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10 Attorneys for Plaintiff  
11 ALZHEIMER'S INSTITUTE OF AMERICA, INC.

12 **UNITED STATES DISTRICT COURT**  
13 **NORTHERN DISTRICT OF CALIFORNIA**

14  
15 ALZHEIMER'S INSTITUTE OF  
16 AMERICA, INC.

17 Plaintiff,

18 v.

19 ELAN CORPORATION, PLC,  
20 ELI LILLY AND COMPANY,  
ANASPEC INCORPORATED,  
21 IMMUNO-BIOLOGICAL  
LABORATORIES, INCORPORATED,  
22 LIFE TECHNOLOGIES CORPORATION  
d/b/a INVITROGEN CORPORATION,  
23 THE JACKSON LABORATORY, and  
PHOENIX PHARMACEUTICALS,  
INCORPORATED,

24 Defendants.

12  
13  
14  
15 **CV 10 482**

16 **DEMAND FOR JURY TRIAL**

17 **COMPLAINT FOR DAMAGES AND**  
18 **INFRINGEMENT**

19 **PLAINTIFF'S COMPLAINT**

20 COMES NOW Plaintiff Alzheimer's Institute of America, Inc. ("AIA"), by and  
21 through its attorneys, and for its Complaint against Elan Corporation, PLC ("Elan"), the  
22  
23  
24  
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FILED  
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RICHARD W. HARRIS  
CLERK OF DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
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1 Eli Lilly and Company (“Lilly”), AnaSpec, Incorporated (“AnaSpec”), Immuno-Biological  
2 Laboratories, Incorporated (“IBL”), Life Technologies Corporation d/b/a Invitrogen  
3 Corporation (“Invitrogen”), The Jackson Laboratory (“Jackson Lab”), and Phoenix  
4 Pharmaceuticals, Incorporated (“Phoenix”) (collectively, “Defendants”), states as follows:

5 **Nature of the Action**

6 1. This Complaint seeks a judgment finding that Defendants have infringed and  
7 continue to infringe upon AIA’s U.S. Patent Nos. 5,455,169 (the “169 Patent”), 5,795,963  
8 (the “963 Patent”), 6,818,448 (the “448 Patent”), and 7,538,258 (the “258 Patent”)  
9 (collectively, the “Patents-in-Suit”). The Patents-in-Suit cover a wide range of  
10 Alzheimer’s Disease-related technology, including, but not limited to: nucleic acids coding  
11 for the Swedish mutation; vectors, cell lines, and transgenic mice expressing the Swedish  
12 mutation containing nucleic acids; and polypeptides encoded by the Swedish mutation  
13 containing nucleic acids. The claimed technology providing important insights and tools  
14 for Alzheimer’s Disease research, including the ability to screen for potential Alzheimer’s  
15 Disease drug candidates, such as, for example, beta-secretase inhibitors. True and accurate  
16 copies of the Patents-in-Suit are attached hereto, respectively, as **Exhibits A, B, C, and D.**

17 **Jurisdiction and Venue**

18 2. This Court has subject matter jurisdiction over this Complaint pursuant to 28  
19 U.S.C. §§ 1331 and 1338(a), and under the patent laws of the United States, 35 U.S.C. § 1,  
20 *et seq.*

21 3. Venue is proper in this judicial district under the provisions of 28 U.S.C.  
22 §§ 1391(b) and 1400(b).

23 **Intradistrict Assignment**

24 4. This action is excepted from intradistrict assignment because it is an  
25 intellectual property matter. Civil L.R. 3-5(b) and 3-2(c).

**The Parties**

1  
2 5. AIA is a corporation organized and existing under the laws of Florida and  
3 having its principal place of business at 7837 Parallel Parkway, Kansas City, KS, 66112.  
4 AIA is the owner of the Patents-in-Suit.

5 6. Elan is a corporation organized and existing under the laws of Ireland and  
6 having its corporate headquarters at Treasury Building, Lower Grand Canal Street, Dublin  
7 2, Ireland. Elan maintains a research facility in this district at 800 Gateway Boulevard,  
8 South San Francisco, California 94080, and, upon information and belief, has committed  
9 acts of patent infringement in this district.

10 7. Lilly is an Indiana corporation having its principal place of business at Lilly  
11 Corporate Center, Indianapolis, Indiana 46285. Upon information and belief, Lilly has, in  
12 the course of its collaborations, committed acts of patent infringement in this district.

13 8. AnaSpec is a corporation organized and existing under the laws of California  
14 and having its principal place of business at AnaSpec New Corporate Headquarters, 34801  
15 Campus Drive, Fremont, California 94555. Upon information and belief, AnaSpec has  
16 committed acts of patent infringement in this district.

