UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

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I. INTRODUCTION

In their First Amended Answer and Counterclaims, dated March 30, 2007, Defendants (collectively "Roche") allege that Amgen committed inequitable conduct in the prosecution of the patents-in-suit in three ways:

(1) That Amgen failed to disclose information purporting to show similarities between recombinant human erythropoietin ("r-EPO") and human urinary erythropoietin ("u-EPO");

(2) That Amgen, in overcoming a double patenting rejection during prosecution of the '179 application, made erroneous legal arguments and material omissions; and

(3) That, during the prosecution of the '178 and '179 Applications, Amgen failed to disclose the basis for the examiners' rejections of purportedly substantially similar claims in co-pending applications.[1]

Because Roche's alleged claims lack evidence of materiality and intent, summary judgment is properly granted in Amgen's favor.

In support of its first claim, Roche simply recycles old arguments that were long ago rejected by this Court and the Federal Circuit. To the extent that Roche raises anything not previously considered by the courts on this topic, it is either immaterial or merely cumulative of information already before the Patent Office. Roche's principal reliance on two declarations of Dr. Strickland, submitted in foreign proceedings, exemplifies the absence of any substance to its inequitable conduct case. Those declarations make *no* comparison between recombinant EPO and urinary EPO; rather, they report that Lin's recombinant EPO invalidated later claims by Genetics Institute. Moreover, the analyses of Amgen's recombinant EPO reported in Dr. Strickland's declarations were reported in other submissions to the Patent Office.

Roche's second claim rests on both a mischaracterization of arguments made by Amgen to the Patent Office and the erroneous premise that legal arguments constitute material information. In addition, Roche cites to nothing that could even be considered a mistake,

[1] *See* Docket #344, Defendant's First Amended Answer and Counterclaims to Plaintiff's Complaint ("Roche Amended Answer"), filed March 30, 2007, ¶¶ 43-88.

misrepresentation or omission in the arguments Amgen made to overcome a double-patenting rejection in the '179 application.

In its third claim, Roche argues that certain examiner rejections were not disclosed to other examiners handling co-pending applications. This argument ignores the fact, however, that no patent issued from these applications until after the interferences, when both applications were examined by the *same* examiner who issued all the patents-in-suit. All the references cited and the rejections made by previous examiners were clearly known to Examiner Martinell who allowed the claims having the entire files of all the Lin patents in front of him. Roche can show no materiality in any failing to cite one examiner's action to another.

Finally, Roche makes no showing of intent with respect to any of its three theories. Its allegations that Amgen intended to deceive the Patent Office are conclusory and are legally inadequate to sustain allegations of inequitable conduct.

As discussed below, there is no genuine issue of material fact as to Roche's defenses of inequitable conduct, and summary judgment should be entered in Amgen's favor.[2]

II. LEGAL STANDARD

In order to prove that a patent is unenforceable due to inequitable conduct, a party must show that the applicant (or his legal representative), with intent to mislead or deceive the Patent Office, failed to disclose to the Patent Office material, non-cumulative information known to the applicant (or his legal representatives) to be material, or submitted materially false information to the Patent Office in arguing for the patentability of a claim.[3] The party asserting inequitable

[2] This motion is directed to the entirety of the three claims of inequitable conduct that are alleged in Roche's Amended Answer. This Court recently denied Roche's attempt to file an untimely Second Amended Answer and Counterclaims, seeking to inject into this proceeding other allegations of inequitable conduct. Amgen opposed Roche's efforts to burden this case by adding numerous new allegations at the last minute, which would have afforded Amgen no opportunity to discover the bases for Roche's claims and would have compelled it to spend much of its post-discovery time, energy and resources, wrestling with a raft of new, substantive allegations. The conclusion was inescapable that Roche chose to mete out its claims of inequitable conduct, with the vast majority coming just as discovery closed.

[3] *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330-31 (Fed. Cir. 2004); 37 C.F.R. § 1.56.

conduct must prove threshold levels of both materiality and intent by clear and convincing evidence,[4] keeping in mind that an otherwise material reference is not material for the purposes of inequitable conduct if it is merely cumulative of information already before the Patent Office.[5]

Further, intent to deceive cannot be inferred solely from the fact that information was not disclosed—there must be a factual basis for a finding of deceptive intent.[6] Nor can intent to deceive be inferred from materiality, which is "a separate and essential component of inequitable conduct."[7] If the Court determines that both the threshold levels of materiality and intent were achieved, then the Court must balance materiality and intent, "with a greater showing of one factor allowing a lesser showing of the other."[8]

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."[9] Although the Court must draw all reasonable inferences in favor of the non-movant,[10] "a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial."[11]

To survive summary judgment, the party claiming inequitable conduct is required to adduce evidence from which a trier of fact could find both materiality and intent by clear and convincing evidence.[12]

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[4] *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984).

[5] *Molins PLC*, 48 F.3d at 1179 (citing *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991)).

[6] *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996) (quoting *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988).

[7] *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir.1990); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 439 F.3d 1335, 1340-41 (Fed. Cir. 2006).

[8] *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001).

[9] Fed. Rule of Civ. Proc. 56(c).

[10] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

[11] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

[12] *Abbott Laboratories v. Torpharm, Inc.*, 300 F.3d 1367, 1379 (Fed. Cir. 2002).

