IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

SANDOZ INC. Plaintiff, v. BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. Defendants.	Civil Action No. 3:10-CV-437-J-99TJC-MCR **JURY DEMANDED**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Sandoz Inc. ("Sandoz") for its Complaint against Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively "Defendants" or "Boehringer") alleges as follows:

THE PARTIES

1. Sandoz is a corporation organized and existing under the laws of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey.

2. Upon information and belief, Boehringer Ingelheim International GmbH ("BII") is a corporation organized and existing under the laws of Germany with an office and place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

3. Upon information and belief, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of Delaware with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

JURISDICTION AND VENUE

4. This action arises under, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendants at least because they conduct substantial business in, and have regular and systematic contacts with, this District and have availed themselves of this District in a prior Hatch-Waxman lawsuit, *Boehringer Ingelheim Pharmaceuticals, Inc. v. Apotex Inc. et al.*, C.A. No. 08-cv-00098 (MMH). Additionally, upon information and belief, Defendants maintain an office in Jacksonville, Florida and conduct substantial business in this District. Accordingly, Defendants are subject to personal jurisdiction in this District.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

U.S. PATENT NO. 4,886,812

8. U.S. Patent No. 4,886,812 ("the '812 patent"), entitled "Tetrahydro-Benzthiazoles, The Preparation Thereof and Their Use as Intermediate Products or as Pharmaceuticals," was issued by the United States Patent and Trademark Office

("PTO") on December 12, 1989. Upon information and belief, BII purports to be the owner of the '812 patent, and BIPI purports to be a licensee under the '812 patent. A true and accurate copy of the '812 patent is attached hereto as Ex. A.

ACTS GIVING RISE TO THE ACTION

9. This action arises out of, *inter alia*, Sandoz's submission of Abbreviated New Drug Application ("ANDA") No. 90-190 to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Defendants' brand-name medication Mirapex® indicated for, *inter alia*, Parkinson's disease. The active ingredient in Mirapex® is known as pramipexole dihydrochloride.

10. Upon information and belief, Boehringer is the current holder of approved New Drug Application ("NDA") No. 20-677 for Mirapex® oral tablets (including the active ingredient pramipexole dihydrochloride in strengths of 0.125 mg, 0.25 mg, 0.5 mg, 0.75 mg, 1.0 mg and 1.5 mg).

11. Upon submission by Defendants, the '812 patent, *inter alia*, was listed in the FDA's compilation of approved drugs and their respective patents, entitled the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." As a consequence of such Orange Book listing, Defendants maintain, and have affirmatively represented to the public, that the '812 patent, *inter alia*, claims the approved drug Mirapex® and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Sandoz, attempting to market a generic pramipexole dihydrochloride product before expiration of the '812 patent.

12. Sandoz seeks to market generic pramipexole dihydrochloride products ("Sandoz's ANDA products") before expiration of the '812 patent. Therefore, as required by the Federal Food Drug and Cosmetic Act, Sandoz certified to the FDA that its ANDA products will not infringe any valid or enforceable claim of the '812 patent and has further notified Defendants of the legal and factual bases for those certifications on September 12, 2008 and February 12, 2009.

13. Sandoz's submission of the so-called Paragraph IV certifications to the '812 patent constitutes an artificial act of patent infringement, putting Sandoz at considerable risk of being sued by Defendants both before and after market entry. Sandoz's Paragraph IV certifications to the FDA creates the necessary case or controversy and subject matter jurisdiction for Sandoz to obtain a declaratory judgment against Defendants.

14. In fact, Defendants have sued other ANDA filers on the same '812 patent in this District. On September 26, 2005, Boehringer filed a complaint for patent infringement in this District against Barr Laboratories ("Barr"), alleging infringement of the '812 patent, including infringement due to Barr's filing of ANDA No. 77-724 for generic versions of Mirapex®. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, C.A. No. 05-cv-700 (JJF) (the "*Barr* litigation"). On December 12, 2005, Boehringer again filed a complaint for patent infringement in this District against Mylan Pharmaceuticals ("Mylan"), alleging infringement of the '812 patent, including infringement due to Mylan's filing of ANDA No. 77-854 for generic versions of Mirapex®. *See Boehringer Ingelheim Int'l GmbH v. Mylan Pharms. Inc.*, C.A. No. 05-

cv-854 (JJF). The case against Mylan was subsequently consolidated with the *Barr* litigation.

