

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD,)	
ROCHE DIAGNOSTICS GMBH,)	
and HOFFMANN-LA ROCHE INC.,)	
)	
Defendants.)	
_____)	

**ROCHE’S OPPOSITION TO AMGEN’S MOTION TO DETERMINE THE
SUFFICIENCY OF ROCHE’S RESPONSES TO AMGEN’S REQUESTS FOR
ADMISSION**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) oppose Amgen’s Motion to Determine the Sufficiency of Roche’s Responses to Amgen’s Requests for Admission.

Introduction

Roche’s responses to Amgen’s Requests for Admission Nos. 3-18 clearly satisfy the requirements of Federal Rule of Civil Procedure 36(a). Indeed, Roche has provided more information in its responses than Rule 36(a) requires, by in addition to denying the requests, providing information as to why Roche could not admit all or part of each request. The truth is that Amgen simply disagrees with Roche’s denials, and in the guise of seeking to determine the “sufficiency” of Roche’s responses, asks this Court to force Roche to admit to certain statements because Amgen takes a contrary view of the evidence and of the meanings of the patent claim terms in dispute. This is an abuse of Rule 36(a), and cannot be tolerated. This is particularly

true with respect to the 15 of the 16 disputed requests that turn on patent claim language not yet construed by the Court. Amgen's motion is also improper to the extent that its requests include scientific or technical terms that require expert interpretation or expert opinions which have not yet been obtained, as expert discovery has not yet commenced. Thus, Roche respectfully requests that the Court deny Amgen's motion, or, in the alternative, order both parties to provide supplemental responses to the respective requests for admission 30 days after the Court's *Markman* rulings and the completion of expert discovery, after which the parties may seek to have the Court rule on their sufficiency.

A. Roche's Responses To Amgen's Requests For Admission Are "Sufficient" Within The Meaning of Rule 36(a), And Their Accuracy Cannot Be Challenged At This Stage In The Litigation

Requests for Admission are governed by Federal Rule of Civil Procedure 36(a). Under Rule 36(a), the responding party may provide (1) an admission; (2) a denial; (3) a detailed explanation as to why the matter can neither be admitted nor denied; or (4) a good faith qualified admission that admits certain matters, if possible, but denies or gives a qualified answer to the rest. Fed. R. Civ. P. 36(a). A denial is sufficient under Rule 36 if it is specific and "fairly meet[s] the substance of the requested admission." *Id.* An explanation as to why a request cannot be admitted or denied is sufficient under Rule 36 if it is "set forth in detail." *Id.*

Roche has denied each of Amgen's requested admissions 3-18,¹ and in many cases, has also provided objections and detailed reasons as to why the request cannot be admitted in whole or in part. Roche has therefore met the requirements of Rule 36(a). Amgen apparently quibbles

¹ The single exception to this is Roche's Response to Amgen's Request for Admission No. 11, in which Roche responded that it could neither admit nor deny the request because a determination of every substance "occur[ring] in nature" was not known by Roche, nor was it readily obtainable by Roche through a reasonable investigation. *See* Carter Decl., Ex. 2, p. 17-18.

with the accuracy of Roche's denials, but that is not a proper subject of this motion. As a leading treatise unequivocally states:

A motion to determine the sufficiency of a response to a request for admission is not to be used as an attempt to litigate the accuracy of a response. Rule 36 does not authorize the court to make determinations on the accuracy of responses before trial. Nor may a court order that the subject matter of a request be admitted because the opposing party's denial is unsupported by evidence. An inaccurate statement is not necessarily an insufficient response. A party may prove the inaccuracy of any denial at trial, and then move for fees and costs (or other sanctions) under Rule 26(g)(2) or 37.

JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE ¶ 36.12[3], at 36-41 (3d ed. 2006) (emphasis added) [hereinafter MOORE]; accord WRIGHT & MILLER, FEDERAL PRACTICE & PROCEDURE, § 2263 (Thomson/West 2007) ("If a responding party files a response that contains the proper detail, however, the propounding party may not challenge the denial on the ground that it is unsupported by the evidence."). Indeed, the Advisory Committee Notes to Rule 37 state that if a party obtains a specific denial or a detailed statement as to why a request cannot truthfully be admitted or denied, "Rule 36 does not provide for a pretrial hearing on whether the response is warranted by the evidence thus far accumulated." Fed. R. Civ. P. 37, 1970 Advisory Committee Notes.

