

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
)
 Plaintiff,)
)
 vs.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 AND HOFFMANN-LA ROCHE INC.,)
)
 Defendants)

CIVIL ACTION No.: 05-CV-12237WGY

**DEFENDANTS’ RESPONSE TO AMGEN INC.’S REPORT PURSUANT TO THE
COURT’S MAY 11, 2006 ORDER AND MOTION AND MEMORANDUM FOR
ADDITIONAL DISCOVERY**

Defendants respectfully submit this response to Amgen Inc.’s Report Pursuant to the Court’s May 11, 2006 Order and Motion and Memorandum for Additional Discovery (“Report”), dated May 25, 2006 (Docket No. 90). Defendants have already submitted their status report (Docket No. 89), wherein Defendants demonstrate their compliance with the Court order. However, Amgen’s Report accuses Defendants of flaunting the Court order and suggests that counsel for Defendants was remiss in the meet and confer process. In actuality, Amgen’s law firm proposed to cancel the meet and confer in view of Defendants’ withdrawal of their personal jurisdiction motions (Exhibit A, attached hereto). Tellingly, it was Defendants’ counsel that insisted that the meet and confer go forward in strict compliance with the Court order. *Id.* Thus, for Amgen to argue that Defendants have not complied with the Court order is extremely unfair and false.

Moreover, Amgen's Motion for Additional Discovery, and specifically, its renewed request to deny Defendants' pending Rule 12(b)(6) motion, should be denied for at least the following compelling reasons.

First, as Defendants' moving papers make clear, Defendants are seeking dismissal of Amgen's allegations of current infringement based on Rule 12(b)(6). Amgen's Original and Amended Complaint contain only a single cause of action for Declaratory Judgment of Infringement. (*See e.g.*, Docket No. 62 at 8). Those pleadings list the following activities to support this count: (1) filing a Biologics License Application with the FDA; (2) hiring key management and sales personnel; (3) retaining outside consultants; (4) contacting potential customers; and (5) completing construction of a manufacturing facility in Penzberg, Germany. (Docket No. 52 at 7-8). However, as pointed out in Defendants' moving papers, none of these allegations can form the basis of current infringement under the patent statute, which requires the making, using, or selling of the alleged infringing device or process in the United States. Therefore, even assuming that these contentions are true, as Defendants must under a Rule 12(b)(6) standard, these alleged facts simply cannot support a claim for current infringement. Defendants' pending Rule 12(b)(6) motion is not based on untested representations of fact requiring one to look beyond the pleading, but instead tests the formal sufficiency of the statement of claim for relief in the Complaint and Amended Complaint. Therefore, contrary to Amgen's Report, Defendant's Rule 12(b)(6) motion should not be considered under Rule 56.

Though these allegations are facially defective, Amgen still seeks a declaration that Defendants are "currently" infringing (Docket No. 52 at 9). These types of unsupported and self-serving statements should be dismissed outright because no supporting facts have been plead. Therefore, to the extent that Amgen is seeking current and actual infringement in its

ambiguously crafted pleadings, (even though it has not plead a cause of action for one), this Court should definitively rule that such requests for relief be dismissed under Rule 12(b)(6).

Second, while Amgen states in its Report that it respectfully “renews” its request that the Court deny Defendants’ pending Rule 12(b)(6) motion, Amgen in its opposition papers never seriously challenged the Rule 12(b)(6) section of the motion because it conceded that there was no current infringement. Amgen’s opposing memorandum phrased the sole issue of the motion to dismiss as follows: “Does § 271(e)(1) preclude this Court from exercising jurisdiction where, as here, Roche has performed all of the steps which Roche believes are necessary to obtain FDA approval to sell its accused PEG-EPO product in the United States?” (Docket No. 53-1 at 1). However, this issue goes to whether the Court has subject matter jurisdiction under the Declaratory Judgment Act for imminent acts of alleged infringement, and not to whether there is actual and current infringement in the United States. Lest there be any doubt that Amgen has already conceded that there is no cause of action of current infringement, Amgen states in its opposition papers that:

The Complaint (and First Amended Complaint) **sounds in declaratory relief for future infringement**. Thus Roche’s complaints about Amgen’s failure to allege actual infringement and that Roche’s activities all fall within the protection of the § 271(e)(1) safe harbor **are irrelevant**. (Docket No. 53-1 at 19) (emphasis supplied).

Therefore, since Amgen has already admitted to the Court and Defendants that issues of whether activities fall within the §271(e)(1) safe harbor and current infringement **are irrelevant**, how can Amgen now argue that a cause of action for actual infringement be maintained in this case and not be dismissed? It cannot without confessing to a clear misrepresentation to the Court.

Third, despite this concession, Amgen in its Report now seeks broad discovery into matters that it has already said **are irrelevant**, namely, whether Defendants' activities all fall within the protection of the safe harbor. For example, Amgen currently seeks discovery into Hoffmann LaRoche Inc.'s BLA and other regulatory documents, as well as information regarding former, current, and future clinical trials (Docket No. 90 at 1-2). By doing so however, Amgen is only perpetuating the expensive, resource draining distractions that §271(e)(1) was designed to prevent. This Court and others have specifically recognized this potential for harassment as a means of disrupting a company's diligent efforts to gain FDA approval.

Based on the foregoing, Defendants respectfully request that Amgen's Motion For Additional Discovery be denied, and that Defendants' pending motions to dismiss the Complaint and Amended Complaint for lack of subject matter jurisdiction under Rule 12(b)(1) and failure to state a claim under Rule 12(b)(6) be granted. If the Court should grant the motions to dismiss, or in the alternative, administratively close this case, Defendants specifically request an order stating that Amgen allegations of current and actual infringement have been dismissed.

DATED: Boston, Massachusetts
May 30, 2006

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By its attorneys,

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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Julia Huston

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