

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**AMGEN INC.'S MOTION TO STRIKE MATTERS RAISING UNPLEADED
ALLEGATIONS REGARDING AMGEN'S MOTION FOR SUMMARY JUDGMENT
OF NO INEQUITABLE CONDUCT AND TO STRIKE UNTIMELY EXPERT
TESTIMONY**

I. INTRODUCTION AND LEGAL STANDARD

In opposing Amgen's Motion for Summary Judgment of No Inequitable Conduct ("Amgen's I.C. Motion"), Roche introduced mountains of new theories, facts, and expert evidence that were not pleaded in its First Amended Answer, and in many cases not even *related* to issues pleaded in its First Amended Answer. Roche's attempt to bring back in through summary judgment what it lost on June 7, 2007 when this Court denied its motion to amend the pleadings should not be entertained.

Further, Roche has interspersed throughout its supporting papers facts and arguments ostensibly related to pleaded allegations with those that are not, creating confusion as to the issues properly before the Court. Whether Roche's conduct is intentional or not, the result is no different: Amgen is prejudiced by the frustration of a legal process otherwise intended to narrow the issues for trial. The burden now falls to Amgen and the Court to parse dozens of new allegations, set forth in 352 paragraphs in Roche's Rule 56.1 Statement of Material Fact and in multiple new expert declarations, in order to sort out what actually corresponds to Roche's pleaded allegations and what does not. If Roche had thought these new allegations to be meritorious, it would have disclosed them when given the opportunity to plead with particularity its inequitable conduct defense in its First Amended Answer. Since it failed to do so, Roche should not be allowed to use them in response to Amgen's motion for summary judgment. For these reasons, all of Roche's supporting papers should be stricken from the record of Amgen's I.C. Motion. At the very least, the Court should strike the discrete portions of Roche's opposition materials that address matters outside the pleadings.

In addition, the declarations of Michael Sofocleous offered by Roche in support of or in opposition to the parties' motion for summary judgment include statements and opinions not

contained in his expert reports. Such declarations, coming after the deadline for filing expert reports, are not timely, and should not be considered.

“A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1) [governing expert report disclosure requirements], or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at trial, at a hearing, *or on a motion* any witness or information not so disclosed. . . .”¹ (emphasis added).

II. ALLEGATIONS OF INEQUITABLE CONDUCT THAT ARE NOT PLEADED IN ROCHE’S FIRST AMENDED ANSWER SHOULD BE STRICKEN FROM ITS PAPERS OPPOSING AMGEN’S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

A. UNPLEADED ALLEGATIONS IN ROCHE’S RULE 56.1 STATEMENT

On March 30, 2007, after Amgen objected that the original Answer was not properly pleaded under Rule 9(b), Roche filed its First Amended Answer spelling out its expanded allegations of inequitable conduct.² Thereafter, Roche moved again to amend its answer, this time to add more than a dozen new theories of inequitable conduct, and by Order dated June 7, 2007, the Court denied Roche’s motion to amend.³

As a result, the only theories and allegations of inequitable conduct in this case are those that appear in Roche’s First Amended Answer of March 30, 2007. Yet, throughout Roche’s Rule 56.1 Statement of Material Fact (Rule 56.1 Statement), Roche raises facts and allegations that go

¹ Fed. R. Civ. P. 37(c)(1) (emphasis added).

² Amgen had opposed Roche’s First Amended Answer on the ground that, even as amended, Roche’s pleading failed to meet the requirements of Fed. R. Civ. P. 9(b). *See* D.I. 171. Roche’s motion was granted, however, and thus Roche should not now be permitted to expand beyond those specific allegations.

³ Roche has again sought to re-plead its inequitable conduct case by a second motion to amend with its “Amended Proposed Second Amended Answer.” Amgen is opposing that motion by way of separate brief.

far beyond its pleadings.⁴ Indeed, many of those unpleaded facts and allegations had been set forth in Roche's proposed Second Amended Answer, which this Court rejected when it denied Roche's motion to amend on June 7, 2007.

Moreover, Roche has interwoven within individual paragraphs of its Rule 56.1 Statement) allegations pertaining to issues that *have* been pleaded with those that *have not*. Amgen therefore objects to Roche's Rule 56.1 Statement as unfairly placing on the Court and Amgen the burden to parse out amidst 352 paragraphs and more than 70 pages the issues that might be pertinent to Amgen's motion from those that having nothing to do with it and are not in this case. Unfortunately, there is no option but to undertake such a burden, in order to ensure clarity of the record before this Court and for any eventual appeal. .