Courts have uniformly applied this principle to deny motions to determine the sufficiency of a response to a request for admission where the motion essentially challenges the accuracy and correctness of a response. In the frequently cited case of *Foretich v. Chung*, 151 F.R.D. 3, (D.D.C. 1993) (Greene, J.), the plaintiff denied the defendants' request for an admission that the plaintiff was a public figure for purposes of a defamation lawsuit. In denying the defendants' motion to determine the sufficiency of the plaintiff's response, the court stated:

[T]he plaintiff clearly stated that he was denying defendants' request for an admission that he is a public figure for purposes of this lawsuit. Regardless of its accuracy, this response was appropriate under Rule 36 and the Federal

Rules do not allow the defendants to litigate, at this time, whether the plaintiff was justified in denying their request. The question of whether [the plaintiff] is a public figure is obviously still in dispute between the parties.

Id. at 5. Likewise, the courts in this district recognize that it is not appropriate to rule on the accuracy of responses to requests for admission under the guise of a motion to determine the sufficiency of responses under Rule 36. In *A&V Fishing, Inc. v. Home Ins. Co.*, 145 F.R.D. 285, 287 (D. Mass. 1993), for example, Magistrate Judge Collings found that the defendant sufficiently complied with Rule 36 because:

determining the sufficiency of the answers refers only to whether the answers comply with the requirements of the rule. There is no question but that [defendant]'s denial meets the requirements of the rule, and [plaintiff]'s counsel does not contend otherwise. [Plaintiff]'s argument is that the denial is improper because [defendant] is denying facts which [plaintiff] knows to be true. This is not a proper ground for a motion to determine the sufficiency of the answers under Rule 36(a)

Id. (denying motion to determine sufficiency of admissions); accord *Joseph v. Fratar*, 197 F.R.D. 20, 23 (D. Mass. 2000) (Neiman, M.J.) (“Rule 36 . . . does not provide for a pretrial hearing on whether the response is warranted by the evidence thus far accumulated.”). In short, if the responding party denies a request or otherwise serves a response that contains the proper detail required by Rule 36, a response may not be challenged on the ground that it is unsupported by the evidence.²

² See also *Nat'l Semiconductor Corp. v. Ramtron Int'l Corp.*, 265 F. Supp. 2d 71, 74 (D.D.C. 2003) (Facciola, M.J.) (finding that the determination of the validity or truthfulness of a qualified answer or denial must await trial to see if the party forced to prove what was not admitted can meet the requirements for cost shifting under Rule 37); *United States v. Operation Rescue National*, 111 F. Supp. 2d 948, 968 (S.D. Ohio 1999) (Rice, J.) (holding that party may not seek pretrial determination of accuracy of denial of request for admission merely because evidence does not support that denial); *Lakehead Pipe Line Co., Inc. v. American Home Assurance Co.*, 177 F.R.D. 454, 458 (D. Minn. 1997) (Erickson, M.J.) (refusing to grant motion to determine sufficiency of responses, as the court is not authorized to render determinations concerning accuracy).

Roche's responses to Amgen's Requests for Admission Nos. 3-18 are sufficient under Rule 36(a). In response to each of these requests, in addition to stating its objections unequivocally, Roche has properly provided a specific denial, which in many cases was accompanied by a good faith partial qualified admission, or a detailed explanation as to why Roche cannot fully admit the statement.³ Further, each of Roche's denials addresses the substance of Amgen's request. Roche's response to Amgen's Request for Admission No. 3, reproduced below, to which Amgen refers in its motion, is a good example of this:

REQUEST FOR ADMISSION NO. 3:

RO-0503821 comprises EPO.

