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Attorneys for Plaintiff AgaMatrix, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

AGAMATRIX, INC., a Delaware corporation,

Plaintiff,

vs.

DEXCOM, INC., a Delaware corporation,

Defendant.

Case No. 3:16-cv-536-JE

**FIRST AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

DEMAND FOR JURY TRIAL

Plaintiff AgaMatrix, Inc. (“AgaMatrix”) brings this First Amended Complaint for patent infringement against Defendant Dexcom, Inc. (“Dexcom”), and alleges as follows:

INTRODUCTION

1. This is a patent case involving sensors for continuous glucose monitoring (CGM) in persons having diabetes. Diabetes is a disorder associated with insulin deficiency and hyperglycemia (unusually high blood glucose levels). It is associated with blood glucose concentrations that are outside of the normal range of 80 – 120 mg/dL. Patients with certain

types of diabetes can manage their disease by injecting insulin. They confirm the effectiveness of the previous insulin dose and help determine their next dose by monitoring their blood glucose levels.

2. As the name implies, CGM was developed to provide continuous glucose monitoring for persons having diabetes. CGM allows people with diabetes to track their glucose levels in real time and to determine how quickly they are rising or falling. To provide this continuous monitoring, the CGM sensors at issue in this case are “indwelling” sensors that are at least partially inserted into a patient’s body, such as the patient’s abdomen, where they may remain for several days before being removed.

3. A significant problem with indwelling sensors that existed prior to the sensors of AgaMatrix’s patented inventions is that they typically were made of a weak, electrochemically active metal, such as platinum, that could be difficult to insert and were susceptible to breaking inside the user’s body as the result of repeated flexing from bodily movement. Efforts to render the platinum more flex-resistant produced corresponding undesirable results, such as interfering with the electrochemical functioning of the sensor or excessive cost.

4. Among their other advantages, the sensors described and claimed in AgaMatrix’s patents include a structurally robust core, such as a tantalum core, that is able to withstand repeated flexing without breaking, preserving desired electrochemical activity at a reasonable cost. The electrochemical activity needed for detecting and measuring glucose levels is provided by a thin surrounding layer of an electrochemically active metal, such as platinum.

5. AgaMatrix brings this patent infringement action because, on information and belief, the CGM systems and sensors sold by Dexcom, called the Dexcom G4 Platinum System (“G4”) and the Dexcom G5 Mobile CGM System (“G5”) infringe multiple claims of at least three of AgaMatrix’s patents.

JURISDICTION AND VENUE

6. AgaMatrix's cause of action for patent infringement against Dexcom arises under the patent laws of the United States, 35 U.S.C. § 101 *et seq.* This Court has original jurisdiction over this subject matter pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Dexcom because, on information and belief, it transacts and solicits business in the State of Oregon, including with respect to the infringing products at issue in this case, and because Dexcom is committing and has committed acts of infringement in this district by selling and offering to sell infringing products in this district. Further, on information and belief, Dexcom maintains an Internet site available to consumers within this district on which it advertises its products and hosts an interactive function whereby customers can order Dexcom products, including the infringing products at issue in this case.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) & (c) and 1400(b) because Dexcom regularly transacts and solicits business in this district, including with respect to the infringing products at issue in this case, and because Dexcom is committing and has committed acts of infringement in this district by selling, offering to sell, and distributing products in this district that infringe upon the AgaMatrix Patents. Additionally, the inventors of the AgaMatrix Patents reside in or near Portland, Oregon; the technology embodied in the AgaMatrix Patents was conceived and reduced to practice in Wilsonville, Oregon; and the AgaMatrix facility in Wilsonville, Oregon, acquired at the time AgaMatrix acquired the AgaMatrix Patents at issue, continues to be the exclusive site at which the patented AgaMatrix CGM glucose sensors are produced and tested. Accordingly, many of the relevant witnesses and documents reside in this district.

THE PARTIES

9. Founded in 2001, AgaMatrix is a leading innovator in the field of diabetes care and management, and designs, manufactures, and sells various products developed to monitor

the health of diabetes patients, including blood glucose monitors. Since 2005, AgaMatrix has provided over six million blood glucose monitors and over two billion blood glucose sensors to diabetes patients around the world, earning a reputation for innovation, quality, and accuracy. AgaMatrix is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Salem, New Hampshire. AgaMatrix also maintains a place of business in Wilsonville, Oregon, which is exclusively devoted to manufacture, testing and production of the CGM sensors covered by the AgaMatrix Patents.