15. Discovery in *Barr* commenced on or about January 2006. Upon information and belief, during discovery in *Barr*, defendants Barr and Mylan uncovered evidence showing that the '812 patent was procured by inequitable conduct. Upon information and belief, the defendants uncovered evidence that Boehringer falsely stated that the patent application that matured into the '812 patent was entitled to a priority filing date of two German patent applications. Upon information and belief, this false statement was made to avoid a possible interference proceeding based upon a patent application filed in 1985 by Eli Lilly directed to a chemical genus covering pramipexole.

16. Barr subsequently amended its answer and counterclaims to include unenforceability of the '812 patent based on inequitable conduct. Mylan also sought leave to amend its answer and counterclaims for the same reasons. *See* Dkt. Nos. 107 and 222 in *Barr* litigation. Barr further moved for *in camera* inspection and, pursuant to the crime-fraud exception, moved to compel production of documents that Boehringer withheld under a claim of privilege. *See* Dkt. Nos. 144, 150 and 165 in the *Barr* litigation. After full briefing on the motion, upon information and belief, the parties reached an agreement regarding the inequitable conduct allegations. The defendants stipulated that they would no longer pursue their inequitable conduct defenses and counterclaims. *See* Dkt. Nos. 172 and 177 in the *Barr* litigation.

17. On June 26, 2008, the district court in *Barr* held the '812 patent claims invalid based on obviousness-type double patenting. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 562 F. Supp. 2d 619 (D. Del. 2008). Boehringer appealed.

18. On January 25, 2010, the U.S. Court of Appeals for the Federal Circuit reversed the district court's judgment in *Barr*, holding that the '812 patent was not invalid based on double patenting. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340 (Fed. Cir. 2010). The Federal Circuit did not address the issue of inequitable conduct or the invalidity of the '812 patent.

19. On May 11, 2010, Boehringer's counsel sent a letter to Sandoz, asserting that "[i]n light of the Federal Circuit's ruling upholding the validity of the '812 patent, you are hereby notified that Boehringer would consider any manufacture, use, offer for sale, sale, or importation of any generic pramipexole product in the United States before expiration of the '812 patent **to constitute patent infringement.**" A true and accurate copy of Boehringer's May 11, 2010 letter to Sandoz is attached hereto as Ex. B. (emphasis added). Boehringer's counsel further asserted that "given the statements in Sandoz's notice letters and the circumstances, Boehringer would consider any such conduct to be willful patent infringement under 35 U.S.C. § 284." *Id.*

20. As evidenced by Boehringer's litigation against other generic drug manufacturers on the same '812 patent and Boehringer's explicit statements in its May 11, 2010 letter to Sandoz, there is a substantial controversy between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the '812 patent.

21. Sandoz has taken a number of deliberate steps with the intent to manufacture, offer to sell and sell in the United States Sandoz's ANDA products by satisfying all substantive requirements for approval of its ANDA No. 90-190. Accordingly, Boehringer's actions have put Sandoz in the position of either continuing to seek FDA approval of its ANDA No. 90-190 under the real and immediate threat of litigation, or abandoning its efforts. A declaration of rights between the parties is necessary to establish that Boehringer cannot enforce the '812 patent against Sandoz, and that the '812 patent is invalid.

22. Absent the exercise of jurisdiction by this Court and such declaratory relief, Sandoz and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced generic pramipexole dihydrochloride products.

