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LOS ANGELES

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CLASSEN IMMUNOTHERAPIES, INC.

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8  
9 **UNITED STATES DISTRICT COURT**  
10 **CENTRAL DISTRICT OF CALIFORNIA**  
11 **WESTERN DIVISION**

12 **CLASSEN IMMUNOTHERAPIES,**  
13 **INC.**  
14 **Plaintiff,**  
15 **vs.**  
16 **SOMAXON PHARMACEUTICALS,**  
17 **INC.**  
18 **Defendants.**  
19

Case No.: 12-cv-06643-GAF(PLAx)  
**FIRST AMENDED COMPLAINT**  
**FOR PATENT INFRINGEMENT**  
**JURY TRIAL DEMANDED**

20  
21 Plaintiff, Classen Immunotherapies, Inc. ("Classen"), brings this Complaint  
22 for patent infringement against Defendant Somaxon Pharmaceuticals  
23 ("Defendant") as outlined below.

24 **JURISDICTION AND VENUE**

25 1. This is an action for patent infringement under Title 35 of the United  
26 States Code §§281 and 271 (a) (b) (c) and/or (f) for infringement "during the term  
27 of the patent" both pre and post issuance including ongoing infringement and

1 including “during the period beginning on the date of publication of the application  
2 for such patent” as set forth under Title 35 of the United States Code §154(d) for  
3 the period beginning on June 27, 2002 for US Patent 7,984,069 and August 31,  
4 2006 for US Patent 7,653,639.

5 2. This Court has jurisdiction over patent claims under 35 U.S.C. §281  
6 and 28 U.S.C. §§1331, 1338(a) providing for federal question jurisdiction of  
7 actions relating to patents and trademarks.

8 3. Defendant is currently engaged in making, using, offering for sale and  
9 selling, inducing to use and contributing to the infringing practicing of methods,  
10 products, kits and systems covered under the claims of the patents in suit and is  
11 currently engaged in the distribution of products and practicing of methods which  
12 infringes the patents in suit on an ongoing basis and is liable for these activities  
13 post patent issuance under 35 U.S.C. §271 (a) (b) (c) and/or (f). During the period  
14 after the publication of each of the two patents in suit, but prior to the issuance of  
15 each of the patents, Defendant engaged in making, using, offering for sale and  
16 selling, inducing to use and contributing to the infringing practicing of methods,  
17 products, kits and systems covered under the claims of the patents in suit and  
18 engaged in the distribution of products and practicing of methods which infringed  
19 the patents in suit and is liable for these activities pre- issuance under 35 U.S.C.  
20 §154 (d). Venue is proper in this District pursuant to 28 U.S.C. §1391(b) (c) and  
21 (d) and §1400(a) and (b). Defendant Somaxon Pharmaceuticals, Inc. sells products  
22 in this District.

23 **THE PARTIES AND GENERAL ALLEGATIONS**

24 4. Plaintiff, Classen Immunotherapies, Inc. is a corporation existing in  
25 the State of Maryland and is the owner of United States Letters Patent Numbers  
26 7,653,639 which published on August 31, 2006 and issued on January 26, 2010  
27

1 and 7,984,069 which published on June 27, 2002 and issued on July 19, 2011 (the  
 2 “patents in suit”).

3 5. Defendant Somaxon Pharmaceuticals, Inc. is a corporation existing  
 4 under the laws of the state of Delaware, with its headquarters in San Diego,  
 5 California.

6 6. Defendant Somaxon manufactures and distributes a pharmaceutical  
 7 product known as Silenor® which it markets and sells nationwide, beginning in  
 8 2010. Between July 2006, and April 2007, Defendant conducted drug interaction  
 9 studies on its product Silenor® and identified adverse event information which  
 10 Somaxon commercialized and associated with its product Silenor®.

11 7. Somaxon determined that the efficacy of Silenor® can be affected by  
 12 the timing of consumption of food, including the determination that Silenor®  
 13 should not be taken with 3 hours of the consumption of a meal and protected this  
 14 development through proprietary filings, including:

Patent Application	filed	published	issued
60/832,727	7- 20-2006	2008-0058407 on 3-6-2008	3-29-2011
60/833,617	7-24-2006	2008-0058407 on 3-6-2008	3-29-2011
11/781,165	7-20-2007	2008-0058407 on 3-6-2008	3-29-2011
13/007,334	1-14-2011	2011-0166215 on 7-7-2011	

24 each of which is related to and claims the same priority documents as United States  
 25 Letters Patent 7,915,307 which was filed on July 20, 2007, published on March 6,  
 26 2008 and issued on March 29, 2011. Somaxon’s commercialization activities  
 27 began as early as 2006 and continue through 2012 in both the efforts to acquire

1 intellectual property and the sales of Silenor® in association with the previously  
2 acquired intellectual property.

