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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA
PHOENIX DIVISION

PHARMACEUTICAL TECHNOLOGIES, LLC, AN ARIZONA LIMITED LIABILITY COMPANY, Plaintiff, v. EISAI, INC. AND EISAI MEDICAL RESEARCH, INC., BOTH DELAWARE CORPORATIONS, Defendants.	Civil Action No.: to be assigned by the Clerk of the Court **COMPLAINT** TRIAL DEMANDED

COMPLAINT FOR FALSE PATENT MARKING

Plaintiff, Pharmaceutical Technologies, LLC (hereinafter, "PT, LLC"), by its attorneys, hereby complains against Defendants Eisai, Inc. and Eisai Medical Research, Inc. (hereinafter, "Defendant(s)," "Eisai," or "Defendant(s) Eisai"), and alleges as follows:

THE PARTIES

1. PT, LLC, is an Arizona Limited Liability Company with its principal place of business at 111 W. Monroe St., Suite 320, Phoenix, AZ 85003.

2. Defendants are corporations established under the laws of the state of Delaware, with a joint principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey, 07677.

3. Defendants regularly conduct and transact business in Arizona, throughout the United States, and within the District of Arizona, directly and/or through one or more subsidiaries, affiliates, business divisions, or business units. Defendants can be served with process through any of their registered agents, including officers or directors. Defendants' registered agent with the state of Delaware is the Corporation Service Company located at 2711 Centerville Road, Suite 400, Wilmington, DE 19808 (302) 636-5401.

JURISDICTION AND VENUE

4. This Court has exclusive jurisdiction over this action pursuant to 28 U.S.C. § 1331, as a matter arising under the Constitution and laws of the United States, and specifically under 28 U.S.C. § 1338(a) for a civil action arising under an Act of Congress relating to patents.

5. This Court has personal jurisdiction over Defendants. The Defendants have conducted and does conduct business within the State of Arizona. Defendants, directly, or through subsidiaries or intermediaries, offer for sale, sell, advertise and/or mark the Aricept® tablet articles that are subject matter of of this Complaint in the United States and in the State of Arizona, inclusive of the counties comprising the Phoenix Division of the District of Arizona.

6. Defendants have voluntarily sold the Aricept® tablet articles that are subject matter

of this Complaint in this District, either directly to customers in this District or through intermediaries with the expectation that the Aricept® tablet articles will be sold and distributed to customers in this District. Aricept® tablet articles have been and continue to be purchased and used by consumers in the District of Arizona. Defendants have committed acts of false marking and/or advertising within the State of Arizona, including within the counties comprising the Phoenix Division of the District of Arizona.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1395(a), because: (i) Defendants' Aricept® tablet articles that are subject matter of this cause of action are falsely advertised and/or marked and offered for sale, prescribed for sale, and/or sold in various pharmacies and/or on the Internet in this District; (ii) a substantial part of the events or omissions giving rise to the cause of action stated in this Complaint occurred in this District or on the Internet in this District; and (iii) Defendants are subject to personal jurisdiction in this District, as described above.

NATURE OF THE CASE

8. This is a *qui tam* action for false patent marking under 35 U.S.C. § 292.

9. Defendants have violated 35 U.S.C. § 292 by falsely advertising Aricept® (donepezil hydrochloride tablets) as patented by United States Patent Nos. 5,985,864; 6,140,321; 6,245,911; and 6,372,760 (hereinafter, "the '864 patent," "the '321 patent," "the '911 patent," and "the '760 patent," respectively), with the purpose of deceiving the public. The named patents are attached hereto as Appendices A, B, C, and D, respectively. Defendants have, in a continuous manner from January 7, 2002 through the present, advertised in the United States Food and Drug Administration ("FDA") Orange Book that Aricept® tablets are covered by each

of the '864 patent, the '321 patent, and the '911 patent. (*See* Appendix E, "Patent Term Extension and New Patents" publication for the Orange Book dated January 7, 2002, at page 6, line entries for Application/Product Number 020690 "Donepezil Hydrochloride; Aricept;" *see also* Appendix F, Orange Book website patent listing screenshot taken on March 17, 2011, at page 1, line entries for Application Number 020690, the FDA application number for Aricept® tablets.) Defendants have also, in a continuous manner from September 4, 2002 through the present, advertised in the FDA Orange Book that Aricept® tablets are covered by the '760 patent. (*See* Appendix F, Orange Book website patent listing screenshot taken on March 17, 2011, at page 1, line entries for Application Number 020690, the FDA application number for Aricept® tablets; *see also,* Appendix G, "Patent Term Extension and New Patents" publication for the Orange Book dated September 4, 2002, at page 3, line entries for Application/Product Number 020690 "Donepezil Hydrochloride; Aricept, the FDA application number for Aricept® tablets.")