10. AgaMatrix recently acquired certain assets of a Portland, Oregon-based company named iSense (iSense Acquisition, LLC and iSense CGM, Inc.). These assets include, without limitation, the three patents being asserted against Dexcom in this action, which name as inventors residents of Portland, Oregon. On information and belief, most or all of these inventors continue to reside in the Portland area.

11. AgaMatrix also now operates the former iSense research and development facility located at 27700 SW 95th Avenue in Wilsonville, Oregon. AgaMatrix further has entered into employment or consulting contracts with former iSense employees, including named co-inventor on two of the three patents-in-suit, Richard Sass, iSense's CEO. Former iSense Chief Technical Officer (CTO), Mihailo Rebec, has been named AgaMatrix's CTO for CGM products, operating out of Wilsonville. Other former iSense technical and managerial employees have been hired to operate the Wilsonville facility. Further, the Wilsonville, Oregon facility will continue to be the exclusive center for development, testing and manufacture of the patented AgaMatrix CGM sensors and, after FDA approval is obtained, will be the exclusive site for commercial manufacture of the patented AgaMatrix CGM sensor products. Currently, AgaMatrix is in the process, as was iSense before it, of seeking FDA approval for its CGM sensors and systems. Accordingly, AgaMatrix has not yet had any commercial sales of its patented sensors.

12. Founded in 1999, Dexcom is a Delaware corporation having a principal place of business in San Diego, California. Dexcom had its initial public offering in about 2005 and

remains a publicly-owned company. Dexcom currently derives most of its revenues from sales of the accused G4 and G5 systems, replacement sensors, and peripheral products sold with the G4 and G5 systems, such as software platforms, blue tooth transmitters and the like. On information and belief, Dexcom sells its accused G4 and G5 sensors, systems and related products throughout the United States and the world, including substantial sales to residents of Portland, Oregon.

THE PATENTS-IN-SUIT

13. The AgaMatrix patents-in-suit include U.S. Patent No. 7,146,202 (“the ’202 Patent”), issued in 2006; U.S. Patent No. 8,187,433 (“the ’433 Patent”), issued in 2012; and U.S. Patent No. 7,529,574 (“the ’574 Patent”), issued in 2009. Copies of the ’202, ’433 and ’574 patents are attached as Exhibits A-C hereto, respectively. All three patents, originally assigned to iSense Corporation, are now assigned to AgaMatrix. AgaMatrix thus owns all right, title and interest in and to the ’202, ’433 and ’574 patents.

14. The ’202 and ’433 patents issued from related (divisional) patent applications which claim priority to the same provisional application filed on June 16, 2003, and are commonly titled “Compound Material Analyte Sensor.” Based on this relationship, the specifications and figures of the ’202 and ’433 patents are substantially identical. The ’202 and ’433 patents name as inventors W. Kenneth Ward and Richard G. Sass, both of Portland, Oregon.

15. The ’202 Patent is directed to a method of using a flexible sensing element designed for insertion under a patient’s skin to measure analyte concentrations (such as blood glucose levels) based on an electrical current produced by the sensor.

16. The ’202 Patent discloses the danger of using the prior wire sensors for blood glucose monitoring. Specifically, the patent explains that “fatigue from the flexure caused by bodily movement” can cause a sensor to “break off inside the body.” The patent further explains:

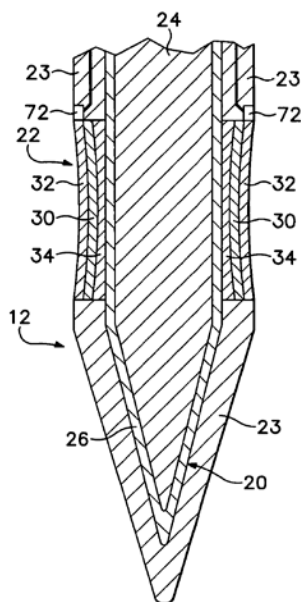
Unfortunately, the typical metal used for such a wire sensor is platinum, which is electrochemically active and generally very useful in sensing applications. Platinum, however, is a weak metal that is easily broken with only a little flexure. Moreover, the electrochemical nature of platinum surfaces is only imperfectly understood. Efforts to make sensors from very thin platinum wires that are stranded together, thereby providing greater flex resistance, have encountered negative effects on the biochemical reactivity of the more complex platinum surface.

