UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 05 Civ. 12237 WGY
v.	)	
	)	
F. HOFFMANN-LAROCHE LTD., ROCHE DIAGNOSTICS GMBH, AND HOFFMANN LAROCHE INC.,	)	
	)	
Defendants.	)	

AMGEN'S MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL ROCHE TO PRODUCE WITNESSES FOR DEPOSITION UNDER RULE 30(B)(6) AND OTHER RELIEF

I. INTRODUCTION

On March 7, 2007, Amgen, Inc. ("Amgen") served its Fourth Notice of Deposition to Defendants Pursuant to Fed. R. Civ. P. 30(b)(6). The Notice contained topics directed to the contentions and factual bases supporting the patent invalidity and unenforceability defenses alleged by Roche in its Amended Answer [Docket 344]. Roche has refused to designate any witnesses for this deposition. Consequently, Amgen hereby seeks an order from this Court compelling Roche to designate witnesses for deposition on the topics in Amgen's Notice. However, fact discovery closes April 2, 2007, and opening expert reports will be served on April 6, such that the consequence of Roche's refusal to produce witnesses for the 30(b)(6) deposition is that Amgen has been deprived of advance time in preparing its expert rebuttal reports responding to Roche's expert reports on its patent defenses. Accordingly, Amgen additionally requests that the Court extend its time to prepare the rebuttal reports on Roche's patent defenses.

Amgen propounded written discovery requests seeking the contentions and factual bases supporting Roche's patent invalidity and unenforceability defenses. Roche's responses to those requests were vague and incomplete. On March 28, 2007, this Court granted Amgen's motion to compel Roche to provide supplemental responses to Amgen's interrogatories concerning Roche's patent defenses within 30 days after the Court's ruling on claim construction [Order dated March 28, 2007].

However, Amgen has the right to seek deposition discovery from Roche to more fully explore and uncover the factual bases that Roche contends support its patent invalidity and unenforceability defenses. Roche's refusal to provide a single witness to testify regarding these topics unduly prejudices and impedes Amgen's efforts to prepare its expert reports concerning Roche's patent defenses and to prepare for trial.

Topics in Amgen's Rule 30(b)(6) deposition notice to Roche are mirror-images of the topics in Roche's First Notice of Deposition to Amgen Pursuant to Rule 30(b)(6). This Court recently granted Roche's motion to compel Amgen to designate witnesses to testify regarding these topics [Order dated March 27, 2007]. Amgen requests that this Court likewise grant the instant motion, compelling Roche to designate witnesses and extending Amgen's time to present its rebuttal expert reports on Roche's patent defenses.

II. FACTUAL BACKGROUND

This is a patent infringement action in which Amgen seeks a declaratory judgment that Roche is infringing or will infringe Dr. Lin's patents directed to products and processes relating to recombinant human erythropoietin ("EPO"). Amgen Amended Complaint [Docket 52]. In its Amended Answer, Roche has alleged myriad defenses asserting that the claims in Dr. Lin's patents are invalid and unenforceable. For example, Roche alleges that the patent claims are invalid for failing to satisfy any of the conditions for patentability under 35 U.S.C. §§101, 102,

103, 112, 116, and/or 262, and for double patenting over the claims of Amgen's other U.S. Patent Nos. 4,703,008 and 4,667,016. Roche has also alleged that the patents are unenforceable due to purported inequitable conduct before the U.S. Patent & Trademark Office.

A. Amgen's Notice of Deposition Pursuant to Rule 30(b)(6)

On March 7, 2007, Amgen served its Fourth Notice of Deposition to Defendants Pursuant to Fed. R. Civ. P. 30(b)(6) ("Amgen's Notice"). *See* Declaration of Mark Izraelewicz ("Izraelewicz Decl."), Ex. 1. The deposition topics in Amgen's Notice are directed to the factual bases underlying Roche's allegations of invalidity and unenforceability defenses of Amgen's patents-in-suit.

