoietin polypeptide expressed by said cells" under Amgen's view corresponds to step 7 of the '016 patent claim 10. Hence, all elements of claim 4 are covered by or obvious from claim 10 of the '016 patent. S ¶ 15.

Claim 5 of the '698 patent adds the limitation of "viral promoter DNA," which was a routine part of the synthesis of recombinant proteins in 1983 and thus an obvious step in light of claim 10 of the '016 patent. S ¶ 16. Claim 6 of the '698 patent is very similar to claim 4, except it adds the limitation of "amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6," and drops reference to promoter DNA. Amplified DNA was routinely used in recombinant protein synthesis in 1983 and would have been a necessary part of the obvious use of claim 10 of the '016 patent process to produce human EPO. S ¶ 17. Claim 7 of the '698 patent adds "amplified marker gene DNA," while the '698 patent claim 8 specifies "Dihydrofolate reductase (DHFR) gene DNA" as the amplified marker. Both were routinely used techniques during synthesis of recombinant proteins in 1983 and thus would have been obvious over claim 10 of the '016 patent. S ¶ 18. Claim 9 of the '698 patent adds the requirement that "mammalian cells" be used, an explicitly covered element of the '016 patent claim 10, and thus would have been obvious over claim 10. S ¶ 19.

Indeed, as discussed below in §IIIB, many of these claim limitations are directed to recombinant DNA techniques that Amgen's expert, Dr. Lodish, has previously said were well-

known and obvious in the field in 1980, several years before Amgen's first EPO-related patent application. S ¶¶ 33-40.

(4) '868 Patent, Claims 1 and 2

The '868 patent claims 1 and 2 are both process claims encompassing the production of rEPO using "mammalian host cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin." Claim 2 specifies CHO host cells. As discussed above, each of the elements in these two claims is either explicitly contained in claim 10 of the '016 patent, or would have been obvious therefrom. It was routine in the art in 1983 when synthesizing recombinant proteins in mammalian cells to transform or transfect the cells with the isolated DNA sequence encoding the desired protein. S ¶ 20.

(5) '349 Patent Claim 7

Claim 7 of the '349 patent recites a process whose elements are either contained in or obvious in light of claim 10 of the '016 patent. To the various limitations discussed above, it adds the requirement that the cells are capable of being propagated *in vitro* and of producing EPO in excess of 100, 500, or 1000 U per 10^6 cells in 48 hours as determined by radioimmunoassay. However, because claim 7 fails to disclose or claim any method for making its rate of production possible, and also appears indefinite, its scope must be limited to what was enabled in the '349 specification, which was incorporated into the '016 patent. If capable of being construed to have a definite scope, claim 7 would have been obvious over claim 10 of the '016 patent. S ¶ 21.

B. Amgen's Admissions Confirm That the Claims-in-Suit are Obvious Over Claim 10 of the '016 Patent

After the 1983 filing for the now-expired '008 Lin patent (and after issuance of the '016 patent), Amgen pursued "a progeny of divisional applications, continuation applications, and

patents that rivals the Hapsburg legacy."[5] Amgen also filed suit the day the '008 Lin patent issued in 1987, and has pursued litigation involving the '008 patent and its "progeny," the patents-in-suit, from that day to this, as part of an aggressive strategy to enforce and extend its patent monopoly for rEPO. During the 16-year prosecution of the patents-in-suit, and in the course of the various related litigations, Amgen has made admissions which confirm that the claims-in-suit are obvious over the '016 patent claim 10. S ¶ 22.

(1) Amgen Admitted That the Patents-in-Suit are Just Different Aspects of the Invention of the EPO Gene Sequence

In order to prevail in interference proceedings[6] with Genetics Institute involving the '178 and '179 applications – from which all of the patents-in-suit claim priority – Amgen argued that the subject matters claimed in the '178 and '179 applications were just different aspects of the same invention as the '008 patent. S ¶ 23. Amgen equated the pending application claims (relating to rEPO, methods of making rEPO, and uses of rEPO) to the claims in the '008 patent (relating to the DNA sequence for EPO):

> While the count [which represents the pending claims] is directed to a process for preparing *in vivo* biologically active EPO using a mammalian host cell …, and the litigation was directed to the purified and isolated DNA sequence and host cells transfected or transformed thereby, it is evident that these are only different manifestations of the same invention …. Clearly, the whole purpose and intent of the purified and isolated DNA sequence encoding human EPO (and host cells transfected therewith) at issue in the litigation was to express *in vivo* biologically active human EPO.

