

EXHIBIT 46

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC.,)	
Plaintiff,)	
v.)	CIVIL ACTION: 05-CV-12237-WGY
)	
F. HOFFMAN-LA ROCHE LTD,)	
ROCHE DIAGNOSTICS GmbH, and)	
HOFFMAN-LA ROCHE INC.,)	
Defendants)	
_____)	

REBUTTAL REPORT OF B. DOUGLAS BERNHEIM, PH.D.

May 11, 2007

III.1. Overview

- (66) A key question addressed in my previous Expert Report and the Expert Reports of Mr. Elhauge and Dr. Stiroh is: what is the likely impact of peg-EPO entry on average prices and Medicare expenditures for anemia products? My previous report identified three potential ways to address this question. First, we can investigate the implications of economic theory. Second, we can attempt to draw conclusions from the planning documents, testimony, data, and other information produced in this case. Third, we can examine pricing patterns in other therapeutic segments, where new entry has occurred under the ASP-based reimbursement system.
- (67) For the most part, Mr. Elhauge and Dr. Stiroh simply assume that competition among the manufacturers of ESAs will create significant downward pressure on prices. Neither report reflects a serious consideration of the implications of the incentives created by the ASP-based reimbursement system for competitive pricing. This omission is particularly jarring in Mr. Elhauge's case, since his report does emphasize the unusual implications of the ASP-based reimbursement system in the context of monopoly; he simply neglects these implications in contexts involving more than one firm. Both the Stiroh report and the Elhauge report overlook the particular circumstances that necessarily give rise to the alternative hypotheses discussed in my report—that, in this peculiar institutional setting, competition could either raise prices or leave them unchanged. Consequently, in contrast to my first Expert Report, neither the Stiroh report nor the Elhauge report provides evidence that might help a fact-finder determine whether Medicare costs are likely to rise or fall as a result of Roche's entry.
- (68) In my first Expert Report, I carefully examined the pertinent economic hypotheses from a theoretical and empirical perspective, and reached the following conclusions.
- First, as a matter of economic theory, new entry can either raise or lower average prices (and hence Medicare reimbursements) under an ASP-based reimbursement system. My analysis was based on an understanding of manufacturers' and purchasers' incentives under the ASP reimbursement system that largely coincides with Mr. Elhauge's, and that has been recognized in the pertinent academic literature.⁵³ My analysis diverges from Mr. Elhauge's in that I explicitly consider the implications of those incentives in the context of oligopoly (and not merely in the case of monopoly), whereas Mr. Elhauge does not. In my previous report, I noted in addition that

⁵³ Danzon, Wilensky, and Means, "Alternative Strategies for Medicare Payment of Outpatient Prescription Drugs—Part B and Beyond," *The American Journal of Managed Care*, Vol 11, No. 3, p. 177