17 9. IBL is a Minnesota corporation having its principal place of business at 8201  
18 Central Avenue Northeast, Suite P, Minneapolis, Minnesota 55432. Upon information and  
19 belief, IBL has, in the course of its sales, committed acts of patent infringement in this  
20 district.

21 10. Invitrogen is a corporation organized and existing under the laws of  
22 California and having its principal place of business at 5791 Van Allen Way, P.O. Box  
23 6483, Carlsbad, California 92008. Upon information and belief, Invitrogen has, in the  
24 course of its sales, committed acts of patent infringement in this district.

25 11. The Jackson Lab is a non-profit corporation organized and existing under the  
26 laws of Maine and having its principal place of business at 600 Main Street, Bar Harbor,  
27 Maine 04609. The Jackson Lab maintains a research facility in this district at 4910 Raley  
28

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1 Boulevard, Sacramento, California 95838, and, upon information and belief, has  
2 committed acts of patent infringement in this district.

3 12. Phoenix is a corporation organized and existing under the laws of California  
4 and having its principal place of business at 330 Beach Road, Burlingame, California  
5 94010. Upon information and belief, Phoenix has committed acts of patent infringement  
6 in this district.

### 7 Facts

8 13. Elan describes itself as a “leader in Alzheimer’s disease research.” Elan’s  
9 research is focused on stopping the “production and accumulation of a toxic protein, beta  
10 amyloid, in the brains of Alzheimer’s disease patients.” In the course of Elan’s research  
11 and drug discovery efforts, Elan has used, among other things, enzyme inhibition assays,  
12 cell line assays, and animal models including the Swedish mutation. Elan has used AIA’s  
13 patented technology to identify and validate potential drug candidates for the treatment of  
14 Alzheimer’s disease.

15 14. Several recently-issued Elan patents describe Elan’s use of enzyme  
16 inhibition assays, cell line assays, and animal models including the Swedish Mutation for  
17 Elan’s drug discovery efforts. As just one example of many, U.S. Patent No. 7,553,831  
18 describes certain cell lines expressing amyloid precursor protein (“APP”) with the Swedish  
19 mutation as the “preferred cells for analysis of beta-secretase activity.” Elan’s ’831 Patent  
20 also describes the use of: (i) Swedish mutation variants of APP for “assays that  
21 demonstrate inhibition of beta-secretase mediated cleavage of APP; (ii) synthetic peptides  
22 of residues 590-596 of the Swedish mutation to raise antibodies useful in immunoassays of  
23 APP and its cleavage products; (iii) a model APP substrate, MBP-C125SW, to analyze  
24 compounds for inhibitory activity of beta-secretase; (iv) human embryonic kidney cell line  
25 HEKp293 “transfected with APP751 containing the naturally occurring double mutation  
26 Lys651Met652 to Asn651Leu652 (numbered for APP751), commonly called the Swedish  
27 mutation”; (v) mouse animal models that “express mutations in APP, such as APP695-  
28 SW.”



1           15. As described in Elan's U.S. Patent No. 7,514,408, Elan is screening libraries  
2 of compounds in these enzyme inhibition assays for their ability "to bind to, or preferably,  
3 to inhibit beta-secretase activity." Such compounds are "then further analyzed for potency  
4 in such assays." Further use of the Swedish mutation technology includes the use of host  
5 cells co-transfected with the Swedish mutation form of APP "for screening for therapeutic  
6 agents that are able to traverse cell membranes." Inhibitor compounds "can then be tested  
7 for prophylactic and therapeutic efficacy in transgenic animals predisposed to an  
8 amyloidogenic disease, such as . . . mice bearing a Swedish mutation of APP." Upon  
9 information and belief, Elan has used AIA's patented technology at each stage of its drug  
10 identification and development efforts and that the identification of promising Alzheimer's  
11 disease drug candidates may not have been possible without the use of the inventions  
12 claimed in AIA's Patents.

13           16. Like Elan, Lilly is active in Alzheimer's disease research, including research  
14 focused on the beta-amyloid cascade hypothesis. Several recently-issued Lilly patents  
15 describe Lilly's use of cell line assays including the Swedish Mutation for Lilly's drug  
16 discovery efforts. As just one example of many, U.S. Patent No. 7,585,885 describes  
17 certain cell lines expressing APP-SW for use in a routine whole cell assay. Lilly appears  
18 to have used this technique repeatedly to identify potential therapeutic candidate  
19 compounds, described in, for example, U.S. Patent Nos. 7,468,365; 7,390,801; 7,153,847;  
20 6,958,330; 6,906,056; 6,861,558; 6,849,650; 6,838,455; 6,774,125; 6,767,918; 6,696,438;  
21 and 6,667,305. Upon information and belief, Lilly has used AIA's patented technology at  
22 each stage of its drug identification and development efforts and that the identification of  
23 promising Alzheimer's disease drug candidates may not have been possible without the  
24 use of the inventions claimed in AIA's Patents.