RESPONSE TO REQUEST FOR ADMISSION NO. 3:

Roche repeats and incorporates herein its General Objections and further specifically objects to this request as vague and ambiguous in its definition for "RO-0503821." Roche further objects to the use of the term "comprises" to describe RO-0503821 as imprecise, misleading and unintelligible, and therefore providing an insufficient basis on which to admit this request. Roche further objects to this request to the extent that "EPO" is improperly defined by incorporating the claim limitation "human erythropoietin," which has yet to be construed by the Court.⁴ Roche further objects to this request to the extent it

³ Amgen's argument that Roche's responses "imply the truth of the requested admission" and are "evasive" is without merit. *See* Amgen's Memorandum, at 3. In *Caruso v. Coleman Co.*, 1995 WL 347003 (E.D. Pa. 1995) (Naythons, J.), relied upon by Amgen, the plaintiff requested that the defendant admit that the lantern involved in the litigation emitted carbon monoxide. The defendant denied the request in part by stating that the lantern did not produce *dangerous* levels of carbon monoxide when used correctly and properly maintained. *Id.* at *2. Unlike the defendant in *Caruso*, Roche has not been evasive, but has denied the requests in whole or in part by specifically stating "Roche denies Amgen's request," or "otherwise denied." Whereas the plaintiff in *Caruso* was left to guess as to the defendant's position with respect to the subject matter of the request, Roche has provided Amgen with responses that clearly convey its position.

⁴ Roche has correctly objected to this request as improperly requiring the construction of patent claim terms. *See* Section B, below. Amgen's definition of "EPO" as "recombinant human erythropoietin, as that term is used in ROCHE's April 2006 Biologics License Application (*see e.g.*, ITC-R-BLA-00004029 and ITC-R-00004178)," is particularly unfair and objectionable because Roche's use of this term in its BLA is not capable of assuming a single definition. *See* Carter Decl., Ex. 1, p. 2 (Definition No. 8). Roche's BLA consists of a voluminous collection of

prematurely seeks expert discovery and expert opinion testimony instead of an admission on any factual matter. Based on the foregoing, Roche denies Amgen's Request for Admission No. 3.

Carter Decl., Ex. 2, p. 8 (emphasis added). In this instance, Roche properly responded to Amgen's request by providing a specific denial. *See United Coal Companies v. Powell Construction Co.*, 839 F.2d 958, 967 (3d Cir. 1988) (Gibbons, J.) (“[W]here . . . issues in dispute are requested to be admitted, a denial is a perfectly reasonable response. Furthermore, the use of only the word ‘denied’ is often sufficient under the rule.”). Even though Roche's response was perfectly adequate, in a good faith effort to resolve the objections raised by Amgen,⁵ Roche invited Amgen to provide clarification of the definition for the term “RO-0503821,” which Amgen subsequently defined as “the currently formulated product currently under consideration for approval by the FDA.” Roche then voluntarily provided the following supplemental response:

SUPPLEMENTAL RESPONSE TO REQUEST FOR ADMISSION NO. 3:

Roche repeats and incorporates herein its General Objections. Roche further objects to this request to the extent that “EPO” is improperly defined by incorporating the claim limitation “human erythropoietin,” which has yet to be construed by the Court. Roche further objects to this request to the extent it prematurely seeks expert discovery and expert opinion testimony instead of an admission on any factual matter. Based on Amgen's clarification regarding its definition of “RO-0503821” to mean only “the currently formulated product currently under consideration for approval by the FDA,” Roche denies Amgen's request in that, among other things, EPO is not used in formulating the product currently under consideration for approval by the FDA.

documents, which were created by many authors and does not necessarily use the term “EPO” in a single, consistent manner. Further, Roche's use of the term “EPO” in its BLA provides no indication as to how that term is properly interpreted in the context of the patents at issue.

⁵ Roche disagrees with Amgen's statements that Roche unreasonably delayed in responding to Amgen's requests. Roche negotiated with Amgen in good faith to resolve any objections and promptly addressed Amgen's concerns. Indeed, it is Amgen's responses to Roche's requests for admissions that are deficient, and it is Amgen who has been non-responsive to Roche's requests to remedy its deficient responses.

Carter Decl., Ex. 2, p. 8-9 (emphasis added). Roche's supplemental response, like its original response, is sufficient under Rule 36. As can readily be seen, Roche has denied the request, and has also, by explaining one of the reasons Roche denied the request, gone beyond the requirements of Rule 36(a).

