

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

WARNER CHILCOTT COMPANY, LLC and)	
HOFFMANN-LA ROCHE INC.,)	
)	
Plaintiffs,)	C.A. No. 08-627-LPS
)	
v.)	(and consolidated cases)
)	
TEVA PHARMACEUTICALS USA, INC.,)	REDACTED PUBLIC VERSION
)	
Defendant.)	

**DECLARATION OF DANIEL SMITH PHD IN SUPPORT OF PLAINTIFFS’
OPPOSITION TO DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT OF
INVALIDITY FOR OBVIOUSNESS UNDER 35 U.S.C. § 103**

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*Attorneys for Plaintiff Warner Chilcott
Company LLC*

Dated: July 20, 2012

I. INTRODUCTION

1. I have been retained by the firm of WilmerHale LLP on behalf of Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. (collectively, “Plaintiffs”) to provide expert testimony in the above-captioned matter regarding U.S. Patent Nos. 7,192,938 (“the ‘938 patent”) and 7,718,634 (“the ‘634 patent”).

2. On behalf of Plaintiffs, I submitted an expert report dated January 21, 2012, regarding the commercial success of Once-A-Month Actonel[®] (hereinafter “Smith Report”). My Rebuttal Report is incorporated herein by reference.

II. INFORMATION REVIEWED OR CONSIDERED IN PREPARING OPINION

3. My opinions are based on a variety of publications and other information, including those listed in Exhibit B of my Rebuttal Report, all of which I hereby incorporate by reference. I also base my opinions on my education and professional experience in marketing.

III. LEGAL PRINCIPLES

4. I understand that a patent shall not issue if the subject matter of the patent would have been obvious to a person having ordinary skill in the art at the time the invention was made. I further understand that in assessing obviousness, a court will consider: (1) the scope and content of the prior art; (2) differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness, including secondary considerations such as long-felt but unresolved needs, failure of others, and commercial success.

5. It is my understanding that, from a legal perspective, to establish commercial success, the patentee must demonstrate: (1) that a product is commercially successful, as

demonstrated by, for example, sales levels, sales growth, total products sold, and market share; and (2) that there is a nexus between that commercial success and the inventions of the patent claims at issue.

IV. ONCE-A-MONTH ACTONEL® IS A COMMERCIAL SUCCESS

6. For the reasons set forth below, it is my opinion that Once-A-Month Actonel® is a commercial success.

A. Sales of Once-A-Month Actonel®

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REDACTED

Levy Decl. Ex. 44, PGOAM 0381086-PGOAM 0381098.

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E

¹ Levy Decl. Ex. 44, PGOAM 0381086-PGOAM 0381098.

² *Id.*

9. Sales by prescription volume. One can also gain a strong sense of physicians' acceptance by examining prescription volume.

REDACTED

The volume of total prescriptions supports my conclusion that Once-A-Month Actonel® is a commercial success.

REDACTED

Levy Decl. Ex. 4, Excerpt from PGOAM 0381085. Source: IMS National Sales Data. Prescriptions for Once-A-Month Actonel®.
(a) 2008 data are for eight months (May – December).

B. Market Share

10. Market share is also a useful measure of commercial success because it reflects the reaction of physicians to a product relative to competing alternatives.

REDACTED

³ Levy Decl. Ex. 4, Excerpt from PGOAM 0381085.

⁴ *Id.*

REDACTED

Levy Decl. Ex. 4, Excerpt from PGOAM 0381085. Source: IMS National Sales Data (U.S.). **Sales** are in millions of dollars. Figures in parentheses are the market shares for each drug based on total market sales of branded drugs.
(a) 2008 data are for eight months (May – December).

⁵ Levy Decl. Ex. 4, Excerpt from PGOAM 0381085.

⁶ *Id.* Alendronate was marketed under the brand name Fosamax®. In February 2008, the FDA approved the first generic versions of alendronate.

11. Market share analysis based on sales revenue, while informative, is affected by differences in prices among competitors. To “remove” the effect of prices of the various branded drugs, I also considered market share based on prescription volume.

REDACTED

Based on this data, it is clear that physicians find Once-A-Month Actonel® an attractive option for many of their patients.

REDACTED

Levy Decl. Ex. 4, Excerpt from PGOAM 0381085. Source: IMS National Sales Data. **Total prescriptions** of branded products. The figures in parentheses are the market shares of each product as a percent of the total prescriptions written for branded products each year.

(a) 2008 data are for eight months (May – December).

12. Market share based on prescriptions can also be considered in terms of new prescriptions written as this is a metric that recognizes, in part, the extent to which new patients are being prescribed a particular treatment. The table below provides a summary of market shares of the branded competitors based on new prescriptions. REDACTED

REDACTED

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Levy Decl. Ex. 4, Excerpt from PGOAM 0381085. Source: IMS National Sales Data. **New prescriptions** of branded products. The figures in parentheses are the market shares of each product as a percent of the new prescriptions written for branded products each year.

