

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JUDGE CROTTY

PROCTER & GAMBLE PHARMACEUTICALS,
INC. and SANOFI-AVENTIS US LLC,

06 CV 34
Civ.

Plaintiffs,

-against-

Complaint

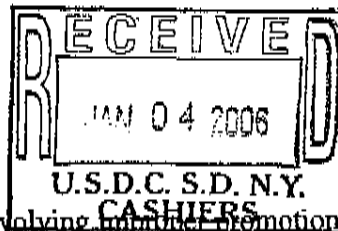
HOFFMAN-LA ROCHE INC. and
GLAXOSMITHKLINE, INC.,

Plaintiff Demands Trial by Jury

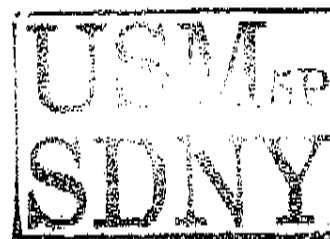
Defendants.

Plaintiffs Procter & Gamble Pharmaceuticals, Inc. ("P&G") and Sanofi-aventis US LLC ("Aventis"), by their attorneys Kramer Levin Naftalis & Frankel LLP, for their complaint against defendants Hoffman-La Roche, Inc. ("Roche") and GlaxoSmithKline Inc. ("GSK"), allege as follows:

Introduction



1. This is a Lanham Act false advertising case involving improper promotion by Roche and GSK of their osteoporosis drug Boniva® (ibandronate sodium). P&G manufactures and co-markets with Aventis a competing drug called Actonel® (risedronate sodium). Both are in a class of osteoporosis drugs called bisphosphonates. In this country, the only other bisphosphonate currently on the market and approved for use in osteoporosis is Fosamax® (alendronate sodium), marketed by Merck & Co. ("Merck").



2. Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures. Although the disease affects men and women of all ages, the vast majority of those who have (or who risk getting) it are postmenopausal women. Fractures associated with osteoporosis are commonly divided into two categories — vertebral (fractures of the spine) and nonvertebral (fractures of other bones in the body). While nonvertebral fractures account for more than half of all fractures (approximately 750,000 each year in the U.S.) they represent more than 90% of the costs associated with osteoporosis related fractures.

3. Although there is no cure for osteoporosis, there are medications that can prevent and reverse bone loss, and reduce the risk of vertebral and/or nonvertebral fractures. Bisphosphonates are the most frequently prescribed osteoporosis drugs. With the exception of Boniva, which was recently approved in a once-monthly dose, they must be taken at least once a week.

4. Although Actonel and Boniva have certain similarities, they are not interchangeable. While both are approved by the Food and Drug Administration (“FDA”) for the treatment and prevention of postmenopausal osteoporosis, and both reduce the risk of vertebral fractures, Actonel has been clinically proven to reduce the risk of nonvertebral fractures and Boniva has not. Indeed, in the only Boniva fracture efficacy study to date, the participants in the treatment arm were at least as likely to experience nonvertebral fractures as those on the placebo arm, a fact that Roche and GSK are required to disclose in the Boniva package insert.

5. Boniva was originally approved as a daily drug in April 2003 but Roche and GSK did not market it because by that time the competitive products, which had proven

nonvertebral fracture protection, were being dosed on a weekly regimen. Accordingly, Roche and GSK conducted a study comparing the 2.5 mg daily tablet to the 150 mg monthly dosing regimen, which demonstrated that the monthly dosing regimen was not inferior to the 2.5 mg daily regimen as measured by increases in bone mineral density ("BMD"). In April 2005, the FDA approved Boniva for monthly use.

6. Within weeks, Roche and GSK launched a major promotional campaign falsely positioning Boniva as a more convenient substitute for the other available bisphosphonates. The campaign includes two television commercials, a Boniva website, and a "detail aid" used by sales representatives to market the drug to physicians. All of these promotional materials contain variants of the same false claim — namely, literal or implied claims that Boniva has demonstrated the same efficacy as the other bisphosphonate drugs or that Boniva has been shown to provide nonvertebral fracture protection. Indeed, the Boniva website goes so far as to refer specifically to hip fractures and then overtly state that Boniva has been shown to lessen the risk of fractures, without any qualification. These and any other such claims are false and misleading and are causing irreparable harm not only to P&G and Aventis but to every osteoporosis patient who decides to take Boniva in the mistaken belief that it has been shown to reduce the risk of nonvertebral fractures.