S ¶ 24.

Thus, Amgen argued that, because Lin was the first to invent an isolated DNA sequence encoding EPO, Lin necessarily was the first to invent the process of expressing and isolating rEPO and the first to invent rEPO itself, since these were just different aspects of the same

[5] *Eli Lilly and Co. v. Barr Labs, Inc.*, 251 F.3d 955, 959 (Fed. Cir. 2001).
[6] Interference Nos. 102,097 and 102,334.

invention. All this additional work was obvious and non-inventive once the DNA sequence was isolated, according to Amgen. S ¶ 25.

The Board of Patent Appeals and Interferences (BPAI) agreed and held that the process steps for making glycosylated *in vivo* biologically active EPO after the EPO gene was known "d[id] not require the exercise of inventive skill." S ¶ 26 (Ex. J, *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1739, 1991 WL 332571, at *2 (BPAI 1991) (emphasis added)). The BPAI, in ruling in Amgen's favor, determined that Amgen's opponent had "adduced no evidence suggesting that the work done at Amgen relating to the expression of the EPO gene in mammalian host cells and isolation of the resulting glycoprotein product involved anything other than the exercise of ordinary skill by practitioners in that field" and that Amgen's opponent even acknowledged "that expression of the EPO gene, once isolated, to obtain a recombinant EPO product would not have required more than ordinary skill." S ¶ 27 (Ex, J, 21 U.S.P.Q.2d at 1739 (emphasis added)).

Thus by Amgen's own admission, all the work done at Amgen encompassed in the '178 and '179 applications – beyond isolating the gene sequence of the '008 patent – involved no inventive activity. Claim 10 of the '016 patent process for harvesting the purified "recombinant erythropoietin from a mammalian cell culture supernatant fluid," is the end of the process for producing rEPO, which begins with determining the sequence of the EPO gene. One in possession of rEPO in accordance with claim 10 of the '016 patent requires no inventive activity, and needs only ordinary skill, to arrive at each of the claims-in-suit. S ¶¶ 22-29.

(2) Prosecution Histories Show the Claims-in-Suit are not Patentably Distinct over the '016 Patent Claims

Amgen has listed Lin as the sole inventor of the patents-in-suit, because – Amgen has asserted – Lin alone identified the DNA sequence claimed in the '008 patent; he asked others including individuals not at Amgen, to perform additional non-inventive tasks, such as choosing

host cells, expressing proteins from host cells, isolating rEPO from the host cell material, and preparing pharmaceutical compositions from purified rEPO. Dr. Lin conceded at deposition that the suggestion to use CHO cells was provided by individuals at the ATCC[7]. Lin has repeatedly testified under oath about his lack of contribution for these additional tasks; his biggest contribution was to refer his colleagues to prior-art literature. S ¶¶ 28-29.

Thus, Amgen and sole inventor Lin admit these additional tasks would have been obvious once the gene sequence for EPO was known. Lin provided no instructions. *Id*. The others working with Lin on the Amgen EPO Project relied simply on the identification of the gene sequence by Lin and on techniques and operating conditions known to those of ordinary skill in the art for expressing recombinant proteins in mammalian cells. The differences in claim language between the '016 patent claims and the claims-in-suit relate to truly non-inventive aspects of work done at Amgen.

Other Amgen actions during prosecution are to the same effect. For example, during the prosecution of the '868 patent, the U.S. Patent and Trademark Office (the "PTO") rejected the pending claims as non-enabled and lacking adequate written description under 35 U.S.C. §112. Amgen traversed this rejection in part by arguing that it would have been obvious to the skilled worker, as of the December 13, 1983, filing date to be able to make glycosylated proteins from available host cells. In particular, Amgen argued that "numerous other mammalian cells [in addition to CHO and COS] capable of effecting glycosylation of expressed polypeptides were known to those skilled in the art at the time of the present invention." S ¶ 30 (Ex. L, '179 File History, Paper 33, 1/3/94 Amendment and Response at 5 (emphasis added)). Thus, Amgen

[7] American Type Culture Collection is a global organization that *inter alia*, serves as a repository for biological materials used in the field.

conceded during the prosecution of the '868 patent that choosing and using host cells capable of effecting post translational glycosylation was obvious at the time of the invention. S ¶ 30.

