IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendants.	)	
	)	

COMPLAINT

Merck & Co., Inc. ("Merck") alleges as follows:

1. This is an action by Merck against Teva Pharmaceuticals USA, Inc. ("Teva") for relief from the judgment entered by mandate of the United States Court of Appeals for the Federal Circuit in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.* (No. 04-1005) as a result of Teva's fraud, misrepresentations, or other misconduct. That appellate judgment was a reversal of the judgment entered in *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, (C. A. No. 01-048) (JJF), which was entered in this Court.

2. In the prior litigation, Teva obtained judgment in its favor by withholding one of its own patent applications, which contains statements that contradict Teva's litigation arguments. Without Teva's withheld patent application before it, the Federal Circuit accepted Teva's litigation arguments, which form the core of the Federal Circuit's opinion holding two claims of a Merck patent invalid. Based upon Teva's fraud, misrepresentations, or other misconduct, Merck seeks relief from the judgment in the prior litigation under Rule 60(b) of the Federal Rules of Civil Procedure.

THE PARTIES

3. Plaintiff Merck is incorporated under the laws of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is incorporated under the laws of Delaware, with its principal office at 1090 Horsham Road, North Wales, Pennsylvania.

JURISDICTION AND VENUE

5. This action arises under the patent laws of Title 35 of the United States Code, and Federal Rule of Civil Procedure Rule 60(b). The Court has subject matter jurisdiction based upon Title 28 of the United States Code Sections 1331, 1332, 1338 and 1367.

6. Venue is proper in this Court under Title 28 of the United States Code Sections 1391(c) and 1400(b) because the defendant is incorporated in this judicial district.

STATEMENT OF FACTS

I. Merck's FOSAMAX® Once-Weekly Tablets

7. In 1995, Merck received approval from the United States Food and Drug Administration ("FDA") for the first effective treatment of osteoporosis. The active ingredient in Merck's treatment is a compound called "(4-amino-1-hydroxybutylidine) bisphosphonic acid monosodium salt trihydrate," which is usually simplified to "alendronate sodium" or "alendronate." Merck's treatment at that time was a tablet containing the equivalent of 10 mg of the free alendronic acid, which patients were to take orally once per day. Merck commercialized its alendronate sodium tablets under the trademark FOSAMAX®. These tablets are usually referred to as 10 mg FOSAMAX® tablets.

8. In April 1997, Merck gained approval for daily 5 mg FOSAMAX® tablets for the prevention of osteoporosis.

9. In 1996, shortly after Merck launched its 10 mg FOSAMAX® tablets, case reports began to circulate of upper gastrointestinal injuries, including severe esophagitis, associated with the ingestion of daily FOSAMAX® tablets. The case reports raised sufficient concern for Merck to warn prescribing physicians about the potential injuries through a "Dear Doctor" letter in March 1996, and to notify the FDA.

10. Alendronate belongs to a class of drugs called bisphosphonates. The commercial development of oral pamidronate, which is the bisphosphonate structurally closest to alendronate, was discontinued after reports of similar side effects.

11. By the time the prestigious *New England Journal of Medicine* published an article entitled "Esophagitis Associated with the Use of Alendronate" in October 1996, Merck scientists had commenced an introspective review of how the dosing regimen for the drug might be changed. Merck undertook research efforts to understand and address the gastrointestinal side effects that were associated with alendronate. Central to these efforts were experimental studies involving beagles performed by Merck scientists. In these experiments, Merck scientists exposed the gastrointestinal tracts of anesthetized beagles to alendronate in simulated gastric juice, and surprisingly discovered that single doses even at high concentrations were not causing the adverse effects that repetitive dosing caused. Although this animal model was extreme, it gave three Merck physicians, Drs. Anastasia Daifotis, Arthur Santora, and John Yates the insight that a multiple of the daily dose administered weekly might be as well tolerated or even better tolerated than daily dosing.

12. The Merck physicians' insight cut against the great weight of the knowledge in the field because the gastrointestinal side effects associated with bisphosphonates had long been reported to be dose related. Therefore, increasing the oral dose by sevenfold was contrary to medical thinking.

13. In 1997, additional beagle studies were undertaken at Merck that surprisingly confirmed the Merck physicians' idea that sevenfold the daily dose of alendronate could be given once per week without exacerbating the side effects, and perhaps with an even better tolerability profile. On July 22, 1997, Merck filed a patent application for the Merck physicians' invention, which described the beagle studies.