Finally, inequitable conduct claims must be pled with particularity as required by Rule 9(b).[13] To comply with Rule 9(b), a plea of inequitable conduct must at least identify with particularity facts showing the materiality of the alleged omissions.[14]

III. ROCHE CANNOT SHOW THAT AMGEN WITHHELD MATERIAL INFORMATION PURPORTING TO SHOW SIMILARITIES BETWEEN R-EPO AND U-EPO WITH AN INTENT TO DECEIVE THE PATENT OFFICE.

Roche argues that Amgen obtained allowance of the '933 patent by withholding information allegedly inconsistent with Amgen's representations to the Patent Office that r-EPO differed from natural u-EPO with respect to molecular weight and glycosylation.[15] Roche utterly fails, however, to show any of the requirements necessary for a claim of inequitable conduct.

A. Roche Cannot Show That Any Material, Non-Cumulative Information Concerning Any Similarities Between r-EPO and u-EPO Was Withheld From The Patent Office.

Roche has the burden of proving by clear and convincing evidence that Amgen withheld material and non-cumulative information relating to similarities between r-EPO and u-EPO. Roche's burden is particularly high here because this issue has been previously examined in depth by this Court, the Federal Circuit and the Patent Office. The references and statements relied upon by Roche were either disclosed to the Patent Office or were cumulative of information that was disclosed. Roche recognizes that most of its arguments have already been rejected by this Court, because it focuses heavily on two declarations of Dr. Strickland,[16] noting that they have "*never been previously considered by this or any U.S. Court*."[17] The Strickland Declarations, however, only report analyses of Amgen's recombinant EPO that 1) do not

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[13] *Cent. Admixture Pharm. Servs. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007).

[14] *Reid-Ashman Mfg. v. Swanson Semiconductor Serv., L.L.C.*, 2007 U.S. Dist. LEXIS 37665, at 19 (N.D. Cal. May 10, 2007) (A claim of inequitable conduct is not particularly pled if it "failed to identify with particularity facts showing that the alleged omissions were material or that [applicant's omission was done with intent to deceive."); *Energy Absorption Systems, Inc. v. Roadway Safety Service Inc.*, 1993 U.S. Dist. LEXIS 13731, at 6 (E.D. Ill. Sept. 16, 1993).

[15] Roche Amended Answer, ¶¶ 74-88.

[16] Exh. 5 (2/13/1992 Declaration of Thomas A. Strickland) ("1992 Strickland Declaration"); Exh. 6 (5/19/1994 Declaration of Thomas A. Strickland) ("1994 Strickland Declaration").

contradict any statement by Amgen and 2) were disclosed to the Patent Office via the submission of other references.

Roche alleges that the two Strickland Declarations, submitted in foreign patent proceedings against Genetics Institute's patents, contradicted positions in an earlier declaration that Dr. Strickland submitted in the U.S. Lin prosecution. But in attempting to establish the materiality of the Strickland Declarations, Roche badly misstates their contents and ignores the fact that the information contained in them was disclosed to the Patent Office. Both of the Strickland Declarations report on analyses of CHO-cell produced r-EPO of the Lin patent (*e.g.*, O-linked glycosylation and monosaccharide data). The declarations were used to prove that G.I.'s later claims to methods of making r-EPO that have O-linked glycosylation and specific monosaccharide composition were invalid for lacking novelty based on the prior sale of CHO-cell produced r-EPO (more specifically prior sale of r-EPO produced in accordance with Lin's Example 10) that had these attributes. The data on CHO-cell produced r-EPO, however, is reported in several other references that were submitted to and discussed by the Patent Office.[18] For example, Amgen's PLA, the Cummings Declaration and the attached Browne 1986 Publication concerned O-linked glycosylation.[19] Additionally, Takeuchi *et al.*[20] and Sasaki *et al.*[21] discuss monosaccharide data. This discussion was disclosed during the '096, '097, and '334 Interferences,[22] as acknowledged by this Court.[23] Beyond that, Examiner Martinell

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[17] Roche Amended Answer, ¶ 77 (emphasis in original).

[18] Exh. 33 (8/16/1994 Office Action, '933 Patent), at p. 4.

[19] Exh. 4 (PLA), at p. 889; Exh. 14 (Cummings Declaration), at pp. 17-18; Exh. 3 (Browne 1986 Publication), at p. 698.

[20] Exh. 34 (Takeuchi, *et al., Comparative Study of the Asparagine-linked Sugar Chains of Human Erythropoietins Purified from Urine and the Culture Medium of Recombinant Chinese Hamster Ovary Cells*, J. Biol. Chem. 263(8) (1988) ("Takeuchi *et al.*"), at 3657, 3659-60.

[21] Exh. 40 (Sasaki, *et al., Carbohydrate Structure of Erythropoietin Expressed in Chinese Hamster Ovary Cells by a Human Erythropoietin cDNA*, J. Biol. Chem. 262, 12059-76 (1987) ("Sasaki *et al.*").

[22] Exh. 36 (Fritsch's Proposed Findings of Fact and Law, '096, '097, and '334 Interferences), at p. 222; Exh. 37 (4/5/1990 Declaration of Thomas A. Strickland, '334 Interference), at p. 6; and Exh. 38 (Lin's Brief, '334 Interference), at p. 46.

described Takeuchi *et al.* as being part of the "record" in his examination of the '933 Patent.[24]

Not only was the information in the Strickland Declarations already before the Patent Office, the information was not material in any manner that Roche now suggests. Roche characterizes the 1992 Strickland Declaration as showing that Lin's r-EPO "was chemically identical to u-EPO" when in fact Strickland's Declaration says nothing about u-EPO and reports no analyses of u-EPO.[25] The only connection that Roche attempts to make to argue materiality of information in the 1992 Strickland Declaration is that G.I.'s '678 patent describes r-EPO as identical to u-EPO. This was certainly not an Amgen statement or position. Moreover, the G.I. '678 patent disclosure is the same G.I. patent disclosure that was at issue in the three interferences, so G.I.'s position was certainly known to the Patent Office.

