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 REPLY TO ROCHE'S OPPOSITION TO MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

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I. INTRODUCTION

In its opposition, Roche failed to raise any genuine issue of material fact with respect to the three allegations of inequitable conduct it pleaded in this case that would preclude the grant of Amgen's Motion for Summary Judgment. Instead, most of Roche's response is directed to trying to cover the inadequacies of the inequitable conduct case that it ***did*** plead in its March 30, 2007 First Amended Answer by asserting a number of unrelated, unsubstantiated allegations of inequitable conduct that it ***did not*** plead.[1]

Amgen properly ignored these other allegations and addressed its motion only to the three pleaded allegations of inequitable conduct — claims related to the issue of double patenting, the differences in molecular weight between rEPO and uEPO, and the rejections in co-pending applications. On these three issues, the prosecution history is clear that Amgen did not misrepresent or fail to disclose any material information, and summary judgment should be granted in its favor.

With respect to issue of the pleaded allegations related to double patenting, Roche fails to show any misrepresentation in Amgen's arguments to the PTO. Amgen correctly stated that the PTO Board of Interferences had previously determined that the subject matter of the process claims in the '179 application was patentably distinct from the DNA claims of the '008 patent. Amgen submitted and correctly described the holding of the Federal Circuit in the appeal of the ITC action as confirming the reality that Amgen did not have process patent claims in the '008 patent. Roche repeats its "same invention" argument and again ignores the fact that Amgen

[1] Roche filed its First Amended Answer on March 30, 2007, adding further detail to its inequitable conduct allegations in response to Amgen's motion to strike Roche's inequitable conduct defense from Roche's original Answer for failure to comply with Rule 9(b). *See* Docket No. 154 (Amgen's 11/27/06 Motion to Strike). On June 7, 2007, the Court properly denied Roche's motion to further amend its pleading to add more than a dozen additional theories of inequitable conduct. Now, Roche cites to the same additional, unpleaded theories as grounds for denying Amgen's motion for summary judgment. But these additional allegations add nothing to support the pleaded allegations, and should be disregarded for purposes of this motion.

plainly stated in the interference brief, the same brief Roche cites to for the "same invention" argument, that the process claims were patentably distinct (not obvious in view of) the DNA claims of the '008 patent. The "same invention" argument was not an admission of double patenting as Roche suggests, but rather Amgen using Fritsch's own argument against Fritsch on the determination of priority. In light of the district court's ruling (later affirmed by the Federal Circuit) that Fritsch had not even conceived of the DNA, Fritsch could not win as to priority on the process claims. Without any case citations to support its position, Roche further wrongly criticizes Amgen's correct statement of the double patenting analysis. Consequently, none of these allegations can legally support a finding of inequitable conduct and summary judgment should be granted.[2]

Concerning the differences in molecular weight between rEPO and uEPO, this Court has heard these allegations before. As this Court previously held, the Browne publication and the Egrie Input file showing gels with the conclusion that rEPO and uEPO migrated identically were disclosed to the PTO. The Interference Board examined all of these allegedly contradictory statements in response to GI's arguments that Amgen was not entitled to claims that recited a difference in glycosylation, and found these claims patentable. While Roche argues that it has "new" allegations of material information not disclosed to the examiner, as Amgen described in its motion, none of the references are material to the claimed products. Much of Roche's response on this issue attempts to bring in new arguments and references that were not pleaded in its First Amended Answer, and this attempt to circumvent the pleading requirement for inequitable conduct and the Court's order should be rejected.

[2] "Exh. ___" refers to exhibits attached to the Declaration of Craig H. Casebeer in Support of Amgen Inc.'s Memorandum in Support of Its Motion for Summary Judgment of No Inequitable Conduct. "Casebeer Reply Exh. ___" refers to exhibits attached to the Declaration Of Craig H. Casebeer In Support Of Amgen Inc.'s Memorandum In Reply To Roche's Opposition To Motion For Summary Judgment Of No Inequitable Conduct.

On Roche's third pleaded allegation, Roche completely ignores the fact that all of the patents-in-suit were issued by the same examiner – Examiner Martinell who was a senior examiner at the time and who was an examiner of one of the grandparent applications leading to the patents-in-suit. Instead, it argues that the rejections of the process claims would have been material to the examination of the product claims. Amgen disputes the materiality, but even if they were material, the rejections from both applications became known to the same examiner. The prosecution record makes clear that both the product and process claims were handled together by Examiner Martinell, who became the primary examiner in both, reviewed both files, and even held interviews for both applications on the same day. Roche's only argument is the unsupported assertion that Examiner Martinell did not thoroughly analyze and fully appreciate the previous rejections and therefore Amgen had a duty to disclose these rejections. The PTO rules however, provide that the new examiner is charged with knowledge of the prior actions, and the undisputed facts reveal that Examiner Martinell had reviewed the prosecution history in each application.