14. On November 30, 1999, United States Patent No. 5,994,329 (the "'329 patent") issued to Anastasia G. Daifotis, Arthur C. Santora II, and John Yates entitled "METHOD FOR INHIBITING BONE RESORPTION." Among other things, the '329 patent discloses and claims methods for the treatment and prevention of osteoporosis while minimizing the occurrence of or potential for adverse gastrointestinal effects by giving sevenfold the daily dose of alendronate sodium once per week. Merck is the owner through assignment of the '329 patent. A copy of the '329 patent is attached as Exhibit A.

15. The beagle studies published in the '329 patent explain Merck's experiments on 42 different beagles that were assigned to various groups, which included a control group, beagles subjected to various dosing regimens with three different concentrations of alendronate, and even beagles dosed with risedronate and tiludronate, which are also bisphosphonates. *See* Exhibit A, "Example 1," col. 14, ln. 9. Additionally, the '329 patent contains detailed observations of the beagle esophagi from each group, including eight full-page

photomicrographs showing a close up view of a representative beagle esophagus from each group. *See* Exhibit A, Figs. 1-8.

16. Merck holds an approved New Drug Application ("NDA No. 20-560") for alendronate sodium tablets sold under its trademark FOSAMAX®. Merck supplemented NDA No. 20-560 and received approval for 70 mg FOSAMAX® once-weekly tablets for the treatment of osteoporosis, and 35 mg FOSAMAX® once-weekly tablets for the prevention of osteoporosis.

II. The FOSAMAX® Once-Weekly District Court Case

17. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") filed an abbreviated new drug application ("ANDA") to gain approval to market generic copies of Merck's high-dose once-weekly 70 and 35 mg FOSAMAX® once-weekly tablets before the expiration of the '329 patent. In response, Merck filed suit against Teva for patent infringement in this Court on November 6, 2001. That case became known as *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, (C. A. No. 01-048) (JJF)(the "FOSAMAX® once-weekly case").

18. In the FOSAMAX® once-weekly case, Teva was represented by the law firm of Kenyon & Kenyon LLP ("Kenyon").

19. On March 19, 2002, Merck served requests for production on Teva. A copy of "MERCK & CO., INC.'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-60) TO DEFENDANT TEVA PHARMACEUTICALS USA, INC." ("RFPs") is attached as Exhibit B.

20. Merck's RFPs sought documents related to Teva's research and development projects for alendronate. A representative document request from Merck's RFPs includes the following:

> DOCUMENT REQUEST NO. 49 All documents and things relating to research and development of alendronate and

> alendronate formulations or any other pharmaceutically active biphosphonate and its formulations.

Exhibit B at 17.

21. Merck's RFPs also requested documents from Teva's parent company, Teva Ltd. (hereinafter, collectively referred to with defendant Teva Pharmaceuticals USA, Inc. as "Teva"). *See* Exhibit B at 4.

22. In response to Merck's RFPs, Teva produced approximately 4,900 pages of documents, most of which were excerpts from Teva's ANDA. Merck realized that Teva's document production was inadequate, particularly when various Teva witnesses admitted during their depositions that their files had never been searched in connection with the FOSAMAX® once-weekly case. On November 11, 2002, Merck moved to compel production from Teva. Merck's motion to compel was filed under seal because it referred to and contained exhibits of documents that Teva designated as "Highly Confidential" under the applicable protective order.

23. In response to additional requests and communications from Merck, Teva produced a few additional pages of documents. On December 11, 2002, a partner attorney at Kenyon sent a letter (the "Kenyon letter") confirming that Teva had finally complied with Merck's RFPs. In particular, the Kenyon letter states:

> As discussed yesterday, I confirm that Teva has conducted a diligent search for documents responsive to Merck's document requests for all persons at Teva involved with the development of Teva's weekly alendronate sodium after the complaint in this action was filed and again after Merck served its document requests on Teva. … As we have now complied with your requests, we expect that Merck will withdraw it's [sic] motion to compel today.

A copy of the Kenyon letter is attached as Exhibit C.

24. Merck relied upon the assurances in the Kenyon letter, and Merck withdrew its motion to compel. As Merck would later discover, the representations of the Kenyon letter were

false, because Teva continued to withhold highly relevant evidence falling within the scope of Merck's RFPs. As will be discussed below, that evidence would have affected the ultimate outcome of the FOSAMAX® once-weekly case.