Roche's attempt to find materiality of the 1994 Strickland declaration also fails. The only thread of relevancy Roche attempts to hang on to is that Strickland reported in his declaration that Lin's EPO showed a molecular weight of "about 34,000 daltons, the same as that of u-EPO as reported at Col. 5, line 48 of the '933 patent, and not higher, as reported in Example 10."[26] But the fact that Lin's r-EPO had been measured to have an apparent molecular weight of about 34,000 daltons on SDS-PAGE was well known long before Dr. Strickland's 1994 declaration. Roche itself cites to the Lin PNAS Publication as reporting that r-EPO has an apparent molecular weight of 34,000,[27] and the Lin PNAS Publication was submitted to the Patent Office as shown on the face of the '933 Patent.[28] Moreover, the issue of the molecular

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[23] *See Amgen*, 126 F.Supp.2d at 144-145.

[24] Exh. 33 (8/16/1994 Office Action, '933 Patent), at p. 4 ("The ***record*** has evidence in it which indicates that the amount of glycosylation of EPO is variable. For example: … Takeuchi *et al.*…").

[25] Roche Amended Answer, ¶ 81.

[26] Roche Amended Answer, ¶ 82.

[27] Roche Amended Answer, ¶ 85.

[28] '933 Patent, at p. 6; *see also*, Exh. 2 (Egrie Input file), at p. 17 ("Recombinant monkey and human EPO produced by COS cells have the same molecular weight as native urinary EPO (Goldwasser's EPO); Exh. 3 (Browne Publication), at p. 696.

weight of Lin's r-EPO was litigated in the first Amgen litigation in this Court. G.I. had a patent, the Hewick patent, that claimed a homogeneous EPO composition having a molecular weight of "about 34,000 daltons on SDS-PAGE." As this Court found, Lin's recombinant EPO had such a molecular weight and was held to infringe this claim.[29] The Federal Circuit later held the Hewick patent invalid and that decision was submitted to the Patent Office.[30]

Under the heading of "Additional Contradictory Statements," Roche asserts that Amgen withheld six references and documents that contained data that "directly contradict positions Amgen has taken before the Patent Office:"[31] 1) the pending litigation against TKT, 2) the Lin PNAS Publication,[32] 3) the Egrie 1986 Publication,[33] 4) the Egrie Input file,[34] 5) the Browne 1986 Publication,[35] and 6) Amgen's PLA submitted to the FDA.[36] The Lin PNAS Publication is listed on the face of the '933 Patent as a reference disclosed to the Patent Office. The other five references were at issue in the HMR/TKT litigation and this Court held that the references or their information were disclosed to the Patent Office.[37]

Roche adds nothing new to the allegations litigated and decided in the HMR/TKT litigation. As this court found, the existence of the then-pending HMR/TKT litigation was

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[29] *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 706 F.Supp. 94, 100-103 (D. Mass. 1989).

[30] *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1215-18 (Fed. Cir. 1991).

[31] Roche Amended Answer, ¶¶ 84-88.

[32] Exh. 39 (Lin *et al.*, *Cloning and Expression of the Human Erythropoietin Gene*, 82 Proc. Nat'l Acad. Sci., 7580, 7582 (1985)) ("Lin PNAS Publication").

[33] Exh. 1 (Egrie, *et al.*, 1986 Characterization and Biological Effects of Recombinant Human Erythropoietin, Immunobiol., vol 172, pp. 213-224 (1986)) ("Egrie 1986 Publication").

[34] Exh. 2 (pages from the lab notebook of Dr. Joan Egrie describing tests she conducted on COS-1 produced r-EPO and Dr. Goldwasser's human u-EPO) ("Egrie Input file"). This exhibit includes the pages referenced by Roche at ¶ 87 of its First Amended Complaint.

[35] Exh. 3, Browne, *et al.*, "Erythropoietin: Gene Cloning, Protein Structure, and Biological Properties," *Cold Spring Harbor Symposia on Quantitative Biology*, vol. L1, pp. 693-702 (1986) ("Browne 1986 Publication").

[36] Exh. 4, Product License Application ("PLA").

[37] *Amgen Inc. v. Hoechst Marion Russell, Inc.*, 126 F.Supp.2d 69, 141 (Fed. Cir. 2001). *See also* Exh. 13 (2/16/1995 Amendment, '874 application) and Exh. 14 (1/16/1994 Declaration of Richard Cummings) for disclosure of Browne (1986), Sasaki (1987) and Takeuchi (1988).

disclosed to the Patent Office by letter the day after the lawsuit was filed.[38] Additionally, while the '349 and '422 patents were still pending, the HMR/TKT litigation disclosed nothing that was material to the examination of the claims of these patents and Roche has cited to nothing.

