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

REPLY TO AMGEN INC.'S OPPOSITION TO 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") submit this Reply memorandum in further support of its Motion for Summary Judgment that the Claims of Patents-in-Suit are Invalid for Double Patenting over Amgen '016 Patent (Docket Item ("D.I.") 490). Amgen's opposition raises no genuine issue of material fact that prevents Roche from prevailing on its motion. Amgen merely misinterprets the law and mischaracterizes the facts.

Amgen seeks to hide behind a patent examiner's incorrect interpretation of the law of obviousness-type double patenting to avoid a finding of double patenting in the present case. However, this Court is not bound to accept—or even give deference to—a patent examiner's interpretation of the law. To the contrary, this Court is bound to follow the Federal Circuit's law on obviousness-type double patenting, which clearly requires that the patents-in-suit should have expired over two years ago when the '016 patent expired.[1]

The legal nature of the disputes being made by Amgen makes clear that Roche is entitled to summary judgment based on obviousness-type double patenting over the earlier-issued and now-expired '016 patent. The positions previously taken by Amgen, including the positions taken by Amgen to prevail in the interference proceedings against Genetics Institute, make the appropriateness of summary judgment even clearer.

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[1] See the discussion of the examiner mistakes in First Sofocleous Decl., ¶¶ 9-13, D.I. 493. Note that Amgen is quick to dismiss the patent examiner's judgment when he stated that under the one-way test there would clearly be obviousness-type double patenting. Nevertheless, the examiner was clearly correct that the claims were obvious over the '016 patent's claims. (*See* Roche Memorandum, D.I. 491, and First Harlow Decl., D.I. 494.) However, Federal Circuit law clearly requires the use in the present case of the one-way test, not the rarely appropriate two-way test. If the examiner applied the correct legal test, Amgen would have been forced to file a terminal disclaimer so as to cause the patents-in-suit to expire at the same time as the '016 patent.

"First Sofocleous Decl.," "Second Sofocleous Decl.," "First Harlow Decl." and "Second Harlow Decl." refer respectively to D.I. 493, D.I. 570, D.I 494 and D.I. 569. "Ex. __" refers to Exhibits attached to the declarations of Kimberly J. Seluga dated June 7, 2007 (D.I. 495)(containing Exs. A-T), June 28, 2007 (D.I. 572)(containing Exs. U-GG and July 9, 2007 (filed herewith)(containing Exs. HH and II).

II. AMGEN'S ASSERTION OF THE PATENTS-IN-SUIT BEYOND THE EXPIRATION OF THE '016 PATENT VIOLATES THE PUBLIC POLICY OF THE DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING

The current case presents a classic example of obviousness-type double patenting, as Amgen has effectively extended the term of the '016 patent by obtaining the patents-in-suit without filing the appropriate terminal disclaimers. Section 804 of the Manual of Patent Examining Procedure describes the public policy behind double patenting:

> … The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that:
>
> > The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.
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> *In re Zickendraht*, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982). …

In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985) also approvingly quotes *In re Zickendraht.*

However, if one attempted to practice the process of claim 10 of the now-expired '016 patent in the U.S., one would face an infringement suit from Amgen. (See Second Harlow Decl. 4, D.I. 569.) Amgen does not, and cannot, even attempt to explain how one could practice the process of claim 10 of the now-expired '016 patent in the U.S. without facing an infringement suit from Amgen.[2]

Thus, Amgen's assertion of the patents-in-suit beyond the expiration date of the '016 patent violates the public policy behind double patenting.

[2] *See, e.g., Geneva Pharmaceuticals, Inc. v. GlaxoSmithkline PLC*, 349 F.3d 1373, 1377-1378 (Fed. Cir. 2003). To the extent a claim-in-suit would not necessarily be infringed by practicing the '016 claim 10 process (e.g., some claims-in-suit require the use of CHO cells, and thus, the '016 patent could be practiced using COS cells without infringing just those particular CHO-cell claims), such claims would have been obvious variants on '016 claim 10. The obviousness of these minor variations has been set forth in Roche Memorandum, D.I. 491, and in First Harlow Decl., D.I. 494.

III. AMGEN'S ASSERTION OF THE PATENTS-IN-SUIT BEYOND THE EXPIRATION OF THE '016 PATENT VIOLATES THE LAW ON OBVIOUSNESS-TYPE DOUBLE PATENTING

A. The Case Law Fully Supports Roche's Double Patenting Analysis and Refutes Amgen's Analysis

1. Amgen's Distinction of *Geneva Pharmaceuticals* Has No Basis in the Facts of that Case or in the Law

In a desperate attempt to trick this Court into applying incorrect law, Amgen blatantly misrepresents the facts of *Geneva Pharmaceuticals, Inc. v. GlaxoSmithkline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003). On page 13 of its Opposition (D.I. 576), Amgen argues *Geneva Pharmaceuticals* is "inapposite because, unlike the Lin and '016 patents, the patents and applications in [that case] all claimed priority from the same original application, and the claims either were filed together in that first-filed application or could have been (since all the inventions were disclosed therein);" this is Amgen's only attempt to distinguish *Geneva Pharmaceuticals.*

However, in *Geneva Pharmaceuticals* the court invalidated U.S. Pat. No. 4,529,720 (the "'720 patent")(Ex. HH) for obviousness-type double patenting over U.S. Patent No. 4,367,175 (the "Fleming patent")(Ex. II), which did not claim priority from the same application as the '720 patent. 349 F.3d at 1377. Indeed, the decision explains that the earlier-issued Fleming patent initially was not even owned by GlaxoSmithkline ("GSK"), and thus the claims could not have been—as Amgen alleges—"filed together in [the] first-filed application," since the claims were not even commonly owned at that time. ("GSK owns the Crowley and Fleming patents because GSK has merged with the original assignees of those patents, Beecham Group, Ltd. and Glaxo Laboratories, Inc." 349 F.3d at 1377.)