III. Trial of the FOSAMAX® Once-Weekly Case

25. Before the bench trial was held in the FOSAMAX® once-weekly case, Merck agreed that it would assert only Claims 23 and 37 of the '329 patent. It was agreed by the parties that if written into independent form, these claims would read as follows:

> **Claim 23.** A method for treating osteoporosis in human comprising orally administering about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.
>
> **Claim 37.** A method for preventing osteoporosis in human comprising orally administering about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

Claim 23 covers Merck's 70 mg FOSAMAX® once-weekly tablets for the treatment of osteoporosis. Claim 37 covers Merck's 35 mg FOSAMAX® once-weekly tablets for the prevention of osteoporosis.

26. A bench trial was held in the FOSAMAX® once-weekly case on March 4-7, 2003. Teva's primary defense was that Merck's patent claims were invalid for anticipation (35 U.S.C. § 102) or obviousness (35 U.S.C. § 103) in light of the April and July 1996 editions of the *Lunar News*, a marketing circular for bone densitometers. The *Lunar News* included a speculative suggestion as to the use of less frequent higher oral doses of alendronate.

27. At the time of the *Lunar News* articles, physicians were concerned about not only the upper gastrointestinal issues surrounding alendronate but also the safety of high oral doses of bisphosphonates. The speculations of the *Lunar News* articles failed to address either of these

concerns, and represented nothing more than an unsupported aspiration that was implausible to the knowledgeable physician.

28. Unlike the *Lunar News* articles, the '329 patent contained Merck's beagle studies and presented data that revealed that less frequent, higher oral doses of alendronate and other bisphosphonates could be given once per week without exacerbating the gastrointestinal side effects, and perhaps with an even better tolerability profile. In contrast, the *Lunar News* articles were nothing more than wishful thinking.

29. Regardless, Teva belittled the beagle studies and argued that they added nothing to the knowledge of those skilled in the art, and therefore added no information beyond the speculations disclosed in the *Lunar News* articles. In its post-trial brief, Teva argued:

> The only data that Merck can allege that it had that was not possessed by people of skill in the art in July 1997 are the results of its dog studies. Merck's reliance on these studies is unfounded. **First, the asserted claims are limited to humans, so a result from an experiment on a beagle, whether expected or not, is not relevant. Second, the dog studies provide no data, expected or not, that is relevant to clinical experience.** [p. 45, (emphasis added)]
>
> The dog studies represent a science project. Whether or not they provide interesting information, they do not demonstrate that following the claimed method to treat or prevent osteoporosis provides any results that are "unexpected." [p. 46]

A copy of Teva's Post-Trial Brief is attached as Exhibit D. In its post-trial reply brief, Teva argued:

> Although Merck will likely argue that the conclusions of its scientists were bolstered by the results of its dog experiments, that argument does not withstand scrutiny. In May 1997, the only pertinent dog experimental results Merck had were the initial comparisons of the effects of five consecutive exposures to acidic alendronate solution to a single exposure with the same solution. [p. 23]

A copy of Teva's Post-Trial Reply Brief is attached as Exhibit E.

30. On August 23, 2004, this Court issued its Opinion and rejected Teva's arguments and affirmed the validity of Claims 23 and 37 of the '329 patent in light of the *Lunar News* articles. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 288 F.Supp.2d 601 (D.Del. 2003). A copy of this Court's opinion is attached as Exhibit F.

IV. Appeal of the FOSAMAX® Once-Weekly Case

31. Teva appealed to the United States Court of Appeals for the Federal Circuit.

32. Teva stood fast to its rejected arguments that Claims 23 and 37 of the '329 patent were invalid for obviousness in light of the *Lunar News* articles.