Also thoroughly litigated in the HMR/TKT litigation was the issue of the SDS-PAGE gels in the Amgen notebooks and publications. Roche cites to the same Egrie 1986 Publication, the Egrie Input file and the Browne 1986 Publication relied on by HMR/TKT as referring to the "identical migration" of r-EPO and u-EPO on SDS-PAGE gels as contradicting the data in Example 10 of the Lin patent. But as this Court found in HMR/TKT, all this information was disclosed to the Patent Office directly in prosecution or in the interference proceedings reviewed by the examiner.[39] Significantly, the Board of Patent Appeals and Interferences also reviewed this same data as argued by Genetics Institute and held that none of the data in the Egrie 1986 Publication, the Egrie Input file or the Amgen PLA contradicted Amgen's position that the carbohydrate composition of r-EPO differed from that of u-EPO. In fact, as the Board found, there was much evidence in the record of the differences between recombinant and urinary

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[38] Exh. 15 (4/16/1997 Peterson Letter).

[39] *Amgen Inc. v. Hoechst Marion Russell, Inc*., 126 F.Supp.2d 69, 141-45 (Fed. Cir. 2001) ("*HMR/TKT*"). The Brown 1986 Publication, the Egrie 1986 Publication and a declaration of Joan Egrie describing her SDS-PAGE experiments and attaching relevant pages from her lab notebook (the Egrie Input file), and a comparison between CHO-produced EPO and various u-EPO products was submitted in the '334 Interference. Exh. 1 (Egrie 1986); Exh. 7 (Lin Notice, '096, '097, and '334 Interferences); Exh. 8-12 (Declaration of Joan Egrie and attachments); Exh. 31 (Notice Pursuant to 37 C.F.R. § 1.682(a) and offer of Official Record from Civil Action No. 87-2617-Y Regarding Testimony of Egrie and Attachments '096, '097, and '339 Interference. The '933 Patent's examiner (Fitzgerald) noted in the '933 Patent's prosecution history that he had reviewed the '334 interference record and opinion, thus confirming that the Egrie 1986 Publication and the Egrie Input file were before the Patent Office during the '933 Patent's prosecution. Exh. 32. This Court has previously so ruled. *Amgen*, 126 F.Supp.2d at 139 ("…the prosecution history demonstrates that the Examiner reviewed and considered the Interference decision and record. After resolution of the Interference proceedings, Examiner David L. Fitzgerald recorded on the file wrapper of the application that led to both the '933 and '080 patents, that ***he had received and, for a two-month period, reviewed the Interference record and decision***….Subsequent notations indicate that ***the Examining Division understood the import of the Interference proceedings.***" (emphasis supplied)). The Browne 1986 Publication, which describes r-EPO and u-EPO as being glycosylated to a similar extent and references the similar molecular weight of r-EPO and u-EPO, was also disclosed in an amendment to the '874 application as an attachment to the Cummings Declaration (which was included with the amendment). Exh. 13 (2/16/1995 Amendment, '874 application); Exh. 14 (1/6/1994 Declaration of Richard Cummings); and Exh. 3 (Browne 1986 Publication).

EPO.[40]

As this Court succinctly stated in its HMR/TKT decision:

> ***In light of the disclosures made directly to the Patent Office as well as those made indirectly through the Interference record, it is hard to believe that the Examiner was somehow left in the dark about the glycosylation differences dispute.*** Amgen presented significant data to the Examiner suggesting glycosylation differences and also disclosed apparently conflicting data. What more can Amgen fairly be expected to do? At some point, the applicant must be permitted the opportunity to argue that some data is more worthy of reliance than other data. Instead, TKT implies that Amgen should have stood by less reliable and incomplete data rather than data obtained from both glycosylated and deglycosylated EPOs. This expectation is unreasonable.
>
> ***Thus, the Court finds that Amgen complied with its duty of candor with respect to data regarding glycosylation differences.***[41]

B. Roche Cannot Show That Amgen Intended To Deceive The Patent Office By Allegedly Withholding Information Purporting to Show Similarities Between r-EPO and u-EPO.

In an effort to show that Amgen intended to deceive the Patent Office, Roche suggests that Amgen suppressed information regarding similarities between r-EPO and u-EPO because it was allegedly inconsistent with Amgen's representations in the specification. To the contrary, however, the Interference Board held that the Egrie Input file (and the other references relied upon by Roche that disclose information relating to the relative migration of r-EPO and u-EPO on SDS-PAGE gels and their similar molecular weights) was "not sufficient to contradict the information disclosed [in] the Lin application,"[42] and this Court found similarly in its HMR/TKT decision: "Contrary to TKT's contentions, then, data in the Egrie Input file is actually consistent (or at least not inconsistent) with Amgen's representations in the patent specification."[43]

During the interference, Dr. Fritsch argued that information from Dr. Egrie's experiments was inconsistent with Dr. Lin's disclosure and contained information important to a reasonable

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[40] *Fritsch v. Lin*, 21 U.S.P.Q.2d 1739, 1741-42 (BPAI 1992).

[41] *Amgen*, 126 F.Supp.2d at 145-46 (emphasis added).

[42] *Fritsch v. Lin*, 21 U.S.P.Q.2d 1739, 1742 (BPAI 1991).