25           17. Upon information and belief, Elan and Lilly have collaborated on certain  
26 Alzheimer's disease research involving use of the Swedish mutation. For example, U.S.  
27 Published Patent Application No. 2006/0223761, which is assigned to both Elan and Lilly,  
28 describes the identification of numerous compounds that were assayed for their ability to

1 inhibit beta-amyloid production in a cell line possessing the Swedish mutation. Similarly,  
2 U.S. Patent No. 7,608,749, which is also assigned to both Elan and Lilly, describes the use  
3 of transgenic mice containing the Swedish mutation. Although both Elan and Lilly are  
4 aware of the Patents-in-Suit, they have not obtained a license to practice the inventions  
5 claimed therein.

6 18. AnaSpec produces and sells enzyme detection reagents and amyloid peptides  
7 containing the Swedish Mutation, including products of catalog numbers 24150, 24197-  
8 025, 60267, 60270, 60604-01, 62060, 62515, 62236, 71144, and 72139. For example, the  
9 product description of AnaSpec's  $\beta$ -Secretase Substrate 5 states, "substrate contains the  
10 sequence (668-674) surrounding the cleavage site of  $\beta$ -Secretase (between leu-asp) found  
11 in Swedish double mutation (K670N/M671L) of the amyloid precursor protein  
12 ( $\beta$ APP770)," and the product description for one Amyloid Precursor Protein describes it as  
13 a "Swedish mutation fragment...."

14 19. Like AnaSpec, IBL sells products which contain the Swedish Mutation,  
15 including catalog number 27723. For example, IBL's Human sAPP  $\beta$ -Swedish Type  
16 Assay Kit supplies Recombinant Human sAPP  $\beta$ -Swedish Type Protein as a standard for  
17 quantitative measurement of the presence of human sAPP  $\beta$ -Swedish Type in cell culture  
18 media.

19 20. Invitrogen sells products which contain the Swedish Mutation, including  
20 products of catalog numbers P2947, P2985, and PV4748. For example, Invitrogen's  
21 BACE1 FRET Assay Kit includes "red FRET peptide substrate based on the "Swedish"  
22 mutant".

23 21. The Jackson Lab uses and sells transgenic mice as a research tool, including  
24 use in Alzheimer's disease research. As just one example of many, Strain B6.129-  
25 Tg(APP<sup>Sw</sup>)40B<sup>tla</sup>/J is described as expressing "all mRNA and protein isoforms of the  
26 human amyloid beta (A<sub>4</sub>) precursor protein *APP* containing the Familial Alzheimer  
27 Disease (FAD) Swedish mutation K670N/M671L." The Jackson Lab appears to possess  
28 and distribute transgenic mouse lines including, for example, Stock Nos. 003375; 004462;

1 004807; 005300; 005864; 005866; 006004; 006005; 006293; 006406; 006409; 006472;  
2 006554; 006555; 007002; 007027; 007049; 007051; 007052; 008609; 008730 and 009126.

3 22. Phoenix sells products which contain the Swedish Mutation, including for  
4 example, substrates with sequences derived from the Swedish Mutation listed as catalog  
5 numbers 018-21 and B-018-21.

6 **COUNT I**

7 **Patent Infringement of U.S. Patent No. 5,455,169**

8 23. AIA incorporates by reference each and every allegation set forth in  
9 paragraphs 1 through 31 of its Complaint as if fully set forth and restated herein.

10 24. The '169 Patent entitled "Nucleic acids for diagnosing and modeling  
11 Alzheimer's disease" was duly and regularly issued on October 3, 1995. AIA is the sole  
12 and exclusive owner of the '169 Patent. At all relevant times, the owner of the '169 Patent  
13 has complied with 35 U.S.C. § 287(a).

14 25. Elan and Lilly, without the authority or consent of AIA, have been and  
15 continue to, upon information and belief, use in the United States, including, but not  
16 limited to, in this judicial district, technologies which infringe upon the '169 Patent. Upon  
17 information and belief, Defendants' infringement of the '169 Patent is knowing and  
18 willful.

19 26. Elan's and Lilly's infringement of the '169 Patent has caused and continues  
20 to cause irreparable harm and other harm to AIA.

21 **COUNT II**

22 **Patent Infringement of U.S. Patent No. 5,795,963**

23 27. AIA incorporates by reference each and every allegation set forth in  
24 paragraphs 1 through 35 of its Complaint as if fully set forth and restated herein.

25 28. The '963 Patent entitled "Amyloid precursor protein in alzheimer's disease"  
26 was duly and regularly issued on August 18, 1998. The inventor of the '963 Patent  
27 assigned all right, title and interest in, to and under the '963 Patent to AIA. AIA is the sole  
28

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1 and exclusive owner of the '963 Patent. At all relevant times, the owner of the '963 Patent  
2 has complied with 35 U.S.C. § 287(a).