'202 Patent at Col. 1: lines 19-28.

17. The '202 Patent further discloses that platinum is expensive.

18. The inventors of the '202 Patent overcame this problem by inventing the use of a core comprised of a structurally robust material, such as tantalum, with a layer comprising an electrochemically active metal, such as platinum, plated onto the core.

19. Figure 1 of the '202 Patent, which shows a cross-section of a sensor wire, is shown below:



20. In this figure, the tantalum core (24) is coated with an electrochemically active layer (26) and coated with a protective layer (23). When a voltage is placed on the wire (20) relative to a reference electrode, a membrane system (22) reacts to the presence of glucose and oxygen (in some preferred embodiments, glucose only) by creating a current.

Measurement of the current level allows the analyte concentration in the body fluids to be measured.

21. Claim 1 of the '202 Patent recites:

1. A method for measuring the concentration of an analyte within an animal body having body fluids, comprising:

(a) providing a sensor having:

(i) a structurally flexible core having an outer surface; and

(ii) a layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core;

(b) placing at least a portion of said sensor into said animal body; and

(c) measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement.

22. Dependent claims 2-11 each recite one or more additional limitations, such as the use of tantalum for the core and the measurement of glucose as the analyte.

23. The claims of the '433 Patent are directed to an analyte sensing element.

24. The '433 Patent has four independent claims. Claim 1 recites:

1. An analyte sensing element, comprising:

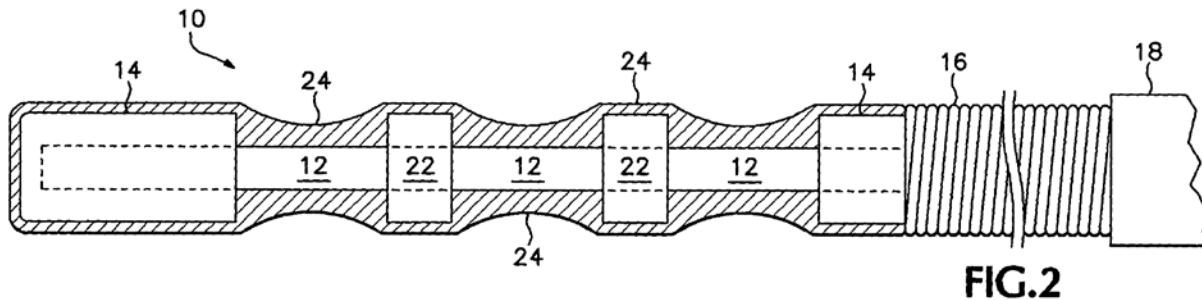
a structurally flexible core having an outer surface; and

a continuous layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core, wherein the electrochemically active metal prevents body fluid from contacting said core and has at least one sensing surface, wherein said layer of electrochemically active metal is at least partially surrounded by a membrane system comprising an enzyme.

25. Dependent claims 2-11 each recite one or more additional limitations, such as the use of tantalum for the core and the measurement of glucose as the analyte.

26. The '574 Patent discloses various embodiments of an indwelling analyte sensor.

For example, the following embodiment is shown in Figure 2:



27. In this embodiment, a wire with an electrochemically-active surface (12) (such as platinum) coated with a layer of dielectric material (14) (such as polyimide) comprises nubs which support an enzyme membrane system (24) permitting the sensor to detect an analyte (such as glucose).

28. Claim 1 of the '574 Patent recites:

1. An indwelling analyte sensor, comprising:

an electrochemically active surface;

at least two nubs of dielectric material extending outwardly from said electrochemically active surface and forming a cavity along said electrochemically active surface and between said at least two nubs; and

a membrane system comprising an enzyme layer, said enzyme layer surrounding said at least two nubs and said electrochemically active surface at least along said cavity.

