UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CLASSEN IMMUNOTHERAPIES, INC. 6517 Montrose Avenue Baltimore, Maryland 21212 **Plaintiff,** vs. SHIONOGI INC., 300 Campus Drive Florham Park, NJ 07932 and MERZ PHARMACEUTICALS, LLC 4215 Tudor Lane Greensboro, NC 27410 **Defendants**.	Civil Action No.: **13-921** **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiff, Classen Immunotherapies, Inc. ("Classen"), brings this Complaint for patent infringement against Defendants Shionogi Inc. and Merz Pharmaceuticals, LLC (collectively "Defendants") as outlined below.

JURISDICTION AND VENUE

1. This is an action for patent infringement under Title 35 of the United States Code §§281 and 271 (a) (b) (c) and/or (f) for infringement "during the term of the patent" both pre- and post-issuance including ongoing infringement and including "during the period beginning on the date of publication of the application for such patent" as set forth under Title 35 of the United States Code §154(d) for the period beginning on June 27, 2002 for US Patent 7,984,069 and August 31, 2006 for US Patent 7,653,639.

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

and trademarks.

3. Defendants are currently engaged in making, using, offering for sale and selling, inducing to use and contributing to the infringing practicing of methods, products, kits and systems covered under the claims of the patents in suit and are currently engaged in the distribution of products and practicing of methods which infringes the patents in suit on an ongoing basis and are liable for these activities post patent issuance under 35 U.S.C. §271 (a) (b) (c) (f) and/or (g). During the period after the publication of each of the two patents in suit, but prior to the issuance of each of the patents, Defendants engaged in making, using, offering for sale and selling, inducing to use and contributing to the infringing practicing of methods, products, kits and systems covered under the claims of the patents in suit and engaged in the distribution of products and practicing of methods which infringed the patents in suit and are liable for these activities pre-issuance under 35 U.S.C. §154 (d). Venue is proper in this District pursuant to 28 U.S.C. §1391(b) (c) and (d) and §1400(a) and (b). Defendants sell products in this District.

THE PARTIES AND GENERAL ALLEGATIONS

4. Plaintiff, Classen Immunotherapies, Inc. is a corporation existing in the State of Maryland and is the owner of United States Letters Patent Numbers 7,653,639 which published on August 31, 2006 and issued on January 26, 2010 and 7,984,069 which published on June 27, 2002 and issued on July 19, 2011 (the "patents in suit").

5. Defendant Shionogi Inc. ("Shionogi") is a corporation existing under the laws of the state of Delaware, with its headquarters in Florham Park, New Jersey. Defendant Shinogi, Inc. is the successor in interest to Sciele Pharma, Inc.

6. In 2008, Sciele Pharma, Inc. ("Sciele") was acquired by Shionogi & Co., Ltd., the

parent company of Defendant Shionogi. Sciele was the assignee of record for several patents relating to the drug glycopyrrolate. In 2010, Sciele changed its name to Shionogi Inc. which is the current assignee of several patents relating to the drug glycopyrrolate.

7. Defendant Shionogi manufactures and distributes nationwide, pharmaceutical products containing the active ingredient known as glycopyrrolate. Drug products in pill formulation which contain glycopyrrolate have been commercially available for over a decade and have been used in the treatment of ulcers. Liquid formulation of the drug glycopyrrolate entered the market in 2010. Robinul®, Robinul Forte®, and CUVPOSA® are brand names of the drug glycopyrrolate used by Shionogi. Between August 2003 and the present, Shionogi (and its predecessor in interest Sciele) identified adverse event information, which Shionogi commercialized and associated with its glycopyrrolate products.

8. Sciele determined that the efficacy of glycopyrrolate can be affected by the timing of consumption of food, including the determination that glycopyrrolate should not be given between 1 hour before to 2 hours after a meal, and protected this development through proprietary filings, including:

Patent Application	filed	issued	Patent No.
10/644,530	8-20-2003	8-15-2006	7,091,236
12/325,755	12-1-2008	12-29-2009	7,638,552
12/648,068	12-28-2009	10-19-2010	7,816,396

Shionogi Inc.'s commercialization activities began in July 2010 or earlier in both the efforts to acquire intellectual property and the sales of glycopyrrolate in association with the previously acquired intellectual property, including the sale of the brand CUVPOSA with the accompanying patent rights to Merz..

