IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 08-627-LPS, C.A. No. 11-81-LPS
WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. APOTEX, INC. and APOTEX CORP., Defendants.	C.A. No. 09-143-LPS, C.A. No. 10-1111-LPS (consolidated with C.A. No. 08-627-LPS)
WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., Defendant.	C.A. No. 10-285-LPS, C.A. No. 11-286-UNA (consolidated with C.A. No. 08-627-LPS)
THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC., Plaintiffs, v. SUN PHARMA GLOBAL, INC., Defendant.	C.A. No. 09-61-LPS, C.A. No. 10-1085-LPS (consolidated with C.A. No. 08-627-LPS)

DECLARATION OF DR. JOHN YATES REGARDING CLAIM CONSTRUCTION ISSUES

I. INTRODUCTION

1. I am a medical doctor with a specialty in bone and mineral metabolism. I have spent approximately 30 years of my career studying and developing treatments related to bone disorders such as osteoporosis. A copy of my Curriculum Vitae is provided as Exhibit A to this Declaration.

2. I receive $500/hour for my study and testimony as an expert in this case.

3. In the past four years, I have testified as a specially retained expert at a deposition in the consolidated cases, *Hoffmann-La Roche Inc. v. Apotex Inc.*, Civil Action No. 07-4417 (SRC) (MAS), *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd.*, Civil Action No. 07-4516 (SRC) (MAS), *Hoffmann-La Roche Inc. v. Watson Laboratories, Inc.*, Civil Action No. 07-4539 (SRC) (MAS), *Hoffmann-La Roche Inc. v. Orchid Chemicals & Pharmaceuticals Ltd.*, Civil Action No. 07-4582 (SRC) (MAS), and *Hoffmann-La Roche Inc. v. Mylan Inc.*, Civil Action No. 07-4661 (SRC) (MAS) pending in the District of New Jersey, that include one of the same patents in suit here and concern the monthly oral dosage form of the bisphosphonate, Boniva® (ibandronate sodium). Any other testimony I have given at trial or deposition has related to and arisen out of my former regular employment, not as a specially retained expert solely for purposes of litigation.

4. I have been retained by the law firm of Husch Blackwell LLP with offices at 120 S. Riverside Plaza, Suite 2200, Chicago, IL 60606 to render opinions regarding US 7,192,938 ("the '938 patent") and US 7,718,634 ("the '634 patent").

5. My opinions as disclosed in this declaration relate to the understanding a person of ordinary skill in the art to which the '938 patent and the '634 patent pertain would have regarding certain language used in the claims of those patents.

6. In forming my opinions, I considered and relied upon my education, background, experience and prior scientific work, including my personal knowledge of osteoporosis, bisphosphonates, and methods of treatment of osteoporosis, my work on this litigation and to an extent, my work in the New Jersey litigation involving ibandronate. My expert reports in the ongoing New Jersey litigation cite numerous references which I considered in that litigation, and to an extent inform my opinions in this case. In addition and more particularly with respect to the present litigation I have reviewed the references cited herein and attached hereto. I have also reviewed and considered the '938 patent and '634 patent and portions of their prosecution histories, and the opinions in the New Jersey case: *Hoffmann-La Roche v. Apotex Inc.*, No. 07-4417, 2010 WL 1875569 (D.N.J. May 10, 2010) and *Hoffmann-La Roche Inc. v. Apotex Inc.*, No. 07-4417, 2010 WL 3522786 (D.N.J. Sep. 2, 2010). I have also reviewed the Declaration Of John P. Bilezikian, M.D. In Support Of Plaintiff's Opening Claim Construction Brief Regarding U.S. Patent No. 7,192,938, dated November 22, 2010.

II. QUALIFICATIONS.

7. I expect to testify regarding my background, qualifications and experience relevant to my opinions. A copy of my Curriculum Vitae is attached as Exhibit A to this report.

8. I received a B. Med. Sci. degree in Clinical Physiology and Pharmacology from the Sheffield University Medical School in Sheffield, U.K. in 1977. I received an

M.B. Ch.B. in Medicine (the U.K. equivalent to M.D. in U.S.) also from Sheffield University Medical School, in 1980. I received an M.D. degree in Bone and Mineral Metabolism also from the Sheffield University Medical School, in 1987. A doctor of medicine (M.D.) degree in the U.K. is a higher postgraduate qualification, equivalent to a Ph.D, obtained following three years of independent research and submission of a research thesis.