It is Roche's position that RO-0503821 is not EPO, and Roche is entitled to take this position. Amgen challenges Roche's denial of Request No. 3 on the basis that it is allegedly not supported by the information Roche supplied to FDA in its BLA and IND.⁶ This is precisely the type of challenge that has been deemed an improper use of a motion to determine the sufficiency of responses to requests for admission, as the treatises, advisory committee notes, and cases discussed above all make clear. Given Roche's denials and the level of clarity and detail in Roche's qualified admissions, where qualified admissions have been made, it is clear that Roche's responses meet the requirements of Rule 36, and the fact that Amgen disagrees with Roche's answers is not an appropriate basis for the present motion.

Contrary to Amgen's contentions, Roche has no obligation to stipulate to any particular fact. *See Nat'l Semiconductor*, 265 F. Supp. 2d at 74 (stating that the common law has never required any party to stipulate to a certain fact, and "the validity, or *bona fides*, of a qualified answer must await trial to see if the party forced to prove what was not admitted can meet the requirements of [Rule 37(c)(2)]."). The purpose of Rule 36(a) is to narrow disputed issues, not to force a determination on the merits of the case halfway through the fact discovery period. *See Russo v. Baxter Healthcare Corp.*, 51 F. Supp. 2d 70, 79 (D.R.I. 1999) (Lagueux, J.) (refusing to impose Rule 37 sanctions for plaintiff's denial of certain requests for admission because requests

⁶ *See* Amgen's Memorandum, at 4 ("Because . . . Roche's own representations to FDA in its BLA and IND prove the factual accuracy of the requested admissions, Amgen respectfully requests that Requests for Admission 3-18 be deemed admitted.").

for admission exist to narrow the issues at trial where the parties unambiguously agree, and the parties must recognize that they will have fundamental disagreements and may reasonably have “different interpretations of both words and events”); *Lakehead Pipe Line Co.*, 177 F.R.D. at 458 (noting that “Requests for Admission are not a discovery device,” and the purpose of Rule 36(a) is to expedite trial by eliminating the necessity of proving undisputed and peripheral issues); *United Coal*, 839 F.2d at 967 (“The purpose of Rule 36(a) is to narrow the issues for trial to those which are genuinely contested.”).

Accordingly, Roche has met the sufficiency requirements of Rule 36(a) in its responses to Amgen’s Requests for Admission. Instead of alleging any actual deficiencies under Rule 36(a), Amgen’s motion improperly requests the Court to prematurely decide a number of genuinely disputed issues of fact. As such, its motion has no basis and must be denied.

B. Roche Has Properly Objected To Amgen’s Requests For Admission Nos. 3-15, 17, and 18 On The Basis That They Require Claim Construction, Which Is A Question Of Law

“[R]equests [for admission] directed towards applying the claims of the patent or requiring application of the claims prior to any Markman ruling are not the application of law to facts relevant to the case, but in reality are requests for legal conclusions and therefore, improper.” *Tulip Computers Int’l B.V. v. Dell Computer Corp.*, 210 F.R.D. 100, 108 (D. Del. 2002) (Thynge, M.J.); *see also Fulhorst v. United Technologies Automotive*, 1997 WL 873548 (D. Del. 1997) (Farnan, J.) (ruling that the requests for admission were improper based on its finding that “[d]etermining whether infringement has occurred involves, in the first instance, claim construction, which is a legal conclusion drawn by the court. By asking Plaintiff to admit to infringement in the context of the hypothetical use of its device, Defendant is improperly asking Plaintiff to draw a legal conclusion, which is not permitted by Rule 36.”) (emphasis

added); *Phillip M. Adams Associates, L.L.C. v. Dell, Inc.*, 2007 WL 128962, *2 (N.D. Utah 2007) (Nuffer, M.J.) (ruling that factual requests for admission regarding prior art should be answered after the Markman rulings because “[e]ven though a request may be phrased to appear factual, if it encroaches on legal turf, or reaches the ultimate decision, of the court, the request will be seen as seeking a legal conclusion and cannot be compelled.”).⁷ The *Tulip* court held that the plaintiff was not required to respond to requests for admission “directed at [the plaintiff]’s, [the defendant]’s or the court’s interpretation of the claim language” because construction of claim terms is a question of law⁸ and, therefore, “any admission or denial would neither facilitate nor narrow the issues at trial.” *Tulip*, 210 F.R.D. at 108.

