IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CLASSEN IMMUNOTHERAPIES, INC. 6517 Montrose Avenue Baltimore, Maryland 21212 Plaintiff v. BIOGEN IDEC 14 Cambridge Center Cambridge, Massachusetts 02142 GALAXOSMITHKLINE One Franklin Plaza Philadelphia, Pennsylvania 19102 CHIRON CORPORATION 4560 Horton Street Emeryville, CA 94608-2916 MERCK & CO., INC. One Merck Drive P.O. Box 100 Whitehouse Station, NJ 08889-0100 KAISER-PERMANENTE, INC. d/b/a Permanente Medical Groups Kaiser Foundation Health Plan, Inc. Permanente Medical Research Institutes 1 Kaiser Plaza Oakland, California 94612 Defendants	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Classen Immunotheripies, Inc., complains of Defendants Biogen, GalaxoSmithKline, Chiron, Merck and Kaiser-Permanente, Inc. as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement under Title 35 of the United States Code §§ 271 (a) (b) (c) and/or (f).

2. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331, 1338(a).

3. Plaintiff, Classen Immunotherapies, Inc. is a corporation existing in the State of Maryland and is the owner of United States Letters Patent Numbers 6,420,139; 6,638,739; 5,728,385 and 5,723,283 (the "patents in suit").

4. Defendant Biogen IDEC, Inc. is a corporation existing under the laws of the state of Delaware, with its headquarters in Massachusetts; Defendant GalaxoSmithKline, Inc. is a corporation existing under the laws of the state of Delaware, with its headquarters in Pennsylvania; Defendant Chiron Corporation is a corporation existing under the laws of the state of Delaware, with its headquarters in California; Defendant Merck & Co., Inc. is a corporation existing under the laws of the state of New Jersey, with its headquarters in New Jersey; Defendant Kaiser-Permanente, Inc. is a corporation existing under the laws of the state of California, with its headquarters in California.

5. The Defendants are engaged in making, using, offering for sale and selling, inducing to use and contributing to the infringing practicing of methods and services covered under the claims of the patents in suit. Each of the Defendants transacts business in Maryland, and the accused products and services are available for sale throughout Maryland in this District. Venue is proper in this District as to Defendants under 28 U.S.C. §1391(b) (c) and (d) and §1400(a) and (b). The Defendants do not all reside in the same state, infringement is nationwide due to the nature of distribution of vaccines and all Defendants are found in Maryland, through sales, advertising,

presence and provisioning of services, information and instructions in and into Maryland.

GENERAL ALLEGATIONS

6. Defendants Biogen, Chiron, GalaxoSmithKline, Merck, and Kaiser-Permanente collectively license, manufacture, use, market, distribute and sell vaccines for human use, the vaccines are known as hepatitis B vaccines, and are also know under the trade names ENGERIX-B and RECOMBIVAX. Defendants' products have participated in studies on the effects of the timing of administration of these vaccines and incidence of chronic immune mediated disorders. The Defendants collectively, publish, encourage, recommend and administer the vaccines according to a protocol which is believed to minimize the risk of incidence of chronic immune mediated disorders.

7. The Defendants, Biogen, GalaxoSmithKline, Chiron, Merck, and Kaiser-Permanente, participated in, facilitated and/or otherwise conducted a study believed to have begun in the late 1990's and continuing through 2001, to evaluate suggested associations between childhood vaccinations, particularly against hepatitis B and Haemophilus influenza type b, and risk of developing type 1 diabetes; and to determine whether timing of vaccination influences risk. The Defendants conducted the study in combination with the Centers for Disease Control and Prevention. This study was published in Pediatrics, in December of 2001; 108(6):E112, and titled: Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes Mellitus. The Defendants have used the results of that study, and others to determine the administration protocol for vaccinations.