Topics 1 to 4 seek testimony concerning any efforts Roche has made or which it relies on regarding characterizing prior art EPO and cells or tissues that produced EPO to support its prior art invalidity defenses. Topic 5 seeks the factual bases for Roche's allegations that the patents are invalid under 35 U.S.C. §102(g) as a result of the efforts of Edward Fritsch to identify, clone, isolate, or express a DNA encoding human EPO. Topics 6 to 11 seek testimony concerning: (a) prior art efforts to identify, clone, isolate, sequence, or express a DNA encoding human EPO; (b) prior art efforts to achieve the recombinant expression of a glycoprotein; (c) prior art administration of any human EPO; (d) prior art isolation or purification of human EPO from mammalian cells; and (e) the structure and properties of urinary EPO. Topic 12 seeks testimony concerning Roche's communications with third parties concerning the validity of the subject matter described and/or claimed in U.S. Patent Application Serial No. 06/675,298. Topics 13 and 14 seek testimony concerning Roche's evidence of the secondary indicia of non-obviousness (commercial success and long-felt need for recombinant human EPO products). Topics 15 and 16 seek testimony concerning the level of one of skill in the art to conjugate a polyethylene glycol moiety to a protein, and to obtain a cDNA encoding human EPO. Topics 17 and 18 seek

testimony concerning assays for measuring human EPO available as of November 30, 1984, and the development, availability, or use of a radioimmunoassay method for determining the amount of human EPO in a sample. Topic 19 seeks testimony concerning the conception, reduction to practice, development and use of any subject matter described and claimed in Amgen's U.S. Patent No. 4,667,016, which Roche relies upon for its obviousness-type double-patenting defense. Topics 24 and 25 seek testimony concerning the prior art references (including the specific combinations thereof) on which Roche will rely to support its invalidity and obviousness-type double patenting defenses. Topic 26 seeks testimony concerning Roche's contentions concerning the knowledge of one of ordinary skill regarding glycosylation of recombinantly expressed proteins as of November 30, 1984. Topic 27 seeks testimony concerning Roche's contention that Dr. Lin's patents are unenforceable due to inequitable conduct before the U.S. Patent & Trademark Office. Topic 28 seeks testimony concerning Roche's contention that Dr. Lin's patents are unenforceable due to prosecution laches. Topic 29 seeks testimony concerning any contention that Dr. Lin's patents are unenforceable due to unclean hands. Topic 30 seeks testimony concerning Roche's contention that Dr. Lin's patents are unenforceable due to patent misuse.[1]

B. Roche's Refusal to Designate Witnesses Responsive to Amgen's Notice

On March 16, 2007, Roche served written objections to Amgen's Fourth Notice of Deposition. Izraelewicz Decl., Ex. 2. Apart from the typical boilerplate objections such as

[1] Topics 20-23 of Amgen's Notice are not included in this list because they are not specifically directed to seeking the factual information underpinning Roche's asserted patent defenses. Topic 20 concerns Roche's definitions for various claim terms which will be considered at the Court's Markman hearing. Topics 21 and 23 are directed to Roche's equitable estoppel defense, which has since been dismissed [Docket 342]. Topic 22 concerns the handling of documents between Roche and predecessor companies who have been litigants against Amgen regarding Dr. Lin's first EPO patent. The instant motion to compel does not address these topics 20-23.

overbreadth, privilege, and burden, Roche stated in response to Topics 1-12 and 17-18 that it "was willing to negotiate an appropriately narrowed scope. . . and to the extent that there is anyone in Roche possessing non-privileged information on this subject matter Roche will provide a witness (or witnesses) on the agreed topic." However, in response to Topics 13-16, 19, and 24-30, Roche stated "because this Topic seeks information that will properly be the subject of expert discovery, Defendants will not offer a witness on this Topic."

The parties' counsel conducted a meet and confer telephone conference on March 28. The result of the telephone conference was that Roche refused to provide any witness on any Topic in the Amgen Notice. It was apparent from the discussion that Roche had already arrived at his position before the call began. Roche's stated position during the meet and confer was that the subject matters of the Amgen Topics were more appropriately handled by responses to interrogatories or in the Roche expert reports scheduled to be served on April 6, 2007.[2]

Roche's refusal to provide any witnesses on any Topic in the Amgen Notice has effectively deprived Amgen of at least one more week of valuable time in which to prepare to rebut Roche's invalidity and unenforceability positions that will now be presented in full (presumably) for the first time on April 6.

III. ARGUMENT

It is beyond dispute that Amgen is entitled to discover the factual bases for Roche's patent defenses in this case. It is likewise apparent that the Topics in Amgen's Fourth Notice of Deposition that are the subject of this motion to compel are directed to the discovery of the bases on which Roche expects to rely, as well as contrary information Roche has learned, concerning its patent defenses. Roche's refusal to provide witnesses to testify under Rule 30(b)(6) on these

[2] During the call, Roche's counsel Thomas Fleming said that "if it isn't in the expert report, then we can't use it at trial."