As *Geneva Pharmaceutical* demonstrates, the law sets forth no requirement whatsoever that the earlier-issued patent must—as Amgen says—"claim[] priority from the same original application" as the later-issued patent in order to invalidate the later patent for obviousness-type double patenting. Amgen concocts this requirement out of thin air in an attempt to trick this Court

into ignoring *Geneva Pharmaceuticals.* All that is required is that the patents be owned by the same party (which is the case with the '016 patent and the patents-in-suit) or that the patents have the same inventor. *See* MPEP § 804. Thus, Amgen's argument that *Geneva Pharmaceuticals* is "inapposite" is completely without merit.

2. By Ignoring the Holdings of *Geneva Pharmaceuticals* and Other Relevant Case Law, Amgen Ignores the Correct Analysis

(a) The Specification Is Examined to Determine the Overlap in the Claim Scope and the Utility of the Claimed Compound

Despite Amgen's attempt to sweep the seminal case, *Geneva Pharmaceuticals,* under the rug, it is in fact much more relevant than the cases on which Amgen relies so heavily. In 2003 the Federal Circuit upheld a summary judgment of double patenting in *Geneva Pharmaceuticals,* and the Federal Circuit considered whether a patent for a method using a compound was invalid over a previously issued patent for the compound itself. In analyzing the claims, the Court found it appropriate to look at the specification in order to understand the overlap in claim scope and to understand the utility of the claimed compound:

> To review the district court's judgment on this point, this Court examines the disclosure of the Fleming claim. Nonetheless, this court does not consider the Fleming claim in a vacuum, as a simple compound, without considering the compound's disclosed utility. ... Standing alone, that claim does not adequately disclose the patentable bounds of the invention. Therefore, this court examines the specifications of both patents to ascertain any overlap in the claim scope for the double patenting comparison. *See In re Avery,* 518 F.2d 1228, 1232 (C.C.P.A. 1975); *In re Zickendraht,* 319 F.2d 225, 228 (1963).
>
> A person of ordinary skill in the art reviewing the disclosure of the Fleming patent would recognize a single use for potassium clavulanate, administration to patients to combat bacteria that produce <<beta>>-lactamase. ... The Fleming patent discloses no other use. The 720 patent simply claims that use as a method.

349 F.3d at 1385 (emphasis added).[3] The '016 specification makes clear that the rEPO of its claims is the same rEPO as the patents-in-suit, and thus there is significant overlap in claim scope. *See* Ex. F, '016 patent, col. 2, line 64 to col. 3, line 6, and col. 4, lines 34-38.

[3] *Accord, Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2005); *Research Corp. Techs., Inc. v. Gensia Labs., Inc.*, 10 Fed. App'x. 856, 864 (Fed. Cir. 2001). Furthermore, although *Geneva Pharmaceuticals* permits

(b) A Claim Is Not Required "Standing on its Own" To Fully Enable Invention

In Amgen Opposition, pp. 16-19, D.I. 576, Amgen essentially argues that a claim in an earlier-issued patent must—by itself—fully enable the claimed subject matter in order for it to be the basis for double patenting.[4] Amgen's (untenable) position is made clear in the Declaration of Harvey F. Lodish, D.I. 578, ¶ 12, where Dr. Lodish argues that the language of "'016 claim 10 ***standing on its own***" would not have "taught the skilled artisans how to produce recombinant EPO in mammalian cell culture." (Italics and bolding in original.) *See also* ¶ 7 of D.I. 578: "The claim does not instruct one skilled in the art how to produce that product in cell culture, nor does it describe what the structure and composition of that product are. …"

However, there is absolutely no basis in the law for Amgen's argument. Indeed, if claims were required to be fully enabling within their four corners, it would be a very, very rare double patenting rejection that the PTO could ever make. One need look no further than the *Geneva Pharmaceuticals* case for an example to show that Amgen's argument is without merit. For example, the earlier-issued Fleming patent in the *Geneva Pharmaceuticals* case had the following claim:

> 1. Potassium clavulanate of the formula … having a molar extinction coefficient as determined in 0.1M aqueous potassium hydroxide using ultraviolet light of wavelength 258 nm of about 17000.

Clearly, this claim on its face cannot, by itself, enable the preparation of "potassium clavulanate." A quick review of the Fleming patent, U.S. Pat. No. 4,367,175, Ex. II, reveals a long, complicated procedure for obtaining this compound. Nevertheless, this earlier-issued claim can serve as the

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one to consider the patent disclosure, in the present case someone of ordinary skill in the field—even without looking at the disclosure of the '016 patent—would have easily understood that the term "recombinant" for a protein meant that the protein was made using recombinant DNA techniques, which were well known by 1983. These are basically the techniques claimed in the patents-in-suit for making rEPO. (Second Harlow Decl. ¶ 3, D.I. 569. *See also* Ex. N of D.I. 495, the Initial Expert Report of Dr. Harvey Lodish, submitted in prior litigation to support a defendant's double patenting defense, wherein Dr. Lodish explained that these recombinant DNA techniques were well known by 1980.)