3 **THE PATENTS IN SUIT**

4 **U.S. Patent No. 7,653,639**

5 8. The 7,653,639 Classen patent in suit (the “‘639 Patent”) is entitled  
6 “COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY”  
7 and includes exemplary independent method claim 1 as follows:

8 Claim 1. A method of generating and commercializing newly identified  
9 proprietary data about a proprietary or nonproprietary product or  
10 device, wherein the method comprises the steps of:

11 accessing at least one adverse event data source that stores adverse  
12 event data associated with the product or device;

13 analyzing the adverse event data to identify at least one new essential  
14 adverse event associated with the product or device, wherein the  
15 essential adverse event is one regulated by a regulatory agency  
16 requiring disclosure of the event in a package insert or data sheet  
17 accompanying the product or device;

18 creating at least one essential adverse event information database,  
19 wherein the creating step comprises analyzing data from the at least one  
20 adverse event data source to identify at least one new proprietary  
21 characteristic or use for the product or device responsive to  
22 identification of the at least one new essential adverse event associated  
23 with the product or device, wherein the creating step further comprises  
24 storing essential adverse event information, and wherein the essential  
25 adverse event information includes the at least one proprietary new use  
26 or characteristic and data related thereto; and

27 commercializing the proprietary essential adverse event information  
stored at the essential adverse event information database, which step  
comprises exclusive disclosure of the newly-identified proprietary  
essential adverse event information which, once identified, must then  
accompany the product or device.

and exemplary apparatus claims 16 and 27, as follows:

1 Claim 16. A proprietary product or device created using the method of  
2 claim 1.

3 Claim 27. A proprietary kit containing a product or device, and labeling  
4 notifying a user of at least one new essential adverse event for the  
5 product or device, wherein the kit is created in accordance with claim  
6 1.

7 A copy of the '639 Patent is attached hereto as Exhibit "A"

8 9. Somaxon has practiced and continues to practice a method which  
9 infringes the method claims of the '639 patent, by which Somaxon generated and  
10 commercialized newly identified proprietary data about Silenor<sup>®</sup>. Somaxon  
11 accessed at least one adverse event data source; analyzed the adverse event data  
12 and identified a food related adverse event associated with Silenor<sup>®</sup> regulated by  
13 the FDA requiring disclosure in a package insert or data sheet accompanying  
14 Silenor<sup>®</sup>. Somaxon identified a new proprietary dosing characteristic for Silenor<sup>®</sup>  
15 and stored the adverse event information, including the new dosing characteristic  
16 and data related thereto; and commercialized the proprietary information by the  
17 requirement of disclosure of the information accompanying Silenor<sup>®</sup>. Somaxon  
18 also commercialized by applying for and by acquiring patent rights in the form of  
19 the '307 patent and continues to commercialize by continuing to seek to obtain  
20 patent rights through continued pending patent applications and continues to  
21 commercialize through the sales of Somaxon.

22 10. Somaxon has sold and continues to sell products and kits which  
23 infringe the apparatus claims of the '639 patent. The products and kits include the  
24 sale of Silenor with the labeling which notifies the user of the food effect adverse  
25 event which is proprietary to Somaxon. This infringement has occurred since 2010  
26 and is ongoing subsequent to the issuance of the patents in suit.

27 11. Somaxon infringes one or more claims of the '639 patent.

1 **U.S. Patent No. 7,984,069**

2 12. The 7,984,069 Classen patent in suit (“the ‘069 Patent) is entitled  
3 “COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY”  
4 and includes exemplary independent method claim 1 as follows:

5 Claim 1. A method of commercializing at least one previously  
6 unreported proprietary method of using a product of manufacture or  
7 device, wherein the proprietary method of using the product or device  
8 is established according to the steps comprising:

9 accessing one or more data sources, wherein at least one data source  
10 stores adverse event data associated with the product or device;

11 analyzing and comparing the stored adverse event data, with at least  
12 one previously-known adverse event associated with the product or  
13 device;

14 identifying at least one previously unreported essential adverse event  
15 associated with the product or device from the adverse event data,  
16 wherein an essential adverse event is one regulated by a regulatory  
17 agency requiring disclosure of the event in a package insert or data  
18 sheet accompanying the product or device, and