7. By this action, P&G and Aventis seek to (i) enjoin Roche and GSK from continuing to make false and misleading claims concerning the efficacy of Boniva and/or falsely comparing it to the other drugs in its class; (ii) require Roche and GSK to disseminate corrective advertising; and (iii) recover damages for the substantial harm caused by defendants' false and misleading promotional campaign.

The Parties, Jurisdiction and Venue

8. P&G is an Ohio corporation with its principal place of business at 8700 Mason-Montgomery Road, Mason, Ohio 45040. P&G is engaged in the business of researching, developing, manufacturing and marketing pharmaceutical products in various disease areas, including musculoskeletal diseases. P&G is a wholly-owned subsidiary of The Procter & Gamble Company.

9. Aventis is a Delaware limited liability company with its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, NJ 08807. Aventis is also engaged in researching, developing, manufacturing and marketing pharmaceutical products in the United States. Aventis is a member of the sanofi-aventis Group, a global pharmaceutical company.

10. Hoffman La Roche is a New Jersey corporation with its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110. Roche is a subsidiary of Roche Group, a Swiss company based in Basel, Switzerland, which is engaged in the manufacture and distribution of pharmaceutical and diagnostic products. Roche advertises, distributes and sells its products throughout the United States, including in New York.

11. GSK is a Delaware corporation with offices at One Franklin Plaza, Philadelphia, Pennsylvania and 5 Moore Drive, Research Triangle Park, North Carolina. GSK advertises, distributes and sells pharmaceutical products throughout the United States, including in New York. GSK is a wholly-owned subsidiary of GlaxoSmithKline, a research-based pharmaceutical company headquartered in the United Kingdom.

12. This action is based on Section 43(a) of the Lanham Act, 15 U.S.C. § 1125, and the common and statutory law of unfair competition. This Court has jurisdiction over the subject matter of this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338, for the claims arising under Section 43(a) of the Lanham Act, and 28 U.S.C. §§ 1332, 1338(b) and 1367, for the claims arising under New York statutory and common law.

13. Venue is properly laid in this district pursuant to 28 U.S.C. § 1391.

The Incidence, Prevention and Treatment of Osteoporosis

14. Bone is living, growing tissue, composed of a combination of collagen and mineral (primarily calcium). Collagen is a protein that provides a soft flexible framework, and the mineral hardens and strengthens the framework. The combination of collagen and mineral makes bone strong and flexible enough to withstand stress.

15. Throughout life, bone is constantly renewed through a two-part process called remodeling or bone turnover, which consists of bone resorption (the breaking down and removal of old bone tissue) and bone formation (replacing old bone tissue with new tissue). Bone resorption is performed by special cells called osteoclasts, which dissolve old bone tissue, creating voids to be filled with new bone. Bone replacement is performed by special cells called osteoblasts, which deposit a collagen scaffold or matrix into those voids. Through a process called mineralization, the collagen fibers then harden into bone. The whole cycle is regulated by several different hormones, including estrogen in women and testosterone in men.

16. During childhood and teenage years, new bone is added faster than old bone is removed. As a result, bones grow larger, heavier and denser. Bone formation continues

to outpace bone resorption until peak bone mass (maximum bone density and strength) is reached at around age 30. At this point, bone resorption and formation shift to a generally balanced state. As people age, bone resorption begins slightly to exceed bone formation, gradually resulting in bone loss. For women, estrogen regulates the balance of bone resorption and bone formation. Due to the sharp decline in the production of estrogen, bone loss occurs rapidly in the first few years after menopause, usually between the ages of 45 and 55. While the accelerated rate of bone loss tends to slow after the first few years after menopause, the imbalance between bone resorption and bone formation (bone loss) continues throughout the postmenopausal years.

17. Osteoporosis, or porous bone, is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures. Osteoporosis develops over time when bone resorption continually exceeds bone replacement.