29. Claims 2-8 each depend directly or indirectly from claim 1, and recite additional limitations relating to, for example, the structure and placement of the nubs, the shape of the active surface, and the structure of the membrane system.

30. The '574 Patent also contains independent claim 9 and claims 10-18, which depend, directly or indirectly, from claim 9.

31. The '574 Patent names as inventors Lawrence B. Jansen and W. Kenneth Ward, both of Portland, Oregon, and Ellen Anderson of Tualatin, Oregon.

DEXCOM'S INFRINGING ACTIVITIES

32. On information and belief, Dexcom makes, offers to sell, sells, uses, and imports its infringing G4 and G5 sensors and systems, and induces its customers to practice infringing

methods of using those sensors and systems, in the United States.

33. On information and belief, the infringing G4 and G5 systems each comprise an electronic receiver device (in the case of the G5 System, a user's own mobile device may serve this function), a wireless transmitter and a sensor wire assembly, wherein the sensor wire is designed to be inserted through a patient's skin and to remain inserted for a period of at least 24 hours or more.

34. On information and belief, once inserted through the skin, the G4 and G5 sensors produce an electrical current that is measured. On further information and belief, the glucose concentration in the user's body fluids is then measured based on the electrical current measurement.

35. On information and belief, the G4 and G5 systems include a glucose sensor comprising a structurally flexible tantalum core having an outer surface.

36. On information and belief, the glucose sensor of the G4 and G5 systems further comprise an electrochemically active platinum layer surrounding, covering, and in contact with the outer surface of the tantalum core, and the platinum layer is adapted to include at least one sensing surface.

37. On information and belief, the G4 and G5 systems include an indwelling analyte sensor comprising at least two nubs of dielectric material extending outwardly from the electrochemically active metal and forming a cavity along the electrochemically active metal between the nubs.

38. On information and belief, the indwelling analyte sensor of the G4 and G5 systems has a membrane system comprising an enzyme layer surrounding the nubs and the electrochemically active layer at least along the cavity.

39. On information and belief, the G4 and G5 systems possess other features and characteristics causing them to infringe multiple claims of each of the patents-in-suit, and have no substantial use that does not infringe the patents-in-suit.

CLAIMS FOR RELIEF

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,146,202

40. AgaMatrix restates and realleges each of the allegations of paragraphs 1-39 as if fully set forth herein.


41. On information and belief, Dexcom has been, and presently is, directly infringing at least claims 1-3, 5-6, and 9-11 of the '202 Patent, literally or under the doctrine of equivalents, by manufacturing, importing, using, selling and/or offering for sale glucose-monitoring systems and sensors, including but not limited to the G4 and G5 systems, and replacement sensors for those systems, in violation of 35 U.S.C. § 271(a).

42. On information and belief, Dexcom has been, and presently is, indirectly infringing at least claims 1-3, 5-6, and 9-11 of the '202 Patent by inducing others to use the G4 and G5 systems and sensors in violation of 35 U.S.C. § 271(b). On further information and belief, Dexcom has induced infringement of the '202 Patent with the specific intent that its customers directly infringe the '202 Patent as the result of its inducement, and/or that Dexcom has induced direct infringement with a willful blindness to the '202 Patent and the direct infringements of that patent resulting from its inducements.

43. On information and belief, Dexcom employees involved with Dexcom's CGM products acquired actual knowledge of the '202 Patent by reading the '202 Patent, including the claims of that patent, by no later than about 2008.


44. On further information and belief, Dexcom has induced and continues to induce infringement of the '202 Patent claims at least by selling its infringing G4 and G5 systems and replacement sensors to its customers who use those products, and by providing written and videographic instructions to its customers with the specific intent that they use the infringing products to practice the methods of at least claims 1-3, 5-6 and 9-11 of the '202 Patent.