Amgen also admitted during prosecution of the '178 application (from which the '933 patent claims priority) that "both the starting material and final product of the ['016 patent] … are included within (dominated by) the recombinant product claims of the present application." S ¶ 31 (Ex. M, '178 File History, Paper 19, 1/10/90 Amendment at 3 (emphasis added)). Where the subject matter product of claim 10 of the '016 patent process is "included within (dominated by)" the later-issued '933 patent claims-in-suit, those later-issued claims must be obvious over the '016 patent claim 10. S ¶ 32.

During the prosecution of the '179 application – from which the '868, '349, '698 and '422 patents claim priority – the Examiner made an obviousness-type double patenting rejection based on the '016 patent. Only the Examiner's erroneous application of the "two-way test" (at Amgen's urging) rescued the pending claims of the '179 application:

> … And while the instantly claimed method is an obvious variation of the process of Lai et al. it is considered that applicant is not responsible for the delay in the prosecution of the instant application which resulted in the prior patenting of a later filed application to an invention derived from the instant invention. …

S ¶ 50 (Ex. Q, '179 File History, Paper 34, 02/15/94 Office Action at 2 (emphasis added)).

The Examiner was wrong as a matter of law to apply the rarely used "two-way test," as is demonstrated below, §IIIC. Under the properly applied "one-way test," the examiner found, and Amgen did not dispute, that the pending claims of the '179 application, from which the '868, '349, '698 and '422 patents claim priority, were obvious in light of the claims of the '016 patent. S ¶ 51.

(3) Amgen's and its Experts' Admissions in Prior Litigations Show That the Claims-in-Suit are Obvious Over Claim 10 of the '016 Patent

(a) Amgen's CHO Cell Strain was Known and Publicly Available

In *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), the defendant argued that Amgen's failure to deposit or fully disclose the "specific genetically-heterogeneous strain of Chinese hamster ovary (CHO) cells, which produced EPO at a rate greater than that of other cells" rendered the '008 patent invalid under 35 U.S.C. §112 for failing to set forth the best mode—in particular, the best mammalian host cells known to Lin as of November 30, 1984, the date Lin filed his fourth patent application, from which the patents-in-suit claim priority. The Federal Circuit found no violation of the best mode requirement, quoting prior case law that "No problem exists when the microorganisms used are known and readily available to the public." S ¶ 7 (Ex. H, 927 F.2d at 1211, 18 U.S.P.Q.2d at 1025).

Thus, limitations relating to the host cells, including the choice of the "specific genetically-heterogeneous strain of Chinese hamster ovary (CHO) cells, which produced EPO at a rate greater than that of other cells" and limitations relating to the host cell's ability to produce EPO at a greater rate (even if assumed for purposes of this motion that such limitations are definite) cannot be considered patentable distinctions over the "mammalian cell culture" of claim 10 of the '016 patent. S ¶¶ 5, 8-12, 27-28, 30 and 35-36.

(b) Amgen's Expert, Dr. Lodish, Has Admitted in Prior Litigation That Claim Distinctions Similar to Those in This Case Would Have Been Obvious Prior to 1983

In prior litigation (*In re Columbia University Litigation*, No. 09-MD-01592, D. Mass.), Amgen's expert in this case, Dr. Harvey Lodish, provided an expert report challenging the validity of patents owned by Columbia University as obvious in light of an earlier-issued patent

also owned by Columbia University. Like the patents-in-suit, the Columbia University patents related to recombinant DNA engineering. In that report, Dr. Lodish admitted that, as of 1980 (long prior to the 1983 critical date in the present case), many of the techniques used in this field were obvious and well-known. S ¶ 33.

For example, Dr. Lodish admitted that the glycosylation of proteins was obvious and well-known in 1980. S ¶ 34. He also admitted that, as of 1980, each of the following was obvious and well-known: the transformation of mammalian cells with exogenous DNA; the use of CHO cells for producing recombinant proteins; amplification of genes in mammalian cell cultures; the use of dihydroflate reductase (DHFR); and the use of viral promoters. S ¶¶ 35-40. In light of these prior admissions of Dr. Lodish regarding the obviousness of recombinant engineering techniques such as these in 1980, several years before Lin's alleged invention, he cannot now be heard to argue that such techniques provide a patentable distinction.

