**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| AMGEN INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LA ROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation,<br><br>Defendants. | Civil Action No.: 05-12237 WGY |

**AMGEN INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL RECONSIDERATION OF THE COURT'S AUGUST 27, 2007 ORDER REGARDING OBVIOUSNESS-TYPE DOUBLE PATENTING OF CLAIM 7 OF THE '349 PATENT**

## I. INTRODUCTION

Roche claims that the Court committed a "clear error of law" by granting summary judgment that Amgen's '349 patent claims are exempt under 35 U.S.C. § 121 from obviousness-type double patenting ("ODP") over the '008 patent claims.[1] But Roche's motion for reconsideration does not identify any new legal authorities that were not addressed in the parties' ODP summary judgment briefs; it simply asks the Court to apply the same law to the same file history to reach the opposite result. The Court was correct to reject Roche's flawed ODP analysis on summary judgment, and should do so again now by denying Roche's motion for reconsideration.

## II. ARGUMENT

### A. SECTION 121 APPLIES TO NEW AND AMENDED CLAIMS, PROVIDED CONSONANCE HAS BEEN MAINTAINED

Roche first contends that '349 claim 7 is not entitled to the benefit of § 121 because no claim with this exact wording existed at the time of the 1986 restriction requirement that required Amgen to prosecute Dr. Lin's multiple inventions in multiple patent applications.[2] This is wrong as a matter of law. The Federal Circuit held in *Symbol* that new or amended claims also are entitled to the benefit of § 121, provided they are consonant with the restriction requirement:

> The corollary to this Court's statement in *Gerber Garment* is that new or amended claims in a divisional application are entitled to the benefit of § 121 if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement.[3]

As other courts have explained, one reason for this rule is that "[i]t is almost inevitable that some

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[1] *See* Defendants' Mem. In Supp. of Its Mot. for Partial Reconsideration of the Court's August 27, 2007 Order Regarding Obviousness-Type Double Patenting of Claim 7 of the '349 Patent ("Roche Br.") (Docket Item ("D.I.") 910), at 2. Roche does not argue any other bases for reconsideration, such as an intervening change in the law, or the discovery of new evidence not previously available.

[2] *See id.* at 2-5.

refinement of the claims will occur after restriction is ordered, since restriction often comes as a preliminary step before the examiner reaches the merits of the patent claims."[4]

Amgen already explained in its opening summary judgment brief that the claims in the patents-in-suit are not identical to the original claims subject to the 1986 restriction requirement.[5] In that same brief, Amgen also explained the Federal Circuit's holding in *Symbol* that new and amended claims are entitled to the protection of § 121, provided consonance is maintained.[6] Roche did not contest this point in its summary judgment opposition brief.[7] Roche again ignored *Symbol* in its motion for reconsideration. Worse yet, Roche did not cite ***any*** case law to support its argument that § 121 does not apply to claims added after a restriction requirement. The only case cited in this section of Roche's brief, *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1348 (Fed. Cir. 2004), does not even address this issue. Thus, Roche's first argument for reconsideration falls well short of establishing that the Court committed a "clear error of law."

### B. AMGEN IS NOT ESTOPPED FROM ARGUING THAT § 121 APPLIES TO '349 CLAIM 7

Next, Roche contends that the Court committed a clear error of law because during prosecution of the '349 claims, Amgen avoided the possibility of a double patenting rejection by arguing the merits of ODP rather than the applicability of § 121. This quasi-judicial estoppel argument is factually and legally incorrect. Moreover, because Roche's argument is based on prosecution history evidence that was previously available but ignored by Roche in its summary

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[3] *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579 (Fed. Cir. 1991).

[4] *Union Carbide Corp. v. Dow Chem. Co.*, 619 F. Supp. 1036, 1060 (D. Del. 1985).

[5] *See* Memorandum In Support of Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 499), at 6.

[6] *See id.* at 12.

[7] D.I. 568.

judgment briefing, it is not a proper basis for reconsideration.[8]

Roche's argument is based on an interview summary by the patent examiner that states in its entirety:

> Exr. indicated that proposed claim 42 versions B and C would overcome 112 rejection and are free of Obviousness Type Double Patenting in connection with claims of US Pat No 4,703,008. Applicant intends to submit amended claims and to remedy minor informalities of claim 44.[9]

This interview summary does not say anything about what Amgen may have argued or "known" regarding ODP or § 121. Therefore, there is no factual support for Roche's contention that "Amgen did not invoke a Section 121 defense based on the 1986 restriction requirement."[10]

Moreover, even if Amgen had elected to stave off a potential ODP rejection by demonstrating the patentable distinctiveness of the claims rather that the applicability of § 121, that would not constitute an admission that § 121 does not apply. The law recognizes that a patent applicant may elect to press one successful argument to overcome a rejection without waiving or admitting that other arguments do not apply.[11] Thus, Roche's second argument for reconsideration also fails.