UNENFORCEABILITY OF THE '812 PATENT

23. The claims of the '812 patent are unenforceable due to inequitable conduct by individuals associated with the filing and prosecution of the application that matured into the '812 patent, including the named inventors, the attorneys who prepared and prosecuted the application that matured into the '812 patent and other persons who were substantively involved in the preparation or prosecution of the application that matured into the '812 patent (collectively, the "Applicants"). Specifically, at least Dr. Rolf Fleischer – who was a patent agent in Boehringer's German patent department and who was the individual responsible for overseeing worldwide prosecution of the pramipexole patent family – knowingly and intentionally caused or permitted material

misstatements of fact to be made concerning the priority date of U.S. Patent Application Serial No. 256,671 ("the '671 application"), which matured into the '812 patent. Dr. Fleischer's knowing and intentional misrepresentation allowed Applicants to claim a much earlier effective filing date in order to avoid U.S. and European patent applications filed by Eli Lilly & Company ("Eli Lilly") directed to overlapping subject matter, namely, the disclosure of a chemical genus covering pramipexole.

24. Initially, those individuals who were substantively involved in the preparation or prosecution of the '671 application, including at least Dr. Fleischer, knowingly and intentionally made the following misrepresentation of fact, *inter alia*, regarding the claim of priority at the time of filing the '671 application:

Prior Foreign Application(s)				Priority Claimed
P 34 47 075.1	West Germany	22 December 1984		(Yes) No
(Number)	(Country)	(Day/Month/Year Filed)		
P 35 08 947.4	West Germany	13 March 1985		(Yes) No
(Number)	(Country)	(Day/Month/Year Filed)		

Ex. D, Boehringer's Decl. for '671 Patent Application (explicitly claiming priority to Boehringer's two earlier filed German Applications).

25. Subsequently, those individuals who were substantively involved in the preparation or prosecution of the '671 application, including at least Dr. Fleischer, knowingly and intentionally made the following misrepresentation of fact, *inter alia*, regarding the applicability of Eli Lilly's U.S. and European patent applications as prior art:

> . . . the compounds of [Eli Lilly's] European '696 represent a subgenus of the compounds disclosed and originally claimed in the above-captioned ['671] application. **However, [Eli Lilly's] European '696 does not represent prior art because its publication date is later than the effective filing date of the above-captioned ['671] application.**
>
> [Eli Lilly's] U.S. Application Serial No. 747,748 contains the same disclosure as [Eli Lilly's] European '696. **It is not available as prior art because its filing date is later than the effective filing date of the above-captioned ['671] application. (The effective filing date of the above-captioned ['671] application is 22 December 1984, the date on which the German application for which Convention priority is claimed was filed).**

Ex. H, Boehringer's Information Disclosure Statement to PTO on December 12, 1988 (the "December 12, 1988 IDS"), p. 3 (admitting that Eli Lilly's European patent application disclosed a subgenus of the compounds claimed in the '671 application, but falsely representing that Eli Lilly's European and U.S. patent applications did not constitute prior art to the '671 application) (emphasis added).

26. These knowing and intentional misrepresentations were material to patentability because Eli Lilly's U.S. and European applications were evidence of prior art to the claims of the '812 patent at least under 35 U.S.C. §§ 102 (a), (f) and/or (g). For example, the Eli Lilly applications demonstrate that the inventions claimed in the '812 patent were: (i) known or used by others in this country; (ii) not invented by Boehringer's co-inventors; and/or (iii) previously made in this country by another who had not abandoned, suppressed or concealed the inventions. Under Federal Circuit law, deceptive and erroneous priority claims are highly material to patentability.