C. The Facts Preclude the Use of the Disfavored "Two-Way Test"

The rarely-applied "two-way test" can be used only if both (i) the PTO was solely responsible for the delay in the issuance of the second patent, and (ii) the applicant could not have filed the claims of the later-issued patent in the same application as the earlier-issued patent.[8] Neither requirement can be met here; thus the one-way test must be applied. S ¶¶ 41-49.

(1) The USPTO Was Not Solely Responsible for the Delay in the Issuance of the Patents-in-Suit

Amgen delayed filing all of the applications that matured into the patents-in-suit until long after the issuance of the '016 patent, on May 19, 1987 – sometimes as long as 8 years after. Hence, this was not a case where sets of claims were pending and the PTO unilaterally

[8] *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 and n.7 (Fed. Cir. 2001); *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

proceeded to issuance a set of later-filed claims. The '016 patent had already issued before Amgen even filed the applications that resulted in the claims-in-suit. Thus, it cannot be said that the PTO was solely responsible for the delay in the issuance of the patents-in-suit. S ¶ 47.

(2) The Claims-in-Suit Could Have Been Filed Along with the Claims of the '016 Patent

In addition, the stand-alone application that matured into the '016 patent could have been filed instead as a continuation-in-part application off of the '298 application, and could have included all the claims-in-suit as well as the claims of the '016 patent. S ¶¶ 43-46. Alternatively, Amgen could have filed the applications that matured into the patents-in-suit earlier and made them continuations-in-part of the '119 application, and could have abandoned the '119 application in favor of pursuing what became the '016 patent claims in these continuations-in-part. S ¶¶ 45-47.

(3) Amgen's Intent is Irrelevant

Amgen surely anticipated that the approach it took would be rewarded with a timewise extension of its patent rights. But even if the additional years were a windfall, and regardless of any legitimate factors Amgen may assert to show that its motives were "pure," Amgen cannot dispute that its decisions about (i) when and how it filed its applications, (ii) when it sought extensions, (iii) when it responded to office actions, and (iv) when it introduced new claims and limitations were major factors in determining when the patents-in-suit were issued. S ¶¶ 42-51.

IV. ARGUMENT

Summary judgment is appropriate under Fed. R. Civ. P. 56 if "there is no genuine issue as to any material fact ... and the moving party is entitled to judgment as a matter of law."[9]

[9] The nonmoving party "must do more than merely raise doubt as to the existence of a fact" to defeat a summary judgment motion. *Avia Group Int'l. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1560 (Fed. Cir. 1988). Evidence that is merely colorable or not significantly probative will not avoid summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986).

Double patenting is a question of law and is therefore particularly amenable to summary judgment. *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997); *see Engineered Prods. Co. v. Donaldson Co.*, 225 F. Supp. 2d 1069, 1092 (N.D. Iowa 2002). Obviousness determinations – which include those in the context of obviousness-type double patenting – are amenable to summary judgment. *See KSR Int'l Co. v. Teleflex Inc.*, 560 U.S. ____, 127 S.Ct. 1727 (2007) (holding summary judgment of invalidity based on obviousness).

A. Obviousness-Type Double Patenting Prevents Patent Owners From Extending Earlier-Issued Patents with Later-Issued Patents

The judicially created doctrine of obviousness-type double patenting prevents extension of patent rights beyond their terms by barring claims that are different, but not patentably distinct, from claims in an earlier-issued, commonly owned patent. *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). A two-step analysis is employed. First, the court construes the claims in the earlier- and later-issued patents and compares them for any differences. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). Second, the court decides whether there are any differences that rise to the level of a patentable distinction. *Id.* If the later claim is not patentably distinct from the earlier claim, then it is invalid. *Id.* A claim is not patentably distinct from an earlier claim if it is merely an obvious variation of the earlier claim from the point of view of one of ordinary skill in the art. *Application of Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (CCPA 1970). Likewise, a later claim that merely discloses the utility of an earlier claim limitation does not constitute a patentable distinction.[10] Thus, courts have equated the second part of the obviousness-type double patenting analysis to that performed under 35 U.S.C. §103