[4] Amgen uses this baseless argument—that a claim in an earlier-issued patent must, by itself, fully enable the claimed subject matter in order for it to be the basis for double patenting—to provide a basis for its argument that rEPO is

basis for obviousness-type double patenting because it—like '016 claim 10—is enabled by the specification. Thus, Amgen's argument that a claim must "standing on its own" be fully enabling has no merit.[5]

(c) Different Classes of Invention Can be Obvious in Light of Each Other

Amgen's obviousness-type double patenting analysis also incorrectly argues—without any legal support—that "[s]ince 'recombinant erythropoietin' is a different invention than the recovery process of '016 claim 10, it is patentably distinct." Amgen Opposition, p. 3, D.I. 576. However, the fact that the '016 patent claim 10 is a process claim that uses the rEPO of the patents-in-suit does not provide a patentable distinction for obviousness-type double patenting. A claim for a method that uses a composition can be obvious in light of a claim directed to the composition itself (*see, e.g., Geneva Pharmaceuticals*; and *In re Lonardo* 119 F.3d 960 (Fed. Cir. 1997)), a claim directed to a product can be obvious in light of a claim directed to a method of producing the product (*see, e.g., In re Freeman*, 166 F.2d 178 (C.C.P.A. 1948)), and a claim directed to a composition can be obvious in light of a claim directed to a method that uses the composition (*see, e.g., Research Corp. Techs., Inc. v. Gensia Labs., Inc.*, 10 Fed. App'x. 856 (Fed. Cir. 2001)). *See also, Phillips Petroleum Co. v. U.S. Steel Corp*, 604 F. Supp 555 (D. Del. 1985). Thus, the various claims-in-suit—even though they may be directed to the rEPO composition or to methods of making or using the rEPO composition—can be obvious in light of the '016 patent claim 10.

(d) Differences in Claim Scope Are Viewed in Light of Prior Art

Amgen also ignores the proper obviousness-type double patenting analysis as set out by the case law. The analysis entails a two-step process. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent, and determines the differences. Second,

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"named but not claimed in '016 claim 10." Amgen Opposition, p. 11, D.I. 576. (*See also* pp. 2 and 17-18 of D.I. 576.) This "named but not claimed" argument is addressed more fully below in Section IV.B of this brief.

[5] It should also be noted that, according to the patent statute, claims are not intended to be self-enabling. *See* 35 U.S.C. § 112, ¶¶ 1 and 2. *See also* Roche Memorandum, p. 4, fn. 4, D.I. 491.

the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over the earlier claim to one of ordinary skill in light of the prior art. *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985); *see also In re Lonardo,* 119 F.3d 960, 967 (Fed. Cir. 1997) (affirming a holding of obviousness-type double patenting because each additional limitation led to only an obvious modification of the device defined in the prior claims). An absence of overlap between the later claim and the earlier claim does not preclude a conclusion that the later claim is patentably indistinct from the earlier claim. *Eli Lilly*, 251 F.3d at 968 n.6; *see also Research Corp. Techs., Inc. v. Gensia Labs., Inc.*, 10 Fed. App'x. 856 (Fed. Cir. 2001) (affirming a holding of obviousness-type double patenting because limitations in composition claims were only an obvious modification over the prior method claims).

(e) It Is Improper to Ignore the Preamble in Interpreting the Claim

Amgen also wrongly urges this Court to reject Roche's obviousness-type double patenting analysis by claiming that Roche has mischaracterized the invention claimed in '016 claim 10. *See* Amgen Opposition at 2, D.I. 576. Amgen contends that Roche has violated a "fundamental principle of ODP law" by incorrectly arguing that the term "recombinant erythropoietin" in the preamble of '016 claim 10 is the invention claimed in claim 10. *Id.* Although Amgen misconstrues Roche's position, courts have repeatedly looked at the claims as a whole, including what is recited in the claim's preamble, in determining whether there are any differences between the two claims in an obviousness-type double patenting analysis. *See, e.g., Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2005) (comparing the terms "sunburn" and "skin disorders" in the preamble of the claims when identifying the differences between two claims in an obviousness-type double patenting analysis); *Eli Lilly*, 251 F.3d at 971-972 (comparing the differences between the

claims as a whole and finding that claims directed to humans were not patentably distinct from claims directed to animals, both terms being recited in the preamble).

The fact that the term "recombinant erythropoietin" appears in the preamble of '016 claim 10 rather than in the enumerated steps of the claimed purification method is of no moment, as rEPO is "necessary to give life, meaning, and vitality to the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305-1306 (Fed. Cir. 1999) (finding preamble term to be a requirement of the claim). The fact that the term "erythropoietin" also appears independently in the enumerated steps of '016 claim 10—including in the final step—strongly supports the position that "recombinant erythropoietin" is claimed and not just named. *Id.* at 1306 (finding preamble language to be "intimately meshed with the ensuing language of the claim" where preamble recited "image of generated shapes made up of spots" and steps claimed "spots").