19 then responsive to identifying of the previously unreported essential  
20 adverse event, identifying at least one previously unreported method of  
21 use for the product or device associated with said identified essential  
22 adverse event; documenting inventorship of the at least one previously  
23 unreported method of use for the product or device; and

24 creating a database of proprietary essential adverse event information,  
25 wherein the database stores at least one record related to at least one of:  
26 a patent, patent application, patent publication, or data contained in at  
27 least one patent, patent application or patent publication, wherein said  
at least one patent, patent application, patent publication, or data  
contained in at least one patent, patent application or patent publication,  
discloses and relates to at least one of the at least one previously  
unreported method of use and the at least one essential adverse event,  
and

1 wherein the at least one previously unreported proprietary method of  
2 using a product or device consists of a use selected from the group  
3 consisting of a restricted use of said product or device, providing  
4 warning(s) about the essential adverse event, providing instruction( s)  
5 for avoiding an essential adverse event, and any combination thereof;  
6 and

7 commercializing the at least one previously unreported proprietary  
8 method of using a product or device, the commercializing comprising  
9 exclusively disclosing the at least one previously unreported  
10 proprietary method of use and the associated at least one previously  
11 unreported essential adverse event information, which information,  
12 once identified, must then accompany the product or device, wherein  
13 commercializing means creating profit from the exclusive disclosure.

14 and includes exemplary apparatus claim 20, as follows:

15 Claim 20. A proprietary kit containing a product or device, and labeling  
16 listing the information which once identified, must accompany the  
17 product or device thus notifying a user of at least one previously  
18 unreported essential adverse event for the product or device, wherein  
19 the information to be listed on the labeling is determined in accordance  
20 with the method of claim 1.

21 A copy of the '069 Patent is attached hereto as Exhibit "B"

22 13. Somaxon has practiced and continues to practice a method, which  
23 infringes the method claims of the '069 patent, of commercializing at least one  
24 previously unreported proprietary method of using Silenor<sup>®</sup> by accessing data  
25 sources with adverse event data associated with Silenor<sup>®</sup>, analyzing and comparing  
26 the adverse event data to identify a food related, previously unreported essential  
27 adverse event associated with Silenor<sup>®</sup> that is regulated by the FDA, and requires  
disclosure accompanying Silenor<sup>®</sup>. Somaxon developed a dosage requirement for  
Silenor<sup>®</sup> and documented inventorship of the new dosage and established a patent  
application and publication containing disclosure related to said new restricted use  
dosage and said food related adverse event. Somaxon commercialized the new  
dosage requirement through the requirement for the information, to mandatorily

1 accompany Silenor<sup>®</sup>. Somaxon also commercialized by applying for and by  
2 acquiring patent rights in the form of the '307 patent and continues to  
3 commercialize by continuing to seek to obtain patent rights through continued  
4 pending patent applications and continues to commercialize through the sales of  
5 Somaxon.

6 14. Somaxon has sold and continues to sell products and kits which  
7 infringe the apparatus claims of the '069 patent. The products and kits include the  
8 sale of Silenor<sup>®</sup> with the labeling which notifies the user of the food effect adverse  
9 event which is proprietary to Somaxon. This infringement has occurred since 2010  
10 and is ongoing subsequent to the issuance of the patents in suit.

11 15. Somaxon infringes one or more of the claims of the 7,984,069 patent.

12 **COUNT I**

13 **PATENT INFRINGEMENT OF 7,653,639**

14 16. Plaintiff re-alleges each and every allegation set forth above and  
15 incorporates them herein by reference.

16 17. Plaintiff owns and has at all times owned and has had standing to sue  
17 for infringement of United States Letters Patent 7,653,639 (the '639 patent) which  
18 was duly and legally issued on January 26, 2010.

19 18. The '639 patent properly names John B. Classen as inventor, is  
20 entitled COMPUTER ALGORITHMS AND METHODS FOR PRODUCT  
21 SAFETY," and is properly assigned to Plaintiff Classen Immunotherapies, Inc.

22 19. Upon information and belief, Defendant Somaxon currently infringes  
23 and has infringed the method and apparatus claims of the '639 patent (35 U.S.C.  
24 §271 and §154) by commercializing information related to Silenor<sup>®</sup> as described  
25 above.



1 20. Plaintiff is entitled to recover damages from Defendant Somaxon,  
2 including reasonable royalties, sustained as a result of Defendant's infringing acts  
3 under 35 U.S.C. §284.