33. Once again, Teva argued that the beagle studies added nothing to the knowledge of those skilled in the art, and therefore provided no information beyond the speculations disclosed in the *Lunar News* articles. In its Federal Circuit brief, Teva argued:

> Before they [the Merck physicians] filed for the '329 patent they did no clinical research or other testing in humans. … Thus, they added nothing to the art that was not already set forth in the *Lunar News*. The only data in the patent was generated in beagles whose esophagi were soaked in alendronate solutions for extended periods. [p. 46]

A copy of Teva's Federal Circuit Brief is attached as Exhibit G. In its Federal Circuit Reply brief, Teva argued:

> The '329 patent does not include data or reports of experimentation proving the workability of an idea that was contrary to some conventional wisdom. Merck's inventors had no such information. On the contrary, the patent provides nothing beyond what [] had already [been] disclosed in the *Lunar News*. **Specifically, the '329 patent includes no clinical trial data or results from studies in people proving the safety and effectiveness of the once-weekly administration of alendronate.** … Recognizing this weakness, Merck now feebly attempts to rely on the beagle experiments described in Example 1 in the '329 patent. [p. 18, (emphasis added)]

A copy of Teva's Federal Circuit Reply Brief is attached as Exhibit H.

34. But this time, the outcome was different. A divided panel of the Federal Circuit accepted Teva's arguments, reversed this Court, and held that Claims 23 and 37 of the '329 patent were invalid as obvious in view of the *Lunar News* articles. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005). A copy of the Federal Circuit's opinion is attached as Exhibit I.

35. In examining the differences between the *Lunar News* articles and the '329 patent, the Federal Circuit panel majority accepted Teva's arguments, and dismissed the experimental results data obtained from the beagle studies.

> The '329 patent sets forth no human clinical or laboratory data showing the safety and tolerability of the treatment methods claimed by the patent. The only data provided in the '329 patent was generated in beagles, an experiment discredited at trial and disregarded by the district court in its decision. So while the district court may be correct in finding the *Lunar News* articles may have invited skepticism based on concerns for dose-related GI problems, the claimed invention adds nothing beyond the teachings of those articles.

395 F.3d at 1374. *See* Exhibit I.

36. Merck petitioned the Federal Circuit for rehearing and rehearing *en banc*. That petition was denied. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 405 F.3d 1388 (Fed. Cir. 2005). Merck filed a writ of certiorari with the United States Supreme Court, and the writ was denied. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 126 S.Ct. 488 (2005).

V. Teva Withheld Crucial Evidence that Would Have Changed the Outcome of the FOSAMAX® Once-Weekly Case

37. In 2002, Merck granted a license to the Procter & Gamble Co. ("P&G") for Merck patents that cover methods for the oral once-weekly dosing of bisphosphonates, including the methods used in P&G's ACTONEL® (risedronate sodium) once-weekly tablets. Risedronate is also a bisphosphonate, and the license extended to claims of the '329 patent.

38. Teva filed an ANDA to bring a generic copies of P&G's ACTONEL® once-weekly products to the market before the expiration of Merck's patents. As permitted by the terms of the license agreement, Merck sued Teva for patent infringement in the United States District Court for the District of Delaware, in a case known as ***Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.***, C.A. No. 04-939 (the "ACTONEL® once-weekly case"). That case is pending, and experts are currently being deposed. Trial is set for late August 2006.

39. On or about April 18, 2006, Merck's counsel reviewed the reports of Teva's experts in the ACTONEL® once-weekly case. In exploring the opinions of Teva's experts, Merck's counsel searched the publicly available patents and applications available from the web site of the United States Patent and Trademark Office ("PTO"). Specifically, Merck's counsel sought any patents or applications assigned to Teva that related to dosing of bisphosphonates.

40. Merck's counsel found a Teva patent application that had been withheld from Merck during the FOSAMAX® once-weekly case. Teva's withheld patent application reflected that Teva performed its own beagle studies, for which the underlying documents have also been withheld. On December 16, 2002, Teva filed a provisional patent application with the PTO entitled "METHOD OF INCREASING BIOAVAILABILITY OF ALENDRONATE OR OTHER BISPHOSPHONATES BY PREDOSE ADMINISTRATION OF ALFACALCIDOL," which was assigned application No. 60/433,685 (the "'685 application"). The withheld '685 application is generally directed to a method for giving a dose of a form of Vitamin D at least six hours before giving a dose of alendronate, which will purportedly increase the bioavailability of alendronate. A copy of the '685 application is attached as Exhibit J.

41. The ’685 application relates to the technology that was in dispute during the FOSAMAX® once-weekly case, and falls within the scope of Merck’s RFPs. *See* Paragraph 20. Yet Teva withheld it from Merck during the FOSAMAX® once-weekly case.

42. Teva withheld the ’685 application even though the same lawyers who were trial counsel in the FOSAMAX® once-weekly case filed the ’685 application on Teva’s behalf. Moreover, the filing date of the ’685 application indicates that the representations in the Kenyon letter were manifestly false.