### C. THE COURT ALREADY HAS DETERMINED THAT THE '349 CLAIMS SATISFY THE CONSONANCE REQUIREMENT FOR § 121 PROTECTION

Third, Roche argues that '349 claim 7 does not satisfy the "consonance" requirement for

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[8] *See* Roche Br. (D.I. 910), at 1-2 (explaining that "a motion for reconsideration should be granted 'only when the movant demonstrates (1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error of law'") (quoting *Davis v. Lehane*, 89 F. Supp. 2d 142, 147 (D. Mass. 2000)).

[9] Roche Br. (D.I. 910), Ex. A.

[10] Roche Br. (D.I. 910), at 5.

[11] *See, e.g., Astra Aktiebolag v. Andrx Pharms.*, Inc., 222 F. Supp. 2d 423, 578 (S.D.N.Y. 2002) ("[T]he fact that Astra elected to make a successful argument about the failure of the documents to teach the invention of the European counterpart to the '505 and '230 patents and did not also contest their status as prior art does not constitute an admission by Astra that the documents are prior art. . . . It was certainly reasonable for Astra to choose to make only one of several alternative arguments available to it in those proceedings.").

§ 121 protection. This argument was the heart of Roche's opposition to Amgen's motion for summary judgment as to the '349 claims, and it was thoroughly briefed by both parties.[12] The Court even allowed Roche to submit an untimely declaration from its expert, Dr. Lowe, which stated new opinions regarding consonance for '349 claim 7 that were not disclosed in any of his expert reports or depositions.[13] With this complete record before it, the Court held that the '349 claims were consonant with the 1986 restriction requirement and that § 121 shielded the '349 claims from Roche's defense of ODP over the '008 claims.

Roche's motion for reconsideration does not dispute Amgen's articulation of the proper legal framework for assessing consonance. As stated in Amgen's summary judgment brief:

> The consonance requirement is satisfied if all claims in the patent fall within the scope of the non-elected restriction groups and "do not cross the line of demarcation drawn around the invention elected in the restriction requirement." *Symbol*, 935 F.2d at 1579. New or amended claims in the patent (i.e., claims not originally present in the application filed as a result of the restriction requirement) also are entitled to the protection of § 121, provided all claims in the patent satisfy the consonance requirement. *Id.* When assessing whether claims are consonant with a restriction requirement, the proper point of reference is the actual restriction groupings (i.e., the substance of the claims in each restriction group), not the examiner's written descriptions thereof. *See Texas Instruments Inc. v. ITC*, 988 F.2d 1165, 1179 (Fed. Cir. 1993).[14]

In granting Amgen's motion for summary judgment, it appears that the Court agreed with Amgen's legal approach to consonance and rejected Roche's approach, which incorrectly compared '349 claim 7 with claim 4 of the '698 patent rather than with the original claims subject to the 1986 restriction requirement.[15] Recognizing that its original consonance argument

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[12] *See, e.g.*, Roche's Opposition to Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 568), at 4-6, 11-12.

[13] *See* 7/18/07 Electronic Order Denying D.I. 612, Amgen Inc.'s Motion to Strike Untimely Expert Testimony Regarding Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting.

[14] *See* Memorandum In Support of Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 499), at 12.

[15] *See* Amgen's Reply Brief In Support of Its Motion for Summary Judgment of No

and expert evidence applied the wrong legal framework, Roche presents entirely new attorney argument in its motion for reconsideration. As a preliminary matter, Roche's new argument relies on evidence (the patents and file histories) that was previously available but ignored by Roche in its summary judgment briefing. Roche's new argument also lacks substantive merit.

Roche now contends that by amending the original cell claims in restriction Group IV to require exogenous promoter regions, Amgen transformed the "natural" vertebrate cells of Group IV, which did not require exogenous DNA, into recombinant "host cells" belonging to Group II. Since Group II was elected and prosecuted to issuance in the '008 patent, Roche contends that these amendments to the '349 claims broke consonance with the restriction requirement, thereby vitiating § 121 protection for the '349 claims over the '008 claims.[16] However, Roche's premise that the original Group IV cells did not include exogenous DNA is false. Those cells ***necessarily*** included exogenous DNA, because no "natural" vertebrate cells grown in culture can produce the high levels of EPO required by the original Group IV claims.[17] Roche's argument that the '349 cell claims are really Group II "host cell" claims because they require exogenous promoter regions is also incorrect, because the Group II claims do not require exogenous promoter regions. Moreover, unlike the Group II host cell claims, the original Group IV claims and the '349 patent claims do not require the cells to have been transformed or transfected with an isolated and purified ***EPO*** DNA.[18] Thus, the '349 claims are consonant with the original Group IV claims

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Obviousness-Type Double Patenting (D.I. 676), at 8-10 (explaining the legal error in Roche's consonance analysis).

[16] *See* Roche Br. (D.I. 910), at 5-7.

[17] *E.g.*, Original claim 42, assigned to Group IV, required: "Vertebrate cells which can be propagated *in vitro* continuously and which upon growth in culture are ***capable of producing in the medium of their growth in excess of 100 U of erythropoietin per $10^6$ cells in 48 hours as determined by radioimmunoassay***." D.I. 502, Ex. D-3 (emphasis added)

[18] *See also* Lodish Decl. In Support of Amgen's Mot. for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 502), at 11-12 (performing legally proper consonance analysis and opining that the '349 claims fall within restriction Group IV, not Group II).

and patentably distinct from the Group II claims.