Roche's attempt to create an issue of fact by drowning the Court and Amgen with irrelevant paper should not be permitted. On this basis, Amgen moves to strike the entirety of Roche's Rule 56.1 Statement. In the alternative, the paragraphs in Roche's Rule 56.1 Statement that most clearly constitute or address matters not contained in the First Amended Answer, and that therefore should be stricken, are the following:

¶¶ 40-45, 64-76; 80-82; 111-120; 122-172; 195-199, 202, and 254-382.⁵

B. UNPLEADED ALLEGATIONS IN ROCHE'S EXPERT DECLARATIONS.

Roche improperly filed expert declarations in opposition to Amgen's I.C. Motion that contain statements and opinions addressing allegations of inequitable conduct that are not contained in Roche's First Amended Answer. In that regard, Michael Sofocleous, Roche's expert on inequitable conduct issues, filed a "Third Declaration" in support of Roche's

⁴ Amgen has further objected to these paragraphs on the ground that they are not statements of fact at all, but rather legal arguments designed to extend the page limit for opposition briefs by dozens of pages.

⁵ Roche's 56.1 Statement of Material Fact in Opposition to Amgen Inc.'s Motion for Summary Judgment of No Inequitable Conduct, July 5, 2007. (Docket No. 648)

Opposition to Amgen's I.C. Motion, in which he rendered opinions on matters outside the scope of the First Amended Answer. A brief synopsis of those opinions, together with the corresponding paragraph numbers of Mr. Sofocleous's Third Declaration, are set forth in Appendix 1 hereto. Because they address matters outside the pleadings in this case, each of the paragraphs of Mr. Sofocleous's Third Declaration that are listed in Appendix 1 should be stricken.

In addition, Charles G. Zaroulis, M.D. gave a declaration, dated July 5, 2007, in support of Roche's opposition to Amgen's I.C. Motion. The entire declaration is devoted to Roche's claims that Amgen failed to disclose material information regarding the radioimmunoassays referenced in the claims of the '349 Patent. Roche relies on the Zaroulis declaration solely in support of its opposition to Amgen's I.C. motion. (See Roche Opposition Brief at 19). By way of summary, Dr. Zaroulis at paragraph 35 of his declaration states:

Dr. Lin neither disclosed nor relied on a special definition for a Unit of erythropoietin, the specification contains no special definition for a Unit of erythropoietin, and in fact cites to many references, including the Miyake *et al* 1977 purification paper, that each confirm that a Unit of erythropoietin is a measure of *in vivo* biological activity.⁶

Roche's First Amended Answer, however, contains no allegations regarding these assertions of inequitable conduct regarding the '349 Patent or the radioimmunoassays that are referenced in the claims of that patent. As a result, they are not in the case and Dr. Zaroulis's Declaration should be stricken in its entirety.

Finally, Dr. Carolyn Bertozzi submitted a declaration in support of Roche's opposition to Amgen's I.C. Motion. Roche only mentions Dr. Bertozzi's declaration once in its opposition

⁶ Declaration of Charles G. Zaroulis, M.D. In Support of Roche's Opposition to Amgen's Motion for Summary Judgment of No Inequitable Conduct, July 5, 2007, para. 35, p. 16. (Docket No. 644-C)

memorandum, with a conclusory sentence that “the withheld documents undercut enablement and patentability of COS rEPO over the uEPO prior art as required by claim 1 and, thus, are material.”⁷ However, Roche’s allegations pertaining to its “COS” theory are found nowhere in the First Amended Answer, but were instead part of the Proposed Second Amended Answer, which this Court did not allow. Again, Roche seeks to demonstrate genuine issues of material fact by improperly injecting allegations and arguments not included in and having nothing to do with its First Amended Answer. The Court should reject this tactic and strike the expert report of Dr. Bertozzi.

III. EXPERT OPINIONS IN THE SOFOCLEOUS DECLARATIONS SUPPORTING ROCHE’S MOTION FOR SUMMARY JUDGMENT OR OPPOSING AMGEN’S MOTION FOR SUMMARY JUDGMENT THAT WERE NOT DISCLOSED IN HIS EXPERT REPORTS SHOULD BE STRICKEN.

Mr. Sofocleous has submitted three expert declarations, one in support of Roche’s motion for summary judgment regarding obviousness-type double patenting (“ODP”) issues, one in opposition to Amgen’s motion for summary judgment regarding ODP issues, and one in opposition to Amgen’s motion for summary judgment regarding inequitable conduct. Each of his declarations contained opinion and other matters not contained in his two expert reports, submitted on April 6, 2007 and May 1, 2007.

