

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**AMGEN INC.'S OPPOSITION TO ROCHE'S MOTION PURSUANT TO FED. R. CIV.
P. 56(f) FOR RELIEF FROM AMGEN'S MOTION FOR SUMMARY JUDGMENT OF
NO INEQUITABLE CONDUCT**

I. INTRODUCTION

Roche's Rule 56(f) motion to delay this Court from ruling on Amgen's Motion for Summary Judgment of No Inequitable Conduct is based on a request for discovery related to an issue that is *not* part of Roche's inequitable conduct allegations, let alone an issue identified in Amgen's motion for summary judgment.

Roche seeks to exploit this Court's recent order for a one-day resumption of the deposition of Amgen's patent counsel, Mr. Borun, by arguing that the erroneous hexose and fucose values in Dr. Lin's patents, an issue which Roche has long known about but chose not to pursue, is somehow part of Roche's inequitable conduct case, thus necessitating discovery on it to oppose Amgen's motion. This contention has no merit. As discussed below, the motion should be denied because Roche cannot sustain its burden of demonstrating 1) that it could not respond to Amgen's summary judgment motion without this further discovery, (2) that the anticipated discovery would provide a basis for precluding the entry of summary judgment, and (3) that Roche could not have earlier obtained the sought-after discovery.

Mr. Borun's renewed one-day deposition will add nothing to the Court's consideration of Amgen's summary judgment motion on inequitable conduct, and Roche's 56(f) motion should be denied.¹

II. BACKGROUND

As the Court is aware, in March 2007, Roche moved to compel production of certain documents relating to issues of inventorship, patentability and infringement that Amgen had withheld on the grounds of attorney-client privilege, arguing that Amgen waived the privilege in some 93 specific instances. By Order dated April 17, 2007, this Court denied Roche's motion, ruling that Amgen did not waive any privilege. The order also noted, however, that Roche was entitled to know the identity of individuals who provided Mr. Borun with certain information

referenced in 2 of the 93 asserted instances (items 49 and 50), and when that information was provided. Items 49 and 50 both concern incorrect carbohydrate data (specifically monosaccharide data, and more specifically, hexose and fucose values) that were included in Dr. Lin's patent specification.

Following the Court's order, Amgen conducted an investigation to determine the information as to "who" and "when," but neither Mr. Borun nor others at Amgen could recall or reconstruct the requested information. Amgen so informed Roche, but Roche nonetheless moved to compel Mr. Borun's further deposition, which the Court has allowed. There is no basis to believe, however, that Mr. Borun will be able to provide any more information than Amgen already provided to Roche in response to the Court's April 17 Order.

More specifically, Roche is permitted to inquire into the subject matter of (1) item 49, which is an excerpt from Mr. Borun's 2000 trial testimony before this Court in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, Civ. Action No. 97—10814 WGY concerning the fact that in approximately 1990-1991 he learned further information concerning the monosaccharide data submitted to the PTO in 1984;² and (2) item 50, which is an excerpt from Mr. Borun's 2002 testimony in *Hoechst Marion Roussel, Inc., v. Kirin-Amgen* in the United Kingdom, also concerning monosaccharide data.³

As is apparent from Mr. Borun's previous testimony in this Court and other courts, the erroneous hexose and fucose values is not a new issue, and was not newly discovered by Roche since it filed its Answer, or First Amended Answer in this case. During discovery, Amgen produced to Roche documents and transcripts relating to the subject matter of items 49 and 50, and in discovery, Amgen produced transcripts and court rulings regarding the errors in the

¹ Amgen has proposed to Roche that Mr. Borun be deposed on July 13, 2007.

² Docket #497, Exh. C.

³ Docket #497, Exh. D.

monosaccharide values from litigations all over the world, including those in which Roche itself was a party (*see infra* re Roche's litigation of this issue in Canada and the UK).