Thus, in view of the discussion above, Amgen's urging of its overly restrictive interpretation of the obviousness-type double patenting analysis is simply not supported by the current case law, and Amgen's analysis is fatally flawed in several respects. Roche's obviousness-type double patenting analysis properly compares the differences in '016 claim 10—properly construed—with the claims-in-suit and determines whether those differences would have been obvious to one of ordinary skill in light of the prior art.

B. The *General Foods* Case Does Not Support Amgen's Position; It Supports Roche's

The facts of *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992), are very different from the current facts. Nevertheless, Amgen tries to place a great deal of emphasis on the 15-year old *General Foods* case, calling it a "seminal" obviousness-type double patenting case.

In *General Foods*, the earlier-issued patent (the '619 patent) to Studiengesellschaft Kohle (SGK) was directed to a process of recovering caffeine. The end product of this earlier '619 patent

was caffeine, not coffee. The coffee could have been damaged by this process and not be potable; indeed it could have been so broken down that it is no longer coffee. The claim is completely silent on what happens to the coffee. Just because someone has figured out how to extract and recover a useable form of caffeine from coffee does not mean that one has figured out how to make a potable decaffeinated coffee.

The later-issued SGK patent (the '639 patent) was directed to decaffeinating coffee. The end product of this later '639 patent was coffee, not caffeine. As discussed above, such a process is not necessarily obvious in light of a caffeine-extraction process. Clearly, the result of *General Foods* would have been different if the earlier claims were to the process of making decaffeinated coffee, and the later claims were to a decaffeinated coffee composition. *See, e.g., Research Corp. Techs.,* 10 Fed. App'x. at 862-864 (affirming a holding of obviousness-type double patenting because limitations in composition claims were only an obvious modification over the prior method claims).

One can readily see that the fact pattern of this *General Foods* case is very different from the present case. In the *General Foods* case, the end products of the earlier and later patents are very different: decaffeinated coffee is very different from caffeine; indeed, they are mutually exclusive. Thus, the claimed subject matter of the later-issued SGK patents was not obvious in light of the claimed subject matter of the earlier-issued SGK patents.

In the present case, the end product of both the earlier and later Amgen patents is rEPO, and thus the claimed subject matter of the later-issued patents must be obvious over the subject matter claimed in the earlier-issued patent. In the '016 patent, Lai and Strickland did not invent a way of recovering a Chinese hamster protein or other impurities from the supernatant fluid; they recovered the rEPO that is the subject of the patents-in-suit.

Therefore, not only is rEPO named in '016 claim 10, it is also claimed. And if one looks at '016 claim 10 as a whole, one appreciates that rEPO is the end product of the '016 claim 10 process. As discussed above, there is no way one could practice '016 claim 10 without facing an infringement suit from Amgen; this confirms that the subject matter of the patents-in-suit must be the same as the subject matter '016 claim 10 or must be obvious variations thereon.

This inability to freely practice the now-expired '016 patent is another very important distinction with the *General Foods* case. In *General Foods*, after the earlier SGK '619 patent expired, one could practice the claimed '619 process without infringing the later SGK '639 patent.[6] The *General Foods* decision makes this distinction quite clear by noting

> Since … none of the '619 claims are infringed by one practicing the decaffeination process claimed in patent '639 without more, the '619 patent did not cover the '639 process and a patent thereon cannot extend the protection granted by the now expired '619 patent.

and finding no double patenting, at least in part, on this basis. 972 F.2d at 1282-1283. (Emphasis added.) In the current case, on the other hand, the earlier '016 patent has effectively been extended by the patents-in-suit.

C. Amgen Improperly Directs the Court's Attention to the '008 Patent in Seeking Application of the Two-Way Test

Amgen approaches the question of whether the normally appropriate one-way test or the rarely appropriate two-way test is applicable as though Roche is trying to invalidate the '008 patent for obviousness-type double patenting. Of course, Roche is not trying to invalidate the '008 patent; that patent is expired and is not one of the patents-in-suit. Therefore, it is irrelevant whether the issuance of '008 patent was delayed by Amgen.

Amgen does not and cannot deny that it delayed the issuance of the patents-in-suit. Indeed, Amgen delayed filing the patents-in-suit throughout the entire period that the '016 patent was

[6] For example, the later '639 patent requires "... recovering a substantially decaffeinated coffee ...," and the process claimed in the earlier '619 patent could be practiced without performing this step.

pending—and beyond—even though Amgen could have filed the patents-in-suit at any time during the pendency of the '016 patent.

Amgen repeatedly refers to the filing of the patents-in-suit as November 30, 1984, but that is the filing date of the '008 patent. The filing date of each of the patents-in-suit can be seen on its cover page, next to the word "Filed," and it is easy to see that they were filed much later than the '008 patent. *See, e.g.*, Exs. A, B, C, D and E. Of course, the patents-in-suit claim priority back to the '008 patent, but nevertheless, the important fact is that their actual filing dates were much later. (See First Sofocleous Decl., ¶ 4, D.I. 493, and Second Sofocleous Decl. ¶¶ 5-15, D.I. 570.) Amgen could have filed all the patents-in-suit at any time between the priority date of the '008 patent and the issuance of the '016 patent. However, Amgen chose to delay the filing of the patents-in-suit, instead of filing them as soon as possible. Whatever rationale Amgen had for delaying the filing of the patents-in-suit, Amgen bears the responsibility for the delay.[7] The law requires that the one-way test apply if Amgen has any responsibility for the delay, and thus, the one-way test is the proper test under this criteria by itself.[8]

[7] Amgen says one cannot infer when the patents-in-suit would have actually issued if it had filed them as soon as possible. Amgen Opposition, page 15, D.I. 576. Whether one could or could not make such an inference is irrelevant; the point is that Amgen did not even try to get the patents-in-suit on file as quickly as it could. Accordingly, Amgen must bear the responsibility for the delay in the issuance of the patents-in-suit, and thus the one-way test is the appropriate test.