43. On December 16, 2002, five days after the Kenyon letter, Teva filed the ’685 application with the United States Patent and Trademark Office. Considering the experiments described in the ’685 application took weeks to perform, documents related to the ’685 application existed. Any doubt about the relevance of the ’685 application is immediately dispelled by its statement that “the therapeutically effective dose of alendronate administered is … especially between about 10 mg and about 70 mg.” *See* Exhibit J at 4. Merck sued Teva in the FOSAMAX® once-weekly case because Teva sought to commercialize generic copies of Merck’s 35 and 70 mg FOSAMAX once-weekly tablets.

44. The content of the withheld ’685 application includes statements that directly contradict Teva’s arguments to this Court and the Federal Circuit. The most egregious of these statements is the revelation that Teva had conducted its own beagle studies to support alendronate dosing patents. *See* Exhibit J at 8.

45. As stated above, Teva dismissed the value of the beagle experiments in the ’329 patent during the FOSAMAX® once-weekly case, and argued that the dog studies in the ’329 patent “added nothing to the prior art” over the disclosures of the *Lunar News*. Teva argued that Merck “feebly” attempted “to rely on the beagle experiments described in Example 1 of the ’329

patent," because the '329 patent contains "no clinical trial data or results from studies in people proving the safety and effectiveness of the once-weekly administration of alendronate." Yet in the '685 application, Kenyon attorneys had submitted Teva's very own beagle studies to the PTO in support of Teva's patent application for methods for dosing alendronate. In the single "Example" of the '685 application, Teva performed oral alendronate experiments in "an *in vivo* study in an animal model" using "six female beagle dogs." *See* Exhibit J at 8.

46. By withholding the '685 application, Teva deprived Merck of the opportunity to depose Teva's inventors about their oral alendronate experiments involving beagles. Teva also deprived Merck of the opportunity to analyze Teva's data, experimental techniques, and laboratory information. In contrast, Merck complied with its discovery obligations and provided Teva with access to the scientists who performed the beagle studies, as well as Merck's scientific and laboratory information underlying Merck's beagle studies.

47. The FOSAMAX® once-weekly case was a classic "close case." Judge Farnan, the PTO, and Judge Rader agreed with Merck, while the two other judges on the Federal Circuit panel agreed with Teva. In such a close case, Teva's withheld beagle studies would have been crucial evidence that would have affected the outcome of the FOSAMAX® once-weekly case.

VI. Teva's Pattern of Discovery Abuse

48. In addition to Merck's motion to compel and the recently discovered '685 patent application, other aspects of Teva's document production from the FOSAMAX® once-weekly case demonstrate that Teva failed to comply with Merck's RFPs.

49. During post-trial briefing in the FOSAMAX® once-weekly case, counsel for Merck discovered U.S. Patent No. 6,476,006 (the "'006 patent") assigned to Teva. The '006 patent was generally directed to delayed-release dosage forms for bisphosphonates, including

alendronate. Just like the '685 patent, Teva withheld the '006 patent from Merck during the FOSAMAX® once-weekly case. The '006 patent also contradicts Teva's arguments that claims 23 and 37 are obvious in light of the *Lunar News*. And like the '685 application, Kenyon filed this application on behalf of Teva. Merck moved to add the '006 patent to the trial record, and a copy of Merck's motion is attached as Exhibit K. The '006 patent was attached as Exhibit A to that motion. This Court granted Merck's motion.

50. Just before this Court issued its opinion in the FOSAMAX® once-weekly case, counsel for Merck discovered another Teva patent application that Teva withheld from Merck. PCT patent application WO 03/057/136 (the "'136 application") was published on July 17, 2003. The '136 application claimed priority from an application filed on December 24, 2001, and once again, Kenyon was the prosecuting law firm. The '136 application relates to tablets sheathed with a powder or granulous layer to prevent contact with irritating ingredients at the center of the tablet. Alendronate is one of the irritating ingredients disclosed in the '136 application. Again, these statements contradict the arguments Teva made throughout the FOSAMAX® once-weekly case. Merck also moved to add the '136 application to the trial record, but this Court did not rule on that motion. A copy of that motion is attached as Exhibit L. The '136 application was attached as Exhibit A to that motion.