18. Because this gradual loss of bone strength is not something that can be readily discerned, osteoporosis is sometimes diagnosed only after a fracture. Osteoporosis can also be diagnosed through a BMD test, which measures bone mass at various sites in the body. BMD refers to the amount of mineralization in an area of bone tissue. The test, which is similar to an X-ray, determines the extent to which mineralization deviates from normal levels, and indicates how dense or porous the bone is. That, in turn, indicates whether the patient has, or is at risk of developing, osteoporosis. These measurements can be taken at the specific bone sites most likely to result in an osteoporosis related fracture, including the lumbar spine, the hip, the wrist and the forearm.

19. Roughly 10 million people in this country alone have osteoporosis and roughly 34 million more have low bone mass, placing them at increased risk for the disease. Although osteoporosis affects both men and women and can occur at any age, the vast majority of those who develop the disease are postmenopausal women. It has been estimated that one out of every two women and one in every four men over age 50 will have an osteoporosis-related fracture during their lifetime.

20. As indicated above, osteoporotic fractures are commonly divided into two broad categories: vertebral fractures (fractures of the spine) and nonvertebral fractures (fractures of any other bones in the body). The most common sites for nonvertebral fracture include the wrist, arm, clavicle (collarbone), rib, hip, pelvis, and leg. More than 50 percent of osteoporotic fractures occur at nonvertebral sites. Specifically, in the U.S. osteoporosis is responsible for more than 1.5 million fractures each year, of which approximately 700,000 are vertebral fractures and 750,000 are nonvertebral fractures. In addition, nonvertebral fractures account for at least 90 percent of the healthcare costs associated with this disease.

21. Only a third of vertebral fractures are symptomatic and come to the attention of patients and physicians. By contrast, nonvertebral fractures are a serious health problem that almost always require immediate treatment, which is why they account for such a large percentage of the treatment costs associated with osteoporosis. For example, hip fractures almost always require hospitalization and major surgery; approximately one out of every four hip fracture patients aged 50 and over die in the year following their fracture; approximately one out of every five who were ambulatory before the fracture require long-term care afterward; and approximately one in five hip fracture patients end up in a nursing home.

22. Diet and lifestyle factors — including adequate calcium intake, weight-bearing exercise, avoidance of smoking, and limiting alcohol consumption — can help strengthen bone and prevent osteoporosis. In addition, although there is no cure, various medications are available to prevent and treat osteoporosis. Treatment, as used in this context, means reducing the risk of fractures in people who already have low bone mineral density or osteoporosis or who have experienced a prior fracture.

23. All osteoporosis drugs work by helping to build bone. They do so in one of two basic ways. Anti-resorptive medications slow the rate of bone resorption, resulting in a small increase in bone mass. In this country, the FDA has approved anti-resorptive medications in the following categories: (i) bisphosphonates, which directly inhibit the activity of the osteoclast cells, thereby reducing bone resorption, usually resulting in a net gain in bone mass; (ii) selective estrogen receptor modulators, known as SERMs, which exert an indirect anti-osteoclast effect by mimicing the effects of the estrogen hormone; (iii) calcitonin, a naturally occurring hormone involved in calcium regulation and bone metabolism; and (iv) estrogen/hormone replacement therapy. In contrast, anabolic medications stimulate bone formation. Teriparatide (parathyroid hormone injections) is currently the only FDA-approved anabolic medication. Of the various FDA-approved medications, only SERMs and bisphosphonates have been approved for both the prevention and treatment of osteoporosis.

FDA Approval of Bisphosphonate Drugs for Osteoporosis

24. To obtain FDA approval for the treatment of postmenopausal osteoporosis, a drug must demonstrate fracture efficacy at three years in a large, randomized, placebo-controlled double blind study in which a reduction in the risk of vertebral fractures is the

primary endpoint. For purposes of this indication, the FDA only requires a demonstration of vertebral fracture risk reduction in a population of patients with established osteoporosis. Nevertheless, the FDA-approved labels distinguish between proven efficacy at the spine versus nonvertebral sites. Moreover, the FDA restricts the specific claims that can be made to proven efficacy at different bone sites, based on the results of the underlying clinical data.

25. In addition to a treatment indication, drugs may also be approved for the additional indication of prevention of postmenopausal osteoporosis. To obtain this indication a drug must demonstrate, in separate studies, that it preserves BMD in a less severe population at risk for osteoporosis.

26. Finally, an osteoporosis drug approved on the basis of a daily dosage regimen may be approved for an extended dosing regimen (weekly or monthly as opposed to daily). Obtaining such an approval requires only a one-year "non-inferiority" study demonstrating that less frequent dosing of the drug results in identical increases in BMD.