9. Defendant Merz Pharmaceuticals, LLC ("Merz") is a corporation existing under the laws of the state of North Carolina, with its headquarters in Greensboro, North Carolina.

10. On or around August 27, 2012, Merz acquired the brand name CUVPOSA® for the liquid form of the glycopyrrolate drug from Shionogi. CUVPOSA® has been commercially available since July 2010. Merz has commercialized adverse event information associated with this glycopyrrolate product and with two of the patent filings listed above in paragraph 8.

THE PATENTS IN SUIT

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

11. The 7,653,639 Classen patent in suit ("the '639 Patent") is entitled "COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY" and includes exemplary independent method claim 1 as follows:

> Claim 1. A method of generating and commercializing newly identified proprietary data about a proprietary or nonproprietary product or device, wherein the method comprises the steps of:
>
> accessing at least one adverse event data source that stores adverse event data associated with the product or device;
>
> analyzing the adverse event data to identify at least one new essential adverse event associated with the product or device, wherein the essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device;
>
> creating at least one essential adverse event information database, wherein the creating step comprises analyzing data from the at least one adverse event data source to identify at least one new proprietary characteristic or use for the product or device responsive to identification of the at least one new essential adverse event associated with the product or device, wherein the creating step further comprises storing essential adverse event information, and wherein the essential adverse event information includes the at least one proprietary new use or characteristic and data related thereto; and
>
> 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:

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

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

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

12. Shionogi Inc. has practiced and continues to practice a method which infringes the method claims of the '639 Patent, by which Shionogi Inc. generated and commercialized newly identified proprietary data about glycopyrrolate. Shionogi Inc. accessed at least one adverse event data source; analyzed the adverse event data and identified a food related adverse event associated with glycopyrrolate regulated by the FDA requiring disclosure in a package insert or data sheet accompanying glycopyrrolate. Shionogi Inc. identified a new proprietary dosing characteristic for glycopyrrolate and stored the adverse event information, including the new dosing characteristic and data related thereto; included this information in patent filings and and commercialized the proprietary information by obtaining patent protection and advocating the requirement of disclosure of the information accompanying glycopyrrolate. Shionogi Inc. also commercialized by applying for and by acquiring patent rights in the form of U.S. Patent Nos. 7,091,236 ("the '236 Patent"), 7,638,552 ("the '552 Patent") and 7,816,396 ("the '396 Patent") and continued to commercialize through the sales of glycopyrolate and sales of glycopyrrolate with labeling and sales of kits with product and labeling; and the sale of the patent protected brand to Merz.

13. Shionogi Inc. has sold products and kits which infringe the apparatus claims of the '639 Patent. The products and kits include the sale of glycopyrrolate with labeling which notifies the user of the food effect adverse event which is proprietary to Shionogi Inc. This infringement has occurred since at least July 2010 and was ongoing subsequent to the issuance

of the patents in suit.

14. Shionogi Inc. infringes one or more claims of the ‘639 Patent.

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

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

> Claim 1. A method of commercializing at least one previously unreported proprietary method of using a product of manufacture or device, wherein the proprietary method of using the product or device is established according to the steps comprising:
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> accessing one or more data sources, wherein at least one data source stores adverse event data associated with the product or device;
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> analyzing and comparing the stored adverse event data, with at least one previously-known adverse event associated with the product or device;
> identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and
> then responsive to identifying of the previously unreported essential adverse event, identifying at least one previously unreported method of use for the product or device associated with said identified essential adverse event; documenting inventorship of the at least one previously unreported method of use for the product or device; and
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> creating a database of proprietary essential adverse event information, wherein the database stores at least one record related to at least one of: a patent, patent application, patent publication, or data contained in at 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
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> wherein the at least one previously unreported proprietary method of using a product or device consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof; and
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> commercializing the at least one previously unreported proprietary method of using a product or device, the commercializing comprising exclusively disclosing the at least