The facts in the instant case are analogous to those in *Tulip*. By asking Roche to make “admissions” of fact which include terms that require claim construction, Amgen has made an improper use of its requests for admission. The majority of Amgen’s Requests for Admission at issue improperly contain terms which require claim construction. For example, a number of Amgen’s Requests for Admission include the term “EPO,” which is improperly defined by Amgen using the claim limitation “human erythropoietin,” and has yet to be construed by the Court. *See, e.g.*, Carter Decl., Ex. 1, p. 5 (Request No. 6). Similarly, the claim term “glycosylated polypeptide” is used in several of Amgen’s Requests for Admission, and also has not been construed by the Court. *See, e.g.*, Carter Decl., Ex. 1, p. 5 (Request No. 7). Both of

⁷ Amgen’s reliance on *Phillip M. Adams Associates* in support of its position that “[o]nce definitions are supplied, or terms are unambiguous, requests for admission should be answered” is misplaced. The court in *Phillip M. Adams Associates* specifically held that because the terms in the requests for admission had not been defined, as is the case here, the defendant was not required to respond to the requests until after the *Markman* rulings. *See* Amgen’s Memorandum, at 13; *Phillip M. Adams Associates*, 2007 WL 128962, at *2.

⁸ *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

these terms will require claim construction by the Court, and will be the subject of extensive *Markman* briefing in the coming weeks. Amgen's Requests for Admission are thus improper to the extent that they require claim construction, and Roche is justified in objecting to them on this basis.

C. Roche Has Properly Objected To Amgen's Requests For Admission On The Basis That They Require Expert Testimony, And Are Therefore Premature

Requests for admission which require expert opinions are improper before the completion of expert discovery. In addition to the fact that Amgen's requests at issue improperly include terms which require claim construction, Amgen's requests are premature, as expert testimony is necessary in at least two respects. First, 15 of 16 of the requests include claim terms, such as the term erythropoietin (EPO), and thus require expert interpretation to determine how a person having ordinary skill in the art would interpret these terms. Second, even after a particular meaning has been established with respect to these terms and the claims have been construed by the Court, application of the construed claim terms to Roche's products and processes at issue will be the subject of expert opinion. These issues are highly technically complex, and therefore the appropriate subject of expert testimony and opinion.

At present, expert discovery has not yet commenced, much less concluded. It is therefore premature for Amgen to solicit admissions from Roche that require expert interpretation and opinion. Amgen's Requests for Admission are thus improper to the extent that they require such expert testimony, and Roche is justified in objecting to them on this basis.

D. In The Alternative, Because It Is Premature To Determine The Sufficiency Of Roche's Responses To Amgen's Requests For Admission Before The Court's *Markman* Rulings And The Completion Of Expert Discovery, Both Roche And Amgen Should Be Ordered To Provide Supplemental Responses 30 Days After The *Markman* Rulings And The Completion Of Expert Discovery

Although Amgen's motion should be denied in its entirety, in the alternative, Roche also opposes Amgen's motion because it is premature to determine the sufficiency of Roche's responses to Amgen's Requests for Admission before the *Markman* rulings and the completion of expert discovery. The parties have not yet submitted their *Markman* briefs, nor have they even begun expert discovery. Until the Court construes the claim terms in dispute following the *Markman* hearing and the parties complete expert discovery, Amgen's requests, in addition to being improper under Federal Rule of Civil Procedure 36(a), are premature. Accordingly, Roche respectfully requests that, in the alternative to denying Amgen's motion outright, the Court order both parties to provide supplemental responses to the respective requests for admission 30 days after the Court's *Markman* rulings and the completion of expert discovery. *See Phillip M. Adams Associates, L.L.C. v. Dell, Inc.*, 2007 WL 128962, *2 (N.D. Utah 2007) (Nuffer, M.J.) (denying motion to compel answers to requests for admission requiring claim construction, and instead requiring supplemental answers within 30 days of the *Markman* rulings).

Conclusion

For all the foregoing reasons, Roche respectfully requests that Amgen's Motion to Determine the Sufficiency of Roche's Responses to Amgen's Requests for Admission be denied. In the alternative, Roche respectfully requests that the Court order both parties to provide supplemental responses to the respective requests for admission 30 days after the Court's *Markman* rulings and the completion of expert discovery.

DATED: Boston, Massachusetts
February 27, 2007

Respectfully submitted,

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/s/ Julia Huston

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