27. Because a drug need not demonstrate efficacy with respect to all types of osteoporosis related fractures to be approved for the treatment and prevention of postmenopausal osteoporosis, the fact that one bisphosphonate drug has the same indication as another does not necessarily mean that both drugs have been proven to reduce the risk of the same types of osteoporosis-related fractures.

28. As noted, the three bisphosphonate drugs that have been approved by FDA for the prevention and treatment of postmenopausal osteoporosis are Actonel, Fosamax and Boniva. Although all three drugs have the same basic mechanism of action and all are indicated for the treatment and prevention of postmenopausal osteoporosis, pivotal clinical trials

demonstrate that only Actonel has been proven to reduce the risk of nonvertebral fractures at a composite endpoint of six common nonvertebral sites: clavicle, hip, humerus, leg, pelvis and wrist. In pivotal clinical trials, Fosamax has been proven to reduce the risk of hip and wrist fractures, but has not demonstrated efficacy against nonvertebral fractures at a composite endpoint. Boniva has demonstrated efficacy only against vertebral fractures.

- *Actonel*

29. Actonel was developed by P&G and is co-promoted in the United States by P&G and Aventis. It was approved in April 2000 as a daily drug for the prevention and treatment of postmenopausal osteoporosis. FDA approval for postmenopausal osteoporosis was primarily based on the results of two vertebral fracture clinical studies with 5mg risedronate daily tablets, which demonstrated increases in BMD, reductions in the risk of vertebral fractures, and reductions in the risk of nonvertebral fractures at a composite endpoint of wrist, hip, leg, pelvis, clavicle and humerus. In May 2002, P&G gained approval for a once-weekly dosing regimen, based on the results of a non-inferiority BMD study comparing 5mg tablet daily to 35 mg tablet weekly.

30. Consistent with the clinical study results, the FDA-approved "Indications and Usage Statement" in the package insert for Actonel reads as follows:

ACTONEL is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

Treatment of Osteoporosis:

In postmenopausal women with osteoporosis, ACTONEL increases BMD and reduces the incidence of vertebral fractures and a composite endpoint of nonvertebral osteoporosis-related fractures (see CLINICAL STUDIES). Osteoporosis may be confirmed by the presence or history of osteoporotic fracture, or by

the finding of low bone mass (for example, at least 2 SD below the premenopausal mean).

Prevention of Osteoporosis:

ACTONEL may be considered in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and to reduce the risk of fracture.

- *Fosamax*

31. Fosamax was developed and is marketed by Merck. It was initially approved by the FDA in 1995 as a daily drug for the prevention and treatment of osteoporosis based on clinical studies that demonstrated efficacy in increasing bone mineral density, reducing the risk of vertebral fractures, and reducing the risk of hip fractures. In 2001, based on the results of a non-inferiority study, Merck gained approval for a weekly dosing regimen.

32. Consistent with the clinical study results, the FDA-approved "Indications and Usage" statement in the package insert for Fosamax reads as follows:

FOSAMAX is indicated for:

Treatment and prevention of osteoporosis in postmenopausal women

- For the treatment of osteoporosis, FOSAMAX increases bone mass and reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures). Osteoporosis may be confirmed by the finding of low bone mass (for example, at least 2 standard deviations below the premenopausal mean) or by the presence or history of osteoporotic fracture. (See CLINICAL PHARMACOLOGY, *Pharmacodynamics*.)

- For the prevention of osteoporosis, FOSAMAX may be considered in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical

outcome is to maintain bone mass and to reduce the risk of future fracture.

- *Boniva*

33. Boniva was developed by Roche and is co-promoted by Roche and GSK. It was initially approved in April 2003 as a daily drug for the prevention and treatment of osteoporosis. Approval for this indication was based on the results of a single study titled “Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis” (the “BONE Study”). The BONE Study demonstrated efficacy in increasing bone mineral density and reducing the risk of vertebral fractures. However, it did not show efficacy in reducing the risk of nonvertebral fractures. It was tested for this effect, at a composite endpoint similar to that used in the pivotal fracture studies for Actonel (although rib was used instead of clavicle). As explained in the journal article reporting the results of the study, the incidence of clinical nonvertebral fractures was “similar” between the placebo and active treatment groups, and “no statistically significant reduction was seen in nonvertebral fractures in the overall population.”