[43] *Amgen*, 126 F.Supp.2d at 144.

examiner.[44] Amgen countered that the information from Dr. Egrie's experiments was not inconsistent with Dr. Lin's disclosure,[45] a position with which the Interference Board agreed.[46] Not only was this information disclosed to the Patent Office, it were also used to argue unpatentability on the same grounds Roche now urges would have been shown during subsequent prosecution. Having already litigated the issue, it simply cannot be said that Amgen later intended to deceive the Patent Office by withholding the same information. Indeed, in its HMR/TKT decision, this court found that Amgen did not intend to deceive the Patent Office,[47] a finding that was affirmed by the Federal Circuit:

> The district court found that TKT had not proven inequitable conduct by clear and convincing evidence, and we have not been persuaded on appeal that a contrary result is compelled. In reaching this conclusion, we need look no further than the district court's determination that TKT's case was doomed because it was ***bereft of evidence of intentional deception***:
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> > ... TKT has failed to prove by clear and convincing evidence that this [experimental] data was material or that it was withheld with intent to deceive...[48]

Roche brings nothing but empty allegations that have been previously reviewed and dismissed by this Court and the Federal Circuit.

IV. ROCHE CANNOT SHOW THAT, IN ARGUING TO OVERCOME A DOUBLE PATENTING REJECTION IN THE '179 APPLICATION, AMGEN MADE ERRONEOUS LEGAL ARGUMENTS OR OMITTED MATERIAL FACTS WITH THE INTENT TO DECEIVE THE PATENT OFFICE.

A. Legal Arguments Do Not Constitute Material Information

Roche alleges in its second inequitable conduct claim that Amgen, in the context of

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[44] Exh. 16 (Fritsch Reply Brief, '334 Interference), p. 36 ("The r-EPO sample migrated ***identically*** with the u-EPO samples…" (emphasis in original)); Exh. 17 (Lin Opposition, '334 Interference) at p. 5 (Fritch points to statements by Egrie and Browne wherein they characterize u-EPO and rEPO as being "very similar" or "essentially the same.").

[45] Exh. 17 (Lin Opposition, '334 Interference) at p. 5 ("However, this does not mean that the two EPOs are ***identical***." (emphasis in original)).

[46] *Fritsch v. Lin*, 21 U.S.P.Q.2d at 1742.

[47] *Amgen*, 126 F.Supp.2d at 145.

[48] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) (quoting

arguing to overcome an obviousness type double patenting rejection in the '179 application, intentionally made various erroneous legal arguments

As discussed below, Amgen's legal arguments were correct. But beyond that, legal arguments to the Patent Office cannot form the basis of an inequitable conduct claim.[49] In *Akzo* the defendants claimed that the applicant committed inequitable conduct by arguing that his invention was not anticipated by two prior art references. The Federal Circuit rejected defendants' inequitable conduct claim, ruling that:

> We uphold the Commission's findings and conclusion that Du Pont's affidavit or ***arguments before the examiner did not constitute material misrepresentations***. As Akzo concedes, the examiner had both the Morgan '645 patent and the Kwolek '542 patents before him throughout the examination process. It was on the basis of these two patents that Du Pont's first three applications were rejected. ***The mere fact that Du Pont attempted to distinguish the Blades process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the Blades process based on the art in front of him.***[50]

First, Roche argues that Amgen's statement, "There has thus been a judicial determination that rights in the subject matter of '008 patent claims do not extend to the subject matter of the process claims herein ....,"[51] somehow misled the examiner that the Federal Circuit had determined that the '008 product claims were patentably distinct from the process claims of the '179 application.[52] That argument fails because Amgen in fact correctly reported to the examiner that the Federal Circuit had determined that the claims of the '008 patent were not process claims within the meaning of 19 USC § 1337, the jurisdictional statute for the

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Amgen, 126 F.Supp.2d at 145) (emphasis added).

[49] *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1481 (Fed. Cir. 1986); *Environ Prods., Inc. v. Total Containment, Inc.*, 951 F. Supp. 57, 61 (E.D. Pa. 1996); *see also Purdue Pharma L.P. v. Boehringer Ingelheim GmBH*, 98 F.Supp.2d 362, 393 (S.D.N.Y. 2000).

[50] *Akzo*, 808 F.2d at 1482. *See also, Environ Prods.*, 951 F. Supp. at 61 ("There is no policy reason which would support the unprecedented expansion of the interpretation of 'material information' to include legal arguments.").

[51] Exh. 18 (10/7/1994 Amendment, '179 Application), at p. 7.

[52] *See* Roche Amended Answer, ¶ 45.

International Trade Commission. As the Court may recall, Amgen brought an action in 1988 in the ITC attempting to enforce the '008 patent against Chugai's importation of r-EPO into the U.S. While the ITC found the Amgen patent claims valid and covering the DNA, the ITC held that it did not have jurisdiction because the claims of the '008 patent were not process claims. In that regard, the Federal Circuit stated: "A host cell claim does not 'cover' intracellular processes any more than or less than a claim to a machine 'covers' the process performed by that machine."[53] Amgen's statement is a correct paraphrase of the Federal Circuit ruling.

In addition, Amgen's characterization of a Federal Circuit opinion is obviously legal argument and thus, as discussed above, is not material. In fact, in the context of expressing its legal position, Amgen provided the Federal Circuit's decision to the examiner,[54] who was certainly capable of reading the Federal Circuit case and making his own determination as to its scope, content and meaning. Amgen's legal argument concerning that decision was not material.