Because Roche has failed to substantiate any of its pleaded allegations of inequitable conduct, Amgen's motion for summary judgment should be granted.

II. AMGEN'S ARGUMENTS TO THE PATENT OFFICE RESPONDING TO THE ISSUE OF DOUBLE PATENTING WERE CORRECT, AND CANNOT SUPPORT ROCHE'S ALLEGATIONS OF INEQUITABLE CONDUCT

As discussed in Amgen's Motion, Roche's allegations of inequitable conduct regarding the double patenting issue focus almost exclusively on *arguments* made by Amgen's patent counsel addressing cases or decisions that were squarely before the examiner. In such circumstance, the examiner is personally able to assess the strength and weaknesses of those arguments, and allegations that such arguments were wrong or misleading cannot sustain a claim

of inequitable conduct.[3] More significantly, Roche is unable to cite to any statement by Amgen that was incorrect or that in any way misled the examiner. The Federal Circuit recently reconfirmed that attorney argument on a submitted reference cannot be inequitable conduct. In *Young v. Lumenis, Inc.*, the Federal Circuit held:

> The examiner had the [reference] to refer to during the reexamination proceeding and initially rejected claim 1 based on that reference. [Patentee] argued against the rejection, and the examiner was free to reach his own conclusions and accept or reject [patentee's] argument. We therefore fail to see how the statements in the October 2005 Response, which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact.[4]

In view of *Young*, the authorities cited by Roche are inapposite.[5] In *Li Second Family LP v. Toshiba Corp.*,[6] applicant failed to disclose a Board decision concerning priority dates and then asserted during prosecution that his claims were entitled to a particular priority date that was inconsistent with the Board's decision. The Federal Circuit found that applicant's arguments constituted affirmative misrepresentations in light of the undisclosed Board decision. Likewise, in *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm.*, applicant withheld material prior art devices and made misleading arguments for patentability "that could not have been made had the art been disclosed." By contrast, Amgen's arguments here were accompanied by full disclosure of the references or opinions upon which those arguments were based. Unlike the examiners in *Li Second Family* and *LaBounty*, but like the examiner in *Young*, the examiners of Amgen's patents

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[3] *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fe.d Cir. 1986); *see also Environ Prods., Inc. v. Total Containment, Inc.*, 951 F. Supp. 57, 61 (E.D. Pa. 1996).

[4] Declaration of Craig H. Casebeer in Support of Amgen Inc.'s Reply to Roche's Opposition to Motion for Summary Judgment of No Inequitable Conduct ("Casebeer Reply Decl."), Exh. 1; 2007 WL 1827845 (Fed. Cir. June 27, 2007); *see also C.R. Bard, Inc. v. Adv. Cardio. Sys.*, 911 F.2d 670, 674 n.2 (Fed. Cir. 1990) (arguments are not evidence).

[5] Roche Opposition Memorandum, p. 6.

[6] 231 F.3d 1373, 1378-1379 (Fed. Cir. 2000).

could review and interpret the references and opinions for themselves.

1. Allegations Regarding Federal Circuit and ITC Decisions

With respect to the ITC decision, Roche asserts that it was misleading to insert the discussion of the ITC decision under the heading "The Subject Matter of the Present Claims Has Already Been Determined to be Patentably Distinct from Claims 1-6 of U.S. 4,703,008." But what is clear from the prosecution record, and Roche omits to mention, is that the first two paragraphs under that heading discuss how the PTO had already determined that the claims were patentably distinct. As discussed in Amgen's motion, (p. 12-13), not only had the PTO instituted separate interferences – which requires patentably distinct claims – but the PTO Board had expressly stated that the claims were patentably distinct. The discussion of the ITC decision then followed and Amgen correctly described the holding of that decision — that Amgen did not have process claims in the '008 patent.

As was true in *Young*, both the Federal Circuit and ITC opinions were before the examiner.[7] Moreover, Amgen expressly and correctly reported to the Examiner that the ITC decision was based on 19 U.S.C. § 1337:

> In proceedings before the International Trade Commission and the subsequent appeal to the Court of Appeals for the Federal Circuit, it was judicially determined that the claims of the U.S. Patent No. 4,703,008 did not "cover" recombinant production processes within the meaning of 19 U.S.C. § 337. (See the CAFC decision attached hereto as Appendix C.) There has **thus** been a judicial determination that rights in **the subject matter** of '008 patent claims did not extend to the **subject matter** of the process claims herein and it correspondingly cannot be argued that issuance of claims herein would operate to "extend" rights already granted in U.S. Patent No. 4,703,008.[8]

Roche cannot support its position that this argument, the source and bases of which were

[7] Exhibit 32 to Declaration of Craig H. Casebeer in Support of Amgen Inc.'s Memorandum to its Motion for Summary Judgment of No Inequitable Conduct ("Exh. 32") (Search Notes, '178 File History); Exh. 18 (10/7/1994 Amendment, '179 Application), at p. 7.

entirely transparent to the examiner, could constitute an affirmative misrepresentation made with intent to deceive.