10. The '864 and the '321 patents were statutorily disclaimed by Defendant(s), effective on May 25, 2007, the date that the United States Patent and Trademark Office ("USPTO") approved the terminal disclaimers that Defendant(s) filed for the '864 and '321 patents. (*See* Appendices H and I: USPTO website screen shots showing historically significant dates for the prosecution histories of application numbers 08/870,394 and 08/774,802: *i.e.*, the patent applications that issued as the '864 and '321 patents, respectively.) A patent that has been terminally disclaimed is dedicated to the public such that no infringement action can be brought on it. So neither the '864 patent nor the '321 patent has covered Aricept® tablets since at least May 25, 2007. It follows that Defendants have, for a period of close to four years, advertised in the FDA Orange Book that each of the '864 patent and the '321 patent covers Aricept® tablets, when in fact neither of those statutorily disclaimed patents has covered Aricept® tablets for at

least close to four years.

11. Moreover, neither of the '911 patent and the '760 patent covers Aricept® tablets because not one claim in either of the '911 patent or the '760 patent reads on Aricept® tablets. Accordingly, Defendants have advertised in the FDA Orange Book that each of the '911 patent and the '760 patent covers Aricept® tablets for a period of just over nine years, when neither of the '911 patent or the '760 patent has ever covered Aricept® tablets.

12. On information and belief, Defendants' advertising in the FDA Orange Book that Aricept® tablets are covered by each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent is done: (i) despite Defendants' actual knowledge that not one of the '864, '321, '911, or '760 patents covers Aricept® tablets, and (ii) to prevent competition in the marketplace. Quelling competition in the United States' market for Aricept® tablets is done both by false marking, as described herein, and by improperly manipulating the Hatch-Waxman Act in a manner that effectively and substantially delays the marketing of a generic version of Aricept® tablets.

13. By way of overview here, the instant false marking violations by Defendants (*i.e.*, Orange Book advertising/listing the '864 patent, the '321 patent, the '911 patent, and the '760 patent) have triggered certain provisions of the Hatch-Waxman Act. And those Hatch-Waxman Act provisions, in combination with affirmative steps taken by Defendants, have operated to keep the generic drug manufacturer, Teva Pharmaceuticals USA, Inc., from bringing its generic version of Aricept® tablets to market in the United States, despite those generic Aricept® tablets being tentatively approved by the FDA. Defendants' bad-faith manipulation of the Hatch-Waxman Act that involve the false marking violations described herein present a pattern of conduct that establishes Defendants' intent to deceive the public.

14. The following paragraphs of this Complaint provide a detailed analysis of the false marking violations committed by Defendants in connection with their Aricept® tablets. The following paragraphs of this complaint also provide a detailed analysis the bad-faith manipulations of the Hatch-Waxman Act engaged in by Defendants in connection with their Aricept® tablets.

FALSE MARKING

15. The false marking statute is a criminal statute enforced with civil penalties, and it exists as a deterrent against those that would deceive the public with false patent marking and/or advertising for the purpose of gaining an illegal market advantage. Congress intended valid patent marking and advertising to be ready means for the public to discern the status of intellectual property embodied in an article of manufacture. And federal patent law balances important public interests. For instance, federal patent law balances an individual's valid intellectual property rights against the right of the public to freely use information in the public domain. Each of the Congressional intent and federal patent law policy interests are clearly injured by false marking, including representing through advertisement that a product is covered by a patent when it is not so covered, because the act of false marking misleads the public into believing that a patentee controls the article in question, and likely related articles. In so doing, the act of false marking externalizes the risk of error in a determination of whether something is properly advertised as patented, burdening the public with that determination rather than the manufacturer or seller of the article. This, in turn, increases the cost to the public of ascertaining whether a patentee in fact controls the intellectual property embodied in an article.

16. In each instance where it is represented that an article is patented, a member of the public desiring to participate in the market for the marked article must incur the cost of

determining whether the involved patents are valid and enforceable. If these costs are not incurred, an infringer can be found to have willfully infringed, a finding which carries with it the potent possibility of treble damages. Falsely marking and/or advertising an article of manufacture as patented therefore increases costs for a potential market participant because those wishing to compete in the market must *unnecessarily* (1) take on the costs of a reasonably competent search for information necessary to interpret each patent, (2) take on the costs of investigating prior art and other information bearing on the quality of the patents, and (3) take on costs related to the analysis thereof.

17. For at least the foregoing reasons, when an entity falsely claims that a product is patented - as Defendants have done in the instant case - the false marker gains an illegal and impermissible market advantage. This illegal advantage directly results in supracompetitive pricing for the falsely marked product, which places the United States' economy in a disadvantaged state due to a misallocation of public and private resources and a lack of confidence in products that are marked as patented. And all of this is done at the expense of the United States' public and government.