3 29. Elan, Lilly, AnaSpec, IBL, Invitrogen and Phoenix, without the authority or  
4 consent of AIA, have been and continue to, upon information and belief, use technologies  
5 in the United States, including, but not limited to, in this judicial district, technologies  
6 which infringe upon the '963 Patent. In addition, AnaSpec, IBL, Invitrogen, and Phoenix  
7 have infringed the '963 Patent, and induced or contributed to the infringement of others, by  
8 selling and offering to sell the products described above. Upon information and belief,  
9 Defendants' infringement of the '963 Patent is knowing and willful.

10 30. Elan's, Lilly's, AnaSpec's, IBL's, Invitrogen's infringement of the '963  
11 Patent has caused and continues to cause irreparable harm and other harm to AIA.

### 12 COUNT III

#### 13 Patent Infringement of U.S. Patent No. 6,818,448

14 31. AIA incorporates by reference each and every allegation set forth in  
15 paragraphs 1 through 39 of its Complaint as if fully set forth and restated herein.

16 32. The '448 Patent entitled "Isolated cell comprising HAPP 670/671 DNAS  
17 sequences" was duly and regularly issued on November 16, 2004. The inventor of the  
18 '448 Patent assigned all right, title and interest in, to and under the '448 Patent to AIA.  
19 AIA is the sole and exclusive owner of the '448 Patent. At all relevant times, the owner of  
20 the '448 Patent has complied with 35 U.S.C. § 287(a).

21 33. Elan and Lilly, without the authority or consent of AIA, have been and  
22 continue to, upon information and belief, use technologies in the United States, including,  
23 but not limited to, in this judicial district, technologies which infringe upon the '448  
24 Patent. Upon information and belief, Defendants' infringement of the '448 Patent is  
25 knowing and willful.

26 34. Elan's and Lilly's infringement of the '448 Patent has caused and continues  
27 to cause irreparable harm and other harm to AIA.



**COUNT IV**

**Patent Infringement of U.S. Patent No. 7,538,258**

35. AIA incorporates by reference each and every allegation set forth in paragraphs 1 through 43 of its Complaint as if fully set forth and restated herein.

36. The '258 Patent entitled "Transgenic mouse expressing an APP 670/671 mutation" was duly and regularly issued on May 26, 2009. AIA is the sole and exclusive owner of the '258 Patent. At all relevant times, the owner of the '258 Patent has complied with 35 U.S.C. § 287(a).

37. Elan, Lilly, and the Jackson Lab, without the authority or consent of AIA, have been and continue to, upon information and belief, use in the United States, including, but not limited to, in this judicial district, technologies which infringe upon the '258 Patent. In addition, the Jackson Lab has infringed the '963 Patent, and induced or contributed to the infringement of others, by selling and offering to sell the products described above. Upon information and belief, Defendants' infringement of the '258 Patent is knowing and willful.

38. Elan's, Lilly's, and the Jackson Lab's infringement of the '258 Patent has caused and continues to cause irreparable harm and other harm to AIA.

**PRAYER**

WHEREFORE, Plaintiff Alzheimer's Institute of America respectfully prays that the Court enter judgment in its favor and award the following relief against Defendants:

- A. Find that Defendants infringed upon the Patents-in-Suit and will continue to infringe said patents unless enjoined therefrom;
- B. Find that the infringement of Defendants upon the Patents-in-Suit was knowing and willful;
- C. Enjoin Defendants and their respective officers, directors, employees, agents, licensees, representatives, affiliates, related companies, servants, successors and assigns, and any and all persons acting in privity or in concert with any of them, preliminarily and permanently, from further infringing upon the Patents-in-Suit;

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1 D. Order that an accounting be made to establish damages arising out of  
2 Defendants' infringement of the Patents-in-Suit;

3 E. Award AIA actual damages pursuant to 35 U.S.C. § 284, in an  
4 amount to be determined at trial, as a result of Defendants' infringement upon the Patents-  
5 in-Suit;

6 F. Award AIA treble damages pursuant to 35 U.S.C. § 284 in an amount  
7 to be determined at trial, as a result of Defendants' knowing and willful infringement upon  
8 the Patents-in-Suit;

9 G. Award AIA its costs and reasonable attorneys' fees incurred in  
10 connection with this action; and


11 H. Award and grant AIA such other and further relief as the Court deems  
12 just and proper under the circumstances.

13 **DEMAND FOR JURY TRIAL**

14 Plaintiff demands a jury trial.

15 Dated: February 2, 2010

**BRYAN CAVE LLP**

17 By:   
18 **ROBERT PADWAY**  
19 Attorneys for Plaintiff  
20 **ALZHEIMER'S INSTITUTE OF AMERICA,**  
21 **INC.**

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