[8] 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, 969 n.7 (Fed. Cir. 2001). The two-way test only applies when an applicant can show BOTH that

(1) the claims of its separate applications could not have been filed in a single application; and

(2) the PTO was solely responsible for the delay that allowed the claims of the later-filed application to issue before the claims of the earlier-filed application.

See, e.g., In re Berg, 140 F.3d at 1437; *Lilly*, 251 F.3d at n.7; *In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997); *see also* MPEP §804 (8th ed. Rev. 5, Aug. 2006). If either one of these criteria is not met, the one-way test applies. Furthermore, the Federal Circuit has acknowledged that the reason for using the rare two-way test has all but been eliminated with the Patent Law Amendments Act of 1984 ("the 1984 Act"), which allows related inventions by different employees of the same company to be filed in a single application. *In re Berg*, 140 F.3d at 1432-1433. The '178 and '179 applications (precursors to the patents-in-suit), as well as the '016 patent application, were all filed after the 1984 Act took effect, and could have therefore been combined into a single application even though different Amgen employees were named as inventors.

Furthermore—as discussed in Roche Memorandum, pp. 14 and 16, D.I. 491, Roche Opposition pp. 15-16, D.I. 568, First Sofocleous Decl., ¶¶ 4-6, D.I. 493, and Second Sofocleous Decl. ¶¶ 5-7, D.I. 570—Amgen had the opportunity to combine the disclosures and claims of the '016 patent and the patents-in-suit into a single continuation-in-part application. Amgen argues that it would have been impossible to file the '008 patent as a continuation-in-part application of the '016 patent; however, that is irrelevant since the '016 patent could have been filed as a continuation-in-part of the application for the '008 patent. Moreover, all of the patents-in-suit claim priority back to either of the '178 or '179 applications—precursors of the patents-in-suit. These applications were both filed after the '016 patent issued. If Amgen did not delay filing these applications, they could easily have been filed while the application for the '016 patent was still pending as continuations-in-part of the '016 and '008 patents, and could have included the '016 patent's disclosure and claims.

Thus, Amgen cannot satisfy either of the two requirements for qualifying for the rare two-way test. Accordingly, the one-way test applies (and would still apply even if Amgen could satisfy just one requirement).

IV. AMGEN CANNOT CREATE A GENUINE ISSUE OF FACT THAT PREVENTS ROCHE FROM BEING ENTITLED TO SUMMARY JUDGMENT ON OBVIOUSNESS-TYPE DOUBLE PATENTING OVER THE AMGEN '016 PATENT

A. Amgen Does Not Use the Correct Test in Disputing the Facts

Amgen repeatedly misapplies the legal standard and blatantly misrepresents the case law, as well as the facts in this case, in an attempt to divert this Court's attention from the fundamental question—whether there are any differences between the claims-in-suit and '016 claim 10 and, if so, whether those differences would have been obvious to one of ordinary skill in light of the prior art. Amgen repeatedly ignores the correct legal test in its Response to Roche's Rule 56.1 Statement of Undisputed Material Facts (D.I. 577). Instead of addressing the differences between the later and

earlier claims, Amgen pretends that nothing is claimed in '016 claim 10, and then disputes Roche's statements of fact as though the present motion (D.I. 490) was based on 35 U.S.C. § 103 obviousness. For example, for Roche's Statement of Fact No. 34, Amgen responded:

> Roche's "Statement of Fact" No. 34 Dr. Lodish admitted that the glycosylation of proteins was obvious and well known in 1980. *See* Seluga Decl., Ex. N, Lodish Report ¶¶ 123, 141, 142, 143 and 145 (stating ". . . In my opinion, the requirement that a protein have an attached carbohydrate chain does not make it patentably distinct from the simple requirement that it be a protein."); *see also* Harlow Decl. ¶ 89.
>
> Amgen's Response to Statement No. 34 Disputed and immaterial. The opinions expressed in Dr. Lodish's expert reports in the *Columbia* case do ***not*** support Roche's argument that the inventions claimed in Dr. Lin's patents-in-suit were obvious and well known. See above response to Roche's "statement of fact" No. 33, which is incorporated herein.

(Emphasis in original.) Of course, the question in an obviousness-type double patenting analysis is not whether "the inventions claimed in Dr. Lin's patents-in-suit were obvious and well known," but rather whether the differences between the claims-in-suit and '016 claim 10 were obvious and well known. Amgen applies this incorrect test throughout its Response to Roche's Rule 56.1 Statement of Undisputed Material Facts (D.I. 577). See Responses to Statement Nos. 5, 9-22, 25-30 and 34-40 in D.I. 577.

