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1 UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

2 -----x  
3 PROCTER & GAMBLE PHARMACEUTICALS,  
4 INC., and SANOFI-AVENTIS US, LLC,

5 Plaintiffs,

6 v.

06 Civ. 34 (PAC)

7 HOFFMANN-LAROCHE, INC.,  
8 GLAXOSMITHKLINE, INC.,

9 Defendants.  
-----x

10 New York, N.Y.  
11 May 25, 2006  
12 9:00 a.m.

13 Before:

14 HON. PAUL A. CROTTY

District Judge

15 APPEARANCES

16 KRAMER LEVIN NAFTALIS & FRANKEL, LLP

Attorneys for Plaintiffs

17 BY: HAROLD P. WEINBERGER  
18 JONATHAN M. WAGNER  
19 MARJORIE E. SHELDON

20 DAVIS POLK & WARDWELL

Attorneys for Defendants

21 BY: ARTHUR F. GOLDEN  
22 JOEL M. COHEN  
CHRISTOPHER H. WITHERS  
23 JEROME G. SNIDER  
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(In open court)

THE DEPUTY CLERK: Your Honor, this is the matter of Procter & Gamble v. Hoffmann-LaRoche, docket No. 06 Civ. 34.

For the plaintiff, please state your appearances.

MR. WEINBERGER: For the plaintiffs, Harold Weinberger, Jonathan Wagner, Marjorie Sheldon, and also the associate general counsel is Matthew Malloy from Procter & Gamble, and Margaret Sparks.

THE COURT: Welcome.

THE DEPUTY CLERK: For the defendants.

MR. GOLDEN: Good morning, your Honor. For the defendants, Arthur Golden, Joel Cohen, Jerome Snider, of Davis Polk, and Jay Matthews of Hoffmann-LaRoche, and Tina Diaz, from GlaxoSmithKline.

THE COURT: Thank you, Mr. Golden.

Mr. Weinberger, do you want to make an opening statement?

You can do it from your table or from the podium.

MR. WEINBERGER: I will do it from the podium.

THE COURT: Whichever is most convenient for you.

MR. WEINBERGER: Thank you, your Honor. I know your Honor has lengthy findings so I will try to keep this brief.

When I first saw the findings from the defendant, I realized that this was the proverbial case of two ships passing

1 in the night, because either the defendants have misunderstood  
2 or have misstated what this case is all about.

3 We are not seeking to prevent them from disseminating  
4 scientific data, whether it is subgroup data or otherwise. We  
5 don't dispute that some of this data is very interesting, that  
6 it is relevant, that doctors are entitled to know about it.  
7 That is not what this case is about.

8 We are seeking to enjoin something very, very  
9 specific, and that is, telling doctors that Boniva has been  
10 proven to reduce the risk of nonvertebral fracture. It is what  
11 the cases call an establishment claim. There are so many cases  
12 about it because in the advertising and promotional world it is  
13 a very powerful claim to say that you have clinical proof of  
14 something.

15 Nowhere in the findings that I saw from defendants do  
16 they dispute that they intended to make or are making an  
17 establishment claim that they have proven that Boniva is  
18 effective to reduce the risk of nonvertebral fracture.

19 They refer to Boniva's nonvertebral fracture, but they  
20 studiously, I am sorry, avoid addressing the issue of whether  
21 they have proof. They refer to Boniva's nonvertebral fracture  
22 efficacy as an aspiration -- these are quotes -- a  
23 scientifically valid proposition, and a legitimate scientific  
24 debate. But they don't say that the BONE study proves that  
25 Boniva has nonvertebral fracture efficacy.

1           Rather than address these issues, most of these  
2 findings, and I suspect most of the evidence they are going to  
3 put on here, is largely going to be addressed to what we regard  
4 as issues that don't go to the core issues before you.

5           First of all, they spent at least 25 percent of their  
6 findings attacking our perception survey, which I will come to  
7 a little later in this opening, but I would submit is largely  
8 irrelevant today based on the evidence that has been uncovered  
9 in discovery.

10           Second, they spend another 25 percent of their  
11 findings attacking our marketing materials and activities, even  
12 though they have never moved for injunctive relief with respect  
13 to any of them, and I think we are going to show that they have  
14 taken extreme liberties with the record -- miscited testimony,  
15 misquoted documents. But even if what they were saying is  
16 true, the law is clear that that doesn't preclude injunctive  
17 relief when you are dealing with matters of public health.

18           So in our view this is, despite the reams of materials  
19 we submitted to you, this is actually a simple case. There are  
20 two issues. Are they communicating claims of proven  
21 nonvertebral fracture efficacy, are they making an  
22 establishment claim. Number one. And number two, are those  
23 claims false.

24           The law is clear that if they are making those claims,  
25 the issue that we have to prove is that the testing that they

1 are citing to support those claims doesn't support those  
2 claims. That is all.

3 The issue is not whether Boniva might work for  
4 nonvertebral fractures. The issue is not whether there might  
5 be some evidence, whether it is likely or that it is assumed,  
6 but is it proven.

7 Now, what you will hear is that there is one pivotal  
8 clinical trial that is relevant here, and that is called the  
9 BONE study. The BONE study was an osteoporosis trial, and it  
10 was what they call powered to determine the incidence of  
11 vertebral fractures between placebo and Boniva.

12 There was a secondary end point. What is common in  
13 these trials is they are also looking to see if there is a  
14 difference on other characteristics, and one of them was for  
15 nonverbal fractures. There is no dispute that when the data  
16 was analyzed they did not show a difference between placebo and  
17 Boniva in nonvertebral fracture efficacy.

18 That doesn't mean that Boniva was shown not to be  
19 effective for nonvertebral fracture efficacy, because the study  
20 wasn't powered to show that. What it means, however, is it  
21 wasn't proven. Because the way it works, you power a study for  
22 a particular end point. If the study doesn't show, if it is  
23 not powered for that end point and the study doesn't show a  
24 difference, then there may be a difference or there may not be  
25 a difference. You don't know. However it is powered, if it

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