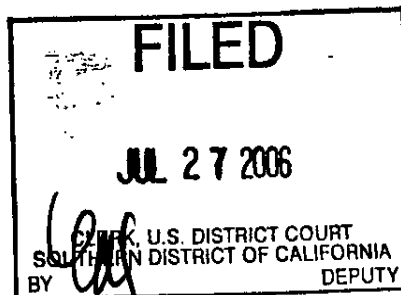


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\*23\*  
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6 David H. Katz, M.D.

7  
8 UNITED STATES DISTRICT COURT  
9 SOUTHERN DISTRICT OF CALIFORNIA

10 DAVID H. KATZ, M.D.,

CASE NO. 06-CV-0496 DMS (LSP)

11 Plaintiff,

FIRST AMENDED COMPLAINT

12 v.

13 AVANIR PHARMACEUTICALS,

DEMAND FOR JURY TRIAL

14 Defendant.

15  
16 For its First Amended Complaint against Avanir Pharmaceuticals ("Avanir"), Plaintiff  
17 David H. Katz, M.D. ("Dr. Katz") alleges, avers and states:

18 THE PARTIES

- 19 1. Plaintiff Dr. Katz is a resident of California.  
20 2. On information and belief, Defendant Avanir is, and at all times referred to in this

21 Complaint was, a corporation organized and existing under the laws of the State of California,  
22 with a principal place of business in San Diego, California.

23 JURISDICTION AND VENUE

24 3. This is an action under 35 U.S.C. § 256 for correction of inventorship, 28 U.S.C. §§  
25 2201 and 2202 for declaratory relief, and 35 U.S.C. § 271 for patent infringement. This Court has  
26 original jurisdiction under 28 U.S.C. § 1338(a) in that Dr. Katz seeks relief as to United States  
27 Patents Nos. 6,271,390, 6,303,645, 6,369,091, 6,759,425, 6,911,462 and 6,919,366, all assigned to  
28 Avanir, and U.S. Patent No. 6,270,746 owned by Dr. Katz.

23



1 an "Invention and Patent Agreement" with MBI ("the MBI Invention Agreement") pursuant to  
2 which the Katz's agreed to comply with MBI's "Bylaws of the Staff of Medical Biology Institute"  
3 ("the MBI Bylaws") and the "Medical Biology Institute Invention and Patent Policy" ("the MBI  
4 Policy"). Section 4 of the MBI Bylaws required "all inventions ... which are conceived or  
5 developed by professional personnel during their period of appointment at MBI shall be assigned  
6 to MBI."

7 11. Pursuant to 35 U.S.C. § 202(c)(7) and the MBI Policy, MBI was required to share  
8 royalties with the inventors of inventions made with Federal agency funding. Further pursuant to  
9 35 U.S.C. § 202(c)(7) and the MBI Policy, MBI was permitted to license (but not to assign) such  
10 inventions to any third party without Federal agency approval.

11 12. All of MBI research's was supported by Federal agency funding, including grants  
12 from the National Institutes of Health ("NIH"). While employed by MBI, Dr. Katz continued to  
13 conduct research in the IgE field he had begun during his tenure at Harvard Medical School. All  
14 of the Katz's inventions in the IgE field, including all of his inventions in the IgE field made while  
15 concurrently employed at Lidak, were subject to their prior obligations to MBI pursuant to their  
16 MBI Employee Invention Assignment Agreements.

17 13. In 1988, Dr. Katz founded Lidak Pharmaceuticals, Inc. ("Lidak"), a for-profit  
18 biotechnology company. Dr. Katz personally provided the "seed financing" for Lidak, and  
19 assumed the roles of CEO and Chairman – with his time allocated equally, in and after 1988,  
20 between MBI and Lidak.