18. False patent marking, including representing through advertisement that a product is covered by a patent when it is not so covered, is a serious problem for other reasons as well. Acts of false marking deter innovation and stifle competition in the marketplace. If an article that is within the public domain is falsely marked, potential competitors may be dissuaded from entering the market, for instance with a lower-cost and/or higher-quality version of the falsely marked product. False marking can deter scientific advancement when research is purposefully cut short under the belief that defending against patent infringement may be too costly. False marking can cause unnecessary investment to design around another's patent. False markings

may create a misleading impression that the falsely marked product is technologically superior to competing products, as articles bearing the term "patent" may be presumed to be novel, useful, and innovative.

19. The false marking statute explicitly permits *qui tam* actions. By permitting members of the public to sue on behalf of the government, Congress allows individuals to help control false marking. Plaintiffs in such actions are often viewed as a private attorney general, assisting the government with enforcing fair competition in a large and sometimes unwieldy free market.

20. PG, LLC, as a private attorney general and on behalf of the United States, brings the present cause of action against Defendants for falsely marking its Aricept® tablet articles of manufacture with each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent, in violation of 35 U.S.C. § 292(a).

DEFENDANTS' PATENT ADVERTISEMENTS FOR ARICEPT®

21. As established in paragraphs 9-12 of this Complaint, Defendants advertise in the FDA Orange Book that Aricept® tablets are covered by each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent. At least part of this FDA Orange Book advertising is done on the Internet, at the website corresponding to the FDA's Orange Book publication. The Orange Book publishes selected information about all pharmaceutical products that the FDA has approved for marketing in the United States, on behalf of the United States government and after safety and efficacy review. The patent and exclusivity information section of the Orange Book lists, for each pharmaceutical product published therein, any United States patent(s) asserted by the owner or licensee of an FDA-approved, pharmaceutical product as covering its product.

Because Defendants listed each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent in the Orange Book as covering Aricept® tablets, Defendants unequivocally advertised and continue to advertise that each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent covers Aricept® tablets.

22. Orange Book patent listings serve as a starting point, for generic drug developers, manufacturers, and marketers, in making determinations about the viability of investing resources towards bringing a generic version of a branded, FDA-approved pharmaceutical to market. The Orange Book search page is www.accessdata.fda.gov/scripts/cder/ob/default.cfm. There, conducting a "Proprietary Name" search using "Aricept" leads to FDA Application Number N020690, to Defendant Eisai, Inc. Clicking on that application number leads to a webpage which shows that the New Drug Application for Aricept® tablets was FDA approved on November 25, 1996, and provides another hyperlink for "Patent and Exclusivity Info for this product [Aricept® tablets]." That hyperlink clicks through to Defendants' Orange Book advertisement that Aricept® tablets are covered by each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent. Of note, it is an FDA-approved manufacturer – such as Defendants – and not the FDA, that decides what patents are advertised as allegedly covering their product in the FDA Orange Book, including the noted FDA Orange Book webpage. This webpage is therefore an advertisement by the Defendants to the public-at-large, including generic drug developers, manufacturers, and marketers, that Aricept® tablets are covered by each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent. A printed version of this webpage is provided herewith as Appendix F.

23. On information and belief, Defendants also marked packaging material for their Aricept® tablets with each of the '864 patent, the '321 patent, the '911 patent, and the '760

patent.

FALSITY OF DEFENDANTS' PATENT ADVERTISEMENTS FOR ARICEPT®

24. Under one approach for finding an article "unpatented" under 35 U.S.C. § 292, it is clear that articles no longer protected by a patent are "unpatented."

25. An additional approach for finding false marking liability under 35 U.S.C. § 292, the article in question and claims of the alleged covering patent are analyzed. The first step of this analysis asks whether the claims of the patent cover the article in question. In patent analysis, it is the claims that provide the "metes and bounds" of the patentee's right to exclude others from practicing, using, and/or selling the claimed invention. And the right to exclude analysis is a two-step process: first requiring a proper interpretation of the scope of the claims, and then requiring an evaluation of whether the properly interpreted claims "read on" the article in question. An article is "unpatented" under the false marking statute if not one claim of the allegedly covering patent "reads on" the article in question.

26. **The '864 and '321 Patents.** Aricept® tablets are unpatented by each of the '864 patent and the '321 patent, for at least the following reasons. As stated in paragraph 10 of this Complaint, Defendant(s) filed with the USPTO terminal disclaimers for each of the '864 patent and the '321 patent. And the USPTO made each of those terminal disclaimers effective as of May 25, 2007. At least because those terminal disclaimers operate to dedicate to the public each of the '864 patent and the '321 patent, such that no infringement suit can be brought based on them, Aricept® tablets have been "unpatented" as to each of the '864 patent and the '321 patent since May 25, 2007. Accordingly, Defendants' advertising in the Orange Book that each of the '864 patent and the '321 patent covers Aricept® tablets has been false since May 25, 2007 or

shortly thereafter.