(a) 2008 data are for eight months (May – December).

13. Once-A-Month Actonel®'s market share is particularly impressive in light of the number of well-established competitors occupying the market at the time of its launch.

REDACTED

14. My analysis of Once-A-Month Actonel®'s market share based on sales revenue, total prescriptions and new prescriptions supports my conclusion that the product embodying the asserted claims of the Once-A-Month Patents is a commercial success.

V. THE SUCCESS OF ONCE-A-MONTH ACTONEL® IS RELATED TO THE PATENTS-IN-SUIT

15. It is my understanding that for a product's commercial success to be relevant evidence of non-obviousness under the patent laws, it is important to demonstrate a nexus between the patented features of the product and the marketplace success of the product. That is, the commercial success of the product must be due to the patented invention, and not to other factors such as marketing.

A. Marketing Communications Activities for Actonel®

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⁷ Levy Decl. Ex. 4, Excerpt from PGOAM 0381085.

⁸ *Id.*

⁹ Levy Decl. Ex. 45, Excerpt from PGOAM 377918.

REDACTED

B. Physician Satisfaction is Tied to the Patented Aspects of Once-A-Month Actonel®

18. There is a high rate of renewal prescriptions written for Once-A-Month Actonel®.

Renewal prescriptions are an objective measure of physician satisfaction with a pharmaceutical product. If these products did not prove to offer benefits over other products in the marketplace for at least some segment of their patients, physicians would simply switch patients to another

¹⁰ http://www.cbo.gov/ftpdocs/105xx/doc10522/12-02-DrugPromo_Brief.pdf.

¹¹ Levy Decl. Ex. 46, Excerpt of August 30, 2011 Deposition of April Mitchell Transcript, at 50:6-8.

¹² Levy Decl. Ex. 45, Excerpt from PGOAM 377918.

¹³ Levy Decl. Ex. 46, Excerpt of August 30, 2011 Deposition of April Mitchell Transcript, at 50:6-8.

¹⁴ Levy Decl. Ex. 4, Excerpt from PGOAM 0381085.

¹⁵ *Id.*

drug. However, renewal prescriptions for Once-A-Month Actonel® indicate that physicians continue to prescribe this product well past a patient's initial introduction to the drug.

REDACTED

19. If Once-A-Month Actonel® was not proving to offer unique benefits when used by their patients, physicians would consistently be discontinuing or reducing prescriptions for the drug, and renewal prescriptions would be a slight fraction of the drug's total prescriptions. The high ratio of renewals to total prescriptions for Once-A-Month Actonel® demonstrates that physicians (and their patients) are satisfied with the clinical benefits of the product and that the product's success in the marketplace is due to its unique benefits which in turn are tied to the patented features.

C.

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¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Levy Decl. Ex. 4, Excerpt from PGOAM 0381085.

¹⁹ *Id.*

²⁰ Levy Decl. Ex. 44, PGOAM 0381086-PGOAM 0381098.

²¹ *Id.*

REDACTED

VI. SUPPLEMENTATION OF OPINIONS

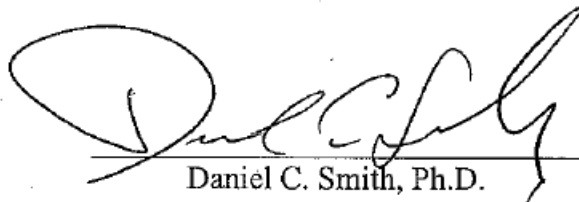
21. I reserve the right to adjust or supplement my analysis in response to any critique of my report or alternative opinions advanced by or on behalf of any Defendant.

VII. EXHIBITS

22. I may rely on visual aids and demonstrative exhibits that demonstrate the bases of my opinions, including, *e.g.*, excerpts from the patents, discovery responses, deposition testimony, trial exhibits, test data, charts, photographs, diagrams, videos, and animations.

23. If it is helpful to the Court, I am ready to provide additional background information, for example, regarding the marketing of prescription pharmaceutical products.

Dated: July 20, 2012



Daniel C. Smith, Ph.D.

²² *Id.*

²³ <http://www.mckennalong.com/news-advisories-2289.html>

²⁴ David Dranove, *The Economic Evolution of American Healthcare*, Princeton University Press, 2002, Chapter 4, page 74), *available at* <http://books.google.com/books?id=5Fw6bDUDEAUC&pg=PA74&lpg=PA74&dq=Managed+care+organization+drug+discounts+dranove&source=bl&ots=r33UmkVI5u&sig=L9D2hkO4eYsXkBd8P7q5tignfh4&hl=en&sa=X&ei=O-cJT5eJKobo0QGwiqnAAg&ved=0CEAQ6AEwAg#v=onepage&q&f=false>).

CERTIFICATE OF SERVICE

I hereby certify that, on July 20, 2012, I electronically filed the foregoing document with the Clerk of Court using CM/ECF, which will send notification of such filing(s), and have sent a true and correct copy by electronic mail to the following:

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