21 14. From 1988 until 1998, both Dr. Katz and Lee R. Katz were concurrent employees  
22 (i.e., "joint employees") of both MBI and Lidak, and their respective duties and obligations to  
23 each entity were well-defined and memorialized in written documents. As did all other Lidak  
24 employees (joint or otherwise), the Katz's signed an "Employee Invention, Assignment, Patent  
25 and Confidential Information Agreement" with Lidak in or about December 1989 ("the Lidak  
26 Employee Invention Assignment Agreement"). The Katz's Lidak Employee Invention  
27 Assignment Agreements did not supercede their MBI Employee Invention Assignment  
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1 Agreement, but were instead non-conflicting with, and junior to, their MBI Employee Invention  
2 Assignment Agreements.

3 15. Lidak partnered with MBI to further advance and develop commercial applications  
4 for certain of the research and development work conducted by MBI. Specifically, in October  
5 1988, MBI and Lidak entered into a License Agreement under which certain other technologies  
6 developed by MBI were licensed to Lidak for potential future development – that License  
7 Agreement did not include any of the Katz’s inventions in the IgE field.

8 16. MBI’s NIH-supported research was largely distinct and separate from the mission  
9 of Lidak, and there was no relationship between the Katz’s NIH-supported IgE research at MBI  
10 and the Katz’s activities on behalf of Lidak for many years after the MBI-Lidak cooperation  
11 began. However, in about 1997, MBI concluded that its research in the IgE field had reached a  
12 stage of potential commercialization. Under the terms of the existing MBI-Lidak License  
13 Agreement, MBI agreed to license a small portion of the Katz’s research and inventions in the IgE  
14 field to Lidak. The licensed inventions related solely to small molecule therapeutic investigations  
15 for treatment of allergy.

16 17. For another ten years, Dr. Katz invested his time, energy and personal finances into  
17 Lidak as Chief Executive Officer, before his departure on March 4, 1998. On or about November  
18 20, 1998, Lidak Pharmaceuticals was renamed Avanir Pharmaceuticals.

19 18. On May 7, 1998, in accordance with the MBI Bylaws and MBI Policy, Dr. Katz’s  
20 caused U.S. patent application No. 09/074,722 (“the ‘722 application”) to be submitted to the  
21 United States Patent & Trademark Office (“USPTO”) on behalf of MBI naming Dr. Katz, Mark L.  
22 Richards, John F. Marcelletti, Lee R. Katz and Jagdish Sircar as co-inventors. The ‘722  
23 application was directed to the work on small molecule technology for regulating the IgE allergic  
24 response conducted by MBI, and funded in large measure by federal grants from NIH. On  
25 September 10, 1999, U.S. patent application Serial No. 09/394,364 (“the ‘364 application”), also  
26 naming Dr. Katz, Dr. Richards, Dr. Marceletti, and Mrs. Katz as the co-inventors, was filed as a  
27 continuation-in-part application of the ‘722 application.

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1           19.    On April 30, 1998, Dr. Katz filed a lawsuit against Lidak and certain of the  
2 company's officers and directors, who cross-complained against Dr. Katz. The case was tried in  
3 1999 and resulted in verdicts for both sides. Dr. Katz was not permitted at that trial to testify  
4 regarding his obligations to MBI or his rights in the IgE technology, including royalty rights,  
5 arising under the MBI Bylaws and MBI Policy. After trial, counsel for Dr. Katz submitted post-  
6 trial motions directed to several issues that were decided in Lidak's favor, including ownership of  
7 the IgE work conducted by MBI. In an effort to avoid further litigation, the parties entered into a  
8 Settlement Agreement on March 23, 2000, resolving all issues between them.

9           20.    In accordance with the terms of the Settlement Agreement, Dr. Katz "assigned" the  
10 '722 and '364 applications to Avanir . As a material condition for this agreement, Avanir agreed  
11 to recognize Dr. Katz as an inventor of the IgE small molecule technology described in the '722  
12 and '364 applications. In connection with the Settlement Agreement, the Katz's relied upon the  
13 representations of Avanir and its counsel that Avanir had obtained the required Federal agency  
14 approvals for the transfers contemplated in the Settlement Agreement, and that Avanir would  
15 comply with the applicable provisions of 35 U.S.C. § 202 by acknowledging Federal government  
16 rights in those inventions honoring the applicable royalty provisions of the MBI Policy. Upon  
17 information and belief, Avanir knew at that time that those representations were false, and made  
18 those misrepresentations to fraudulently induce the Katz's to enter into the Settlement Agreement.  
19 The Katz's justifiably relied on Avanir's misrepresentations in entering into the Settlement  
20 Agreement.