34. Because Boniva had no benefits viz-a-viz the competing bisphosphonates — indeed, it was competitively disadvantaged — Roche and GSK did not begin marketing the drug when it was first approved. Instead, Roche sponsored a non-inferiority BMD study in an attempt to demonstrate that the effectiveness in increasing BMD with a monthly dosing regimen was similar to the daily regimens. If successful, that would set Boniva apart from its competitors in that regard.

35. The non-inferiority study was titled “Monthly Oral Ibandronate Therapy in Postmenopausal Osteoporosis (the “MOBILE Study”). Although the study is not yet

complete, the one-year results demonstrated comparable effectiveness regarding BMD increases between the daily and monthly dosing regimens. In April 2005, based on these results, Roche obtained FDA approval to market Boniva as a once-monthly drug for the treatment and prevention of osteoporosis.

36. Quoting from the results of the BONE Study (the only study to date that tested the fracture efficacy of Boniva), the FDA-approved package insert for Boniva explains that the drug has not been proven to reduce the risk of nonvertebral fractures:

Effect on Nonvertebral Fractures

There was a similar number of nonvertebral osteoporotic fractures at 3 years reported in women treated with BONIVA 2.5 mg daily [9.1%, (95% CI: 7.1%, 11.1%)] and placebo [8.2%, (95% CI: 6.3%, 10.2%)]. The two treatment groups were also similar with regard to the number of fractures reported at the individual nonvertebral sites; pelvis, femur, wrist, forearm, rib, and hip.

37. This fact is also made clear in the FDA-approved "Indications and Usage" section of the package insert. Unlike the Indications and Usage statements in the Actonel and Fosamax package inserts, the insert for Boniva does not reference any nonvertebral fracture reduction benefit:

BONIVA is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

Treatment of Postmenopausal Osteoporosis

In postmenopausal women with osteoporosis, BONIVA increases BMD and reduces the incidence of vertebral fractures (see CLINICAL STUDIES). Osteoporosis may be confirmed by the presence or history of osteoporotic fracture or by a finding of low bone mass (BMD more than 2 standard deviations below the premenopausal mean [ie, T-score]).

Prevention of Postmenopausal Osteoporosis

BONIVA may be considered in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and to reduce the risk of fracture.

Defendants' False and Misleading Promotional Campaign for Boniva

38. Following approval of the monthly dosage regimen for Boniva, Roche and GSK embarked on an extensive advertising campaign to promote the drug, including television advertising, promotion to physicians using sales aids and creation of a Boniva website. In each medium Roche and GSK have falsely claimed, either literally or impliedly, that Boniva has been demonstrated to provide the same benefits as other bisphosphonates.

- *The Substitutability Claim in the Television Commercials*

39. Beginning in late July, 2005, Roche and GSK began airing two 60-second television commercials for Boniva. A videotape of both commercials is annexed as Exhibit A. The first is titled "Women In Restaurant" and features four women, clearly of postmenopausal age, sitting in a restaurant discussing osteoporosis medications. One woman pulls a package of Boniva out of her bag and says: "Oh check this out." Her friends ask what it is and she tells them: "It's to strengthen my bones." As they pass it around the table, one woman asks: "Let me see that. Once a month?" and another says: "Oh wow, that's great."

40. The voiceover then states:

Introducing Boniva. A new once monthly prescription treatment for post menopausal osteoporosis. Clinically proven to build and maintain bone density.

One of the women then asks "Where did you get it?" and the first woman responds: "My doctor prescribed it." Another woman then says: "I didn't know you could take just one tablet a month for anything."

41. The commercial then cuts to a full-screen image of a monthly desk calendar with four pills lined up next to each other — one for each week in the month — and shows a hand sweeping away all four pills and replacing them with a single one. While the weekly pills are being swept away and replaced, the first woman responds: "Yeah, with Boniva you can," and the voiceover then states: "And unlike treatments you take every week, you only need Boniva once a month." Two other women then react to this, saying "All I can say is wow" and "Wow, once a month." The voiceover goes on to describe the side effects and contraindications and then concludes with the following statement: "You do the right thing to treat your osteoporosis. To build and maintain strong healthy bones, ask your doctor about Once Monthly Boniva. There's only one." A copy of the storyboard for the "Women In Restaurant" commercial is annexed as Exhibit B.