51. In the ACTONEL® once-weekly case, Teva also failed to produce the '685 application and any underlying data, including data from Teva's beagle experiments, even though Merck served the following document requests on Teva:

> Request for Production No. 44 All documents and things relating to Defendant's research and development of tablets containing risedronate.
>
> Request for Production No. 45 All documents and things relating to patent applications, including the patents themselves, filed in

> any country by Defendant referencing, referring, or relating to risedronate.

Exhibit M at 25. In the ’685 application, Teva told the PTO that “the bisphosphonates useful in the practice of the present invention include … risedronic acid and pharmaceutically acceptable salts thereof (hereinafter, collectively known as “risedronate”).” *See* Exhibit J at 6.

52. The ’006 patent, the ’136 application, and the ’685 application are Teva’s patent filings, and specifically refer to risedronate in addition to alendronate. All of these were filed and prosecuted by Teva’s litigation counsel Kenyon. Even though all of these fall within the scope of Merck’s document requests in the ACTONEL® once-weekly case, Teva has failed to produce them.

53. Considering Teva’s repeated failure to produce highly relevant documents, Teva has an intentional strategy to withhold documents that contradict Teva’s litigation arguments and support Merck’s positions.

54. Teva still has not produced any of the experimental data underlying the ’685 application, including data from Teva’s beagle experiments with oral alendronate.

55. Teva must possess many more relevant documents beyond the ’685 application that were never produced during the FOSAMAX® once-weekly case, including documents that Merck is still unaware of.

56. Teva’s repeated withholding of evidence and knowing misrepresentations to the Federal Circuit, this Court, and Merck erroneously caused claims 23 and 37 of the ’329 patent to be rendered invalid in the FOSAMAX® once-weekly case in a grave miscarriage of justice.

COUNT 1

57. Merck realleges paragraphs 1 through 56 above as if fully set forth herein.

58. Through Teva's fraud and misconduct in failing to produce documents reflecting Teva's own beagle experiments with oral alendronate and other documents such as the '685 application and its file history, Teva caused a grave miscarriage of justice that resulted in Claims 23 and 37 of the '329 patent being rendered invalid.

59. Through knowingly misrepresenting that it had complied with Merck's RFPs, Teva effectuated a fraud or other misconduct upon this Court, the Federal Circuit, and Merck that caused a grave miscarriage of justice that resulted in Claims 23 and 37 of the '329 patent being rendered invalid.

60. Pursuant to Rule 60(b) of the Federal Rules of Civil Procedure, it is requested that this Court vacate the judgment entered in the FOSAMAX® once-weekly case holding Claims 23 and 37 of the '329 patent invalid, or grant any other appropriate relief from that judgment because of Teva's fraud, misrepresentation, and other misconduct.

COUNT 2

61. Merck realleges paragraphs 1 through 56 above as if fully set forth herein.

62. Through Teva's fraud, misrepresentations, or other misconduct in the FOSAMAX® once-weekly case, Teva caused a grave miscarriage of justice.

63. The findings from the Federal Circuit decision in the FOSAMAX® once-weekly case infect other litigations, including the ACTONEL® once-weekly case, and thus further the grave miscarriage of justice that Teva caused in the FOSAMAX® once-weekly case.

64. It is requested that this Court enjoin Teva from asserting any estoppel based upon the findings from the Federal Circuit's opinion in the FOSAMAX® once-weekly case.

REQUESTED RELIEF

Plaintiff Merck respectfully requests the following relief:

a. To vacate the judgment entered in the FOSAMAX® once-weekly case holding Claims 23 and 37 of the ’329 patent invalid, or any other appropriate relief from that judgment;

b. That the Court enjoin Teva, its officers, agents or attorneys and employees, and those acting in privity or in concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of alendronate sodium and any therapeutic composition covered by Claims 23 and 37 of the ’329 patent.

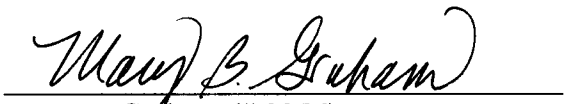
c. That the Court enjoin Teva from asserting any estoppel based upon the findings from the Federal Circuit’s opinion in the FOSAMAX® once-weekly case;

d. That Teva pay all of Merck’s costs and attorneys’ fees in bringing the FOSAMAX® once-weekly case;

e. That Teva pay all of Merck’s costs and attorneys’ fees in bringing this litigation; and

f. That this Court award such other and further relief as the Court may deem just and equitable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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