21           21.    Avanir subsequently abandoned the '722 and '364 applications. Instead, Avanir  
22 included the inventions described and claimed in the '722 and '364 applications in a series of  
23 subsequently filed patent applications, including U.S. patent application Serial Nos. 09/316,870,  
24 filed May 21, 1999 ("the '870 application"); 09/422,397, filed October 21, 1999 ("the '397  
25 application"); 09/422,304, filed October 21, 1999 ("the '304 application"); 09/983,054, filed  
26 October 16, 2001 ("the '054 application"); 10/090,044, filed February 27, 2002 ("the '044  
27 application"); and 10/103,258, filed March 20, 2002 ("the '258 application"). In breach of the  
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1 Settlement Agreement, and in violation of applicable provisions of the Patent Law, Avanir omitted  
2 Dr. Katz as a co-inventor of those applications.

3 22. Upon information and belief, Avanir did not intend to recognize Dr. Katz's  
4 contribution as an inventor of the IgE Technology claimed in the '722 and '364 applications at the  
5 time the Settlement Agreement was executed. Upon information and belief, Avanir knew at that  
6 time that Avanir would pursue patent applications directed to the inventions claimed in the '364  
7 and '722 applications, and that Avanir would not recognize Dr. Katz as contributing to those  
8 inventions. Upon information and belief, Avanir misrepresented that it would comply with  
9 Section 1.5 of the Settlement Agreement to fraudulently induce the Katz's to enter into that  
10 agreement. The Katz's justifiably relied on Avanir's misrepresentations with respect to Section  
11 1.5 of the Settlement Agreement in entering into that agreement.

12 23. The '870 application, entitled "Suppression of the IGE-Dependent Allergic  
13 Response by Benzimidazole Analogs" issued as U.S. Patent No. 6,271,390 ("the '390 patent") to  
14 Avanir on August 7, 2001. The '390 patent (attached as Exhibit A) describes and claims various  
15 compounds for use in treating or preventing an allergic reaction caused by an increase in plasma  
16 IgE levels, including compounds described and claimed for such use in the '722 and '364  
17 applications that were co-invented by Dr. Katz.

18 24. The '397 application, entitled "Benzimidazole Derivatives As Modulators of IGE"  
19 issued as U.S. Patent No. 6,303,645 ("the '645 patent") to Avanir on October 16, 2001. The '645  
20 patent (attached as Exhibit B) describes and claims pharmaceutical compositions for treating or  
21 preventing an allergic reaction associated with increased IgE levels, including compositions  
22 described and claimed for such use in the '722 and '364 applications that were co-invented by Dr.  
23 Katz.

24 25. The '304 application, entitled "Benzimidazole Analogs as Down-Regulators of  
25 IgE" issued as U.S. Patent No. 6,369,091 ("the '091 patent") to Avanir on April 9, 2002. The  
26 '091 patent (attached as Exhibit C) describes and claims pharmaceutical compositions for treating  
27 or preventing an allergic reaction associated with increased IgE levels, including compositions  
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1 described and claimed for such use in the '722 and '364 applications that were co-invented by Dr.  
2 Katz.

3 26. The '054 application, entitled "Benzimidazole Derivatives As Modulators of IGE"  
4 issued as U.S. Patent No. 6,919,366 ("the '366 patent") to Avanir on July 19, 2005. The '366  
5 patent (attached as Exhibit D) describes and claims pharmaceutical compositions for treating an  
6 allergic reaction associated with increased IgE levels, including compositions described and  
7 claimed for such use in the '722 and '364 applications that were co-invented by Dr. Katz.