> one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure.

and includes exemplary apparatus claim 20, as follows:

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

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

16. Defendants have practiced and continue to practice a method, which infringes the method claims of the '069 Patent, of commercializing at least one previously unreported proprietary method of using glycopyrrolate by accessing data sources with adverse event data associated with glycopyrrolate, analyzing and comparing the adverse event data to identify a food related, previously unreported essential adverse event associated with glycopyrrolate that is regulated by the FDA, and requires disclosure accompanying glycopyrrolate. Shionogi Inc. developed a dosage requirement for glycopyrrolate 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. Shionogi Inc. commercialized the new dosage requirement through the requirement for the information, to mandatorily accompany glycopyrrolate. Shionogi Inc. also commercialized by applying for and by acquiring patent rights in the form of the '236 Patent, the '552 Patent, and the '396 Patent and continued to commercialize by continuing to seek to obtain patent rights through continued pending patent applications and continued to commercialize through the sales of glycopyrrolate and sales of glycopyrrolate with labeling and sales of kits with product and labeling; and by the sale if the patent protected brand to Merz.

17. Merz commercializes by continuing to seek to obtain patent rights through continued pending patent applications, through maintaining and enforcing its patent rights and through the sales of glycopyrrolate.

18. Defendants have sold and continue to sell products and kits which infringe the apparatus claims of the ‘069 Patent. The products and kits include the sale of glycopyrrolate with the labeling which notifies the user of the food effect adverse event which is proprietary to Defendants. This infringement has occurred since at least July 2010 and is ongoing subsequent to the issuance of the patents in suit.

19. Defendants infringe one or more of the claims of the ‘069 Patent.

COUNT I
PATENT INFRINGEMENT OF 7,653,639

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

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

22. The ‘639 Patent properly names John B. Classen as inventor, is entitled COMPUTER ALGORITHMS AND METHODS FOR PRODUCT SAFETY,” and is properly assigned to Plaintiff Classen Immunotherapies, Inc.

23. Upon information and belief, Defendant Shionogi and Merz currently infringe and have infringed the method and apparatus claims of the ‘639 Patent (35 U.S.C. §271 and §154) by commercializing information related to glycopyrrolate as described above.

24. The acts of infringement under 35 U.S.C. §154, for which Plaintiff is entitled to a reasonable royalty, include the activities of Shionogi beginning on August 31, 2006 and

continuing to the present which comprise practicing the steps of the method claims of the '639 patent, as outlined above, wherein Shionogi commercialized newly identified proprietary data about glycopyrrolate, by accessing adverse event data; analyzing the adverse event data; identifying at least one new essential adverse event associated with glycopyrrolate and creating a proprietary new use which requires mandatory disclosure; and seeking exclusive rights to the disclosure of the newly-identified proprietary essential adverse event information.

25. Infringement under 35 USC §271 began on August 31, 2006 and became actionable on January 26, 2012. Infringement under 271(a) by Shionogi includes the continued practice of the method claims of the '639 patent through continued commercialization and sale of products and kits which infringe the apparatus claims of the '639 patent.

26. Infringement under 35 USC §271 began on August 31, 2006 and became actionable on January 26, 2010. Infringement under 271(a) by Shionogi and Merz includes infringement of the apparatus claims of the '639 patent by sale of products and kits which infringe the apparatus claims of the '639 patent.

27. Infringement under 35 USC §271 began on August 31, 2006 and became actionable on January 26, 2010. Infringement under 271(g) by Shionogi and Merz includes the importation into the United States and/or offer to sell, sales, and/or use within the United States, during the term of the '639 patent, of products and kits (including Robinul®, Robinul Forte®, and CUVPOSA® with package labeling and/or inserts) which are made by the process patented in the '639 patent.

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

29. Defendant has been aware of Plaintiff's rights in the patents in suit and of

Plaintiffs' intent to enforce those rights. Defendant has, with full knowledge of those rights, willfully proceeded to infringe, in disregard of Plaintiff's rights. Plaintiff is entitled to enhanced damages under 35 U.S.C. §284.