2. Allegations Regarding Fritsch v. Lin Interferences

Roche affirmatively misstates the record in arguing that the "interference proceedings actually contained critical admissions by Amgen that the two groups of claims were 'the same invention.'" First, it is clear from the briefing that this "same invention" statement was originally made by Fritsch and Amgen was citing that position against Fritsch's arguments on priority. Far from being a "critical admission," the record is also clear that in addressing the differences between the DNA and process claims Amgen expressly stated that the process and DNA claims were patentably distinct.

Roche fails to respond in any way to the facts, referenced in Amgen's motion, (1) that ***in the very same interference brief*** where the "same invention" statement occurs, Amgen, in addressing obviousness rather than priority, expressly argued that it was ***not*** obvious from the DNA claims that *in vivo* biologically active rEPO could be made by the claimed process; and (2) in its responses to both Motion G and Motion Q in the Interference, where Fritsch first used the "different manifestation of the same invention" language, Amgen argued that there was no "evidence in support of the bare allegation of 'same invention,'" and that "Lin contends that the two counts are ***not*** the same invention."[9]

Because the Board had already determined that the process and DNA claims were patentably distinct and Amgen took the same position in the '097 Interference, there was nothing to disclose to the later examiner. Roche's effort to cherry-pick and contort a single out-of-context statement from the interference briefing does not create a genuine issue of material fact.

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[8] Exh. 18 *10/7/1994 Amendment, '179 Application) (emphasis added).

[9] *See* Exh. 21 (Brief of Senior Party Lin, Interference No. 102,097); Exh 22 (Lin Oppositions to Interference Nos. 102,096 and 102,097, *Fritsch v. Lin*, Opposition G – To Motion to Combine

3. Other Allegations

Roche merely repeats the allegation in its answer that Amgen wrongfully represented to the examiner that he could not rely upon prior art in making an ODP rejection. Roche does not respond to the authority cited in Amgen's motion demonstrating the correctness of Amgen's statement of the law,[10] nor (once again) does it even attempt to address how such a legal argument could constitute inequitable conduct, when the examiner was fully capable of assessing the merits of the argument for himself. Roche's meager arguments do not satisfy Roche's burden to avoid summary judgment under Rule 56.[11]

Finally, Roche's assertions of deceptive intent, a required element, amount to nothing more than lurid and unsupported charges that Amgen had an incentive to cheat in order to obtain issuance of the patents.[12] Such allegations are legally sufficient to show intent.[13]

III. CHARGES OF INEQUITABLE CONDUCT REGARDING MOLECULAR WEIGHT OF rEPO AND uEPO[14]

Roche fails to overcome a significant burden of arguing an issue previously decided in Amgen's favor by this Court. While Roche says that its allegations are based upon "new, specific evidence"[15] not previously considered by this Court, the only "new, specific evidence" it

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Interference No. 102,097 with the Instant Interference).

[10] Amgen Memorandum, at pp. 13-14.

[11] Roche devotes two sentences to its claim that Amgen should have disclosed arguments it made in European proceedings involving G.I. and Kirin-Amgen claims. But, again, Roche simply paraphrases the allegations in its answer, without responding to Amgen's motion on the issue. Please refer to Amgen's Memorandum at pp. 15-16.

[12] *See, for example*, Roche Opposition, at p. 9.

[13] *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).

[14] To the extent that Roche's allegations rely upon references not included in Roche's First Amended Answer, Amgen does not address these allegations because they are not in the case. Since Roche does not address the disclosure of the *TKT* litigation, Amgen presumes that Roche does not disagree that the *TKT* litigation was properly disclosed to the Patent Office.

[15] Roche Opp. Memo., at p. 9.

provides is irrelevant material from foreign proceedings, including a court decision[16] squarely ***dismissing*** many of the assertions Roche now makes in its Opposition. Roche also attempts to assert new allegations of withholding that it failed to plead, which the Court should not consider.

In addition, having been forced to acknowledge that many of the allegedly withheld references were actually disclosed to the Patent Office, Roche has abandoned its non-disclosure argument and now accuses Amgen of "burying" these references, which is an implicit acknowledgement that Amgen submitted the references to the Patent Office. Finally, Roche's opinion of the importance of the disclosures in these references has now flip-flopped: when it wrongly contended they were withheld, Roche asserted that these references clearly disclose the similarities between the molecular weight of rEPO and uEPO; now that Roche is compelled to admit that the references were before the Patent Office, the clarity of those references has apparently dimmed and they supposedly constitute insufficient disclosure.