8 27. The '044 application, entitled "Benzimidazole Compounds For Modulating IgE  
9 And Inhibiting Cellular Proliferation" issued as U.S. Patent No. 6,759,425 ("the '425 patent") to  
10 Avanir on July 4, 2004. The '425 patent (attached as Exhibit E) describes and claims  
11 pharmaceutical compositions for treating an allergic reaction associated with increased IgE levels,  
12 including compositions described and claimed for such use in the '722 and '364 applications that  
13 were co-invented by Dr. Katz.

14 28. The '258 application, entitled "Benzimidazole Compounds For Regulating IGE"  
15 issued as U.S. Patent No. 6,911,462 ("the '462 patent") to Avanir on June 28, 2005. The '462  
16 patent (attached as Exhibit F) describes and claims pharmaceutical compositions for treating an  
17 allergic reaction associated with increased IgE levels, including compositions described and  
18 claimed for such use in the '722 and '364 applications that were co-invented by Dr. Katz.

19 29. Avanir's failure to name Dr. Katz as an inventor on the '390, '645, '091, '366 '425  
20 and '462 patents constitutes a material breach of the Settlement Agreement. Because Dr. Katz  
21 was fraudulently induced by Avanir to enter into the Settlement Agreement by Avanir's  
22 misrepresentations, and Dr. Katz justifiably relied on Avanir's misrepresentations in entering into  
23 the Settlement Agreement, Dr. Katz is entitled to rescission of the Settlement Agreement.

24 30. U.S. patent application Serial No. 09/251,175, entitled "Assay For The  
25 Identification Of IgE Antibody Suppressors," was filed on February 17, 1999, naming Dr. Katz as  
26 the sole inventor. This application was duly and legally issued as U.S. Patent No. 3,270,746 ("the  
27 '746 Patent") on August 7, 2001. A copy of the '746 patent is attached as Exhibit G. The claims  
28 of the '746 patent are directed to a screening method for identifying agents having IgE suppressor



1 activity in living experimental animals.. The methods described and claimed in the '746 patent  
2 provide an early and "immediate" tool for evaluating the potential clinical toxicity of an active  
3 IgE suppressor compound, since the health and continued viability of the test animal may be  
4 readily ascertained. The method claimed in the '746 patent constitutes an advance over previously  
5 known tests for anti-allergic activity, such as those which rely on acute examination of lung  
6 responses, as such previously known tests require that the animal be immediately euthanised  
7 before potential whole animal toxicity could be observed.

8 31. The assay methods described in the '746 Patent do not fall within the scope of ("the  
9 IgE Technology") defined in the Settlement Agreement, which is expressly defined as "the small  
10 molecule composition technology" claimed in the '722 and '364 applications. Moreover, because  
11 the inventions claimed in the '746 Patent were made in the course of Federally sponsored research  
12 conducted at MBI, those inventions were subject to Dr. Katz's obligations under the MBI  
13 Invention Agreement, and accordingly Lidak obtained no interest in the '746 Patent by operation  
14 of the Lidak Employee Invention Assignment Agreement.

15 32. Upon information and belief, Avanir claims in the alternative that if it did not  
16 obtain title to the '746 Patent pursuant to the Settlement Agreement, then it obtained title to the  
17 '746 Patent by virtue of a Settlement Agreement and Mutual General Release ("MBI-Lidak  
18 Settlement Agreement") entered into in September 1998, between Lidak and MBI, under which  
19 "the Institute will deliver an Assignment to Lidak of all right, title and interest in any IgE  
20 technology for which it possesses any property rights of any nature whatsoever." Upon  
21 information and belief, neither Avanir nor MBI ever obtained the required Federal agency  
22 approvals for the technology transfers contemplated, and agreed upon, in the MBI-Lidak  
23 Settlement Agreement, and thus that agreement is both illegal and void.

24 33. Upon information and belief, Avanir has screened for identifying agents having IgE  
25 suppressor activity in vivo in animals in its research and development work.