4 21. Defendant has been aware of Plaintiff's rights in the patents in suit  
5 and of Plaintiffs' intent to enforce those rights. Defendant has, with full  
6 knowledge of those rights, willfully proceeded to infringe, in disregard of  
7 Plaintiff's rights. Plaintiff is entitled to enhanced damages under 35 U.S.C. §284.

8 **COUNT II**

9 **PATENT INFRINGEMENT OF 7,984,069**

10 22. Plaintiff re-alleges each and every allegation set forth above and  
11 incorporates them herein by reference.

12 23. Plaintiff owns and has at all times owned and has had standing to sue  
13 for infringement of United States Letters Patent 7,984,069 (the '069 patent), which  
14 was duly and legally issued on July 19, 2011.

15 24. The '069 patent properly names John B. Classen as inventor, is  
16 entitled "COMPUTER ALGORITHMS AND METHODS FOR PRODUCT  
17 SAFETY," and is properly assigned to Plaintiff Classen Immunotherapies, Inc.

18 25. Upon information and belief, Defendant Somaxon currently infringes  
19 and has infringed the method and apparatus claims of the '069 patent (35 U.S.C.  
20 §271 and §154) by commercializing information related to Silenor<sup>®</sup> as described  
21 above.

22 26. Plaintiff is entitled to recover damages from Defendant Somaxon,  
23 including reasonable royalties, sustained as a result of Defendant's infringing acts  
24 under 35 U.S.C. §284.

25 27. Defendant has been aware of Plaintiff's rights in the patents in suit  
26 and of Plaintiffs' intent to enforce those rights. Defendant has, with full  
27

1 knowledge of those rights, willfully proceeded to infringe, in disregard of  
2 Plaintiff's rights. Plaintiff is entitled to enhanced damages under 35 U.S.C. §284.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

5 28. That Defendant be held to have infringed the 7,653,639 patent under  
6 35 U.S.C. §281, §271 and §154.

7 29. That Defendant be held to have infringed the 7,984,069 patent under  
8 35 U.S.C. §281, §271 and §154.

9 30. That Defendant acted with knowledge of one or more of the patents in  
10 suit.

11 31. That judgment be entered for Plaintiff against Defendant, for  
12 reasonable royalties under 35 U.S.C. §284, for Plaintiff's actual damages  
13 according to proof, and for any additional profits attributable to infringements of  
14 Plaintiffs' patent rights, in accordance with proof and for enhanced damages under  
15 35 U.S.C. §284 and §285.

16 32. That judgment be entered for Plaintiff against Defendant, for  
17 reasonable royalties and/or other statutory damages based upon Defendant's acts of  
18 patent infringement and for their other violations of law under 35 U.S.C. §284 and  
19 §285.

20 33. That Defendant be required to account for all gains, profits, and  
21 advantages derived from their acts of infringement and for their other violations of  
22 law and that Plaintiff be awarded damages in the amount of such profits under 35  
23 U.S.C. §284 and §285.

24 34. That the actions of Defendant be found willful.

25 35. That judgment be entered for Plaintiff and against Defendant, for  
26 trebling of the damages awarded for patent infringement under 35 U.S.C. §284 and  
27 §285.

1           36. That the actions of Defendant be found exceptional under 35 U.S.C.  
2 §285.

3           37. That Plaintiff be granted judgment against the Defendant for  
4 Plaintiff's costs and attorney's fees under 35 U.S.C. §285 and or the inherent  
5 powers of the Court.

6           38. That the Court grant such other, further, and different relief as the  
7 Court deems proper under the circumstances.

8  
9 DATED: December 6, 2012

Respectfully submitted,

DNL ZITO

11 By \_\_\_\_\_/s/ Benjamin Deming\_\_\_\_\_

12 Benjamin Deming, Esq.  
13 Attorneys for Plaintiff  
14 Classen Immunotherapies, Inc.

14 **Of Counsel**

15 Joseph J. Zito

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1 **DEMAND FOR JURY TRIAL**

2 Pursuant to Fed. R. Civ. P. 38(b), Plaintiff hereby demands a trial by jury on  
3 all issues raised by the complaint which are properly triable to a jury.  
4

5 DATED: December 6, 2012

Respectfully submitted,

6 DNL ZITO

7 By           /s/ Benjamin Deming          

8 Benjamin Deming, Esq.  
9 Attorneys for Plaintiff  
10 Classen Immunotherapies, Inc.

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