A. AMGEN ADEQUATELY DISCLOSED INFORMATION DESCRIBING APPARENT MOLECULAR WEIGHT SIMILARITIES BETWEEN rEPO AND uEPO.

First, Roche argues that Amgen failed to disclose the Egrie Input file,[17] the Egrie 1986 Publication,[18] the 1994 Strickland Declaration,[19] and Amgen's PLA[20] showing that Dr. Lin's rEPO and uEPO have the same apparent molecular weight of 34,000 daltons. The Egrie Input file and the Egrie 1986 Publication (which included SDS-PAGE data described in Amgen's

[16] Casebeer Reply Decl., Exh. 5, *Hoechst Marion Roussel v. Kirin-Amgen Inc.* ([2002] EWHC 471 (Patents)) ("British Case"). The British court ultimately found that Amgen's patents were infringed. The British court also found that Amgen's failure to disclose information regarding the molecular weight of rEPO and uEPO was not attributable to a want of good faith. *British Case*, at ¶¶ 165-166.

[17] 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.

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

[19] Exh. 6 (5/19/1994 Declaration of Thomas A. Strickland) ("1994 Strickland Declaration").

PLA), however, were called to the attention of any reader of the '334 Interference record (including the Interference Board and Examiner Fitzgerald).[21] Further, as acknowledged by Roche in its First Amended Answer,[22] the '933 Patent specification states that the molecular weight of natural EPO was "approximately 34,000 dalton"[23] and Lin's 1985 PNAS paper (which was disclosed to the PTO) says the same thing for his recombinant EPO. As discussed, other references also before the PTO disclosed the similarity in apparent molecular weights of rEPO and uEPO as measured by SDS-PAGE.[24]

Moreover, Amgen's PLA was an exhibit in the '334 interference, the record of which was reviewed by Examiner Fitzgerald.[25] Also, this Court has determined that the SDS-PAGE gel submitted to the FDA was described in the Egrie 1986 Publication which, along with the Egrie Input file, was disclosed to the Patent Office during the prosecution of the '933 Patent.[26] As a result, this Court ruled that Amgen did not commit inequitable conduct,[27] a decision that was affirmed by the Federal Circuit.[28] Roche flouts the doctrine of *stare decisis* by ignoring these

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

[21] Amgen's Motion, at pp. 8-9, fn. 39. Examiner Fitzgerald's search notes read: "Reviewed interference file # 102,334…Oct-Nov 1993 Fitzgerald." Exh. 32 (Search Notes, '178 Application). Any argument that Examiner Fitzgerald reviewed only a portion of the '334 interference file is necessarily a presumption. *J.P. Stevens & Co. v. Lex Tex, Ltd.*, 747 F.2d 1553, 1564 (Fed.Cir. 1984) ("…where inequitable conduct is at issue, mere possibilities are insufficient.").

[22] Roche's First Amended Answer, at p. 25-26.

[23] '933 Patent, at col. 5:48-50.

[24] 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"), at p. 693 ("Purified human urinary EPO has an apparent molecular weight of about 34,000").

[25] Casebeer Reply Exh. 2 (Notice of Claimed Investigational Exemption for Recombinant Human Erythropoietin (r-HuEPO)) ("Amgen's IND"), at p. 968; Exh. 32 (Search Notes, '178 File History).

[26] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 143 (D. Mass. 2001).

[27] *Id*. at 141-145.

[28] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357-581 (Fed. Cir. 2003).

previous rulings, but offers nothing beyond what was argued in TKT to prove its allegations. Roche's attempt to rely on the Strickland declarations from Europe to create "new" information not previously considered by the Court fails completely. Strickland did not compare rEPO with uEPO but only reported characteristics of Amgen's rEPO, such as an apparent molecular weight of 34,000, characteristics that were already before the examiner through the submission of other references.

Second, Roche asserts that the disclosed references do not mention molecular weight as measured by SDS-PAGE. Again, Roche's assertion is incorrect. The Egrie 1986 Publication and the Egrie Input file, both recognized by this Court to be disclosed to the Patent Office, respectively state that "[a]fter electrophoresis on a 12.5% ***SDS polyacrylamide gel***,…purified rHuEPO migrates identically to human urinary EPO ***with an apparent molecular weight of approximately 36,000 daltons***," and that rEPO and uEPO have "the same molecular weight."[29]

Third, Roche now complains that the Lin 1985 PNAS Publication does not clearly state that rEPO and uEPO have the same apparent molecular weight.[30] Yet, in its First Amended Answer, Roche insisted that Dr. Lin "knew as of 1985 that the molecular weights of r-EPO and u-EPO were the same" because Dr. Lin reported in the Lin PNAS publication that "[r-EPO] has an apparent [molecular weight] of 34,000 when analyzed in an electrophoretic transfer blot" and because the '933 Patent's specification "states that the molecular weight of natural EPO was also 'approximately 34,000 dalton.'"[31] The similarity of rEPO's and uEPO's molecular weights are also noted in other references disclosed to the Patent Office (*e.g.*, the Browne 1986 Publication,

[29] Exh. 1 (Egrie 1986 Publication), at p. 218, Exh. 2 (Egrie Input file), at p. 17.