Second, Roche alleges that Amgen misrepresented to the examiner of the '179 application that it had been the position of the the Patent Office that the DNA and process claims were patentably distinct. In fact, Amgen correctly characterized the Patent Office's position. The fact that the Patent Office had instituted two counts, one for the DNA claims and one for the process claims, reflects its conclusion that the two sets of claims were patentably distinct.[55] Indeed, the Patent Office itself had explicitly recognized the patentably distinct quality of the DNA and process claims:

> More particularly, Interference No. 102,096 involves a host cell and a DNA sequence encoding EPO. Interference No. 102,097 involves a method of using the host cell to make r-EPO. The new interference will involve r-EPO. While the subject matter of the three interferences is ***deemed to be patentably distinct***, the subject

[53] *ITC Case*, 902 F.2d at 1538.

[54] Exh. 18 (10/7/1994 Amendment, '179 application) (emphasis added).

[55] The Patent Office operates under the following rule: "A 'count' defines the interfering subject matter between (1) two or more applications or (2) one or more applications and one or more patents. When there is more than one count, each count shall define a ***separate patentable invention***." 37 C.F.R. 1.601(f) (1994) (emphasis added).

matter is nevertheless related.[56]

Beyond that, Amgen's statement with respect to the Patent Office position was legal argument. Amgen specifically noted to the examiner that "separate interferences were drawn for the DNA-related subject matter of U.S. 4,703,008 and the production process subject matter claimed herein,"[57] and then stated: "It has thus been the position of the Patent and Trademark Office that the production process subject matter claimed herein was patentably distinct from the DNA-related subject matter claimed in U.S. 4,703,008."[58] Information concerning the separate interferences was before the examiner, who was capable of assessing the merits of Amgen's legal arguments for himself. For the reasons discussed above, such legal arguments are not, as a matter of law, material for inequitable conduct purposes.

Third, Roche argues that Amgen "misstated the law" by allegedly arguing that it was inappropriate to consider prior art in conjunction with the claims of the '008 Patent in assessing whether the pending claims of the '179 application were obvious.[59] Roche, however, mischaracterizes this statement. As the following statement of the examiner makes plain, Amgen was responding to an Office Action in which the examiner incorrectly used the prior art—the general method disclosed in Yokota—as the starting point of his obviousness-type double patenting analysis rather than the proper starting point required by the law—in this case, the claims of the Lin '008 patent:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art ***to modify the method of Yokota et al.*** by substituting the instant erythropoietin encoding DNA for the DNA encoding GM-CSF.[60]

Thus, Amgen was correct in pointing out the examiner's failure to properly apply the

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[56] Exh. 20 (2/9/1990 Office Action, '178 application), p. 2 (emphasis added).

[57] *Id.*,at 443.

[58] Roche Amended Answer, ¶¶ 46-48.

[59] Roche Amended Answer, ¶ 50.

[60] Exh. 30 (8/11/1994 Office Action, '179 Application), p.2 (emphasis added).

obviousness-type double patenting test.[61] In any event, Roche acknowledges that its claim is based on Amgen's legal argument, the merits of which the examiner was capable of assessing for himself. As discussed above, legal arguments cannot be the basis for inequitable conduct.

As with the other claims of inequitable conduct, Roche cannot demonstrate deceptive intent on Amgen's part. Roche's argument that intent is reflected by the nature of Amgen's legal arguments and characterizations is insufficient. As the Federal Circuit said, a case that is "bereft of evidence of intentional deception" is "doomed." [62]

B. The Omissions Alleged by Roche Were Not Material.

Roche alleges that Amgen failed to inform the examiner that it had made statements during the '097 interference that Roche alleges were inconsistent with statements it made during the '179 application's prosecution.[63] In particular, Roche points to a passage in Amgen's brief in the '097 Interference that "it is evident that [the subject matter of the Count in the '097 Interference and the subject matter of the litigation directed to the DNA claims] are only different manifestations of the same invention as acknowledged by Fritch et al in the Motion Q herein (and Motion G in Interference No. 102,096)."[64] Roche seeks to use that statement, which Amgen made in the context of a priority argument, to suggest that Amgen was claiming during the Interference that the DNA and process claims were not patentably distinct.

Roche's allegation makes no sense, given that Amgen made clear during that same Interference that it ***rejected*** the notion that the DNA and process claims were the same invention. In fact, the "manifestation of the same invention" phrase was language used by G.I.'s Fritch in the context of moving to combine the two interferences. In its Opposition G to that motion, Amgen, after quoting Fritch's position, stated:

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[61] *In re Zickendraht*, 50 C.C.P.A. 1529, 319 F.2d 225, 232, 138 U.S.P.Q. (BNA) 22, 27 (1963)

[62] *Amgen*, 314 F.3d at 1357 (quoting *Amgen*, 126 F. Supp. 2d at 145).

[63] Roche Amended Answer, ¶¶ 47-53.

[64] Roche Amended Complaint, para 47; *See*, Exh. 21, (Lin Opposition G, '096 and '097 Interference), p. 26.

> Since Fritsch does not even attempt to supply any argument or evidence in support of the bare allegation of "same invention," it is apparent that it was not a serious contention. Suffice it to say that Lin contends that the two counts are ***not*** to the "same invention."[65]

Roche ignores that express position by Amgen, and instead seeks to find inconsistency by contorting an argument made in a legal brief having nothing to do with whether the claims were patentably distinct. Rather, Amgen's priority argument referred to district court and Federal Circuit findings regarding the fact that, as between Fritsch and Lin, Dr. Lin was the first to clone the DNA encoding EPO as well as the first to use a process to produce *in vivo* biologically active EPO.[66] When Amgen actually addressed the issue of obviousness (as opposed to priority) during the '097 interference, it expressly stated:

> Furthermore, it was not obvious that *in vivo* biologically active recombinant human EPO could be made by the claimed process. Until Lin obtained the sequence, Browne used it in expression and Egrie with Dukes found the product had *in vivo* biological activity, the process at best was only a wish." [67]

Roche's attempt to claim inequitable conduct by mischaracterizing attorney argument made in the context of priority of invention, to suggest that Amgen was advocating a position that is ***expressly rejected*** by the unambiguous arguments it actually made during the course of the Interference as well as the Patent Office's expressly stated position, does not create a genuine issue of material fact.