Boehringer's '671 Application

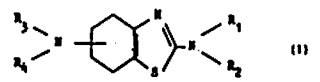
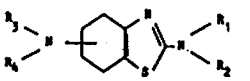
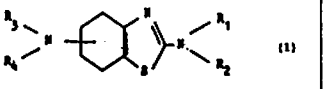
27. On October 12, 1988, the Applicants filed the '671 application, which issued as the '812 patent. The '671 application disclosed a general formula that described tetrahydrobenzothiazoles ("the '671 General Formula I") and claimed tetrahydrobenzothiazoles of that general formula. In the '671 General Formula I, the substituent R1 is defined to include, *inter alia*, "a phenyl alkyl or phenyl alkanoyl group having 1 to 3 carbon atoms in the alkyl part, *whilst the above mentioned phenyl nuclei may be substituted by 1 or 2 halogen atoms.*" Ex. C, Boehringer's '671 application, pp. 1-2 (emphasis added); *see also* Ex. A, '812 patent, claim 1. In other words, the '671 application and the issued '812 patent, disclose and claim compounds with halogen-substituted phenyl groups at the R1 position of a general chemical formula.

Boehringer's Two Previously Filed German Patent Applications

28. During prosecution of the '671 application (which was filed on October 12, 1988), the Applicants falsely claimed priority to two German applications, DE 3447075 and DE 3508947, which were filed by Boehringer on December 12, 1984 and March 13, 1985, respectively (collectively, the "German Applications"). *See* Ex. D, Boehringer's Decl. for '671 Patent Application.

29. The German Applications disclosed a general formula that described tetrahydrobenzothiazoles (hereinafter, "German General Formula I") and claimed tetrahydrobenzothiazoles of that general formula. In German General Formula I, the substituent R1 was defined to only include, *inter alia,* "a phenyl alkyl or phenyl alkanoyl group having 1 to 3 carbon atoms in the alkyl part." *See* Ex. E and F, Certified

English Translations of German Patent Nos. DE 3447075 and DE 3508947. Unlike the '671 application, the German General Formula I did not disclose in its definition of R1 *the substitution of the phenyl nuclei with 1 or 2 halogen atoms*:

German Applications	**'671 Application**	**'812 Patent, Claim 1**
This invention relates to new tetrahydrobenzothiazoles of general formula  (I)	This invention relates to new tetrahydrobenzothiazoles of general formula  (I)	A tetrahydro-benzthiazole of the formula:  (I)
. . . In general formula I above R_1 represents a hydrogen atom, an alkyl group having 1 or 6 carbon atoms, an alkenyl or alkynyl group each having 3 to 6 carbon atoms, an alkanoyl group having 1 to 6 carbon atoms, a phenyl alkyl or phenyl alkanoyl group having 1 to 3 carbon atoms in the alkyl part	. . . In general formula I above R_1 represents a hydrogen atom, an alkyl group having 1 or 6 carbon atoms, an alkenyl or alkynyl group each having 3 to 6 carbon atoms, an alkanoyl group having 1 to 6 carbon atoms, a phenyl alkyl or phenyl alkanoyl group having 1 to 3 carbon atoms in the alkyl part, **whilst the above mentioned phenyl nuclei may be substituted by 1 or 2 halogen atoms**	Wherein R_1 is a hydrogen atom, an alkyl group having 1 or 6 carbon atoms, an alkenyl or alkynyl group each having 3 to 6 carbon atoms, an alkanoyl group having 1 to 6 carbon atoms, a phenyl alkyl or phenyl alkanoyl group having 1 to 3 carbon atoms in the alkyl part, **wherein the above mentioned phenyl nuclei may be substituted by 1 or 2 halogen atoms**. . . .

See Ex. E and F; Ex. C, pp. 1-2 (emphasis added); Ex. A (emphasis added).

30. Therefore, *the substitution of the phenyl nuclei with 1 or 2 halogen atoms* at the R1 position in the '671 General Formula I is new matter that was not part of the scope of the German Applications. Specifically, Dr. Rolf Fleischer – who drafted the first German Application – admitted that the halogen-substituted phenyl compounds "are not part of the scope of the German patent application" during his deposition in

Barr. *See, e.g.*, Ex. G, Fleischer Dep. Tr. in *Barr* litigation, 167:10-168:13, 213:15:15-214:2.