[30] Roche Opp. Memo., pp. 10-11; 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").

[31] Roche's First Amended Answer, at ¶ 85 (*quoting* Exh. 39 (Lin PNAS publication), at p. 7582, and '933 Patent specification, at col. 5:48-50).

and the Egrie Input file[32]).

Curiously, Roche argues that "Lin's rEPO had the same apparent molecular weight as uEPO," but that this knowledge did not keep Amgen from pursuing a claim "to a higher molecular weight EPO … a plainly invalid claim." As the Court may know, Roche and its predecessors have been embroiled in litigation with Amgen on related patents around the world for nearly 20 years. One such case was litigated in Canada where Amgen obtained claims to a rEPO having a higher molecular weight on SDS-PAGE than uEPO, a closely identical claim to '933 claim 2. Roche challenged the validity of that patent and lost. Amgen also demonstrated that both Amgen's and Roche's EPO product infringed the claim and Roche was enjoined from selling its product on the Canadian market.[33]

Some years later in January 2001, after this Court's decision in *TKT* which held '933 claims and 1 and 2 invalid, the parties entered into a settlement agreement to resolve all the ex-U.S. litigation, in which Roche acknowledged the validity of the Canadian decision and injunction. As the Canadian Court held, the claim is directed to those rEPOs that have a higher molecular weight on SDS-PAGE. The fact that some rEPOs do not infringe the claims does not negate the patentability of the claims. Similar claims were also issued in Europe in face of the same evidence as argued here, and Roche was unsuccessful in before the European Patent Office to invalidate the claims. So, Roche's position that such a claim was "plainly invalid" is belied by its own actions and failed efforts to invalidate the SDS-PAGE claim elsewhere.

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[32] 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"), at p. 693 ("Purified human urinary EPO has an apparent molecular weight of about 34,000"); 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)").

[33] Docket No. 689, Exhibit 1 (*Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.*, [1999] Fed. Ct., Docket T-2784-97 (Reasons for Judgment) at para. 3 (dispute over validity of molecular weight limitation) and 95 (conclusion) (AM-ITC 00811917-811955).

Fourth, relying on the 2002 UK decision in *Hoechst Marion Roussel v. Kirin-Amgen Inc.*,[34] Roche asserts that the British Court found that Dr. Lin's COS rEPO and CHO rEPO had the same molecular weight as "some urinary EPOs."[35] But that court also determined that Dr. Goldwasser's uEPO had a lower molecular weight than Dr. Lin's CHO rEPO, and that the other types of uEPO that were shown to have a higher molecular weight than Dr. Lin's COS rEPO "did not in fact represent prior art EPO so far as the Patent was concerned, and that they were therefore irrelevant for the purposes of novelty, and could effectively be discarded."[36] It also noted that disclosure of the similarity between the molecular weights of the other types of uEPO and CHO rEPO to the FDA was appropriate since the FDA was not concerned with the novelty of the invention.[37] While the British Court did find that "some urinary EPOs" had the same molecular weight as COS rEPO and CHO rEPO, the British Court ultimately found that Dr. Lin's disclosure regarding the molecular weights of COS and CHO rEPO relative to that of uEPO was not attributable to a want of good faith.[38]

Finally, Roche asserts that the disclosed references do not mention molecular weight as measured by SDS-PAGE. Yet, the Egrie 1986 Publication and Egrie input file, both recognized by this Court to be disclosed to the Patent Office, discuss the similar apparent molecular weights of rEPO and uEPO as measured by SDS-PAGE.[39]

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[34] Casebeer Reply Decl., Exh. 5, [2002] EWHC 471 (Patents) ("British Case").

[35] Roche Opp. Memo., at p. 10.

[36] Casebeer Reply Decl., Exh. 5, *British Case*, at ¶ 130 ("On any fair reading of the [Egrie Input file], it seems to me that, at least in Dr. Egrie's view, the position was tolerably clear and was as follows. If one confined oneself to comparing recombinant EPOs with Goldwasser uEPO, CHO rEPO had a somewhat higher molecular weight than urinary EPO, but COS rEPO had the same apparent molecular weight as urinary EPO.").

[37] *Id.* at ¶ 151.

[38] *Id.* at ¶¶ 165-66.