[10] Here, some of the limitations set forth in the claims-in-suit but not explicitly set forth in claim 10 of the '016 patent are directed to the utility of rEPO. The utility of rEPO included the *in vivo* biological activity of causing bone cells to increase production of reticulocytes and red blood cells, as well as its use as a pharmaceutical composition, use for treating kidney dialysis patients, and use for humans. By simply setting forth the utility of rEPO, the claims-in-suit do not provide any patentable distinction over the rEPO of the '016 patent's claim 10. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed Cir. 2003).

obviousness. *In re Longi*, 759 F.2d at 982 n.4; MPEP § 804. Accordingly, the recent Supreme Court decision in *KSR* is pertinent here.

B. Different Classes of Claims Can Be Found to Be Obvious Over Each Other

As discussed in §§IIIA and B above, to the extent the language of the claims-in-suit differs from claim 10 of the '016 patent, each difference is merely an obvious variation of claim 10. That claims in the later-issued patent are in a different class from the earlier issued claims does not provide a patentable distinction under obviousness-type double patenting. Thus, claims directed to methods of using a composition can be obvious in light of claims directed to the composition (*see, e.g., Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed Cir. 2003); *In re Lonardo* 119 F.3d 960, 43 U.S.P.Q.2d 1262 (Fed. Cir. 1997)); claims directed to a product can be obvious in light of claims directed to producing the product (*see, e.g., In re Freeman*, 166 F.2d 178, 76 U.S.P.Q. 585 (CCPA 1948)); and claims directed to a composition can be obvious in light of claims directed to a method of using the composition (*see, e.g., Research Corp. Techs., Inc. v. Gensia Labs., Inc.* 10 Fed. Appx. 856 (Fed. Cir. 2001)). *See also Phillips Petroleum Co. v. U.S. Steel Corp*, 225 U.S.P.Q. 1149, n.29 (D. Del. 1985). Thus, the various claims-in-suit – even though they may be directed to the rEPO composition or methods of using the rEPO composition – can be obvious in light of the '016 patent claims directed to a method of recovering the rEPO.

C. The One-Way Test Should Apply to Invalidate Each of the Claims-in-Suit

Under the "one-way" test, the dispositive issue is whether later-issued claims are obvious in light of earlier-issued claims. Although courts have, in unusual circumstances, applied a "two-way" test, in which later-issued claims are rejected for double patenting only where both the later claims are obvious in light of the earlier claims and the earlier claims are obvious in light of the later claims, the Federal Circuit has repeatedly held that the two-way test is a rare

exception to the general rule. *See, e.g.*, *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 at n.7; *In re Berg,* 140 F.3d 1428, 1432 (Fed. Cir. 1998).

Although Amgen persuaded the Examiner to apply the two-way test during prosecution, the factual and analytical underpinnings for Amgen's argument are insufficient to withstand judicial scrutiny and must now be rejected. S ¶ 51. In *Berg*, the Federal Court first observed that the rationale for applying the two-way test in limited circumstances was to prevent double patenting rejections "when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing." *In re Berg*, 140 F.3d at 1432. Accordingly, the court held that the two-way test applied only where the patent holder could not have avoided separate filings, and, even then, only where the PTO was solely responsible for the fact that the later-filed claims issued first. *Id.* at 1435, 1437.

The Federal Circuit underscored this holding in *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), where the court affirmed the district court's holding that the one-way test applied where the patent holder could not prove that it was "forced to file separately." *Geneva Pharm., Inc., v. Glaxosmithkline et al.*, 2002 U.S. Dist LEXIS 27413, at *12 (E.D. Va. 2002) (emphasis in original), *aff'd,* 349 F.3d 1373 (Fed. Cir. 2003). In this case, Amgen clearly was not "forced" to file the claims of the '016 patent separately from the claims of the Lin patents, especially in light of the similarity of the subject matter, the inventors' professed collaboration regarding numerous aspects of the inventions at issue, and the fact that Amgen co-owned the patents, among other factors. S ¶¶ 41-47.

