UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC., Defendants.	)	Civil Action No.: 05 Civ. 12237 WGY

MOTION *IN LIMINE* TO PRECLUDE PLAINTIFF FROM ARGUING TO THE JURY THAT EPOGEN IMPROVES QUALITY OF LIFE WHERE THE FDA DOES NOT SUPPORT THE INCLUSION OF SUCH CLAIMS ON THE PRODUCT LABEL

I. INTRODUCTION

Amgen has indicated that it will argue to the jury that its Epogen® product improves the quality of life of patients.[1] It's attempt to introduce such evidence should be precluded for the following reasons:

- The FDA has prohibited Amgen from making claims of quality of life benefits in the Epogen label, making it misleading for Amgen to present evidence contrary to the label to the jury.
- The FDA has expressed concern that other quality of life claims Amgen makes regarding its product are unsupportable.

II. ARGUMENT

A. Amgen Should Not Be Permitted To Offer Evidence of Claimed Quality of Life Improvements That It Has Told the FDA Are Unsupportable

In March of 2007, the FDA, in response to the disturbing results of several clinical studies involving erythropoiesis-stimulating agents ("ESAs"), sold by Amgen under the trade

[1] Roche disputes that Epogen® is a product that can be produced according to the patents-in-suit and by this motion does not concede this point.

names Epogen and Aranesp®, and by Ortho, under the trade name Procrit®, issued a public health advisory alerting the public to various health risks of those ESAs. At the same time, the FDA compelled Amgen to change its label to include a "black box" warning recommending that doctors prescribe the lowest dose possible to increase hemoglobin concentration.[2] At the same time, the FDA requested Amgen to reassess the data supporting various claims that Epogen improved the "quality of life" of patients, as described within the Clinical Experience section of the label, given FDA concerns that such claims were not supportable.[3] After review, Amgen admitted that it could not validly make several of the "quality of life" claims in the label. Specifically, Amgen admitted to the FDA that data did not support claims that Epogen improved patients' quality of life regarding, "energy and . . . sleep and eating behavior, health status, satisfaction with health, sex life, well-being, psychological effect, life satisfaction, and happiness."[4] After the FDA challenges, Amgen submitted a modified label that withdrew many of its "quality of life" claims.

Thus, Amgen may not make any claim on its label that using its products will result in improvements to "quality of life . . . including energy and . . . sleep and eating behavior, health status, satisfaction with health, sex life, well-being, psychological effect, life satisfaction, and happiness" because there is insufficient data supporting these claims. Because Amgen has admitted that there is no data to support these claims, Amgen should not be allowed to present evidence at trial that the use of its ESA products have led patients to experience any of these supposed benefits. Indeed, any such testimony by an expert would necessarily be scientifically unreliable under the rule of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

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[2] Toms Exhibit A, FDA Alert, pg. 1, 3/9/2007 *available at* http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE2007HCP.htm.
[3] Toms Exhibit B, FDA Advisory Committee Briefing Document Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Committee, 9/11/2007, pg. 18.
[4] Id. at 18-19.

B. Amgen Should Not Be Permitted To Offer Evidence of Claimed Quality of Life Improvements That the FDA Has Stated Are Not Supported by Sufficient Data

In addition to the label changes that the FDA has implemented regarding quality of life claims, the FDA has also stated that the data regarding Amgen's other claims that Epogen improves the quality of patient lives is "deficient." Specifically, the FDA has questioned whether there is a valid scientific basis for Amgen to claim that Epogen improves patients' "activity level and functional ability, energy, shortness of breath, and muscle weakness" -- quality of life claims that Amgen seeks to retain on its Epogen label.[5] In reviewing these claims, however, the FDA has stated that "[b]ased upon the current state of the clinical science pertaining to [patient reporting outcomes ("PRO")], the safety risks evidenced for ESAs and the need to update product labeling when important new information becomes available, FDA has reviewed the supplied information and ***has detected important deficiencies within the data***." (emphasis added)[6] Accordingly, the FDA has indicated that it may require the removal of such quality of life claims from the label as well.[7] Indeed, the FDA has stated that the supplied clinical data do not supply sufficient evidence of efficacy for the label to retain <u>any</u> of the quality of life claims in light of the current regulatory and clinical science expectations for these types of data[8] Because the FDA has stated that the data are insufficient to support these claims, Amgen should likewise be prohibited from offering any evidence or eliciting any testimony at trial that the use of Epogen improves the quality of patients' lives regarding activity level, functional ability, energy, shortness of breath, or muscle strength -- claims that the FDA has said have insufficient support in the scientific data.

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[5] Id. at 19.
[6] Id. at 19 (emphasis added).
[7] Toms Exhibit C, F.D.A. Advisory Panel Opposes Curb on Anemia Drugs, New York Times, 9/12/07, *available at* http://www.nytimes.com/2007/09/12/business/12anemia.html?_r=1&oref=slogin.
[8] Toms Exhibit B, FDA Advisory Committee Briefing Document Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Committee, 9/11/2007, pg.6.

III. CONCLUSION

For the foregoing reasons, Amgen should be precluded from presenting evidence at trial asserting that Epogen improves the quality of life for patients.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

DATED: Boston, Massachusetts
September 23, 2007

Respectfully submitted,

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

By their Attorneys,

/s/ Keith E. Toms
Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO # 663853)
Kimberly J. Seluga (BBO# 667655)
ROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel: (617) 443-9292
ktoms@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

/s/ Keith E. Toms
Keith E. Toms

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