[39] Exh. 1 (Egrie 1986 Publication), at p. 218 ("After electrophoresis on a 12.5% SDS polyacrylamide gel,…purified rHuEPO migrates identically to human urinary EPO with an apparent molecular weight of approximately 36,000 daltons."); Exh 2 (Egie Input file), at p. 17

B. AMGEN ADEQUATELY DISCLOSED INFORMATION REGARDING CHO rEPO AND uEPO.

Roche has given up on asserting that references disclosing similarities in the glycosylation of CHO rEPO and uEPO were not disclosed, and has switched gears to accuse Amgen of "burying" these references. Roche asserts that Amgen "buried"[40] the information about the similar apparent molecular weights of rEPO and uEPO by disclosing references that allegedly do not mention molecular weight by SDS-PAGE (Takeuchi, Sasaki, 1990 Strickland Declaration, PLA, Fritsch's Proposed Findings of Fact and Law, Lin's Brief, and 1991 Egrie Declaration) and a reference that allegedly does not clearly state that rEPO and uEPO have similar apparent molecular weight (Lin 1985 PNAS Publication). But, this issue was litigated in the interference and is reported in the decision. Amgen can hardly be accused of "burying" the information. In the face of the same SDS-PAGE gels that Roche argues here as evidence of "migrating identically," the PTO Board found that Egrie's gels did not preclude Amgen from claiming those r-EPO products that differed from u-EPO.

In support of its theory of "burying," Roche cites *eSpeed, Inc. v. BrokerTec USA LLC.*[41] However, *eSpeed* is distinguishable by its particular facts that are not found in this case. In *eSpeed*, the court found inequitable conduct based on false declarations submitted by the applicants, and the submission of correct information in a "blizzard of paper" did not negate the false statement. The facts of this case are clearly distinguishable from *eSpeed*. Roche has not and cannot cite to any false statement in any declaration. The allegedly buried documents were front and center in the interference and the Board found for Amgen. Many other references

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(describing uEPO and rEPO as having "the same molecular weight").

[40] *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) (rejecting "burying" theory of inequitable conduct applied by district court).

[41] 480 F.3d 1129, 1137 (Fed. Cir. 2007).

disclosed the same information. Indeed, as Roche previously observed, the Lin PNAS Publication coupled with the '933 Patent Specification clearly showed that rEPO and uEPO had similar apparent molecular weights.[42]

Roche claims that the Egrie Input file and the Egrie 1986 Publication were "buried" within the '334 interference file. However, as explained above, the work of Dr. Egrie was prominently litigated in the interference, argued by the parties, and considered by the Interference Board during the '334 interference and Examiner Fitzgerald.[43] The Board reported its conclusions of the facts that Dr. Egrie had gels showing "certain u-EPO and r-EPO samples … had 'approximately the same size.'"[44] Examiner Fitzgerald specifically noted in the '933 patent's search notes that he had analyzed the interference record and opinion for two months.[45]

Second, in complaining that information regarding the similar glycosylation of rEPO and uEPO was not disclosed, Roche claims that the Browne 1986 Publication[46] was "buried" because it was cited for a limited purpose only. The Cummings Declaration, which was attached to an amendment submitted to the Patent Office during the prosecution of the '874 Application (parent to the '933 Patent), cites to the Browne 1986 Publication as support for "only about 60% of the protein from BHK cells was found to be O-glycosylated whereas it is known that ***urinary EPO***

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[42] Roche's First Amended Answer, at ¶ 85.

[43] Indeed, Dr. Egrie's work as described in the Egrie Input file, her other laboratory notebooks, her articles, and her testimony was offered into evidence via a notice entitled: "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***." Exh. 31. Attached directly to the notice was page 17 of the Egrie Input file which states, "…recombinant EPO is glycosylated to the same extent as the native protein."

[44] *Fritsch v. Lin*, 21 U.S.P.Q.2d 1739, 1742 (BPAI 1992).

[45] Exh. 32 (Search Notes, '178 File History).

[46] 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").

(as well as rEPO from CHO cells) is nearly 100% glycosylated."[47] The "limited purpose" for which the Browne publication is cited is related to the purpose for which Roche claims Browne should be cited—similarities in glycosylation of CHO rEPO and uEPO.

Roche argues that while Amgen submitted evidence that CHO cell rEPO was different from uEPO to support its claims, it had information that COS rEPO was not different from uEPO. First, these points and the cited references in Roche's Statement of Facts (130) were not pleaded in Roche's First Amended Answer and are not part of Roche's allegations in this case. Second, the COS cell information is cumulative to other information that was submitted, e.g., the Egrie Input file, and considered by the PTO.[48]

IV. CHARGES OF INEQUITABLE CONDUCT REGARDING DISCLOSURE OF REJECTIONS IN CO-PENDING APPLICATIONS

Roche repeats its allegations that Amgen failed to disclose rejections in the co-pending '178 and '179 applications. But Amgen demonstrated in its motion that, before issuance of any patents from those applications, Examiner Martinell became the principal examiner on ***both*** applications, and thus had knowledge of the prosecution history of both applications. In its response, Roche ***does not deny that fact,*** and indeed implicitly admits it.[49] It chooses largely to ignore it, however, in favor of spending virtually all of its time arguing the materiality of the rejections. But materiality is of course irrelevant if the information claimed to be withheld was

[47] Exh. 13 (2/16/1995 Amendment, '874 Application); Exh. 14 (1/6/1994 Declaration of Richard Cummings; and Exh. 3 (Browne 1986 Publication).