Even if Amgen were able to show that the '016 patent claims could not have been filed together with the Lin claims as a continuation-in-part or otherwise, Amgen cannot dispute that its

own strategy for prosecuting the various Lin claims was largely responsible for the rate of prosecution of those claims. Thus, Amgen cannot show that the PTO is solely responsible for the delay. S ¶¶ 47-49 and 51.

The facts in this case are similar to those in *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993), where the applicant filed both "genus" and "species" claims in a single application. After the Examiner allowed the narrower "species" claims but rejected the broader "genus" claims, the applicant chose to allow the narrower claims to issue while pursuing the broader claims in a continuation. The broader claims were then rejected for obviousness-type double patenting over the narrower claims. The Federal Circuit held that the one-way test applied, and rejected the two-way test. *Id.* at 1053.

Contrary to Amgen's assertions before the PTO, it was not interferences that caused the delay of 10 years between the filing date of the '016 patent and the issuance of the first patent-in-suit. First, during the prosecution of the '298 application, Amgen chose to cancel claims directed to processes for the production of polypeptides while pursuing related claims directed to the polypeptides themselves, in spite of the Examiner's restriction requirement that had grouped those claims together in one invention. S ¶ 49.

Second, Amgen consistently responded to PTO correspondence on the last possible day, filed multiple continuations, many of which were later abandoned, and sought and received numerous extensions. S ¶ 48. These facts are similar to those the Federal Circuit considered in *In re Emert*, 124 F.3d 1458 (Fed. Cir. 1997), where the court once again declined to apply the two-way test, holding that the applicant had "orchestrated the rate of prosecution" with a strategy that included requesting numerous time extensions, waiting the maximum period to respond to

office actions, and filing a series of continuations while abandoning a substantially similar predecessor. *Id.* at 1460-61.

Finally and most importantly, Amgen waited until after the '016 patent issued to file the continuation applications that matured into the patents-in-suit, in most cases as long as eight years. S ¶ 47. Thus, the PTO could hardly be blamed for the delay in these applications issuing; if the PTO allowed the applications the same day they were filed, they still would have issued after the '016 patent. Thus, here the PTO was indisputably not solely responsible for the fact that the claims-in-suit issued after the claims of the '016 patent. These facts are similar to those in *Eli Lilly*, where the Federal Court declined to apply the two-way test, noting that the prosecution delay was not solely caused by the PTO where the later-issued claims were issued from a continuation-in-part, which stemmed from a continuation, which in turn stemmed from a divisional of the original application, and where a patent expert testified that certain claims could have been presented earlier than they were. *Eli Lilly*, 251 F.3d at 955 n. 7. Therefore, this Court need only accept Amgen's prior admissions and conclude that the claims-in-suit are obvious in light of the '016 patent claims, in order to hold the former invalid for obviousness-type double patenting.

D. Amgen is Judicially Estopped From Arguing That the Foregoing Differences in Claim Language Render the Patents-in-Suit Patentably Distinct from the '016 Patent

Amgen successfully argued to the BPAI that the composition claims and the process claims "are only different manifestations of the same invention" and that "the whole purpose and intent of the purified and isolated DNA sequence encoding human EPO (and host cells transfected therewith) ... was to express *in vivo* biologically active human EPO." S ¶ 24. Since this must be taken as true, it must have been obvious to one of skill in the art in December 1983 to use the mammalian cell culture to recover recombinant EPO (as claimed in the '016 patent)

thereby producing glycosylated, biologically active EPO protein (as claimed in the '868, '698 and '933 patents) at levels exceeding "1000 U" (as claimed in the '349 patent) for use in a pharmaceutical composition (as claimed in the '422 and '933 patents) to be used to treat kidney dialysis patients (as claimed in the '933 patent). Thus, the processes, compositions and use of same in treatments described in the asserted claims are just a rewording or obvious variation of the process claims of the '016 patent.

V. CONCLUSION

As explained above and as demonstrated in the accompanying declarations, claim 10 of the '016 patent renders the claims-in-suit obvious. The prior admissions and arguments by Amgen and Amgen's experts, as well as the prosecution histories, underscore the invalidity of the claims-in-suit by the doctrine of obviousness-type double patenting. Amgen is thus precluded from enforcing the claims-in-suit beyond the now-expired term of the '016 patent.

Based on the foregoing, Roche requests summary judgment that the claims-in-suit are invalid for obviousness-type double patenting.

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Respectfully submitted,

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