### D. ROCHE, NOT AMGEN, MISREPRESENTS THE *SYMBOL* CASE

Roche contends that Amgen misrepresented *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991), by providing the following citation as part of its response to Roche's argument that '349 claim 7 (a process claim) is not consonant with the original Group IV claims, which were not process claims: "*Cf. Symbol Techs.*, 935 F.2d at 1580 (rejecting defendant's argument that consonance was destroyed by the addition of "apparatus" claims where the corresponding restriction group contained "method" claims and was described as a "method" in the restriction requirement)."[19] Roche's accusation is ridiculous.

First, although *Symbol* was an electronic arts case, the Court did not "explicitly limit[ ]" the above-cited proposition to the electronic arts, as Roche contends. Second, Amgen never represented that *Symbol* was a chemical arts case. Third, *Symbol* does not stand for, or even acknowledge, Roche's proposition that, in the chemical arts, consonance is destroyed by the addition of a process claim where the restriction group contained only composition claims. Nor does the *Studiengesellschaft* case, cited in *Symbol*. The cited portion of *Studiengesellschaft* holds that there is no ***same invention double patenting*** where two patents claim different statutory classes of subject matter; the cited section does not address ***obviousness-type double patenting*** or the consonance requirement for § 121 protection.[20] Moreover, elsewhere in *Studiengesellschaft*, the Court held that § 121 applied.[21] Thus, Roche is the one misreading the case law.

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[19] *See* Amgen's Reply Brief In Support of Its Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 676), at 10.

[20] *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 354-55 (Fed. Cir. 1986).

[21] *Id.* at 355-56.

### E. ROCHE FAILED TO RAISE ANY GENUINE ISSUE OF MATERIAL FACT

Lastly, Roche argues that the untimely declaration from its expert, Dr. Lowe, raised a genuine issue of material fact sufficient to preclude summary judgment. As explained in Amgen's summary judgment reply brief, however, Dr. Lowe's consonance analysis was legally flawed and insufficient to avoid summary judgment:

> . . . . But even if Dr. Lowe's opinions had been disclosed during discovery, they would be insufficient to avoid summary judgment because Dr. Lowe applied the wrong legal framework in his consonance analysis. The consonance of an issued claim is properly determined by comparing the claim to the original restriction groupings (*i.e.*, the original claims assigned to each restriction group by the PTO). *Texas Instruments*, 988 F.2d at 1179. Instead of comparing '349 claim 7 to the original claims in the 1986 restriction requirement, however, Dr. Lowe assessed consonance by comparing '349 claim 7 with claim 4 of the '698 patent, which issued in 1997. (D.I. 571, ¶¶ 20-21.) Roche repeated this error in its brief. (D.I. 568, at 5-6, 12.)
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> It is not surprising that Roche avoids any comparison of '349 claim 7 to the original claims in the 1986 restriction requirement, because '349 claim 7 is significantly different from the original Group II claims. Unlike the Group II claims, all of which require either a DNA sequence encoding EPO or cells transformed or transfected with a DNA sequence encoding EPO, the original Group IV claims and '349 Claim 7 impose no such requirement. Instead, the Group IV claims require vertebrate cells that, when propagated *in vitro*, are capable of producing recited levels of erythropoietin. There is no requirement that the cells encompassed within Group IV be transformed or transfected with a DNA encoding EPO. The Group IV invention resides in the use of vertebrate cells capable of producing certain recited levels of EPO, however made, not in the insertion of a DNA sequence encoding EPO. Just like the original Group IV claims, the '349 patent claims vertebrate cells capable upon growth in culture of producing certain levels of EPO over time. Nothing in '349 claim 7 (or any other '349 claim) requires cells that are transformed or transfected with a DNA encoding EPO. (*See* D.I. 502, Ex. C.)[22]

As explained in Amgen's summary judgment briefing, the applicability of § 121 is a question of law,[23] and is frequently decided on summary judgment.[24] The Court was correct to grant

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[22] *See* Amgen's Reply Brief In Support of Its Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 676), at 9.

[23] *In re Metoprolol Succinate Patent Litig.*, 2007 U.S. App. LEXIS 17463, at *10-11 (Fed. Cir. July 23, 2007); *Bristol-Myers Squibb*, 361 F.3d at 1348 n.1 (Fed. Cir. 2004).

summary judgment in this case.

## III. CONCLUSION

Roche has failed to demonstrate any legal error in the Court's holding that § 121 shields the '349 patent claims from ODP over the '008 patent claims. The Court should deny Roche's motion for reconsideration (D.I. 908).

[24] *See, e.g.*, *Gerber Garment tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 685 (Fed. Cir. 1990); *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, No. 01-cv-3751, 2002 U.S. Dist. LEXIS 27230 (D.N.J. July 25, 2002); *Union Carbide*, 619 F. Supp. at 1055-60.

Respectfully Submitted,

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