In addition, Roche claims that Amgen should have disclosed arguments it made in

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[65] Exh. 22 (Lin Opposition G, '096 and '097 Interferences), p. 81 (emphasis in original).

[66] *Amgen, Inc. v. Chugai Pharmacuetical Co.*, 13 USPQ2d 1737, 1759 (D. Mass. 1989), *aff'd* ., 927 F.2d 1200 (Fed. Cir. 1991).

[67] Exh. 21 (Lin's Brief, '097 Interference), at p. 56. Along the same lines, Roche also alleges failure to disclose arguments Amgen made in its motion to terminate the '097 interference. Roche Amended Complaint, ¶ 48. Just as with the first interference statement identified by Roche, Amgen's arguments were based on this Court's decision in *Amgen v. Chugai*. In resolving the issue of whether Amgen or Genetics Institute was first to invent the claims of the '008 patent, Magistrate Saris found not only that Dr. Lin was first to clone the gene for erythropoietin (a necessary material for reducing the process Count of the '097 Interference to practice), but also first to produce *in vivo* biologically active polypeptide using that gene sequence. *Amgen v. Chugai*, 13 USPQ2d at 1748-51. Again, Amgen's priority argument based on those findings was in no way inconsistent with Amgen's position of patentable distinctiveness during prosecution of the '179 application.

European proceedings involving G.I. and Kirin-Amgen patent claims that Roche says bear on whether the process and DNA claims were distinct.[68] Roche claims such arguments were material because they were inconsistent with unidentified Amgen arguments, allegedly made during the prosecution of the '179 application, but Roche points to nothing in particular.

Arguments Amgen made under European law were directed at demonstrating a lack of novelty of a G.I. patent. Such arguments, made in an entirely different context than that in which Roche seeks to use them here, and made in the context of foreign laws and regulations, are not relevant to U.S. prosecution.[69] More importantly, Roche improperly points to statements based on the specification of the European counterpart of Dr. Lin's U.S. patents. As a matter of law, the *specification* of Dr. Lin's patented inventions is not pertinent to whether the claims of the '179 application are obvious in light of the *claims* of the '008 patent.[70] Of course, what was only known *after* Dr. Lin's patented achievements is not relevant to obviousness-type double patenting. As a result, such information would not be important to a reasonable examiner in assessing patentability, and are thus not material.

Finally, Roche's allegations are devoid of proof of specific intent on Amgen's part to deceive the Patent Office, and fail for that reason as well.

V. ROCHE CANNOT SHOW THAT, DURING THE PROSECUTION OF THE '179 AND '178 APPLICATIONS, AMGEN WITHHELD THE BASIS FOR THE EXAMINERS' REJECTIONS OF SUBSTANTIALLY SIMILAR CLAIMS IN CO-PENDING APPLICATIONS WITH THE INTENT TO DECEIVE THE PATENT OFFICE.

Roche's third and last inequitable conduct claim in its Amended Answer alleges that Amgen intentionally withheld the fact of or bases for rejections of claims in the '179 application

[68] Roche Amended Answer, ¶ 49.

[69] *See, e.g., ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998) ("The details of foreign prosecution are not an additional category of material information.").

[70] *Gen. Foods. Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1281 (Fed. Cir. 1992) ("Our precedent makes clear that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims."); *In re Longi*, 759 F.2d 887, 892 n.4 (Fed. Cir. 1985); *In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986).

from the '178 application's examiner, and vice versa. Again, Roche cannot show that Amgen failed to disclose material information or that it intended to deceive the Patent Office.

A. Roche Cannot Show That Amgen Withheld The Fact Of Or Bases For The Examiner's Rejections To Substantially Similar Claims In Co-Pending Applications.

Relying on *Dayco Prods., Inc. v. Total Containment, Inc.*,[71] Roche contends that a rejection of claims in the '179 application which occurred in 1988 should have been disclosed during the prosecution of the '178 application line, and that rejections of claims in the '178 application that occurred in 1988 and 1989 should have been disclosed during the prosecution of the '179 application line.[72] Roche's argument, however, cannot survive summary judgment because, as discussed below, no patent issued on these applications until after they were brought together before the same examiner in 1994 who had before him the earlier rejections in both lines of application together with the references upon which the rejections were based, and who discussed both lines of applications with Amgen representatives during interviews *on the same day*.

Beginning at least in September 1994, a single examiner—Examiner Martinell—took charge of examining both the '178 and '179 application lines.[73] Although different examiners had previously been assigned to the applications, Examiner Martinell necessarily considered the actions (including rejections) of his predecessors in order to properly examine the '178 and '179 application lines.[74] As primary examiner of both the '933 and '422 Patents, Examiner Martinell was also required to have knowledge of the '178 and '179 applications' histories.[75]

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[71] 329 F.3d 1358, 1367-68 (Fed. Cir. 2003).

[72] Roche Amended Answer, ¶¶ 58-73.