27. **The '911 Patent.** Aricept® tablets are unpatented by the '911 patent because no claim of the '911 patent reads on Aricept® tablets, for at least the following reasons. The '911 patent contains 21 claims, three of which are independent. Independent claims 1-3 of the '911 patent are directed to polymorphic crystal forms of donepezil A, B, and C, respectively, each of which have specified signal peaks in their powder x-ray diffraction patterns and/or infrared absorption spectrums. (Appendix C, the '911 patent, Column 22, line 35 – Column 24, line 41.) The powder x-ray diffraction patterns for the A, B, and C crystal forms of donepezil, as claimed by independent claims 1-3, are illustrated in Figures 1-3 of the '911 patent, respectively. (Appendix C, the '911 patent: Figures 1-3 and Column 2, lines 30-37.)

28. By way of preliminary matters, it would be necessary for Aricept® tablets to contain the crystal forms of donepezil A, B, and/or C described and claimed in the '911 patent in order for any claim of the '911 patent to read on Aricept® tablets. To this end, a person with ordinary skill in the art of x-ray diffraction analysis would understand that if Aricept® tablets indeed contained the crystal forms of the donepezil A, B, and/or C described and claimed in the '911 patent, then at least the strong signal peaks in the x-ray diffraction patterns of crystal forms of donepezil A, B, and/or C would be reflected and/or apparent in the x-ray diffraction pattern of Aricept® tablets. The '911 patent, however, teaches the x-ray diffraction patterns of ***pure*** crystal forms of donepezil A, B, and/or C, *and not the x-ray diffraction pattern of Aricept® tablets, the product that is actually advertised as patented by the '911 patent.*

29. United States Patent No. 6,734,195 (hereinafter, "the '195 patent") teaches the x-ray diffraction pattern of Aricept® tablets in the bottom trace of its Figure 2. (Appendix J, the '195 patent: Figure 2 and Column 2, lines 33-37.) As shown in Figure 2, and in contrast to those

diffraction patterns claimed by the '911 patent, the x-ray diffraction pattern of actual Aricept® tablets is so deficient as to prevent the product from being covered by the claimed diffraction patterns for the A, B, and C crystal forms of donepezil recited in claims 1-3 of the '911 patent.

30. For example, Figure 1 of the '911 patent shows that the A crystal form of donepezil recited in claim 1 of the '911 patent has a strong signal peak in its x-ray diffraction pattern at angle 2Θ = 17.5; whereas the bottom trace of the '195 patent's Figure 2 shows that Aricept® tablets have a trough in their x-ray diffraction pattern at angle 2Θ = 17.5. Based on at least this discrepancy, the teachings of the '195 patent inform a person with ordinary skill in the art that Aricept® tablets do not contain the A crystal form of donepezil defined by independent claim 1 of the '911 patent. So independent claim 1 of the '911 patent does not read on Aricept® tablets.

31. In addition, Figure 2 of the '911 patent shows that the B crystal form of donepezil recited in claim 2 of the '911 patent has a strong signal peak in its x-ray diffraction pattern at angle 2Θ = 21.75; whereas the bottom trace of the '195 patent's Figure 2 shows that Aricept® tablets have a trough in their x-ray diffraction pattern at angle 2Θ = 21.5. Based on at least this discrepancy, the teachings of the '195 patent inform a person with ordinary skill in the art that Aricept® tablets do not contain the B crystal form of donepezil defined by independent claim 2 of the '911 patent. So independent claim 2 of the '911 patent does not read on Aricept® tablets.

32. Further still, Figure 3 of the '911 patent shows that the C crystal form of donepezil recited in claim 3 of the '911 patent has twin signal peaks in its x-ray diffraction pattern at angle 2Θ range = 13.5 - 15; whereas the bottom trace of the '195 patent's Figure 2 shows that Aricept® tablets have a flatline in their x-ray diffraction pattern at angle 2Θ range = 13.5 - 15. Based on at least this discrepancy, the teachings of the '195 patent inform a person with ordinary skill in the art that Aricept® tablets do not contain the C crystal form of donepezil defined by independent

claim 3 of the '911 patent. So independent claim 3 of the '911 patent does not read on Aricept® tablets.

33. At least the foregoing points and discussion establish that Aricept® tablets do not contain the crystal forms A, B, and/or C of donepezil defined in claims 1-3 of the '911 patent. Several plausible circumstances might explain why the crystal forms for A, B, and/or C of donepezil as defined in claims 1-3 of the '911 patent are not present in Aricept® tablets. It could be that no crystal form A, B, or C of donepezil is used in the manufacturing process for Aricept® tablets. It could also be that certain steps or events in the manufacturing process for Aricept® tablets transform any crystal form A, B, and/or C of donepezil used in the manufacturing process for Aricept® tablets into other forms of donepezil. An example of such a transforming step or event is wetting (even partial wetting) that dissolves and thereby destroys any crystal form A, B, and/or C of donepezil used in the manufacturing process for Aricept® tablets. Another example of such a transforming step or event could be compression that physically destroys any crystal form A, B, and/or C of donepezil used in the manufacturing process for Aricept® tablets.