42. The second commercial is titled "Women Talk Before Taking A Walk" and features 4 women, also clearly of postmenopausal age, dressed in workout clothes and discussing osteoporosis medications while preparing to take a brisk walk in the woods. It contains virtually the same narrative as the Restaurant ad, including the voiceover: "Introducing Boniva. A new once-monthly prescription treatment for postmenopausal osteoporosis, clinically proven to build and maintain bone density." It also contains the same sweep-and-replace visual, which is again accompanied by a voiceover that states: "And unlike treatments you take every week, you only need Boniva once a month." A copy of the storyboard for the "Taking A Walk" commercial is attached as Exhibit C.

43. The literal and implied message conveyed by both commercials is that Boniva has been proven to be a more convenient substitute for the weekly osteoporosis drugs, and that postmenopausal women with osteoporosis no longer need to take the weekly medications. Because those other drugs have been clinically proven to deliver nonvertebral fracture benefits while Boniva has not, this claim is false and misleading.

- *The Fracture Risk Reduction Claim on the Boniva Website*

44. If one enters the website at www.Boniva.com, clicks on the word "Consumer" and then clicks on "Importance of Treatment," the following three-paragraph description of osteoporosis and the benefits of Boniva appears on the screen:

. . . Osteoporosis affects every bone in the body, but the most common places where fractures occur are the back, hip, and wrists.

Because osteoporosis thins bones, weakening them and making them more susceptible to fractures, it is essential that you talk to your healthcare provider about treatment options upon diagnosis. The disease is particularly serious because you don't see or feel your bones thinning, putting you at increased risk of experiencing a fracture from ordinary activities like bending and lifting or from a more traumatic event like falling. *Hip fractures can be especially traumatic and osteoporosis is responsible for approximately 300,000 of these fractures annually.*

Fortunately, there are medicines like once-monthly BONIVA available today. BONIVA has been shown to prevent further bone loss and even increase bone density, lessening your risk of fractures. With BONIVA, you can continue to take care of yourself. Ask your healthcare provider about treatment and find out if BONIVA is right for you.

(Emphasis added). A copy of the relevant page from the Boniva website is annexed as Exhibit

D.

45. The literal meaning and necessary implication of this page, when read in its entirety, is that Boniva has been proven to “lessen the risk” of all fractures, including hip fractures. Because Boniva has not been shown to lessen the risk of hip fractures or any other nonvertebral fractures, this claim is false.

- *The “Bisphosphonate Efficacy” Claim in the Professional Marketing Brochure*

46. The centerpiece of the marketing campaign for Boniva addressed to professionals is an eight-page brochure (the “Primary Sales Aid”) that highlights the “convenience of less frequent dosing” while conveying the message that Boniva is otherwise comparable to the weekly Bisphosphonate drugs. A copy of the Primary Sales Aid is annexed as Exhibit E.

47. The cover page of the brochure states: “One tablet . . . once a month . . . Announcing the only once-monthly bisphosphonate.” The sales aid then opens up to side-by-side pages. On the left is the heading “Once-monthly BONIVA —” which continues on the right side with the statement “delivers bisphosphonate efficacy.” Both pages display charts containing selected results from the BONE trial, notably omitting the fact that the trial did not demonstrate efficacy in reducing the risk of nonvertebral fractures. The claim “Boniva delivers bisphosphonate efficacy” is the central element of the professional advertising campaign and appears prominently in most promotional materials for the drug.

48. The claim “Boniva delivers bisphosphonate efficacy” is always footnoted to the common indication statement found in the labels for all three bisphosphonates. For example, in the Primary Sales Aid, the following footnote appears toward the bottom of the page and quotes from the FDA-approved label:

***BONIVA is indicated for the treatment and prevention of osteoporosis in postmenopausal women.** In postmenopausal women with osteoporosis, BONIVA increases BMD and reduces the incidence of vertebral fractures. BONIVA may be considered in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and to reduce the risk of fracture.

The use of the common indication statement conveys the impression that these drugs are interchangeable. But the footnote does not disclose that BONIVA has not been proven to reduce the risk of nonvertebral fractures, as is disclosed elsewhere in the FDA-approved label.