Despite having full knowledge of this issue, Roche chose not to pursue it. There are no allegations of inequitable conduct surrounding the erroneous monosaccharide values in Roche's Answer, First Amended Answer, or even its proposed Second Amended Answer (which this Court denied in any event). Moreover, Roche deposed Mr. Borun during fact discovery, but chose not to question him on anything to do with the subject matter of items 49 and 50.

Nevertheless, by its Rule 56(f) motion, Roche contends that the information it seeks from Mr. Borun is germane to its claims of inequitable conduct. Such a contention is without support. But even if it were true, Roche, having not properly plead this issue or pursued it in fact discovery, cannot now assert it as a basis for denying or delaying Amgen's motion for summary judgment.

III. RULE 56(f)

Under Fed. R. Civ. P. 56(f), where a party demonstrates that it cannot "present by affidavit facts essential to justify the party's opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just."

Before postponing a summary judgment ruling pending further discovery, courts will generally require the moving party to show with particularity: (1) what facts it hopes to obtain by discovery, (2) how those facts would raise a genuine issue of fact precluding the entry of summary judgment, and (3) why this discovery had not been or could not have been obtained earlier.⁴

The party moving to delay consideration of a summary judgment motion under this rule

⁴ *Exigent Tech Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1310 (Fed. Cir. 2006)

bears the burden of demonstrating the requisite basis for relief under the rule.⁵

IV. THE BORUN DEPOSITION PROVIDES NO BASIS TO DELAY CONSIDERATION OF AMGEN'S MOTION OF NO INEQUITABLE CONDUCT, MUCH LESS A BASIS TO DENY IT

A. ROCHE CANNOT MEET ITS BURDEN TO SHOW THAT IT SOUGHT THE REQUESTED DISCOVERY IN A TIMELY MANNER.

Motions under Rule 56(f) are freely granted where a party moves early for summary judgment, before the other party has had the opportunity to conduct discovery.⁶

That is not the case here, where fact discovery closed long before the filing of motions for summary judgment. Beyond that, defendants have already taken the deposition of Mr. Borun, and had every opportunity to ask him questions about the monosaccharide data they are now focused on, yet did not do so. In fact, Roche never questioned Mr. Borun about anything having to do with the carbohydrate composition of recombinant EPO or uEPO, let alone about the erroneous hexose and fucose values. Notably, Roche has not stated otherwise. Roche also had the opportunity to fully explore those issues with other Amgen fact witnesses. Roche offers no explanation whatsoever for why it could not have much earlier pursued and developed the evidence it now says it needs to be able to oppose Amgen's Motion for Summary Judgment of No Inequitable Conduct.

Beyond that, of course, Roche has now filed literally more than a hundred pages of memoranda, counter statement of facts, and declarations in opposition to Amgen's motion, so it can hardly contend that it cannot respond to that motion without further discovery.

⁵ See *Summers v. Leis*, 368 F.3d 881, 887 (6th Cir. 2004).

⁶ See, *Burlington No. Santa Fe R. Co. v. Assiniboine & Sioux Tribes of Fort Peck Reservation*, 323 F.3d 767, 773-74 (9th Cir. 2003)

B. ROCHE CANNOT MEET ITS BURDEN OF SHOWING THAT THE DISCOVERY WOULD PRECLUDE THE ENTRY OF SUMMARY JUDGMENT

1. The Information and Issues Surrounding the Carbohydrate Data Claims by Roche Were Fully Disclosed and Discussed During the Fritsch Interference, Reviewed by the Examiner, and Therefore Cannot Be the Basis of Inequitable Conduct.

Roche contends that the information it wants from Mr. Borun relates to its inequitable conduct claims. In particular, Roche contends that certain narrow, specific monosaccharide data (specifically hexose and fucose data) were incorrect as stated in the patent application, and that Mr. Borun never disclosed that fact to the Patent Office. As Roche claimed when it moved to further depose Mr. Borun:

In his trial testimony in prior litigations against Hoechst Marion Roussel referenced in these summaries numbered 49 and 50, Mr. Borun disclosed that he learned at least as early as in 1990, during his prosecution of the patents-in-suit, that his 1984 submission to the USPTO of the hexose value of the recombinant product was most likely false and his 1984 submission of the fucose value for the recombinant and the urinary product was also likely false.