[48] Roche asserts, without supporting authority, that the duty of disclosure includes a duty to submit a balanced volume of COS- and CHO-related references. Such a theory is not only unsupported, but is flatly contrary to the principle that the duty of disclosure encompasses only non-cumulative information. 37 C.F.R. § 1.56(b). Similarly, Roche's argument that the withdrawal during prosecution of a COS-related claim is somehow probative of bad faith, is also unsupported in the case law. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991) ("An applicant has the absolute right to decline to do work suggested by the PTO, and to withdraw claims that had been presented for examination, without incurring liability for inequitable conduct.").

[49] Roche Opp. Memo., pp 15-16.

in fact before the examiner.

Roche's only effort to avoid the obvious consequences of that fact is to argue (1) that Examiner Martinell's obligation to give full faith and credit to previous rejections "undercuts Amgen's excuse he would have painstakingly reanalyzed the rejection for an interview years later;" and (2) "any belief by Amgen that Examiner Martinell appreciated the import of the previous rejections 'is irrelevant' to Amgen's duty to disclose, citing *Rohm & Haas Co. v. Crystal Chem. Co.*"[50] Neither argument is valid.

First, as discussed below, the standard is whether the allegedly material information was before the examiner in time for him to act on it. There is no question that occurred here. The MPEP standards that address what a later examiner may do with information concerning actions of earlier examiners do not change that fact. Roche's apparent effort to create a new standard—evidence that an examiner "painstakingly reanalyzed" the earlier rejections—is neither logical nor supported.

The undisputed facts show that the examiner conducted interviews on both applications on a single day in 1994, and rejections in both lines of application were discussed at that time.[51] Roche does not contest that fact. Plainly, therefore, the examiner had actual knowledge of and necessarily considered the prior rejections in advance of approving the claims. In that regard, the applicable law is clear that when a reference is before an examiner, it cannot be deemed to have been withheld from the examiner.[52]

Beyond that, Roche fails to explain the pertinence of *Rohm & Haas* here, and indeed it has none. There, the applicant had made intentional misrepresentations of material fact to the

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[50] 722 F.2d 1556 (Fed. Cir. 1983).

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

[52] *See, e.g., Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991).

examiner in a sworn affidavit, and during renewed prosecution following an interference, applicant sought to cure such misrepresentations by providing accurate data to the examiner. The Federal Circuit found the "cure" to be insufficient as a matter of law, because there was no evidence that applicant informed the examiner that it had previously made misrepresentations, where those misrepresentations had been made, or how they were being corrected.[53] The facts here are far different.

In *Young v. Lumenis,*[54] defendant claimed inequitable conduct in that applicant failed to disclose material deposition testimony to the examiner during reexamination, until the issue of that non-disclosure was raised in a parallel district court litigation. The Federal Circuit concluded:

> The examiner was therefore fully apprised of the [deposition] testimony and was able to fully consider it and any potential effects it may have on the patentability of the claims before issuing his second Office Action. Thus, we cannot agree that there was inequitable conduct resulting from the "failure to disclose material information" when that information was disclosed to the PTO in time for the examiner to consider it. The essence of the duty of disclosure is to get relevant information before an examiner in time for him to act on it, and that did occur here.

As in the present case, defendant in *Young* cited *Rohm & Haas,* but the Federal Circuit regarded that case as "distinguishable, involving different facts, particularly because in that case the issue related to an alleged false affidavit, where a cure hurdle may be higher than here. In [*Young*], the issue related to an alleged omission, and that omission was cured by a timely submission."[55] Here, there is no allegation of a false affidavit, and *Rohm & Haas* is inapplicable.

Roche argues that the rejections in the co-pending applications were material, citing

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[53] *Rohm & Haas*, 722 F.2d at 1572-73.

[54] Casebeer Reply Decl., Exh. 1, 2007 WL 1827845, at *9 (Fed. Cir. June 27, 2007);.

[55] *Id.* at p. 12.

McKesson Information Systems v. Bridge Medical, Inc.[56] As discussed above materiality is not an issue here given the evidence that Examiner Martinell *did* have knowledge of the co-pending applications and the rejections in each. But, in any event, Roche's argument on materiality is misplaced. The Federal Circuit in *Dayco Products, Inc. v. Total Containment, Inc*.[57] concluded that co-pending applications were not material where the claims are patentably distinct, but are material if a co-pending application "could have conceivably served as the basis of a double patenting rejection."[58] Here, as Amgen discussed in its motion papers, the claims of the '178 and '179 applications had already been determined to be patentably distinct,[59] thus eliminating any claim that one of those applications could serve as the basis of a double patenting rejection.