9. I am presently an independent consultant in the area of pharmaceutical drug development. From 2007 to 2008 I was Chief Medical Officer for Array Biopharma, Inc. From 2004 to 2007 I was President of Takeda Global Research & Development, Inc. where I was responsible for the clinical development of more than 25 different drugs in a variety of medical disorders. From 1990 to 2003, I worked for Merck & Co. Inc. in a variety of positions. From 2000 to 2003, I was Vice President, U.S. Medical & Scientific Affairs, during which time I was responsible for all U.S. phase 4 clinical studies supporting 15 marketed or soon-to-be marketed pharmaceutical products. From 1990 through 2000, I had positions of increasing seniority and led the clinical development of Fosamax®, a bisphosphonate used for the treatment and prevention of osteoporosis as well as treatment of Paget's disease of bone. I am a named inventor of the once-weekly regimen for Fosamax®, which was responsible for the product exceeding $3.5 billion per year in worldwide sales and occupying over 50% of the entire osteoporosis market.

10. From 1989 to 1990, I was Assistant Professor, Department of Medicine, Division of Endocrinology at the University of Texas Health Science Center in San Antonio, Texas. Prior to that, from 1988 to 1989, I was an Instructor in the Department of Medicine, Division of Endocrinology at the University of Texas. While in San Antonio, I

continued my studies in the area of bone and mineral metabolism, including spending about 75% of my time on laboratory-based work. I also saw patients in general medicine, and endocrinology.

11. I have published over 70 papers in peer-reviewed publications and have authored over 120 abstracts. I have designed or contributed to the design of more than 100 clinical trial protocols and authored numerous documents used in regulatory submissions for drug registration with the FDA and other regulatory agencies worldwide. I am also the named inventor of over ten patents or patent applications.

III. APPLICABLE PRINCIPLES

12. It is my understanding that terms in a patent claim are given the meaning ascribed to them by one of ordinary skill in the art, unless the patent applicant acted as his own lexicographer and provided a special definition of those terms in the patent specification.

13. Furthermore, it is also my understanding that the proper construction of patent terms can also be affected by the course of communication between the applicants and the patent office during examination, which is reflected in the administrative record called the prosecution history or file wrapper of the patent.

IV. THE PERSON OF ORDINARY SKILL IN THE ART.

14. In my opinion, the hypothetical person of ordinary skill in the art of the ’938 patent and the ’634 patent as of May 10, 2002, or May 6, 2003, would have a very high level of skill. He or she would have typically been an M.D. or Ph.D. with a number of years of experience with bone diseases including osteoporosis and would have been

well versed in the relevant scientific literature. Such a person would have been familiar with the technical literature on the development and use of bisphosphonates and the treatment of osteoporosis, including dosing amounts and schedules. Such a person would also be familiar with pre-clinical and clinical studies related to bisphosphonates and would have the ability to analyze and draw inferences from such studies.

V. THE ASSERTED CLAIMS

15. It is my understanding that Plaintiffs have asserted infringement of Claims 1, 3, 5, 6, 8, 9, 13, 14, 15, 16, 18, 20, 21, 23, 24, 28, 29, and 30 of the '938 patent. These claims read:

> 1. A method for treating or inhibiting osteoporosis comprising commencing treatment by orally administering to a subject in need of such treatment, a first dose, on a single day, of a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 100 mg to about 150 mg of said bisphosphonic acid and continuing said treatment by orally administering, once monthly on a single day, a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent [sic] to from about 100 mg to about 150 mg of bisphosphonic acid.
>
> 3. The method according to claim 1, wherein the pharmaceutical composition comprises about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 150 mg of bisphosphonic acid.
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> 5. The method of claim 1 wherein the pharmaceutical composition comprises 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to 150 mg of bisphosphonic acid.
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> 6. The method of claim 1 wherein said bisphosphonic acid is risedronic acid or a pharmaceutically acceptable salt thereof.
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> 8. The method of claim 3 wherein said bisphosphonic acid is risedronic acid or a pharmaceutically acceptable salt thereof.
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> 9. The method of claim 5 wherein said bisphosphonic acid is risedronic acid or a pharmaceutically acceptable salt thereof.
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> 13. The method of claim 6 wherein said pharmaceutical composition is a solid pharmaceutical composition.

> 14. The method of claim 8 wherein said pharmaceutical composition is a solid pharmaceutical composition.
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> 15. The method of claim 9 wherein said pharmaceutical composition is a solid pharmaceutical composition.
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> 16. A method for treating or inhibiting osteoporosis consisting of orally administering to a subject in need of such treatment, once monthly, a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 100 mg to about 150 mg of said bisphosphonic acid.
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> 18. The method according to claim 16, wherein the pharmaceutical composition comprises about 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to about 150 mg of bisphosphonic acid.
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> 20. The method of claim 16 wherein the pharmaceutical composition comprises 150 mg of bisphosphonic acid or an amount of a pharmaceutically acceptable salt thereof that is equivalent to 150 mg of bisphosphonic acid.
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> 21. The method of claim 16 wherein said bisphosphonic acid is risedronic acid or a pharmaceutically acceptable salt thereof.
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> 23. The method of claim 18 wherein said bisphosphonic acid is risedronic acid or a pharmaceutically acceptable salt thereof.
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> 24. The method of claim 20 wherein said bisphosphonic acid is risedronic acid or a pharmaceutically acceptable salt thereof.
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> 28. The method of claim 21 wherein said pharmaceutical composition is a solid pharmaceutical composition.
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> 29. The method of claim 23 wherein said pharmaceutical composition is a solid pharmaceutical composition.
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> 30. The method of claim 24 wherein said pharmaceutical composition is a solid pharmaceutical composition.