Topics deprives Amgen of a significant discovery tool to which it is entitled under the Federal Rules of Civil Procedure. Roche's refusal to provide such witnesses during fact discovery deprives Amgen of needed additional time to prepare expert rebuttal reports dealing with Roche's patent defenses. Amgen was entitled to learn during fact discovery factual information relating to Roche's patent defenses.

A. Rule 30(b)(6) Requires Roche to Produce Witnesses on the Amgen Topics

The discovery provisions of the Federal Rules of Civil Procedure "are based on the assumption that voluntary compliance with the rules by the parties is to be expected." *Transportes Aereos de Angola v. Ronair, Inc.*, 104 F.R.D. 482, 498 (D. Del. 1985). Under Fed. R. Civ. P. 37(a)(2)(B), if a corporation or entity fails to designate a witness under Rule 30(b)(6), the other party is entitled to compel the designation of a witness or witnesses.

The Rules are designed to avoid the very sandbagging that Roche is trying to achieve by refusing to provide witnesses for Amgen's Rule 30(b)(6) topics. *Calzaturficio S.C.A.R.P.A. v. Fabiano Shoe Co., Inc.*, 201 F.R.D. 33, 36 (D. Mass 2001) ("This [broad] interpretation [of Rule 30(b)(6)] is necessary in order to make the deposition a meaningful one and to prevent the "sandbagging" of an opponent by conducting a half-hearted inquiry before the deposition but a thorough and vigorous one before trial.") Moreover, to the extent that Roche has any information on these topics, which it must, Roche must educate its witnesses and provide them to Amgen for a deposition. *United States v. Mass. Indus. Fin. Agency,* 162 F.R.D. 410, 412 (D. Mass 1995)(rejecting corporation's arguments that it was not required under Rule 30(b)(6) to educate its witness about actions taken by former employees of the corporation). It is apparent that Roche has made no effort to obtain information from any of its employees (both past and present) and has not made a good-faith effort to find and make any witness available for a deposition.

Roche's position that Amgen must wait until Roche serves its expert reports or supplemental responses to interrogatories finds no support in any case law or in the Federal Rules of Civil Procedure. Fed. R. Civ. P. 26(b)(1) broadly defines the subject matter on which Amgen can rightfully seek testimony of a 30(b)(6) witness: a party "may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party," and that such relevant information "need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Roche cannot pick and choose how Amgen will obtain its discovery; rather, Roche must make an effort to comply with Amgen's Notice. *Securities and Exchange Commission v. Morelli*, 143 F.R.D. 42, 45 (S.D.N.Y. 1992) (quoting *Mitsui & Co. (U.S.A.), Inc. v. Puerto Rico Water Resources Authority*, 93 F.R.D. 62, 67 (D. P.R. 1981))("under Rule 30(b)(6), the deponent 'must make a conscientious good-faith endeavor to designate the persons having knowledge of the matters sought by [the party noticing the deposition] and to prepare those persons in order that they can answer fully, completely, unevasively, the questions posed ... as to the relevant subject matters.'"). Roche has failed to meet its obligations under the Rule.

B. Amgen Is Prejudiced by Roche's Refusal to Provide Any Witnesses on These Topics

As of March 19, Roche reported that it had retained 47 experts in this case, some or all of whom will undoubtedly submit expert reports in support of Roche's patent defenses on April 6. Thus deprived by Roche of the opportunity as part of fact discovery to learn the factual bases for Roche's invalidity and unenforceability contentions, Amgen is unduly prejudiced because these details will not be revealed until Roche serves its expert reports on April 6. Even this assumes that Roche's expert reports will be specific and complete as to the evidence which Roche will present at trial in support of its patent defenses. Amgen is further disadvantaged because,

regardless of the completeness of the Roche expert reports, counter-factual information learned by Roche which could be discovered through the Amgen 30(b)(6) deposition will presumably not be divulged in the expert reports.