THE PATENTS IN SUIT

6,420,139

8. The 6,420,139 Classen patent in suit is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae." and includes independent claim 1 as follows:

> 1. A method of immunizing a mammalian subject while reducing the risk of said subject thereby developing at least one chronic immune-mediated disorder, which comprises:
> (I) screening a plurality of immunization schedules, by
> (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and
> (b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),
> where the first dose of at least one infectious disease-causing organism associated immunogen given to both groups is given sooner after birth according to one or more of the screened immunization schedules than according to one or more of the other screened immunization schedules, each such immunogen so administered being hereafter referred to as an "early" immunogen regardless of its time of administration in the latter schedule(s),
> where at least one of said chronic immune-mediated disorders is diabetes,
> where said mammalian subject is or said mammals are humans,
> where at least one of said early immunogens is one other than BCG or pertussis immunogen, and
> (II) immunizing said subject according to a subject immunization schedule, according to which at least one of said early infectious disease-causing organism-associated immunogens is administered to the subject at about the same dates, relative to the date of birth as it was administered to the mammals in said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

9. The Defendants collectively immunize people, according to an immunization schedule, which reduces the risk of the person developing at least one chronic immune-mediated disorder, including diabetes, selected by screening a plurality of immunization schedules from at least a first immunization schedule, and a second different immunization schedule, where at least one schedule difference is the time between birth and the first dose of the immunogen, prior to selection each schedule was used to immunize different groups of people with one or more doses of one or more infectious disease-causing organism-associated immunogens, other than BCG or pertussis immunogen, and the effectiveness of the different immunization schedules in protecting against or inducing a chronic immune-mediated disorder was compared, potentially identifying which immunization schedule may be identified as a lower risk immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s).

10. Defendants infringe at least claims 1, 2, 3, 4, 26, 28, 36, 37, 60, 63, 64 and/or 65 of the 6,420,139 patent. Defendants are also believed to infringe claims 5-25, 27, 29, 38-59, 62, 66-67, 69 and 70, based upon reasonable belief, subject to additional information anticipated during discovery.

6,638,739

11. The 6,638,739 Classen patent in suit is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae " and includes independent claim 1 as follows:

1. A method of immunizing a mammalian subject which comprises:

(I) screening a plurality of immunization schedules, by

> (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or

more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s),

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.

12. The Defendants collectively immunize people, according to an immunization schedule, selected by screening a plurality of immunization schedules from at least a first immunization schedule, and a second different immunization schedule, prior to selection each schedule was used to immunize different groups of people with one or more doses of one or more infectious disease-causing organism-associated immunogens, and the effectiveness of the different immunization schedules in protecting against or inducing a chronic immune-mediated disorder was compared, potentially identifying which immunization schedule may be identified as a lower risk immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s).

13. Defendants infringe at least claims 1-6, 8-12, 16, 21, 25-28, 30, 31, 34, 35, 38-40, 42, 45, 46, 52, 53, 55-58, 62, 66-68, 71-73, 75-83, 85, 88-91, 96, 97, 109, 110, 112, and/or 113 of the 6,638,739 patent. Defendants are also believed to infringe claims 13-15, 19, 20, 22-24, 29, 32, 33, 36, 37, 41, 43, 44, 47-51, 54, 59-61, 63-65, 69, 70, 74, 84, 92-95, 98-103, 107 and 108, based upon reasonable belief, subject to additional information anticipated during discovery.

5,728,385

14. The 5,728,385 patent is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae"and includes independent claim 1 as follows:

> 1. A method of immunizing a mammal less than 96 months of age against at least one infectious disease, while decreasing the incidence of an autoimmune disease, comprising
>
> administering to said mammal one or more pharmaceutically acceptable pharmaceutical preparations, comprising one or more immunogens, according to an immunization schedule according to which, at specific times after birth, the mammal receives one or more pharmaceutically acceptable doses of one or more immunogens;
>
> said mammal thereby receiving, for each said infectious disease, a suitable immmogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;
>
> said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence of an autoimmune disease in such mammals;
>
> said mammals are selected from the group consisting of humans, and nonhuman mammals which are animal models of a human autoimmune disease,
>
> the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,
>
> where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG,
>
> where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, whole cell pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, at least one of the following conditions applies: (a) immunogens are administered on at least three different dates prior to 42 days after birth, or (b) immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less,
>
> where said autoimmune disease is selected from the group consisting of diabetes mellitis and systemic lupus erythrematosis.