49. The last page of the brochure sums up the main messages in a series of bullet points. First, it instructs physicians to “Choose Boniva” “When a bisphosphonate is appropriate for postmenopausal osteoporosis,” and to “Ask your newly diagnosed and current bisphosphonate patients if they would prefer once-monthly dosing.” It then reiterates the claims that once-monthly Boniva “Delivers bisphosphonate efficacy*” and “Offers the convenience of monthly dosing.” The asterisk following the bisphosphonate efficacy claim references a footnote toward the bottom of the page that simply quotes the shared FDA indication (“BONIVA is indicated for the treatment and prevention of osteoporosis in postmenopausal women”).

50. As a whole, the Primary Sales Aid — and in particular the claim that Boniva “delivers bisphosphonate efficacy” and the many charts and references to the clinical trials for Boniva — implies that Boniva has been proven to provide the same efficacy as other drugs in the bisphosphonate class. When made without qualification, as it is in the Primary Sales Aid, this claim is false and misleading because, while both Actonel and Fosamax have been proven to reduce the risk of nonvertebral fractures, Boniva has not.

- *Other False and Misleading Claims*

51. Defendants are also making claims of nonvertebral fracture efficacy by manipulating the data from the BONE Study. For example, in a promotional slide kit, attached as Exhibit F, defendants are claiming that Boniva did demonstrate efficacy against nonvertebral fractures in a high-risk subgroup comprising 13 percent of the overall study population based on a post hoc analysis of the subgroup data (the "Subgroup Claim"). The Subgroup Claim is flawed, even with respect to the subgroup itself, as a matter of basic statistical analysis and clinical study design. It is also false and misleading to the extent it is being used to imply that the study as a whole supports a claim of nonvertebral fracture efficacy.

52. In addition, Roche and GSK, like most other major pharmaceutical companies, promote their products to professionals primarily in the form of face-to-face visits by sales representatives to physicians — a practice commonly known as "detailing." In detailing for Boniva, sales representatives of Roche and GSK — in addition to disseminating the Primary Sales Aid — are making oral claims of proven nonvertebral fracture reduction and substitutability, similar in substance to the false and misleading claims in the Primary Sales Aid, the television commercials and the website described above.

Plaintiffs' Unsuccessful Attempts to Have the Claims Withdrawn

53. Since May 2005, when defendants began disseminating these false and misleading claims, P&G has written three times to the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC"), asking DDMAC to require that Roche and GSK cease making false and misleading claims about the efficacy of Boniva and disseminate appropriate corrective advertising. DDMAC has acknowledged the initial correspondence, has

indicated that P&G's claims have merit and that DDMAC is investigating further, but it has not yet taken enforcement action against Roche and GSK in response to P&G's requests.

54. P&G has also written directly to Roche, explaining that the claims of nonvertebral fracture efficacy are not supported by the existing data and urging Roche to stop disseminating these claims. Roche has steadfastly maintained that none of the Boniva promotional materials is false or misleading in any respect, and that all of its claims are adequately supported by the clinical data.

The Harm to Plaintiffs and to the Public

55. Defendants' false and misleading Boniva advertising has caused and will continue to cause plaintiffs irreparable injury. P&G was the first company to invent a bisphosphonate drug three decades ago (etidronate, marketed as Didronel). P&G marketed Actonel after an investment of 15 years and has spent over \$800 million on research and development before and since launch. P&G and Aventis have jointly spent over \$1 billion in marketing and sales expenses to promote Actonel, which now accounts for more than 25 percent of the market for osteoporosis drugs and generates approximately \$838 million in annual sales in the U.S.

56. Through a combination of false statements and material omissions, the Boniva advertising unfairly capitalizes on the shared indication for bisphosphonates and piggybacks on the results of its competitors' clinical studies, to convey the false and misleading message that a common indication implies identical efficacy. By falsely communicating that these drugs can be used interchangeably, Roche and GSK are also necessarily sending the

message that the existing weekly medications are inferior, and should be rejected by doctors and patients, because they do not offer the state of the art benefit of monthly dosing.