...

Moreover, Mr. Borun has admitted that during the prosecution of the patents in suit, he did nothing to notify the USPTO that he previously filed this false and material information on the key issue as to whether recombinant is different from naturally occurring EPO.⁷

However, this issue was squarely before the Board during the course of the Fritsch Interference. In the Proposed Findings of Fact and Conclusions of Law for the Party Fritsch, the incorrect carbohydrate data is discussed at length at pages 221-230. For example, at page 223, Fritsch proposed the following findings:

VI-6. The hexose value of 15.09 exceeds the average value reported in the literature for hexose saccharide components by a factor of nearly 10 and is erroneous. [Citations omitted.]

⁷ Docket #497, Memorandum in Support of Defendants' Motion to Compel Continued Deposition of Michael Borun, June 13, 2007, p. 3.

VI-7. The hexose carbohydrate composition data in the Lin application has been shown to be invalid and unreliable for other reasons. This data is derived from a certain carbohydrate analysis performed by Dr. Yu in late 1984 on two rEPO samples, B and C, and one uEPO sample, A. . . . Example 10 of the Lin application incorporates the Yu data for sample A and sample C However, Dr. Yu's data indicates that the total mass of the various carbohydrate components alone exceed the mass of the rEPO sample itself. This is a clear impossibility, . . . and the reported contribution of one or more carbohydrate components is incorrect by a substantial margin.

. . .

VI-8. Dr. Yu apparently looked for fucose and N-acetylgalactosamine in the uEPO and rEPO samples . . . , but he reported no results. . . . A correct analysis⁸ should have revealed the presence of those monosaccharides.

Examiner Fitzgerald noted that he had reviewed the '334 interference record where the issue was disclosed.⁹ Examiner Martinell thereafter took over the examination of the '178 and '179 applications, who was charged by the MPEP to give "full faith and credit" "to the search and action of the previous examiner."¹⁰

Thus, the information concerning purported mistakes in the carbohydrate data, which are to be the subject of Mr. Borun's deposition, were before the Patent Office, and such information, therefore, supports Amgen's motion for summary judgment. Roche certainly has failed to meet its burden of showing that such information would preclude entry of summary judgment.

2. The Allegations of Inequitable Conduct Regarding The Monosaccharide Data Are Not in The Case.

As discussed, Roche's theory of inequitable conduct that it claims to be relevant to the renewed Borun deposition and to this motion, is that Mr. Borun presented false hexose and fucose data to the Patent Office in 1984, learned of that fact in approximately 1990-1991, but did

⁸ Docket #547, Exh. 36, Proposed Finding of Fact and Conclusions of Law for the Party Fritsch, *Fritsch v. Lin*, Interference Nos. 102,096, 102,097 and 102,334, Before the Board of Patent Appeals and Interferences, USPTO, pp. 223-24.

⁹ Docket #547, Exh. 32, '178 File History Search Notes.

¹⁰ *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 126 F. Supp. 2d 69, 139-40.

nothing to correct that data or inform the Patent Office of the error.

This particular theory of inequitable conduct, however, is *not* contained in Roche's First Amended Answer, and its attempt to add new allegations of inequitable conduct by way of further amendment was denied by this Court on June 7, 2007. Notably, Roche doesn't even try to point to any paragraph(s) in its First Amended Answer as supporting this allegation

Moreover, Roche has no justifiable excuse for failing to address this issue earlier. Not only was this issue raised in the interferences against Party Fritsch, *supra*, and the *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 146 (D. Mass. 2001) litigation in this Court, Roche itself has litigated the issue of the errors in Dr. Lin's patent specification in other jurisdictions (as have many other entities). In Canada, Roche argued the erroneous values as a basis for invalidity of Dr. Lin's claims.¹¹ And in the UK, Roche argued that amendment of the patent to delete reference to the erroneous values constituted new matter and should not be allowed.¹² Roche cannot suggest that this theory of inequitable conduct was only developed during or after discovery in this litigation