34. Finally, claims 4-21 of the '911 patent all recite processes for producing the donepezil crystal forms A, B, or C defined by claims 1-3 of the '911 patent. At least because, as explained above, Aricept® tablets do not contain the A, B, or C crystal forms of donepezil defined by claims 1-3 of the '911 patent, the processes for producing the A, B, or C crystal forms of donepezil recited by claims 4-21 of the '911 patent cannot read on Aricept® tablets. Accordingly, not one claim of the '911 patent reads on Aricept® tablets, and Aricept® tablets have therefore always been "unpatented" as to the '911 patent. Defendant Eisai's advertising in the Orange Book that the '911 patent covers Aricept® tablets has therefore been false since January 7, 2002 or shortly thereafter.

35. **The '760 Patent.** Aricept® tablets are unpatented by the '760 patent because no claim of the '911 patent reads on Aricept® tablets, for at least the following reasons. The '760 patent contains 10 claims. Independent claim 1 of the '760 patent recites: "An antidementia medicament composition, comprising: an antidementia medicament and **an organic acid**, wherein the antidementia medicament is donepezil and **the organic acid is selected from the group consisting of tosyllic acid, mesyllic acid, benzoic acid, salicylic acid, tartaric acid, citric acid and combinations thereof**, wherein the organic acid is not added to form a salt." (Emphasis added.) (Appendix D, the '760 patent, Column 4, lines 58-65.)

36. Claim 1 of the '760 patent therefore defines antidementia medicaments that must contain the drug donepezil and one or more of the following organic acids: tosyllic acid, mesyllic acid, benzoic acid, salicylic acid, tartaric acid, and citric acid. Aricept® tablets, however, do not contain any of the named organic acids or combinations thereof. (*See* Appendix K, prescribing information for Aricept®, Section 11, pages 6-7.) Because Aricept® tablets do not contain tosyllic acid, mesyllic acid, benzoic acid, salicylic acid, tartaric acid, citric acid, or combinations thereof, claim 1 of the '760 patent does not read on Aricept® tablets. Further, nothing in claims 2, 6, 7, and 8 of the '760 patent, which depend from claim 1, operates to alter the present analysis; so claims 1-2 and 6-8 of the '760 patent do not read on Aricept® tablets.

37. Independent claim 3 of the '760 patent recites: "A method for stabilizing an antidementia medicament, which comprises the step of: **adding an organic acid** to an antidementia medicament, wherein the antidementia medicament is donepezil and **the organic acid is selected from the group consisting of tosyllic acid, mesyllic acid, benzoic acid, salicylic acid, tartaric acid, citric acid and combinations thereof**, wherein the organic acid is not added to form a salt." (Emphasis added.) (Appendix D, the '760 patent, Column 5, lines 1-

8.)

38. Claim 3 of the '760 patent therefore defines a method for stabilizing an antidimentia medicament that contains the drug, donepezil. The stabilization method defined by claim 3 requires that one or more of the following organic acids be added to donepezil: tosyllic acid, mesyllic acid, benzoic acid, salicylic acid, tartaric acid, and citric acid. Aricept® tablets, however, do not contain any of the named organic acids or combinations thereof. (*See* Appendix K, prescribing information for Aricept®, Section 11, pages 6-7.) Because Aricept® tablets do not contain tosyllic acid, mesyllic acid, benzoic acid, salicylic acid, tartaric acid, citric acid, or combinations thereof, claim 3 of the '760 patent does not read on Aricept® tablets. (Appendix K, prescribing information for Aricept®, Section 11, pages 6-7.) Further, nothing in claims 4-5 and 9-10 of the '760 patent, which depend from claim 3, operates to alter the present analysis; so claims 3-5 and 9-10 of the '979 patent do not read on Aricept®.

39. Since not one claim of the '760 patent reads on Aricept® tablets, Aricept® tablets have always been "unpatented" as to the '760 patent. Defendant Eisai's advertising in the Orange Book that the '911 patent covers Aricept® tablets has therefore been false since September 4, 2002 or shortly thereafter.