Roche appears to argues that, under *McKesson, rejections* in co-pending applications need to be disclosed if the claims in the co-pending applications are substantially similar, even if patentably distinct. While *McKesson* does not appear to address that question directly, it makes no sense to read *Dayco* and *McKesson* to say that co-pending applications with patentably distinct claims are not material and need not be disclosed, but rejections in those same applications are material and do need to be disclosed.[60]

V. ROCHE IMPROPERLY ARGUES ALLEGATIONS OF INEQUITABLE CONDUCT THAT ARE NOT IN ITS PLEADING OR IN THIS CASE

In the final section of Roche's response, entitled "Amgen Ignores Roche's Complete

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[56] 2007 WL 1452731 (Fed. Cir. 2007).

[57] 329 F.3d 1358 (Fed. Cir. 2003).

[58] *Id.* at 1365, quoting from *Akron Polymer Container Corp. v. Excel Container, Inc.*, 148 F.3d 1380,1382 (Fed. Cir. 1998).

[59] Amgen's Motion, at pp. 10-14.

[60] It is noteworthy that the version of the MPEP that followed and references *Dayco* refers to the need to disclose "information as to" co-pending applications where those applications are material. Presumably such information would include rejections in those applications, from which a reasonable inference may be drawn that where the applications themselves are not material under *Dayco* (where claims are patentably distinct), the "information" as to those applications need not be disclosed.

Allegations of Inequitable Conduct," Roche proceeds to argue the importance of other allegations of inequitable conduct (1) that do not appear in Roche's First Amended Answer, and (2) which Amgen did not include in its summary judgment motion, since they are not in the case. Specifically, the allegations made at pages 12 to 13, and 16 through 20 of Roche's Opposition are not in the case and have nothing to do with the motion for summary judgment before the Court. Moreover, although Roche has now filed a new motion to get the Court to change its mind and allow the new allegations, it conveniently did so only after the deadline for filing summary judgment motions and a full month after the Court denied its first motion to add these allegations to its pleadings.

Roche argues that, notwithstanding the Court's denial of its motion to amend, it can still make the dozens of new allegations of inequitable conduct part of this case, apparently just as if the motion ***had*** been granted. Roche cites *Bonilla v. Trebol Motors Corp.*[61] for the proposition that papers in opposition to a motion for summary judgment can be used to "effectively amend or supplement pleadings" that would otherwise be deficient under Rule 9(b), requiring particularity in pleading, including in connection with allegations of inequitable conduct.

Nothing in *Bonilla* permits a party to use discovery responses to cure deficient pleadings or, as here, to add new claims entirely,[62] and it certainly does not permits an applicant to "effectively amend" its pleading when the same proposed amendment was specifically rejected by the Court. This same tactic is reflected in Roche's 56.1 Statement of Material Facts. Roche

[61] 150 F.3d 77 (1st Cir. 1998).

[62] *See, Goss Int'l Americans, Inc. v. MAN Roland, Inc.*, 2006 DNH 62; 2006 U.S. Dist. LEXIS 36386; 2006-2 Trade Cas. (CCH) P75,392 (D. N.H. 2006) ("While discovery responses may be used to add details to an otherwise sufficient pleading (citation omitted) they may not be used to cure deficient pleadings or to add new claims entirely," distinguishing *Bonilla* on the grounds that the plaintiff there "sought simply to add specific fraudulent acts to a complaint that set out with some precision the nature of the fraudulent scheme alleged."); *Nichols Motorcycle Supply, Inc. v. Dunlop tire Corp.*, 1994 U.S. Dist. LEXIS 3790 (N.D. Ill. 1994) (plaintiff's contention that its interrogatory answers provide the particularity required by Rule 9(b) fails because plaintiff "cannot indirectly amend its complaint to include its responses to interrogatories.")

responds to Amgen's Rule 56.1 Statement in 30 paragraphs over 9 pages, and then proceeds to submit and additional **352** paragraphs over an additional 76 pages, which purports to be a "statement of undisputed facts." Those supposedly "undisputed facts" really amount to extended legal argument and conclusions that Roche apparently could not fit within its 20 page opposition memorandum. In addition, the statements consists of disparate and scattered allegations and arguments that are not tied to any coherent position and are certainly not specifically responsive to Amgen's arguments in its summary judgment motion. Finally, a large number of the supposed "undisputed facts" relate to matters outside of Roche's First Amended Answer; they are not in this case, not addressed in Amgen's motion, and should be disregarded. Roche's tactic is to drown the proceeding in hundreds of random and unconnected allegations of bad acts, hoping it will lead to a conclusion that there must be a disputed issue of fact somewhere. That tactic should not be allowed to prevail.

Amgen respectfully requests that the Court disregard the arguments in Sections IIIC and III F of Roche's Opposition and corresponding portions of its accompanying evidentiary submissions.

VI. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court grant summary 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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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.

/s/ Patricia R. Rich
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