As discussed above, such opinions, therefore, are not timely and should be stricken. A list of the paragraphs of Mr. Sofocleous’ three declarations that should be stricken on this ground is set forth in Appendix 2 hereto.⁸

⁷ See Roche Opposition at 12. (Docket No. 633)

⁸ In that regard, it also appears that Roche deliberately used expert declarations filed in the summary judgment process to fill in gaps in its experts' reports. For example, during his deposition, Mr. Sofocleous was unable to identify any place in his two expert reports where the word “intent” was used, leading to the conclusion that he had expressed no opinions on whether Lin or Amgen intended to deceive the patent office. See Sofocleous deposition, 6/22/07, 196:2–198:6. [Declaration] Perhaps not coincidentally, his declaration in opposition to Amgen's I.C. Motion, submitted after his deposition, contained numerous opinions regarding Amgen's alleged intent. See,

Roche's tactic of causing expert witnesses to make declarations containing opinions not set forth in their expert reports clearly defeats the disclosure regimen of Rule 26. It would permit experts to render opinions and explanations at will, without the other party having any opportunity to test those opinions by deposition or otherwise. Importantly, because experts are foreclosed from testifying at trial as to opinions that are not expressed in their expert reports, it would make no sense to allow them to offer those same inadmissible opinions for the purpose of trying to defeat or support summary judgment.

Mr. Sofocleous' expert opinions that are not set forth in one of his two expert reports have no place in this case and should be stricken.

IV. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that this Court grant its motion to strike from the record, in connection with the Court's consideration of Amgen's Motion for Summary Judgment of No Inequitable Conduct, the following:

(1) Roche's Rule 56.1 Statement of Undisputed Facts, or in the alternative, ¶¶ 40-45, 64-76; 80-82; 111-120; 122-172; 195-199, 202, and 254-382 contained therein (D.I. 648);

(2) Declaration of Charles G. Zaroulis, Ph.D. in Support of Roche's Opposition to Amgen's Motion for Summary Judgment of No Inequitable Conduct (D.I. 644);

(3) Declaration of Carolyn Bertozzi, Ph.D. in Support of Roche's Opposition to Amgen's Motion for Summary Judgment of No Inequitable Conduct (D.I. 645); and

Appendix 2 hereto, Third Declaration of Michael Sofocleous, paragraph nos. 25, 35, 46, 52, 57, 62, 65, 71, 76. (Docket No. 636) This is an improper circumvention of the expert discovery process.

(4) The paragraphs of the three declarations of Michael Sofocleous that are identified in Appendix 1 and Appendix 2 hereto.

Dated: July 16, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried

D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4204
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (*pro hac vice*)
DAY CASEBEER, MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede, III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 non-registered participants on the above date.

/s/ Michael R. Gottfried
Michael R. Gottfried

APPENDIX 1**Third Declaration of Michael Sofocleous**

¶ No.	Portions of Declaration to Strike as Pertaining to Theories of Inequitable Conduct Not Contained in First Amended Answer
23-24	Allegations of Dr. Egrie's and Strickland's substantive involvement in prosecution
33-34	Pertains to Roche's theory relating to Lai '016 ODP rejections
35-45	Pertains to Roche's theory relating to apparent molecular weight of rEPO and uEPO, and parallels the allegations in Roche's proposed (and rejected) Second Amended Answer
46-51	Pertains to Roche's theory relating to COS rEPO, and parallels the allegations in Roche's proposed (and rejected) Second Amended Answer
52-56	Pertains to Roche's theory relating to CHO rEPO, and parallels the allegations in Roche's proposed (and rejected) Second Amended Answer
62-64	Pertains to Roche's theory relating to 1411-H cell line
65-70	Pertains to Roche's theory relating to tPA and interferon prior art
71-75	Pertains to Roche's theory relating to RIA and specification of units
76-85	Pertains to Roche's theory relating to Baron-Goldwasser and Garcia 1971

APPENDIX 2

Declaration of Michael Sofocleous

¶ No.	Portions to Strike as Not Contained in Expert Reports (<i>Comments</i>)
10-12	Entire paragraphs (<i>sets forth opinions concerning ODP analysis as between Lai '016 patent and Lin '178 application; expert report addresses only '016 patent vs '179 application</i>)
13	Reference to '178 application (<i>same</i>)

Second Declaration of Michael Sofocleous

¶ No.	Portions to Strike as Not Contained in Expert Reports (<i>Comments</i>)
8-15	Entire paragraphs (<i>sets forth opinions to the effect that Amgen delayed prosecution of the patents in suit vis-à-vis issuance of '016 patent; expert report addresses only the converse opinion -- that the PTO was not responsible for delay</i>)

Third Declaration of Michael Sofocleous

¶ No.	Portions to Strike as Not Contained in Expert Reports (<i>Comments—unless otherwise specified, reason to strike is that identified material was not contained in Mr. Sofocleous' expert reports</i>)
12	“Once an interference is declared, the examiner of the underlying application will not see the application until the interference is terminated.” (<i>expert report states that the examiner “...generally will not see the application...”</i>)
15	“Therefore, an examiner does not have time to conduct extraneous reviews of interference files.”
17	Entire paragraph
18-24	Entire paragraphs (<i>substantial expansion of conclusory statements in ¶ 274 of 4/6/07 expert report</i>)
25, 35, 46, 52, 57, 62, 65, 71, 76	Entire paragraph (<i>expert reports did not include (a) clear identification of who allegedly breached duty of disclosure, or (b) any opinion whatsoever as to intent</i>)