45. For example, attached as exhibits D and E hereto are excerpts from written instructions that Dexcom provides customers with its G4 and G5 systems, respectively. These excerpts teach customers how to infringe the '202 Patent by “placing at least a portion of [the] sensor into [an] animal body” and “measuring any electric current produced by said sensor and forming a measurement of analyte concentration based on said current measurement.” Additionally, on its website at <http://dexcom.com/tutorials>, Dexcom provides its customers a number of video tutorials on the infringing use of its products. Reproduced below are representative images teaching Dexcom’s customers to follow steps of the '202 Patent:



Calibration Tips

- Make sure a glucose reading is displayed at the top of the Trend Graph—or a Blood Drop Symbol is displayed in the top right corner of the Trend Graph—before calibration



I Have Watched the Video

Dexcom G5 mobile

[Home](#)
[Back](#)
[Replay](#)
[Next](#)

46. On information and belief, Dexcom’s customers have directly infringed the '202 Patent claims by using the G4 and G5 systems in accordance with Dexcom’s written and videographic instructions. On further information and belief, the sole and intended use of the G4 and G5 systems and replacement sensors is in practicing the methods of the '202 Patent claims to measure glucose concentrations in the body fluids of Dexcom’s customers. (*See, e.g.*, paragraphs 33-36 above).

47. On information and belief, Dexcom has been, and presently is, contributorily infringing at least claims 1-3, 5-6, and 9-11 of the '202 Patent in violation of 35 U.S.C. § 271(c) by selling and offering to sell within the United States or importing into the United States a component of a patented manufacture constituting a material part of the invention, or an apparatus for use in practicing a patented process, knowing the same to be especially made or

adapted for use in an infringement and not a staple article of commerce suitable for substantial non-infringing uses. More specifically, on information and belief, Dexcom sells the infringing G4 and G5 systems and replacement sensors for those systems to its customers in the United States, knowing the sensors and systems to be especially made or adapted for use in practicing the methods of claims 1-3, 5-6, and 9-11 of the '202 Patent; knowing that said systems and sensors are not staple articles of commerce suitable for substantial non-infringing uses; and knowing that its customers are and have been directly infringing those patent claims by using the Dexcom products in the prescribed manner. (*See, e.g.*, paragraphs 33-36 above).

48. Dexcom is not licensed or otherwise authorized by AgaMatrix to manufacture, import, use, sell, offer for sale, or induce others to make, use, sell or offer for sale any glucose-monitoring system or sensor, use of which is covered by the '202 Patent and its conduct is, in every instance, without AgaMatrix's consent.

49. Dexcom will continue to manufacture, import, use, sell and offer for sale, and induce others to make, use, sell and/or offer for sale its products which are especially made for infringing uses unless enjoined by this Court.

50. Due to Dexcom's infringement of the '202 Patent, AgaMatrix is entitled to recover from Dexcom the damages it has sustained as a result of Dexcom's wrongful acts in an amount to be proven at trial, but in no event less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

51. Due to Dexcom's infringement of the '202 Patent, AgaMatrix has suffered, is suffering, and will continue to suffer irreparable injury and damage for which AgaMatrix has no adequate remedy at law. AgaMatrix is therefore entitled to a permanent injunction against Dexcom's further infringing conduct.

52. On information and belief, Dexcom has willfully infringed the '202 Patent with specific knowledge of that patent, and its claims, since at least as early as 2008, and with the specific intent that the patent be infringed. Notwithstanding its actual knowledge of the

'202 Patent and the claims of that patent, Dexcom proceeded to make and sell its infringing G4 and G5 systems to its customers, and to instruct its customers to use those products in a manner that directly infringes the claims of the '202 Patent. Indeed, on information and belief, Dexcom induced and contributed to its customers' direct infringements knowing that the products are especially made to be used in an infringing manner and that they have no substantial non-infringing use. (*See, e.g.* paragraphs 33-36 and 42-46 above). At a minimum, Dexcom acted despite an objectively high likelihood that its actions infringe the '202 Patent and, on information and belief, Dexcom acted with specific intent to cause direct infringement by its customers. As a result of Dexcom's willful infringements, AgaMatrix is entitled to recover trebled damages to be awarded in the sound discretion of the Court.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,187,433

53. AgaMatrix restates and realleges each of the allegations of paragraphs 1-52 as if fully set forth herein.

54. Dexcom has been, and presently is, infringing at least claims 1-3, 5-6, and 8-11 of the '433 Patent, literally or under the doctrine of equivalents, by manufacturing, importing, using, selling and/or offering for sale glucose sensors, including but not limited to the G4 and G5 systems and sensors that embody the patented invention disclosed in the '433 Patent, in violation of 35 U.S.C. § 271(a).