26 34. Upon information and belief, Avanir has practiced the screening method for  
27 identifying agents having IgE suppressor activity claimed in the '746 Patent.  
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**FIRST CLAIM FOR RELIEF**

(For Correction of Inventorship)

35. Dr. Katz realleges and incorporates by reference the allegations set forth in paragraphs 1 through 34 above as though set forth in full.

36. Avanir's '390, '645, '091, 366 '425 and '462 patents describe and claim inventions co-invented by Dr. Katz.

37. Avanir's '390, '645, '091, 366 '425 and '462 patents do not name Dr. Katz as an inventor.

38. Pursuant to 35 U.S.C. §111, Avanir was obligated to name Dr. Katz as an inventor of the applications maturing as the '390, '645, '091, 366 '425 and '462 patents.

39. Dr. Katz is entitled to correct inventorship of the '390, '645, '091, 366 '425 and '462 patents under 35 U.S.C. § 256.

40. Correction of Avanir's '390, '645, '091, 366 '425 and '462 patents to include Dr. Katz as an inventor is necessary to reflect the true inventorship of the inventions described and claimed in those applications.

**SECOND CLAIM FOR RELIEF**

(For Assignment of Intellectual Property to Dr. Katz)

41. Dr. Katz realleges and incorporates by reference the allegations set forth in paragraphs 1 through 40 above as though set forth in full.

42. In accordance with the terms of the Settlement Agreement, Avanir was obligated to recognize Dr. Katz as the inventor of the inventions described and claimed in the '722 and '364 applications. The Patent Law imposed an obligation on Avanir to recognize Dr. Katz as the inventor of the inventions described and claimed in the '722 and '364 applications, regardless whether those applications were prosecuted to issuance or those inventions were described and claimed in any other application pursued by Avanir.

43. Avanir breached the Settlement Agreement by failing to name Dr. Katz as an inventor on the '390, '645, '091, 366 '425 and '462 patents.

1           44. Dr. Katz's assignment of the inventions described and claimed in the '722 and '364  
2 applications was premised upon Avanir's agreement to perform its contractual duties under the  
3 Settlement Agreement.

4           45. Dr. Katz is entitled to a declaration that Avanir has breached the Settlement  
5 Agreement by failing to recognize Dr. Katz as an inventor of the inventions described and claimed  
6 in the '390, '645, '091, 366 '425 and '462 patents.

7           46. Dr. Katz, as the successor-in-interest to MBI, is entitled to recover title to the  
8 inventions described and claimed in the '722 and '364 applications previously filed on behalf of  
9 MBI, as manifested in the '390, '645, '091, 366 '425 and '462 patents.

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**THIRD CLAIM FOR RELIEF**

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(For Infringement of the '746 Patent)

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47. Dr. Katz realleges and incorporates by reference the allegations set forth in paragraphs 1 through 46 above as though set forth in full.

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48. Dr. Katz is the owner of the '746 Patent.

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49. Upon information and belief, Avanir has practiced the inventions claimed in the '746 Patent.

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50. Avanir has infringed the '746 Patent.

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51. Avanir's infringement of the '746 Patent was willful.

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52. Dr. Katz is entitled to damages based on Avanir's infringement of the '746 Patent.

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53. Dr. Katz is entitled to treble damages based on Avanir's willful infringement of the '746 Patent.

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54. Dr. Katz is entitled to reasonable attorney's fees based on Avanir's willful infringement of the '746 Patent.

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**FOURTH CLAIM FOR RELIEF**

(For Rescission Based on Fraudulent Inducement)

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3 55. Dr. Katz realleges and incorporates by reference the allegations set forth in  
4 paragraphs 1 through 54 above as though set forth in full.

5 56. Upon information and belief, Avanir induced Dr. Katz to enter into the Settlement  
6 Agreement by knowingly misrepresenting to Dr. Katz that Avanir had obtained the required  
7 Federal agency approvals for the transfers contemplated in the Settlement Agreement, and that  
8 Avanir would comply with the applicable provisions of 35 U.S.C. § 202, including acknowledging  
9 Federal government rights in the inventions claimed in the '722 and '364 applications and  
10 honoring the applicable royalty provisions of the MBI Policy.