DEFENDANTS' INTENT TO DECEIVE

40. Under Federal Circuit case law, the combination of a false statement and knowledge that the statement was false creates a rebuttable presumption of 'intent to deceive the public' within the meaning of the false marking statute. For at least the reasons set forth in paragraphs 9-12, 24 and 26 of this Complaint, Defendants have, in a continuous manner from at least May 25, 2007 through the present, falsely advertised that each of the '864 patent and the

'321 patent covers Aricept® tablets. For at least the reasons set forth in paragraphs 9-12, 25, and 27-39 of this Complaint, Defendants have, in a continuous manner from January 7 or September 4, 2002 through the present, falsely advertised that each of the '911 patent and the '760 patent covers Aricept® tablets.

41. Defendants therefore made false statements by advertising that each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent covers Aricept® tablets. Defendants have actual knowledge that the instant patents do not cover Aricept® tablets, in view of at least the following facts.

42. **The '864 and '321 Patents.** Defendant(s) filed with the USPTO the terminal disclaimers for each of the '864 patent and the '321 patent. Defendants are sophisticated companies with many years of experience in procuring, licensing, and enforcing United States patents. On information and belief, Defendants have sophisticated in-house counsel, and regularly retain sophisticated outside legal counsel, including United States patent counsel.

43. Defendants therefore know that the terminal disclaimers filed for the '864 patent and the '321 patent effectively ended any protection that those patents may have had as to Aricept® tablets on the date the USPTO approved those terminal disclaimers: *i.e.*, May 25, 2007. Defendants therefore had actual knowledge that neither the '864 patent nor the '321 patent has covered Aricept® tablets since at least May 25, 2007.

44. **The '911 and '760 Patents.** As stated above, Defendants are sophisticated companies with many years of experience in procuring, licensing, and enforcing United States patents. On information and belief, Defendants have sophisticated in-house counsel and regularly retain sophisticated outside legal counsel, including United States patent counsel. Defendants therefore know that patents do not have unlimited scope; but rather a scope limited to

that which is claimed.

45. Defendant(s) procured from the USPTO the '911 patent and the '760 patent on November 16, 1999 and October 31, 2000, respectively. Defendants therefore had actual knowledge of the scope of the claims in each of the '911 patent and the '760 patent on or before the respective issuance dates of the '911 and '760 patents. Defendant(s) also procured from the FDA New Drug Application: N020690 (*i.e.*, the application for Aricept® tablets) on November 25, 1996. Defendants therefore had actual knowledge of the contents and makeup of Aricept® tablets prior to November 25, 1996. Accordingly, Defendants have had actual knowledge that neither the '911 patent nor the '760 patent has covered Aricept® tablets since 2002.

46. As stated above, well-established Federal Circuit case law holds that the instant combinations of false statements and knowledge that the statements are false gives rise to presumptions of 'intent to deceive the public' under the false marking statute. Moreover, the 'intent to deceive the public' presumptions that arise here are heightened as to each of the '911 patent and the '760 patent, because those patents are presently unexpired and do not contain one claim that reads on Aricept® tablets. Further still, all of the 'intent to deceive the public' presumptions that arise here are substantially bolstered on at least the following grounds.

47. By maintaining its false Orange Book advertisings/listings for each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent for Aricept® tablets – despite actual knowledge that none of those patents cover Aricept® tablets – Defendant(s) have, in the past and present, engaged in conduct that violates the false marking statute. By way of that unlawful conduct, Defendants are also quelling competition in the United States market for Aricept® tablets, at least by manipulating the Hatch-Waxman Act in a manner that effectively and substantially delays the generic drug manufacturer, Teva Pharmaceuticals USA, Inc., from

bringing its generic version of Aricept® tablets, which has been tentatively approved by the FDA, to market in the United States. An analysis of the Hatch-Waxman Act follows. And the Hatch-Waxman analysis is followed by an analysis of the effects of Defendants' unlawful false-advertising of the '864 patent, the '321 patent, the '911 patent, and the '760 patent in connection with its Aricept® tablets.

48. Hatch-Waxman. The Hatch-Waxman Act requires a drug company seeking to market a new pharmaceutical product in the United States to prepare and file a New Drug Application (hereinafter, "NDA"), which must be approved by the FDA prior to marketing the new drug. *See* 21 U.S.C. §§ 355(a) and (b). As part of the NDA approval process, NDA applicants must submit to the FDA information regarding the drug's safety and efficacy and identify all patents that "could reasonably be asserted if an entity not licensed by the owner engaged in the manufacture, use, or sale of the NDA drug." 21 U.S.C. §§ 355(b)(1) and (c)(2). When an NDA is approved, the FDA lists the patent information provided by the NDA applicant along with the approved drug in its Orange Book publication. *See* 21 U.S.C. §§ 355(b)(1), (j)(2)(A)(ii).