For example, to prove a claim is anticipated by prior art under 35 U.S.C. § 102, Roche must show that a single reference discloses each and every limitation of the claim. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003) ("An anticipating reference must describe all of the elements and limitations of the claim in a single reference."). To invalidate a claim as obvious in view of prior art under 35 U.S.C. § 103, Roche must establish that a specific combination of prior art references includes: (1) all the limitations of the claim; (2) a motivation to combine the steps of the combination in the manner claimed; and (3) a reasonable expectation of success for the steps of the combination in the manner claimed. *See Micro Chem. Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1546 (Fed. Cir. 1997). In response to Amgen's Interrogatory No. 9 seeking explanation of Roche's assertion of prior art invalidity, Roche merely listed about 70 patents and publications and stated "all underlying work of inventors named in the above patents and patent applications." Roche has never explained, for instance, how any reference would be applied and against which of the patent claims. Topic 24 in Amgen's Fourth Notice of Deposition seeks testimony concerning this information.[3]

To prove that an asserted claim is invalid for obviousness-type double patenting, Roche must compare the claims of the allegedly invalidating patent to the claims allegedly invalidated and demonstrate that the same invention is claimed in both patents. *General Foods Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1279-80 (Fed. Cir. 1992). Roche has yet to explain at any time during fact discovery what prior art teachings, if any, are being combined

[3] Topic 24 seeks testimony concerning "[a]ll prior art (including the specific combinations thereof) on which Roche will rely to support its 35 U.S.C. §102 and 103 defenses."

with the claims of the alleged invalidating patents to demonstrate obviousness-type double patenting by the later claims. Topic 25 in Amgen's Fourth Notice of Deposition seeks testimony concerning this information.[4]

C. The Court Ordered Amgen to Produce Witnesses Under Rule 30(b)(6) for Similar Topics in Roche's Notice of Deposition

Earlier in this case, Roche served a First Notice of Deposition to Amgen Pursuant to Rule 30(b)(6). Izraelewicz Decl., Ex. 3. In its Notice, Roche included topics related to Amgen's characterization of human EPO, including the prior art EPO derived from urine, recombinant EPO, and non-recombinant human EPO expressed in cells and tissue. *See* Roche Notice Topics 1 and 3, Ex. 3 at 8-10. Similarly, the Amgen Notice Topics 1 to 4 seek possible Roche's efforts, such as experiments, to characterize human EPO, whether for the purpose of substantiating or refuting Amgen's work. *See* Amgen Notice Topics 1-4, Ex. 1 at 6-7. Roche's Notice Topic 4 concerned efforts by Amgen prior to 1985 to produce a biologically any active glycosylated protein, such as EPO, in any mammalian cell. *See* Roche Notice Topic 4, Ex. 3 at 10-11. Amgen's Notice Topic 10 is directed to the same subject matter, seeking the factual information relied on by Roche concerning the expression of a biologically active mammalian glycoprotein by any mammalian cell before November 30, 1984. *See* Amgen Notice Topics 10, Ex. 1 at 8.

Thus, topics in Amgen's Notice are mirror-images of Fed. R. Civ. P. 30(b)(6) topics served on Amgen by Roche. In its March 27, 2007 Order pertaining to discovery, this Court compelled Amgen to produce witnesses for deposition under Roche's Notice Topics, including the topics which correspond with Amgen's Notice. Amgen now respectfully requests that the Court likewise compel Roche to produce witnesses for deposition pursuant to Amgen's 30(b)(6)

[4] Topic 25 seeks testimony concerning "[a]ll prior art (including the specific combinations thereof) on which Roche will rely to support its obviousness-type double patenting defense(s)."

Notice. However, the Amgen witnesses were produced in timely fashion, during fact discovery. This will not happen in Amgen's case since fact discovery has closed on April 2. In addition to compelling Roche to produce witnesses responding to the 30(b)(6) Topics, Amgen requests additional time to prepare its rebuttal expert reports on the patent defenses.

IV. CONCLUSION

There is no justification for Roche to refuse to produce witnesses to testify concerning the topics in Amgen's Fourth Notice of Deposition. Amgen was deprived of a 30(b)(6) deposition covering the factual bases for Roche's alleged patent defenses during fact discovery. The Court should order Roche to designate witnesses to testify as to Topics 1-19 and 24-30 in Amgen's Fourth Notice of Deposition, and provide Amgen with additional time to prepare its rebuttal expert reports on the patent defenses.

DATED: April 2, 2007

Respectfully Submitted,

AMGEN INC.,

/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: (617) 289-9200
Facsimile: (617) 289-9201

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

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

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 OF SERVICE

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

/s/ Michael R. Gottfried
Michael R. Gottfried