55. Dexcom is not licensed or otherwise authorized by AgaMatrix to manufacture, import, use, sell or offer for sale any glucose sensor covered by the '433 Patent and its conduct is, in every instance, without AgaMatrix's consent.

56. Dexcom will continue to manufacture, import, use, sell and offer for sale its infringing products unless enjoined by this Court.

57. Due to Dexcom's infringement of the '433 Patent, AgaMatrix is entitled to recover from Dexcom the damages it has sustained as a result of Dexcom's wrongful acts in an

amount to be proven at trial, but in no event less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

58. Due to Dexcom's infringement of the '433 Patent, AgaMatrix has suffered, is suffering, and will continue to suffer irreparable injury and damage for which AgaMatrix has no adequate remedy at law. AgaMatrix is therefore entitled to a permanent injunction against Dexcom's further infringing conduct.

COUNT III
INFRINGEMENT OF U.S. PATENT 7,529,574

59. AgaMatrix restates and realleges each of the allegations of paragraphs 1- 58 as if fully set forth herein.

60. Dexcom has been, and presently is, infringing at least claims 1, 4-6, 8-10, 15-17, and 19 of the '574 Patent, literally or under the doctrine of equivalents, by manufacturing, importing, using, selling and/or offering for sale glucose sensors, including but not limited to the G4 and G5 systems and replacement sensors, that embody the patented invention disclosed in the '574 Patent, in violation of 35 U.S.C. § 271(a).

61. Dexcom is not licensed or otherwise authorized by AgaMatrix to manufacture, import, use, sell or offer for sale any glucose sensor covered by the '574 Patent and its conduct is, in every instance, without AgaMatrix's consent.

62. Dexcom will continue to manufacture, import, use, sell and offer for sale its infringing products unless enjoined by this Court.

63. Due to Dexcom's infringement of the '574 Patent, AgaMatrix is entitled to recover from Dexcom the damages it has sustained as a result of Dexcom's wrongful acts in an amount to be proven at trial, but in no event less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

64. Due to Dexcom's infringement of the '574 Patent, AgaMatrix has suffered, is suffering, and will continue to suffer irreparable injury and damage for which AgaMatrix has no adequate remedy at law. AgaMatrix is therefore entitled to a permanent injunction against Dexcom's further infringing conduct.

PRAYER FOR RELIEF

WHEREFORE, AgaMatrix respectfully requests that the Court enter judgment in its favor against Defendant Dexcom, granting the following relief:

- A. A declaration that each of the AgaMatrix Patents is valid and enforceable;
- B. A judgment and declaration that Dexcom has infringed the AgaMatrix Patents literally and/or under the doctrine of equivalents, directly and/or indirectly;
- C. A grant of permanent injunction, pursuant to 35 U.S.C. § 283, enjoining Dexcom and its agents, servants, officers, directors, employees, affiliated entities and all persons acting in concert or privity with them, from infringing any of the AgaMatrix Patents;
- D. A judgment and order requiring Dexcom to pay AgaMatrix all damages caused by Dexcom's infringement of the AgaMatrix Patents, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court, pursuant to 35 U.S.C. § 284;
- E. Trebling of the damages award based on Dexcom's willful infringement of Agamatrix's '202 Patent pursuant to 35 U.S.C. § 284;
- F. A judgment and order requiring Dexcom to pay AgaMatrix supplemental damages for any continuing post-verdict infringement up until the entry of a final judgment, with an accounting, if needed;
- G. A determination that this action is an exceptional case pursuant to 35 U.S.C. § 285;
- H. An award of AgaMatrix's attorneys' fees, costs and expenses incurred in bringing and prosecuting this action, pursuant to 35 U.S.C. § 285; and

I. Such other and additional relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), AgaMatrix respectfully requests a trial by jury of all issues so triable.

Dated this 6th day of June, 2016.

Respectfully submitted,
SCHWABE, WILLIAMSON & WYATT, P.C.

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