The Lodish Declaration (D.I. 578) also applies the incorrect test for obviousness-type double patenting. In addition to making the incorrect assumption (discussed above in Section III.A.2.b) that a claim must "standing on its own" fully enable an invention, (D.I. 578, ¶ 12), Dr. Lodish does not consider whether the differences between the later claims and the earlier claims would have been obvious to one of ordinary skill in light of the prior art, as required by, *e.g., In re Longi* and *In re Lonardo*. Instead he continues to look only within the four corners of the claim. For example, in ¶ 104 of the Lodish Declaration (D.I. 578), Dr. Lodish declares: "… Moreover, dependent claim 2 has the further limitation of production in a CHO cell that is not suggested by '016 claim 10."[9] Dr.

[9] Interestingly, Dr. Lodish used the correct obviousness-type double patenting analysis in the Initial Expert Report (Ex. N of D.I. 495) that he submitted in a prior litigation to support a defendant's double patenting defense. In that report, he looked at the differences of the later-issued claims from the earlier issued claims and considered whether or not those

Lodish makes similar statements in ¶¶ 92, 96 and 108. Thus, in these ways and others, Dr. Lodish fails to use the correct test for obviousness-type double patenting and thus the opinions he offers on this issue cannot defeat the present motion for summary judgment (D.I. 490). If one were to correctly look to see whether only the differences between the claims were obvious and well known, Dr Lodish's analysis would collapse. Indeed, even the patent acknowledges that CHO expression was well known and published prior to the time of the invention. *See* Ex. E, '933 patent, col. 25, lines 39-45 ("The present example describes expression systems employing Chinese hamster ovary (CHO) DHFR^{-} cells and the selectable marker, DHFR. [For discussion of related expression systems, see U.S. Pat. No. 4,399,216 and European Patent Applications 117058, 117059 and 117060, all published Aug. 29, 1984.]"). (Bracketed material in original.)

B. Amgen's Dispute of the Facts is Based Entirely on its "Named but not Claimed" Argument

Amgen argues that rEPO is "named but not claimed in '016 claim 10," hoping to twist the holding and facts of *General Foods* to its favor. Amgen Opposition, p. 11, D.I. 576. (*See also,* pp. 2 and 17 of D.I. 576, and Amgen's Response to Roche's Rule 56.1 Statement, pp. 3- 4, D.I. 577.) However, the end product of '016 claim 10 is rEPO, the same rEPO that is the subject of the later-issued patents-in-suit.[10] Thus, as explained above, and as explained in the Roche Memorandum

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differences would have been obvious in light of the prior art; he did not ignore the prior art in considering what was obvious in light of the earlier claim. For example in ¶ 123 of Ex. N, Dr. Lodish relies on a prior art reference to show that glycosylation would have been obvious in 1980. Dr. Lodish then goes on in subsequent paragraphs (¶¶ 123, 141, 142, 143 and 145) to list many more prior art references to support his opinion on the obviousness of glycosylation. In the present case, on the other hand, he ignores the prior art and merely looks at what is explicitly stated within the four corners of the earlier claim.

[10] It is interesting that Amgen, which normally touts the complexity and difficulty of its claimed inventions, would use the grossly over-simplified and inapt "car wash" analogy to try to argue that '016 claim 10 does not claim rEPO. When Amgen patented rEPO, it was not like making a car – Amgen's rEPO was more akin to a very specific type of vehicle to which Amgen claimed exclusive rights, and this vehicle needed a very specific type of purification process because otherwise the vehicle would not be useable. (Second Harlow Decl. ¶ 6, D.I. 569.) For example, while it is true that there is no need for a car wash until the car was invented, there was no need for unpurified EPO as its use in a pharmaceutical composition would pose serious health risks. Also, if the wrong purification process was used, the EPO could be damaged. Once Amgen made its vehicle – rEPO – the subject of claim 10 of the '016 patent, the rEPO was in the possession of the ordinary artisan and the clock on Amgen's patent monopoly started to tick. The subject matter of the patents-in-suit and the '016 patent are inextricably intertwined, and are indeed two parts of the same invention: to be used as a pharmaceutical, the EPO needs to be purified.

(D.I. 491) and Roche Opposition (D.I. 568), the claimed subject matter of Amgen's later-issued patents must be obvious over the subject matter claimed in its earlier-issued patent. That this is so can be clearly seen by considering whether one can now freely practice the process of the now-expired '016 patent, and there is no useful way one could practice the process claimed in the earlier '016 patent without facing an infringement suit from Amgen. *See* Second Harlow Decl. ¶ 4, D.I. 569. Thus, pursuant to *General Foods,* the subject matter of the claims-in-suit must be the same as the subject matter of '016 claim 10 or must be obvious variations thereon.[11]

Since Amgen's dispute of the facts is based entirely on its incorrect interpretation of the law, summary judgment in favor of Roche is appropriate.

C. The Present Motion Can Easily be Decided in Roche's Favor Without Considering the Many Admissions Made by Amgen and its Experts in the Past

After arguing in its Opposition (D.I. 576) that when "[r]ead in context … many of Amgen's statements have the exact opposite meaning as that which Roche ascribes to them …," Amgen promised to address "each of Roche's many mischaracterizations in Amgen's response" to Roche's Rule 56.1 Statement. However, Amgen fails to deliver. For example, as described above in Section IV.A, Amgen avoids directly disputing Roche's statements of fact, and as a result, Amgen disputes statements different from those that Roche has made. Since Amgen ignores the "meaning as that Roche ascribes to" Amgen's many prior admissions, Amgen fails to explain how its prior statements could "have the exact opposite meaning as that which Roche ascribes to them."