15. The Defendants collectively immunize people with one or more pharmaceutically acceptable pharmaceutical preparations, according to an immunization schedule according to which, at specific times after birth, the person receives one or more pharmaceutically acceptable doses of one or more immunogens; the person receiving, for each said infectious disease, a suitable immmogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease; which results in an immune response sufficient to substantially reduce the incidence of an autoimmune disease, the first dose being administered before 42 days after birth, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, and (a) the immunogens are administered on at least three different dates prior to 42 days after birth, or (b) the immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less.

16. Defendants infringe at least claims 1, 9, 12, 16, 17, 32 and/or 41 of the 5,728,385 patent. Defendants are also believed to infringe claims 2-6, 8, 10, 11, 13, 14, 15, 18, 25, 36, 39, 40, and 42, based upon reasonable belief, subject to additional information anticipated during discovery.

5,723,283

17. The 5,723,283 patent is entitled: "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae" and includes independent claim 1as follows:

> 1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of

mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

18. The Defendants collectively determine the affect of an immunization schedule on the incidence or severity of a chronic immune-mediated disorder by comparing people in a treatment group with the incidence, prevalence, frequency or severity of a chronic immune-mediated disorder with people in a control group.

19. Defendants infringe at least claims 1, 2, 4-6, 9, 10, 20-22, 25, 26, 29, 37, 38, 41, 46 and/or 47 of the 5,723,283 patent. Defendants are also believed to infringe claims 7, 8, 14-19, 23, 24, 31-16, 39, 42, 44, and 45, based upon reasonable belief, subject to additional information anticipated during discovery.

20. Plaintiff has contacted each of the Defendants to notify each of the Defendants of the infringement and to begin license discussions. Plaintiff has exchanged correspondence with each of the Defendants without resolving the issues of infringement.

21. Without benefit of a license, Defendants have continued to distribute information, induce, contribute, manufacture, market and sell vaccines and provide services which infringe one or more of the patents in suit.

22. Plaintiff, on information and belief, alleges that the Defendants intend to continue their course of conduct and to wrongfully use the intellectual property of Plaintiff and infringe upon, induce

contribute, sell, license and otherwise profit from Plaintiffs' intellectual property. As a direct and proximate result of the acts alleged above, Plaintiff have been damaged. Plaintiffs seek remedy at law to redress the injuries Defendants have caused and intend to cause by their conduct. Plaintiff will continue to suffer damage until this Court awards proper compensatory damages to Plaintiff.

COUNT I
PATENT INFRINGEMENT OF 6,420,139

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

24. Plaintiff owns and has at all times owned and has had standing to sue for infringement of United States Letters Patent 6,420,139 (the '139 patent) which was duly and legally issued on July 16, 2002.

25. The '139 patent properly names John B. Classen as inventor, is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae", is properly assigned to Plaintiff Classen Immunotherpies, Inc.

26. Upon information and belief, Defendants Biogen and Chiron induce the infringement of the '139 patent by providing instructions and/or recommendations on a proper immunization schedule for vaccines.

27. Upon information and belief, GalaxoSmithKline, Chiron and Merck contribute to infringement, induce infringement and infringe the patents in suit through the manufacture and supply of vaccines and by providing instructions and/or recommendations on a proper immunization schedule

for vaccines and by administration of vaccines according to the patented method.

28. Upon information and belief, Kaiser-Permanente infringes the patents in suit through the administration of vaccines according to the patented method.

29. Plaintiff is entitled to recover damages from Defendants, including reasonable royalties, sustained as a result of Defendants' infringing acts.

30. Defendants have been notified 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, wilfully proceeded to infringe, in disregard of Plaintiff's rights.

COUNT II
PATENT INFRINGEMENT OF 6,638,739

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

32. Plaintiff owns and has at all times owned and has had standing to sue for infringement of United States Letters Patent 6,638,739 (the '739 patent) which was duly and legally issued on October 28, 2003.

33. The '739 patent properly names John B. Classen as inventor, is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae", is properly assigned to Plaintiff Classen Immunotherpies, Inc.

34. Upon information and belief, Defendants Biogen and Chiron induce the infringement

of the '739 patent by providing instructions and/or recommendations on a proper immunization schedule for vaccines.

35. Upon information and belief, GalaxoSmithKline, Chiron and Merck contribute to infringement, induce infringement and infringe the '739 patent in suit through the manufacture and supply of vaccines and by providing instructions and/or recommendations on a proper immunization schedule for vaccines and by administration of vaccines according to the patented method.