¶ No.	Portions to Strike as Not Contained in Expert Reports (<i>Comments—unless otherwise specified, reason to strike is that identified material was not contained in Mr. Sofocleous’ expert reports</i>)
26, 27, 28, 29, 30, 33, 53, 67, 68, 69, 73, 77, 80, 85	“This information would have been important to a reasonable examiner and to patentability under 37 C.F.R. § 1.56” ⁹ or variations thereof
27	“The declaration of separate interferences was merely an administrative matter at the time that the <i>Fritsch v. Lin</i> interferences were declared, as an examiner could not have declared an interference with an issued patent and an application owned by the same party without a terminal disclaimer. (<i>See R. Ex. 65 (Caesar & Rivas excerpt)</i>).”
28	First two sentences (<i>improper attempt to provide sur-rebuttal to Amgen responsive contentions</i>)
29	“...was a material omission, as Amgen’s position in those proceedings directly contradicted Amgen’s argument that the ‘008 and ‘179 claims were patentably distinct.” (<i>new argument for materiality</i>)
31	Entire paragraph (<i>improper attempt to provide sur-rebuttal to Amgen responsive contentions</i>)
32	(1) reference to ‘698 patent, and (2) opinion that the patents “would not have issued” (<i>expert report states the patents “would likely have been rejected”</i>)
34	“It is also my opinion that based on Mr. Borun’s duty of disclosure and the facts set forth in Roche’s memo and Roche’s Statement of Facts, an intent to deceive the Patent Office can be inferred.” (<i>expert reports contained no mention of intent</i>)
37-38	Entire paragraphs (<i>although the references listed were identified in the expert reports allegations of knowledge of those references and of their materiality are new</i>)
39	Entire paragraph (<i>UK TKT opinion was not mentioned in expert reports</i>)

⁹ Additionally, this sentence, which is repeated frequently throughout Mr. Sofocleous’s Third Declaration, contains two legal errors. First, the “reasonable examiner” test, under the 1977 version of 37 C.F.R. § 1.56 or relevant case law, is whether a reasonable examiner would substantially likely have considered the information important in determining whether to allow the application to issue as a patent. It is not, as Mr. Sofocleous suggests, merely whether the information would have been important to a reasonable examiner. Second, patentability is not determined under 37 C.F.R. § 1.56.

¶ No.	Portions to Strike as Not Contained in Expert Reports (<i>Comments—unless otherwise specified, reason to strike is that identified material was not contained in Mr. Sofocleous’ expert reports</i>)
40	Entire paragraph (<i>improper attempt to provide sur-rebuttal to Amgen responsive contentions</i>)
41	First two sentences and last sentence (<i>Lin PNAS publication not discussed in expert reports</i>)
42-45	Entire paragraphs (<i>includes improper attempts to provide sur-rebuttal to Amgen responsive contentions</i>)
49	First sentence (<i>improper attempt to provide sur-rebuttal to Amgen responsive contentions</i>)
50	Entire paragraph (<i>improper attempt to provide sur-rebuttal to Amgen responsive contentions</i>)
51	Entire paragraph
54	Last two sentences (<i>improper attempt to provide sur-rebuttal to Amgen responsive contentions</i>)
56	Entire paragraph
58	Entire paragraph (<i>apparent effort to add opinions that conform to Federal Circuit’s ruling in McKesson case</i>)
59-61	Entire paragraphs (<i>includes improper attempts to provide sur-rebuttal to Amgen responsive contentions</i>)
64	“...was a misrepresentation ...” (<i>expert reports did not assert that this statement was a misrepresentation</i>)
67	Last three sentences (<i>expert reports did not acknowledge disclosure of EP ‘619 application during prosecution, or opine that disclosure of reference did not cure misrepresentations</i>)
68	First two sentences (<i>expert reports did not opine on materiality, or Borun’s knowledge of ‘075 patent</i>)
70	Entire paragraph
74	“... as there would be no ability for one to tell if he/she was infringing the claims of Amgen’s ‘349 patent.” (<i>expert reports did not include even this much explanation of opinion on materiality</i>)
75	Entire paragraph
78	Portion of block quote before the ellipsis
79	Last sentence of block quote
80	Characterization of memorandum as “...directed towards the patentability of claim 2 of the ‘422 patent ...”

¶ No.	Portions to Strike as Not Contained in Expert Reports (<i>Comments—unless otherwise specified, reason to strike is that identified material was not contained in Mr. Sofocleous' expert reports</i>)
81-84	Entire paragraphs (<i>includes improper attempts to provide sur-rebuttal to Amgen responsive contentions</i>)
85	Entire paragraph