In any event, since—as discussed above—Amgen and Dr. Lodish do not use the correct analysis for obviousness-type double patenting, they cannot create a genuine issue of material fact and, therefore, the Court need not consider how Amgen has changed its position on various issues

[11] *General Foods,* as noted above, found no obviousness-type double patenting at least in part on the basis that "[s]ince … none of the '619 claims are infringed by one practicing the decaffeination process claimed in patent '639 without more, the '619 patent did not cover the '639 process and a patent thereon cannot extend the protection granted by the now expired '619 patent." 972 F.2d at 1282-1282. (Emphasis added.)

over the decades. Amgen's prior admissions are merely useful for confirming that whatever minor difference there may be between '016 claim 10 and the claims-in-suit such a difference cannot provide a patentable distinction.

For example, *Geneva Pharmaceuticals* holds that the utility of a composition cannot provide a patentable distinction over the composition itself. 349 F.3d at 1386. (*See* Roche Memorandum, p. 10, fn. 15, D.I. 491.) Thus, when a claim-in-suit explicitly sets forth the "in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells"—which is the utility of rEPO—that claim limitation cannot provide a patentable distinction over the rEPO of '016 claim 10, even though that language is not explicitly set forth in '016 claim 10.[12] Thus, it is unnecessary to consider that Amgen has made admissions on this issue in the past.

D. Amgen Cannot Explain Away Earlier Statements that Refute its Current Position

Although Amgen's prior admissions are not believed to be necessary for the Court's determination that summary judgment should be granted to Roche on the issue of obviousness-type double patenting, it is important to note that Amgen cannot explain away these prior statements.

Apparently, during the nearly quarter century that Amgen has been pursuing and enforcing its EPO patents, Amgen sometimes argued one thing and sometimes argued the opposite thing. Amgen uses its inconsistent statements to try to explain that, when the various Amgen statements

[12] Furthermore, there are several other reasons why *in vivo* biological activity cannot patentably distinguish the claims-in-suit over '016 claim 10, including:
1) As explained in Roche Memorandum, pp. 9-10, D.I. 491, and First Harlow Decl. ¶¶ 83, 110-118, D.I. 494, Amgen's decision to list Lin as the sole inventor—when his inventive contribution was, at most, just the isolation of the DNA sequence, and when he had no inventive contribution to the work of using the isolated DNA sequence to produce rEPO with *in vivo* biological activity—is proof that Amgen did not consider the *in vivo* biological activity of rEPO to be a patentable distinction beyond rEPO itself, or beyond the isolated DNA sequence for EPO. Otherwise, other Amgen employees, in particular those employees who worked on the transfection of the host cells etc., should also have been listed as inventors on the patents-in-suit.
2) The '016 patent does not provide any examples showing that its process works with something without *in vivo* biological activity. The only examples of rEPO provided in the '016 patent have *in vivo* biological activity. In fact, the '016 patent describes the specific purpose of its invention as isolating biologically active rEPO. *See, e.g.,* '016 patent col. 1, lines 7-14, col. 2, lines 57-63 and col. 3, lines 9-15.
3) The prior literature described EPO's *in vivo* biological activities and properties. First Harlow Decl., ¶¶ 27 and 102.
4) That rEPO would have the same "*in vivo* biological activity or property of causing bone marrow cells to increase production of reticulocytes and red blood cells" as EPO would have been reasonably expected. First Harlow Decl. ¶¶

quoted by Roche are read in context of all the Amgen statements, the statements quoted by Roche actually must "have the exact opposite meaning." (Amgen Opposition, page 1, D.I. 576.) Regardless of Amgen's struggles to reconcile its past positions with the positions it now tries to advance, the fact remains that Amgen argued that the '178 and '179 applications (precursors to the patents-in-suit) were "manifestations of the same invention" as the '008 patent (which was directed to the EPO DNA sequence and host cells transfected therewith) 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." And as a result of this argument, Amgen won the interferences. *See, Fritsch v. Lin,* 21 U.S.P.Q.2d 1737 (BPAI 1991) and *Fritsch v. Lin,* 21 U.S.P.Q.2d 1739 (BPAI 1991), and First Harlow Decl. ¶¶ 99-100, D.I. 494.

Amgen brought suit against Genetics Institute based on the '008 patent on the day that the '008 patent issued. The PTO eventually declared three interferences between Genetics Institute (Fritsch) and Amgen (Lin) for each of the '008 patent, the '178 application and the '179 application. Amgen won its infringement suit against Genetics Institute at the trial court, and Amgen's victory was upheld on appeal.

Right after Amgen prevailed in the appeal to the Federal Circuit, Amgen argued to the PTO that the Federal Circuit's holding that Amgen had priority over Genetics Institute on the '008 patent was binding on the PTO in the interference involving the '008 patent. However, Amgen did not stop there; Amgen went on to also argue that the Federal Circuit's holding on the '008 patent was also binding in the interferences involving the '178 and '179 applications.[13] It was in this context

13, 34, 51, 104, 108 and 119, D.I. 494.