31. Dr. Fleischer further admitted that he was involved in all substantive submissions to the PTO. Ex. G, 151:22-153:9. Yet, as the individual responsible for overseeing the worldwide prosecution of the '812 patent family, including in the United States, Dr. Fleischer allowed submission of a false declaration that Boehringer was entitled to claim priority back to the German Applications, knowing that the new matter actually prohibited a proper claim of priority. Ex. D.

32. In addition, Dr. Fleischer caused or knowingly permitted material misstatements concerning the priority date of the '671 application in Applicants' December 12 IDS to the PTO. Specifically, the December 12, 1988 IDS falsely states that "The effective filing date of the ['671] application is 22 December 1984, the date on which the German application for which Convention priority is claimed was filed." Ex. H, December 12, 1988 IDS, p. 3.

33. At least claim 1 of the '812 patent includes the addition of new matter that was not supported by the German Applications and thus cannot claim a priority date to December 22, 1984, the date the first German Application was filed.

Eli Lilly's Prior U.S. and European Applications

34. On or about June 19, 1985, Eli Lilly filed U.S. Application Serial No. 747,748 ("Eli Lilly's U.S. Application") with the PTO. Eli Lilly's U.S. Application had a foreign equivalent, European Patent Application No. 207,656, which published on or about January 7, 1987 ("Eli Lilly's European Application"). Both Eli Lilly applications

disclosed and claimed tetrahydrobenzothiazoles. A true and accurate copy of each application is attached hereto as Ex. I and J.

35. Eli Lilly's U.S. and European Applications were filed after Boehringer's first German application (which was filed on December 12, 1984), but before the '671 application's filing date of October 12, 1988. Eli Lilly's U.S. Application also predated the filing date of Boehringer's first U.S. application in the '812 patent family (i.e., December 19, 1985).

36. Boehringer has admitted that it became aware of Eli Lilly's European Application at least as early as February 2, 1987, which is more than twenty (20) months before Boehringer filed the '671 application on October 12, 1988. *See* Boehringer's response to Interrogatory No. 11 in *Barr* litigation, attached hereto as Ex. K.

37. Boehringer delayed approximately twenty-two (22) months in disclosing Eli Lilly's European Application (and the existence of Eli Lilly's U.S. Application) to the PTO until submitting the December 12, 1988 IDS. Ex. H, p. 3. The December 12, 1988 IDS provides no explanation for Boehringer's considerable delay in disclosing Eli Lilly's European Application (and the existence of Eli Lilly's U.S. Application).

38. One or more individuals substantively involved with the preparation or prosecution of the '671 application with a duty of disclosure to the PTO, including prosecuting attorneys Dr. Fleischer and Alan R. Stempel, admitted that Eli Lilly's U.S. and European Applications "disclosed a subgenus of the compounds disclosed and originally claimed in the ['671] application." Ex. H, p. 3.

39. Dr. Fleischer further admitted that he was involved in all substantive submissions to the PTO. Ex. G, 151:22-153:9.

40. Dr. Fleischer – who drafted the first German Application – knew that the '671 application included new matter and therefore could not properly claim priority to the German Applications. *See* Ex. G,167:10-168:13, 213:15:15-214:2 (testifying that the claimed halogen-substituted phenyl compounds "are not part of the scope of the German patent application. They are not part of the substance.").

41. Even though Dr. Fleischer knew that the '671 application included new matter and thus could not properly claim priority to the German Applications and that Eli Lilly's U.S. and European Applications contained overlapping subject matter – and claimed an earlier priority date than the first U.S. application in the '812 patent family – Dr. Fleischer, on information and belief, knowingly and intentionally caused or permitted the filing of the December 12, 1988 IDS, which misrepresented the effective filing date of the '671 application. Ex. H, p. 3.

42. Specifically, the IDS misrepresented that Eli Lilly's European Application "does not represent prior art because its publication date is later than the effective filing date of the above-captioned ['671] application" and Eli Lilly's U.S. Application, which has the same disclosure and claims of the European application, "is not available as prior art because its filing date is later than the effective filing date of the above-captioned application. (The effective filing date of the above-captioned application is 22 December 1984, the date on which the German application for which Convention priority is claimed was filed)." Ex. H, p. 3.