49. Under the Hatch-Waxman Act, generic drug companies may obtain expedited approval of generic drugs by preparing and filing with the FDA an Abbreviated New Drug Application (hereinafter, "ANDA"). 21 U.S.C. §§ 355(j). Once an ANDA applicant demonstrates bioequivalence of its generic drug with the NDA drug, it is not required to conduct its own, independent clinical trials to prove safety and efficacy. 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(8)(B). An ANDA applicant must include a certification as to each patent listed in the Orange Book with respect to the NDA drug that either: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and the FDA's

approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). Respectively, these filings are referred to as Paragraph I, II, III, and IV certifications.

50. The FDA's approval of an ANDA is dependent upon the type of certification sought by the generic drug manufacturer. The approval of a Paragraph IV ANDA depends upon two factors: (1) whether the NDA drug company brings an infringement action within 45 days of learning of the Paragraph IV ANDA filing, and (2) whether the ANDA applicant was the first one to file an ANDA containing a Paragraph IV Certification against an Orange Book listed patent. Under the Hatch-Waxman Act, the filing of a Paragraph IV certification against an Orange Book listed patent constitutes an "artificial" act of patent infringement, for purposes of establishing jurisdiction in federal court. 35 U.S.C. § 271(e)(2).

51. After filing a Paragraph IV certification and receiving the FDA's tentative approval of its ANDA, an ANDA filer must provide, to the patentee and the NDA holder, notice of the factual and legal bases for the Paragraph IV certification. 21 U.S.C. § 355(j)(2)(B). Within 45 days of receiving this notice, the patentee and NDA holder may bring suit against the Paragraph IV filer for patent infringement, which triggers an automatic stay of final approval of the ANDA by the FDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does file an infringement suit within 45 days, the FDA may not approve the ANDA until either the 30 month stay has expired or a court rules that the patent is invalid or not infringed by the ANDA. 21 U.S.C. §§ 355(c)(3)(C). If, however, the patentee does not bring suit within that period, the FDA may issue a final approval of the ANDA once the requirements for approval have been satisfied.

52. The Hatch-Waxman Act grants the first party to submit an ANDA containing a

Paragraph IV certification against an Orange Book listed patent (hereinafter, the "first-filer") a 180-day period of generic marketing exclusivity. 21 U.S.C. §§ 355(j)(2)(A)(iv). The first-filer may obtain this 180-day exclusivity period regardless of whether or not it successfully establishes that the challenged patents are invalid or not infringed by the drug described in its ANDA. All that is required for the first-filer to receive the 180-day generic exclusivity period is that it submits a substantially complete ANDA that contains a Paragraph IV Certification. 21 U.S.C. § 355 (j)(5)(B)(iv)(II)(bb). The Hatch-Waxman Act provides that the 180-day period of generic exclusivity begins either on the date that the first-filer markets its generic drug, or on the date of a final court decision finding the relevant Orange Book listed patents invalid or not infringed, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Only the first-filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I). In contrast, subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger. In addition, the FDA cannot give its final approval to subsequent Paragraph IV ANDAs until the first-filer's 180-day exclusivity period expires.

53. With the foregoing in mind, attention is directed to the following facts. The FDA has tentatively approved two ANDAs for generic versions of Aricept® tablets. Both of these generic Aricept® tablet ANDAs were filed with Paragraph IV certifications against each Orange Book listed patent for Aricept® tablets that are subject matter of this Complaint (*i.e.*, the '864 patent, the '321 patent, the '911 patent, and the '760 patent). Ranbaxy Pharmaceuticals, Inc. (hereinafter, "Ranbaxy") is the first-filer of the tentatively-approved, Aricept® tablet Paragraph IV ANDAs, and Teva Pharmaceuticals USA, Inc. (hereinafter, "Teva") is the subsequent ANDA filer.

54. On information and belief, Defendants received notifications from each of Ranbaxy and Teva that the FDA had tentatively approved their generic Aricept® Paragraph IV ANDAs, these notifications setting forth factual bases for each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent being invalid and/or not infringed by the Paragraph IV ANDAs for Aricept® tablets.

55. Defendants did not sue either Ranbaxy or Teva for infringement of any of the '864 patent, the '321 patent, the '911 patent, and the '760 patent within 45 days of receiving the notifications at hand. Instead, Defendants granted covenants not to sue Ranbaxy and Teva for infringement of the '911 and '760 patents in connection with their Aricept® tablet Paragraph IV ANDAs. Though Ranbaxy has apparently been free to market its generic Aricept® tablets since November 25, 2010, it is believed that Ranbaxy has not commercially marketed its generic Aricept® tablets as of today.

56. Teva cannot obtain final approval of its Aricept® tablet Paragraph IV ANDA from the FDA (and thereby bring its generic Aricept® tablets to market) for several reasons. First, Defendants maintain and Orange Book listings/advertisements for Aricept® tablets of the '864 patent, the '321 patent, the '911 patent, and the '760 patent. Accordingly, the FDA cannot give its final approval to Teva's generic Aricept® tablet Paragraph IV ANDA, which was filed subsequent to Ranbaxy's Aricept® tablet Paragraph IV ANDA, until Ranbaxy's generic exclusivity period has expired. And Ranbaxy's generic exclusivity period is not triggered until Ranbaxy commercially markets its generic Aricept® tablets or there is a court judgment that the Orange Book listed patents for Aricept® tablets are invalid or not infringed by the generic Aricept® tablets of either Ranbaxy's or Teva's paragraph IV ANDAs for the same.