[13] Brief for the Senior Party Lin, Interference No. 102,097, dated July 29, 1991 at 26, AM-ITC 00337678. Ex. I. Apparently, prior to its Federal Circuit victory against Genetics Institute, Amgen did not take the position that the '008 patent and the '178 and '179 applications were the same invention. Nevertheless, in order to prevail in the interference proceedings, Amgen successfully argued in its final brief that the three interferences were about the same invention. Later on to overcome the double patent rejection, Amgen argued that the '008 patent and the '178 and '179 applications were for different inventions. Nevertheless, these later arguments by Amgen cannot overcome the fact that, in order to prevail in the interference proceedings, Amgen successfully argued that the three interferences were about the same invention.

that Amgen made its argument that the subject matter of the '178 and '179 applications and the '008 patent were all "manifestations of the same invention," and in particular, Amgen argued to the Board of Patent Appeals and Interferences (BPAI) 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."[14] Ex. I, Brief for the Senior Party Lin, Interference No. 102,097, dated July 29, 1991 at 26, AM-ITC 00337678. Amgen succeeded in this argument when the BPAI accepted this position noting that the issues of priority were identical for the '008 patent and the '178 and '179 applications.[15]

Amgen had to say this in order to succeed on its argument, because the count in the interference relating to the '008 did not recite the language "*in vivo* biological property" (*Fritsch v. Lin,* 21 U.S.P.Q.2d 1731 at 1733 (BPAI 1991)), whereas the counts in the interferences of the '178 and the '179 applications did recite this language (21 U.S.P.Q.2d 1737 at 1738, and 21 U.S.P.Q.2d 1739 at 1740). Thus, Amgen made the argument that "*in vivo* biological property" provided no patentable distinction beyond the "purified and isolated DNA sequence" of the '008 patent. (Of course, Amgen was not forced to make this argument, but it wanted to make sure it won all the interferences—not just the one relating to the '008 patent.)

The BPAI agreed and accordingly held that the priority issues were essentially identical in the three interferences. Furthermore, the BPAI also held that the process steps for making glycosylated *in vivo* biologically active EPO after the EPO gene was known "d[id] not require the

[14] Amgen now argues that the interference proceedings have no connection with the patents-in-suit. *See, e.g.,* Amgen's Response to Roche's Rule 56.1 Statement, pp. 9 and 23, D.I. 577. However, this argument by Amgen is inconsistent with its argument that it diligently pushed the patents-in-suit through the PTO. If Amgen is arguing that the subject matter of the interference proceedings had no connection with the subject matter of the patents-in-suit, then there is a period of at least several years when Amgen completely withheld the subject matter of the patents-in-suit from consideration by the PTO.

[15] *Fritsch v. Lin,* 21 U.S.P.Q.2d 1737 at 1738 ("Of the issues above, all except issue No. 8 are essentially identical to the issues already considered in related Interference No. 102,096 [which related to the '008 patent].") *Fritsch v. Lin,* 21 U.S.P.Q.2d 1739 at 1742 ("Of the issues above, all except issues Nos. 6-9 are essentially identical to the issues already considered in related Interference No. 102,096.") *See also* First Harlow Decl. ¶¶ 99-100, D.I. 494.

exercise of inventive skill." *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737 at 1739 (BPAI 1991) (emphasis added).

Having successfully argued that *in vivo* biological activity did not provide a patentable distinction over the EPO DNA sequence, Amgen cannot now say that *in vivo* biological activity can provide a patentable distinction over the rEPO of the '016 claim 10. In other words, *in vivo* biological activity cannot be made a patentable distinction of claims-in-suit over '016 claim 10, if it had not been a patentable distinction of the subject matter of the interferences involving the '178 and '179 application over the subject matter of the interference involving the '008 patent. Having won the interferences with its prior argument, Amgen cannot now take the opposite position, even if at different times over the last quarter century it had taken different positions.

Thus, by Amgen's own admissions, all the work done at Amgen encompassed in the '178 and '179 applications involved no inventive activity beyond isolating the gene sequence of the '008 patent. For the '016 claim 10 process to harvest the purified "recombinant erythropoietin from a mammalian cell culture supernatant fluid" there needs to have been the EPO gene to make the rEPO. Thus, one in possession of rEPO in accordance with '016 claim 10 requires no additional inventive activity, and needs only ordinary skill, to arrive at each of the claims-in-suit. First Harlow Decl. ¶¶ 99-100, D.I. 494.

Other examples of Amgen's prior arguments supporting Roche's position on obviousness-type double patenting are set forth in Roche Memorandum, pp. 7-13, D.I. 491, and First Harlow Decl. ¶¶ 87-100 and 105-121, D.I. 494.

Unless the Court accepts Amgen's suggestion that when it said one thing it meant the opposite (Amgen Opposition, p.1, D.I. 576.), these previous statements by Amgen confirm that whatever small difference there may be between the rEPO of the '016 claim and the rEPO of the claims-in-suit, such a difference must be an obvious, non-patentable difference.

V. CONCLUSION

As discussed above, the current case presents a classic example of obviousness-type double patenting, as Amgen has effectively extended the term of the ‘016 patent by obtaining the patents-in-suit without filing the appropriate terminal disclaimers.

As described above, Amgen’s attempt to avoid summary judgment on obviousness-type double patenting is filled with mischaracterizations of the law and attempts to obfuscate the facts. However, the law of obviousness-type double patenting, the public policy behind the doctrine of obviousness-type double patenting, and the facts of this case all support the termination of Amgen’s patent rights in rEPO with the expiration of the ‘016 patent in June 2005.

Based on the foregoing, Roche requests that its motion for obviousness-type double patenting over the Lai ‘016 patent (D.I. 490) be granted.

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Respectfully submitted,

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