43. Upon information and belief, one or more individuals who were substantively involved with the preparation or prosecution of the '671 application with a duty of disclosure to the PTO, including Dr. Fleischer, had knowledge that the representations to the PTO concerning the priority date of the '671 application were false, and those statements were made and maintained with the intent to deceive the PTO for Boehringer's benefit.

44. Upon information and belief, the statements were made because, *inter alia,* one or more individuals who were substantively involved with the preparation or prosecution of the '671 application with a duty of disclosure to the PTO, including Dr. Fleischer, knew that if Applicants did not erroneously claim priority to the German Applications, and instead relied on the filing date of Boehringer's first U.S. application in the '812 patent family (i.e., December 19, 1985), then the Applicants would not have been able to predate Eli Lilly's earlier U.S. Application filed on June 24, 1985.

45. As a result of Applicants' material misrepresentations regarding the priority date of the '671 application, Boehringer improperly avoided an interference that would have established Eli Lilly's earlier invention of the claimed subject matter, which would have prevented Boehringer from obtaining some, if not all, of the claims of the '812 patent at issue. Therefore, the Applicants' inequitable conduct before the PTO renders the '812 patent unenforceable.

COUNT 1

DECLARATORY JUDGMENT OF INVALIDITY OF THE '812 PATENT

46. Sandoz restates Paragraphs 1 to 45 as if set forth fully herein.

47. Unless Defendants are enjoined, Sandoz believes Defendants will continue to assert that Sandoz is infringing valid claims of the '812 patent and will continue to interfere with Sandoz's business with respect to its ANDA for pramipexole dihydrochloride tablets and those products it proposes to manufacture, use, offer for sale and sell.

48. Sandoz will be irreparably harmed if Defendants are not enjoined from continuing to assert the '812 patent and from interfering with Sandoz's business.

49. The '812 patent is invalid under 35 U.S.C. §§ 101 *et seq.*, including §§ 101, 102, 103 and/or 112.

50. An actual and justiciable controversy exists between Sandoz and Defendants as to the invalidity of the '812 patent. Therefore, Sandoz is entitled to a declaratory judgment that the claims of the '812 patent are invalid.

COUNT II

DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '812 PATENT

51. Sandoz restates Paragraphs 1 to 45 as if set forth fully herein.

52. Unless Defendants are enjoined, Sandoz believes Defendants will continue to assert that Sandoz is infringing valid claims of the '812 patent and will continue to interfere with Sandoz's business with respect to its ANDA for pramipexole

dihydrochloride tablets and those products it proposes to manufacture, use, offer for sale and sell.

53. Sandoz will be irreparably harmed if Defendants are not enjoined from continuing to assert the '812 patent and from interfering with Sandoz's business

54. The '812 patent is unenforceable based on Applicants' inequitable conduct.

55. An actual and justiciable controversy exists between Sandoz and Defendants as to the unenforceability of the '812 patent. Therefore, Sandoz is entitled to a declaratory judgment that the '812 patent is unenforceable and that Defendants are enjoined from asserting or otherwise seeking to enforce the '812 patent against Sandoz.

DEMAND FOR JURY TRIAL

Trial by jury is demanded on all issues for which a jury trial is available.

PRAYER FOR RELIEF

WHEREFORE, Sandoz asks the Court to enter judgment in its favor and grant the following relief:

1. Declare the claims of the '812 patent invalid;

2. Declare the '812 patent unenforceable;

3. Permanently enjoin Boehringer, its officers, agents, directors, servants, employees, subsidiaries and assigns, and all those acting under the authority of or in privy with any of them, from asserting or otherwise seeking to enforce the '812 patent against Sandoz;

4. Find this case to be exceptional within the meaning of 35 U.S.C. § 285 and award Sandoz its attorneys' fees, costs and expenses incurred in this action; and

5. Grant such other and further relief as the Court may deem just and proper.

Dated: May 19, 2010

Respectfully submitted,

By: _____

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