57. Immediately after defendants launched their promotional campaign, prescription and sales of Actonel declined and have continued to decline ever since. That is no surprise: Market research reveals that the vast majority of women who use osteoporosis drugs would prefer a monthly regimen to a weekly one, all things being equal. But, market research also reveals that, if consumers are told that the monthly drug has been proven to protect against fractures of the spine but does not protect the bones outside the spine from fracture, 87.5 percent would opt for the weekly medications. Unless and until defendants are ordered to cease making false and misleading claims about the efficacy of Boniva, P&G and Aventis stand to suffer a continued loss of their hard-earned sales, as well as the goodwill and consumer confidence associated with the Actonel brand, which cannot be quantified and which they may never be able to recoup.

58. Perhaps more importantly, defendants' false and misleading claims for Boniva potentially pose a serious public health risk. Obviously taking away the intended message that these drugs are interchangeable, significant numbers of postmenopausal women who either have or are at risk to develop osteoporosis are switching from Actonel to Boniva, and many first-time users are choosing Boniva over the other bisphosphonates. Most if not all of these women either have suffered, or risk suffering, nonvertebral fractures. With the appropriate medication, the risk of such fractures may be reduced. As a direct result of defendants' false and misleading advertising, these women — predictably drawn to the convenience of monthly dosing — are choosing the one drug in this category that has not been proven to reduce that risk.

First Claim for Relief

59. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 58 of the complaint.

60. The claims and comparisons made by Roche and GSK in their Boniva advertising are false and misleading and violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

61. Unless defendants are enjoined by this Court from continuing to make these claims and ordered to retract and correct them, the false and misleading Boniva advertising will continue to cause P&G and Aventis to suffer a loss of consumer confidence, sales, profits and goodwill which will irreparably injure P&G and Aventis.

62. P&G and Aventis have no adequate remedy at law.

Second Claim for Relief

63. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 58 and 61 of the complaint.

64. The above described acts constitute unfair competition under the common law of the State of New York.

Third Claim for Relief

65. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 58 and 61 of the complaint.

66. The above described acts constitute a deceptive act in violation of Sections 349 and 350 of the New York General Business Law.

Wherefore, P&G and Aventis respectfully request that the Court

(i) issue a preliminary and permanent injunction ordering GSK and their agents, servants, employees, representatives, subsidiaries refrain from directly or indirectly using in commerce or causing published or otherwise disseminated any promotional materials containing any of the false and misleading claims described in the including the false and misleading claims appearing in the promotional materials referenced in this complaint;

(ii) issue a preliminary and permanent injunction ordering GSK and their agents, servants, employees, representatives, subsidiaries refrain from directly or indirectly using in commerce any statement, or comparison that

a. states or implies that clinical data supports a Boniva has demonstrated nonvertebral fracture efficacy, that Boniva demonstrated efficacy comparable to the other bisphosphonate drugs that Boniva can be used interchangeably with the other bisphosphonate drugs;

b. states or implies that Boniva reduces the number of nonvertebral fractures, that Boniva is comparable to

bisphosphonate drugs, or that Boniva can be used interchangeably with the other bisphosphonate drugs;

(iii) issue a preliminary and permanent injunction directing Roche and GSK to include, in all written advertising and promotional materials and activities and websites for Boniva, the following statement: "In the BONE Study, there was a similar number of nonvertebral osteoporotic fractures at 3 years reported in women treated with Boniva and placebo, and the two treatment groups were also similar with regard to the number of fractures reported at the individual nonvertebral sites: pelvis, femur, wrist, forearm, rib and hip";

(iv) issue a preliminary and permanent injunction ordering Roche and GSK to issue appropriate corrective advertisements, reasonably designed to reach all people to whom their advertisements and oral communications were directly or indirectly disseminated, retracting the false and misleading claims contained in those advertisements and oral statements;

(v) award P&G and Aventis

a. defendants' profits, gains and advantages derived from their unlawful conduct, such damages to be trebled pursuant to 15 U.S.C. § 1117,

b. all damages sustained by P&G and Aventis by reason of defendants' unlawful conduct, including all expenditures required to correct the false, misleading, unfair, and disparaging descriptions and

representations alleged herein, such damages to be trebled pursuant to 15 U.S.C. § 1117,

c. exemplary and punitive damages as the Court finds appropriate to deter any future willful conduct, and

d. interest on the foregoing sums;

(vi) award P&G and Aventis attorneys' fees and the costs and disbursements of this action; and

(vii) grant such other and further relief as the Court deems just and proper.

Dated: New York, New York
January 4, 2006

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