36. Upon information and belief, Kaiser-Permanente infringes the '739 patent in suit through the administration of vaccines according to the patented method.

37. Plaintiff is entitled to recover damages from Defendants, including reasonable royalties, sustained as a result of Defendants' infringing acts.

38. Defendants have been notified 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, wilfully proceeded to infringe, in disregard of Plaintiff's rights.

COUNT III
PATENT INFRINGEMENT OF 5,728,385

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

40. Plaintiff owns and has at all times owned and has had standing to sue for infringement of United States Letters Patent 5,728,385 (the '385 patent) which was duly and legally issued on March 17, 1998.

41. The '385 patent properly names John B. Classen as inventor, is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae", is properly assigned to Plaintiff Classen Immunotherpies, Inc. (NOTE: Check Assignment)

42. Upon information and belief, Defendants Biogen and Chiron induce the infringement of the '385 patent by providing instructions and/or recommendations on a proper immunization schedule for vaccines.

43. Upon information and belief, GalaxoSmithKline, Chiron and Merck contribute to infringement, induce infringement and infringe the '385 patent in suit through the manufacture and supply of vaccines and by providing instructions and/or recommendations on a proper immunization schedule for vaccines and by administration of vaccines according to the patented method.

44. Upon information and belief, Kaiser-Permanente infringes the '385 patent in suit through the administration of vaccines according to the patented method.

45. Plaintiff is entitled to recover damages from Defendants, including reasonable royalties, sustained as a result of Defendants' infringing acts.

46. Defendants have been notified 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, wilfully proceeded to infringe, in disregard of Plaintiff's rights.

COUNT IV
PATENT INFRINGEMENT OF 5,723,283

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

48. Plaintiff owns and has at all times owned and has had standing to sue for infringement of United States Letters Patent 5,723,283 (the '283 patent) which was duly and legally issued on March 3, 1998.

49. The '283 patent properly names John B. Classen as inventor, is entitled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae", is properly assigned to Plaintiff Classen Immunotherpies, Inc.

50. Upon information and belief, Defendants Biogen and Chiron induce the infringement of the '283 patent by providing instructions and/or recommendations on a proper immunization schedule for vaccines.

51. Upon information and belief, GalaxoSmithKline, Chiron and Merck contribute to infringement, induce infringement and infringe the '283 patent in suit through the manufacture and supply of vaccines and by providing instructions and/or recommendations on a proper immunization schedule for vaccines and by administration of vaccines according to the patented method.

52. Upon information and belief, Kaiser-Permanente infringes the '283 patent in suit through the administration of vaccines according to the patented method.

53. Plaintiff is entitled to recover damages from Defendants, including reasonable

royalties, sustained as a result of Defendants' infringing acts.

54. Defendants have been notified 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, wilfully proceeded to infringe, in disregard of Plaintiff's rights.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgement against Defendants as follows:

55. That Defendants be held to have infringed the 6,420,139 patent.

56. That Defendants be held to have infringed the 6,638,739 patent.

57. That Defendants be held to have infringed the 5,728,385 patent.

58. That Defendants be held to have infringed the 5,723,283 patent.

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

60. That judgement be entered for Plaintiff against Defendants, for Plaintiff's actual damages according to proof, and for any additional profits attributable to infringements of Plaintiffs' patent rights, in accordance with proof.

61. That judgement 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.

62. That Defendants 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.

63. That the actions of Defendants be found willful.

64. That judgement be entered for Plaintiff and against Defendants, for trebling of the damages awarded for patent infringement.

65. That the actions of Defendants be found exceptional.

66. That Plaintiff has judgement against the Defendants for Plaintiff's costs and attorney's fees.

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

JURY TRIAL DEMAND

68. Plaintiff demands a TRIAL BY JURY on all issues so triable.

Verified:

John B Classen CEO

John B. Classen
For: Classen Immunotherapies, Inc.
Plaintiff

Respectfully submitted,

Joseph J. Zito 05640
Kendal M. Sheets
Zito tlp
26005 Ridge Road
Suite 203
Damascus, Maryland 20872
Tel: (301) 601-5010
Fax: (301) 482-0779