(the ’938 patent, cols. 7–8.)

16. It is my understanding that Plaintiffs have asserted infringement of Claims 9 and 10 of the ’634 patent. Those claims read:

> 9. A method for treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis by administration of a pharmaceutically acceptable salt of risedronic acid, comprising:
>
> (a) commencing the administration of the pharmaceutically acceptable salt of risedronic acid by orally administering to the postmenopausal woman, on a single day, a first dose in the form of a tablet, wherein the tablet comprises an amount of the

pharmaceutically acceptable salt of risedronic acid that is equivalent to about 150 mg of risedronic acid; and

(b) continuing the administration by orally administering, once monthly on a single day, a tablet comprising an amount of the pharmaceutically acceptable salt of risedronic acid that is equivalent to about 150 mg of risedronic acid.

10. A method for treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis by administration of a pharmaceutically acceptable salt of risedronic acid, consisting essentially of orally administering to the postmenopausal woman, once monthly on a single day, a tablet comprising an amount of the pharmaceutically acceptable salt of risedronic acid that is equivalent to about 150 mg of risedronic acid.

(the '634 patent, cols. 7–8.)

VI. THE TERM SUBJECT INCLUDES VETERINARY USES.

17. A person of ordinary skill in the art would have understood that the word "subject" as used in the patent claims is not limited to a human patient, but would also encompass other animals. A person of ordinary skill in the art in this field (at times including 2002 or 2003) would have understood that bisphosphonates can have a variety of uses including veterinary uses.

18. Osteoporosis, for example, particularly in the form of immobilization osteoporosis, is recognized as a problem in horses. Fractures in horses can be very serious, and are a significant cause of mortality, especially among racehorses. Horses that become lame are generally confined to stables, during which time they lose bone as a result of immobilization leading to increased bone resorption. Upon re-exposure to stress the osteoporotic bone is at increased risk of fracture.

19. Persons of ordinary skill in the art at that time were considering and exploring veterinary uses of bisphosphonates, and my own research included a significant

amount of consultation with the veterinary side of the company at my employer, Merck & Co, Inc. Merck did in fact conduct studies of alendronate in horses prior to 2002, although to my knowledge the results of these studies were never published. Also, other authors have used the bisphosphonate, tiludronate, to treat horses for bone loss. *See* Delguste, C., et al., "Pharmacological effects of tiludronate in horses after long-term immobilization," Bone, Vol. 41, pp. 414-421, (2007) (Exhibit B); Denoix, J. M., "Tiludronate as a new therapeutic agent in the treatment of navicular disease: a double-blind placebo-controlled clinical trial," Equine vet. J., Vol. 35(4), pp. 407-413 (2003) (Exhibit C).

20. Accordingly, a person of ordinary skill in the art reading the word "subject" in a patent claim, where the specification describes "humans and mammals," would have understood that the word "subject" was not limited to human subjects, but that it could instead encompass mammals other than humans. As a further example of the lack of restriction of osteoporosis to humans, or even to mammals, osteoporosis is a common and problematic condition among laying hens. *See* Webster, A.B., "Welfare Implications of Avian Osteoporosis," Poultry Science, Vol. 83, pp. 184-192 (2004) (Exhibit D); Farm Animal Welfare Council, "Opinion on Osteoporosis and Bone Fractures in Laying Hens," (December 2010) (Exhibit E).

VII. SUPPLEMENTATION AND EXHIBITS

21. I reserve the right to amend or supplement my declaration, or to respond in rebuttal to positions taken in other declarations regarding claim construction issues.

22. I may use exhibits (including demonstrative exhibits I have not yet created) if called for a tutorial or at a hearing in connection with the issue of claim

construction to summarize and illustrate my opinions. In the event that additional information becomes available, I may supplement this declaration to take into account such additional information.

23. If it is helpful to the Court, I am ready to provide additional background regarding, for example, the treatment and inhibition of osteoporosis.

I declare under penalty of perjury that the foregoing is true and correct to the best of my own personal knowledge.

Dated: 4/18/2011

John Yates, M.D.