11 57. Upon information and belief, Avanir knew at that time that those representations  
12 were false, and made those misrepresentations to fraudulently induce Dr. Katz and Lee R. Katz to  
13 enter into the Settlement Agreement. The Katz's justifiably relied on Avanir's misrepresentations  
14 in entering into the Settlement Agreement.

15 58. Upon information and belief, Avanir did not then, and has never, obtained  
16 appropriate Federal agency approvals to support the transfers of the '722 and '364 applications set  
17 forth in the Settlement Agreement, and Avanir has neither acknowledged Federal agency rights in  
18 those inventions nor honored the applicable royalty provisions of the MBI Policy.

19 59. Further upon information and belief, Avanir did not intend to recognize Dr. Katz's  
20 contribution as an inventor of the IgE Technology claimed in the '722 and '364 applications at the  
21 time the Settlement Agreement was executed. Upon information and belief, Avanir knew at that  
22 time that Avanir would pursue patent applications directed to the inventions claimed in those  
23 applications, and that Avanir would not recognize Dr. Katz as contributing to those inventions.

24 60. Consistent with that prior knowledge, Avanir failed to name Dr. Katz as an  
25 inventor on the '390, '645, '091, 366 '425 and '462 patents.

26 61. Upon information and belief, Avanir misrepresented that it would comply with  
27 Section 1.5 of the Settlement Agreement to fraudulently induce the Katz's to enter into that  
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1 agreement, and the Katz's justifiably relied on those misrepresentations in entering into that  
2 agreement.

3 62. Because the Katz's were fraudulently induced by Avanir to enter into the  
4 Settlement Agreement by Avanir's misrepresentations, and justifiably relied on Avanir's  
5 misrepresentations in entering into the Settlement Agreement, Dr. Katz is entitled to rescission of  
6 the Settlement Agreement.

7 63. Dr. Katz is entitled to recover title to the inventions described and claimed in the  
8 '722 and '364 applications previously filed on behalf of MBI, as manifested in the '390, '645,  
9 '091, 366 '425 and '462 patents.

10  
11 **PRAYER FOR RELIEF**

12 WHEREFORE, Dr. Katz respectfully asks this Court to enter a judgment in its favor:

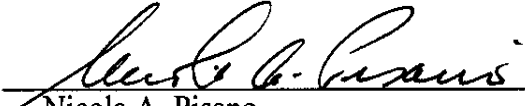
- 13 A. Correcting the inventorship of the '390, '645, '091, 366 '425 and '462 patents;  
14 B. Adjudging that Avanir breached the Settlement Agreement;  
15 C. Adjudging that title to Dr. Katz's inventions described and claimed in the '722 and  
16 '364 applications, as manifested in the '390, '645, '091, 366 '425 and '462 patents, be reassigned  
17 to Dr. Katz;  
18 D. Adjudging that Avanir has infringed the '746 patent and that such infringement was  
19 willful;  
20 E. Adjudging that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding to  
21 Dr. Katz his attorneys' fees;  
22 F. Granting an award to Dr. Katz for its costs of suit;  
23 G. Adjudging that Dr. Katz is entitled to an award of damages according to its proofs;  
24 and  
25 H. Granting such other and further relief as this Court may deem just and proper.  
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DATED: July 25, 2006

Respectfully submitted,

LUCE, FORWARD, HAMILTON & SCRIPPS LLP

By:   
Nicola A. Pisano  
Attorneys for David H. Katz, M.D.

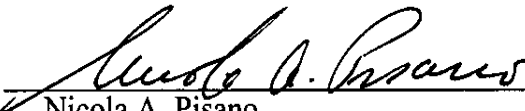
**JURY DEMAND**

Plaintiff demands trial by jury of all issues so triable.

DATED: July 25 2006

Respectfully submitted,

LUCE, FORWARD, HAMILTON & SCRIPPS LLP

By:   
Nicola A. Pisano  
Attorneys for David H. Katz, M.D.

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