Because the issue was not plead, Amgen did not move for summary judgment on it. Had it been plead, Amgen certainly would have done so, since the theory has no merit as previously decided by this Court in the *TKT* matter.¹³ Thus, further discovery on it is irrelevant from the

¹¹ Declaration of Craig H. Casebeer in Support of Amgen's Opposition to Roche's Motion Pursuant to Fed. R. Civ. P. 56(f) for Relief from Amgen's Motion for Summary Judgment of No Inequitable Conduct ("Casebeer Decl."), Exh. 1, [AM-ITC 00811917-811955] *Kirin-Amgen Inc. v. Hoffman-La Roche Ltd.*, [1999] Fed. Ct., Docket T-2784-97 (Reasons for Judgment) at p. 19 ("Nor does the fact that there are admitted erroneous results reported in the first and second full paragraphs on page 65. The inventors erroneously thought they could characterize rhEPO as different from uEPO by reference to the composition of the carbohydrate branches. It is admitted that the results reported are erroneous. This does not affect the validity of the preceding paragraphs that describe the difference in molecular weights observed on SDS-PAGE."); Casebeer Decl., Exh. 2, Canadian Patent 1,339,047 (first page and page 65). [AM-ITC 00317607 and 672]

¹² Casebeer Decl., Exh. 3 [AM-ITC 01060424-425 and 01060591-594].

¹³ Amgen did move for summary judgment on the inequitable conduct allegations regarding the comparison of rEPO and uEPO that *are* in Roche's First Amended Answer, to wit: that Amgen

perspective of inequitable conduct, and is certainly not needed to respond to Amgen's motion.

3. Roche is Fully Aware of The Substance of Mr. Borun's Anticipated Testimony, Which Will Add Nothing to This Court's Consideration of Amgen's Motion For Summary Judgment.

Finally, as discussed, following the Court's order of April 17, 2007, Amgen conducted a full inquiry into the "who" and "when" questions that the Court said Roche was entitled to inquire into. Part of that inquiry involved talking again to Mr. Borun. Amgen subsequently informed Roche by letter dated May 16, 2007 that information was no longer available to answer the questions.¹⁴ As Amgen stated in its memorandum in opposition to Roche's request to further depose Mr. Borun:

Amgen asked Mr. Borun to identify who provided him the information and when the information was provided to him. Mr. Borun is unable to identify who provided him with the information more than 15 years ago and is unable to identify a more specific date than the 1990/1991 time frame that he testified to at the 2000 trial. Amgen also conducted an investigation similar to that of a 30(b)(6) witness due diligence investigation. Amgen searched documents and asked its employees for the information. Amgen could not reconstruct the events that happened more than 15 years ago.¹⁵

As a result, Roche is aware of what Mr. Borun will say on that topic, and it therefore cannot bear its burden of demonstrating that the information it will generate would preclude the entry of summary judgment.

failed to disclose information to the Patent Office purporting to show similarities in the molecular weight and glycosylation as between rEPO and uEPO. Roche never alleged, however, the particular theory that Amgen had failed to disclose that it had submitted false empirical data regarding the monosaccharide composition of rEPO and uEPO.

¹⁴ Docket #497, Exh. 6, May 16, 2007 Letter from W. Gaede to N. Rizzo.

¹⁵ Docket #554. Amgen Inc.'s Memorandum in Opposition to Defendants' Motion to Compel Continued Deposition of Michael Borun, June 27, 2007, p. 5.

V. CONCLUSION

For the reasons stated above, there is no substance to Roche's motion. The renewed deposition of Mr. Borun on the topics allowed obviously will have no impact whatsoever on the Court's consideration of Amgen's Motion for Summary Judgment of No Inequitable Conduct. It is simply an effort to delay and defer, and should be denied.

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Respectfully Submitted,

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