[73] *See* Exh. 25 (9/7/1994 Interview Summary '178 Application); Exh. 26 (9/7/1994 Interview Summary, '179 Application).

[74] For example, examiners are instructed that "full faith and credit should be given to the search and *action* of the previous examiner" and "the second examiner should not take an entirely new approach to the application or attempt to reorient the point of view of the previous examiner." MPEP § 704.01 (8th ed. Rev. 5 Aug. 2006).

[75] MPEP §§ 609.02 and 904 (8th ed. Rev. 5, Aug. 2006). In addition, Examiner Martinell brought with him much institutional knowledge relative to Dr. Lin's EPO inventions because he

Examiner Martinell's knowledge of the interrelationship of the '178 and '179 application lines, as well as their prosecution histories, is evidenced, for example, by the personal interviews he conducted on September 7, 1994 with Amgen's representatives during which rejections in both application lines were discussed.[76] Plainly, contrary to Roche's allegations, Examiner Martinell was aware of the genesis, history, and interrelationship of the '178 and '179 application lines.

In any event, Roche's reliance upon *Dayco* is misplaced because the factual predicate on which the *Dayco* ruling is founded, does not exist in this case. While the Federal Circuit ruled in *Dayco* that the rejection of claims in one application (examined by one examiner) was material to the patent-in-suit (examined by another examiner) and should have been disclosed, the Federal Circuit relied on the following language from the Manual of Patent Examiner Procedure ("MPEP"): "…if an inventor has different applications pending in which similar subject matter but ***patentably indistinct*** claims are present that fact must be disclosed to the examiner of each of the involved applications."[77]

Dayco cannot apply here, because, as discussed in section IV.A, supra, the inventions in the '178 and '179 applications were determined *by the Patent Office* to be patentably distinct.[78] In addition, *Dayco* involved two different examiners on the relevant applications. Here, the applications were before the same examiner before issuance of either of the affected patents-in-suit.

The issue of disclosure in the context of co-pending applications was also discussed in a

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also played a role in examining the '024 Application, the application from which the '178 and '179 Applications stem. Exh. 27 (3/7/1985 International Search Report, '008 Patent).

[76] Exh. 25 (9/94 Interview Summary, '178 application), Exh. 26 (9/7/1994 Interview Summary, '179 application).

[77] MPEP § 2001.06(b) (emphasis added).

[78] Exh. 20 (2/9/1990 Office Action, '178 Application); Exh. 23 (6/16/1986 Office Action, '298 Application), at p. 3; *ITC Case*, 902 F.2d at 1538, '008 Patent; 37 C.F.R. 1.601(f). Additionally, Amgen terminally disclaimed any portion of the '422 Patent ('179 Application line) that overlapped with the '933 Patent (the '178 Application line). Exh. 24 (4/24/1999 Terminal Disclaimer, '422 Patent).

more recent case, *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, where although a single examiner was involved in two different pending applications (with a second examiner involved in a third co-pending application), that examiner was presumed not to have made a connection between the two lines of applications.[79] Here, by contrast to both of those cases, Examiner Martinell was the sole examiner on the two applications prior to the issuance of the patents, and he had before him the earlier rejections in both lines of application and knowledge of the interrelationship of the two, as evidenced by his interviews with attorneys for Amgen in both applications on the same day. *McKesson* is further distinguished because there a prior art reference uncovered by one examiner was not disclosed to the examiner of the other two applications. Here, all of the references in the '178 application were disclosed during the '179 application's prosecution, and vice versa.[80]

B. Roche Cannot Show That Amgen Intended To Deceive The Patent Office By Allegedly Withholding The Basis For The Examiner's Rejections To Substantially Similar Claims In Co-Pending Applications.

Roche must show by clear and convincing evidence that Amgen withheld information about rejections from co-pending applications with the intent to deceive the Patent Office. Rather than attempting to meet that burden, Roche improperly conflates intent to deceive with failure to disclose,[81] as though the latter proves the former. However, intent to deceive is a separate and independent element of an inequitable conduct claim, and must therefore be separately asserted and proven.[82]

Roche cannot show that Amgen intended to deceive the Patent Office. In *Dayco*, the Federal Circuit found no intent to deceive because, by disclosing the existence of one line of applications to the examiner in another line of applications, the applicant "put the Patent Office

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[79] 2007 WL 1452731, *20 (Fed. Cir. May 18, 2007).

[80] Exh. 28 (4/8/1994 IDS, '874 Application); Exh. 29 (1/3/1994 IDS, '179 Application).

[81] Roche Amended Answer, ¶ 57.

[82] *See Manville Sales*, 917 F.2d at 552 (describes intent as "a separate and essential component of inequitable conduct.").

on notice of the co-pendency of the two applications" which "points away from an intent to deceive."[83]

As discussed above, the co-pendency of the '178 and '179 application lines obviously was known to the single examiner handling those applications, and Amgen's participation in that process, including attendance in meetings with that examiner on both applications on the same day, is certainly inconsistent with any intent to deceive.

VI. CONCLUSION

For the forgoing reasons, Amgen respectfully requests that the Court grant summary judgment in Amgen's favor on the entirety of Roche's Seventh Affirmative Defense of Inequitable Conduct in Roche's March 30, 2007 First Amended Answer.

Respectfully Submitted,

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[83] *Dayco*, 239 F.3d at 1366 (quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1383-84 (Fed. Cir. 1988)).

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CERTIFICATE OF SERVICE

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

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