COUNT II
PATENT INFRINGEMENT OF 7,984,069

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

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

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

33. Upon information and belief, Defendants currently infringe and have infringed the method and apparatus claims of the '069 Patent (35 U.S.C. §271 and §154) by commercializing information related to glycopyrrolate as described above.

34. The acts of infringement under 35 U.S.C. §154, for which Plaintiff is entitled to a reasonable royalty, include the activities of Shionogi beginning on June 27, 2002 and continuing to the present which comprise practicing the steps of the method claims of the '069 patent, as outlined above, wherein Shionogi commercialized a previously unreported proprietary method of using glycopyrrolate by accessing adverse event data associated with gycopyrrolate; analyzed the adverse event data; identified a previously unreported essential adverse event regulated by the FDA; documented inventorship of and obtained exclusivity to a previously unreported method of use; and commercialized the exclusivity by disclosing the proprietary method of use.

35. Infringement under 35 USC §271 began on June 27, 2002 and became actionable on July 19, 2011. Infringement under 271(a) by Shionogi includes the continued practice of the method claims of the '639 patent through continued commercialization and sale of products and kits which infringe the apparatus claims of the '639 patent.

36. Infringement under 35 USC §271 began on June 27, 2002 and became actionable on July 19, 2011. Infringement under 271(a) by Shionogi and Merz includes infringement of the apparatus claims of the '069 patent by sale of products and kits which infringe the apparatus claims of the '639 patent.

37. Infringement under 35 USC §271 began on June 27, 2002 and became actionable on July 19, 2011. Infringement under 271(g) by Shionogi and Merz includes the importation into the United States and/or offer to sell, sales, and/or use within the United States, during the term of the '069 patent, of products and kits (including Robinul®, Robinul Forte®, and CUVPOSA® with package labeling and/or inserts) which are made by the process patented in the '069 patent.

38. Plaintiff is entitled to recover damages from Defendants, including reasonable royalties, sustained as a result of Defendants' infringing acts under 35 U.S.C. §284.

39. Defendants have been aware of Plaintiff's rights in the patents in suit and of Plaintiffs' intent to enforce those rights. Defendants have, with full knowledge of those rights, willfully proceeded to infringe, in disregard of Plaintiff's rights. Plaintiff is entitled to enhanced damages under 35 U.S.C. §284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

40. That Defendants Shionogi and Merz be held to have infringed U.S. Patent No.

7,653,639 under 35 U.S.C. §154, §271, and §281.

41. That Defendants Shionogi and Merz be held to have infringed U.S. Patent No. 7,984,069 under 35 U.S.C. §154, §271, and §281.

42. That Defendants acted with knowledge of one or more of the patents in suit.

43. That Defendants' infringement was willful.

44. That judgment be entered for Plaintiff against Defendants, for reasonable royalties under 35 U.S.C. §284, for Plaintiff's actual damages according to proof, and for any additional profits attributable to infringements of Plaintiffs' patent rights, in accordance with proof and for enhanced damages under 35 U.S.C. §154, §284 and §285.

45. That judgment be entered for Plaintiff against Defendants, for reasonable royalties and/or other statutory damages based upon Defendants' acts of patent infringement and for their other violations of law under 35 U.S.C. §154, §284 and §285.

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

47. That the actions of Defendants be found willful.

48. That judgment be entered for Plaintiff and against Defendants, for trebling of the damages awarded for patent infringement under 35 U.S.C. §154, §284 and §285.

49. That the actions of Defendants be found exceptional under 35 U.S.C. §285.

50. That Plaintiff be granted judgment against the Defendants for Plaintiff's costs and attorney's fees under 35 U.S.C. §285 and or the inherent powers of the Court.

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

DATED: March 26th, 2013

Respectfully submitted,
DNL ZITO

By /s/ Joseph J. Zito_____
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DEMAND FOR JURY TRIAL

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

DATED: March 26, 2013

Respectfully submitted,

DNL ZITO

By /s/ Joseph J. Zito_____
Joseph J. Zito
Attorneys for Plaintiff
Classen Immunotherapies, Inc.