57. Teva sought to trigger Ranbaxy's generic exclusivity period for Aricept® by

obtaining a court judgment that its Aricept® tablet Paragraph IV ANDA does not infringe the '911 and '760 patents. In particular, Teva filed a Declaratory Judgment action against Eisai, Inc., seeking a judgment that Teva's (generic) Aricept® tablets Paragraph IV ANDA does not infringe the '911 and '760 patents. In response, Defendant Eisai successfully moved for dismissal of Teva's action, on the grounds that Teva lacked standing to bring its Declaratory Judgment action in District Court because Defendant Eisai had given Teva a covenant not to sue on the '911 and '760 patents in connection with Teva's Aricept® tablet Paragraph IV ANDA. Teva successfully appealed the dismissal of its Declaratory Judgment action against Defendant Eisai to the Court of Appeals for the Federal Circuit. (A copy of the Federal Circuit's decision is attached hereto as Appendix L.)

58. It is important to note that Defendant Eisai has, at all times, been free to delist each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent from its Orange Book patent listings for Aricept® tablets. Such delistings would immediately: (i) allow the FDA to give its final approval to Teva's Aricept® tablet ANDA, and (ii) allow Teva to market its generic Aricept® tablets in the United States.

59. Taken together, the foregoing facts clearly establish the following. Defendants have intentionally deceived the FDA and the public as to each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent covering its Aricept® tablets, by illegally advertising those patents in its Orange Book patent listings for Aricept® tablets. Defendants' purpose for illegally advertising/listing in the Orange Book that each of the '863 patent, the '321 patent, the '911 patent, and the '760 patent covers Aricept® is to quell competition in the United States market for its Aricept® tablets. And Defendants have achieved their purpose, at least by substantially delaying Teva in bringing its generic Aricept® tablets to the market in the United States.

CAUSES OF ACTION FOR FALSE PATENT MARKING

60. PT, LLC incorporates by reference the foregoing paragraphs as if fully set forth herein.

61. Each independent false patent advertising event for Aricept® tablets by Defendants substantially and cumulatively discourages and deters persons and companies from commercializing competing products.

62. Defendants' false Orange Book advertising/listing of each of the '864 patent, the '321 patent, the '911 patent, and the '760 patent for its Aricept® tablets has wrongfully quelled competition with respect to such products, thereby causing harm to PT, LLC, the United States, and the public-at-large.

63. Defendants have wrongfully, illegally, and falsely advertised and/or marked their Aricept® tablets as under multiple patent monopolies which they do not possess for Aricept® tablets; and, as a result, Defendants have wrongfully benefited by maintaining an illegal market advantage.

64. Defendants know that patents provide the patent holder with market power to monopolize the invention claimed therein.

65. Defendants know that all monopoly rights in a patent terminate irrevocably when terminally disclaimed.

66. Defendants know that all monopoly rights in a patent are limited to subject matter claimed in the patent.

67. Upon information and belief, Defendants know, or reasonably should have known, that advertising and/or marking Aricept® tablets with false patenting statements was, and is,

illegal under Title 35 § 292 of the United States Code.

68. Each falsely advertised/marked Aricept® article is a separate "offense" under 35 U.S.C. § 292.

PRAYER FOR RELIEF

69. WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendants as follows:

70. A decree that Defendants have falsely advertised and/or marked Aricept® tablets in violation of 35 U.S.C. § 292;

71. An award of monetary damages, pursuant to 35 U.S.C. § 292, in the form of a civil monetary fine of $500 per falsely advertised and/or marked Aricept® tablet article, or an alternative amount as determined by the Court, one half of which shall be paid to the United States of Government and one-half of which shall be paid to PT, LLC, as a private attorney general acting on behalf of the United States;

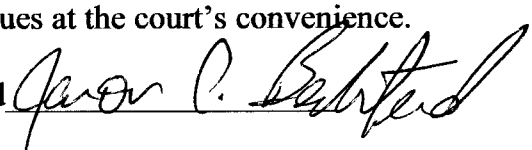
72. Enter a judgment and order requiring the Defendants to pay PT, LLC, prejudgment interest on awarded damages;

73. Order Defendants to pay PT, LLC's costs and attorney fees; and

74. Grant PT, LLC, such other and further relief as it may deem just and equitable.

DEMAND FOR TRIAL

75. Plaintiff hereby demands a trial on all issues at the court's convenience.

Signed 

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