IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

CERNER CORPORATION,)
	Plaintiff,))
v.)
VISICU, INC.,)
	Defendant.)

Case No. 04-1033-CV-W-GAF

<u>CERNER CORPORATION'S FOURTH AMENDED COMPLAINT AND REQUEST</u> <u>FOR DECLARATORY JUDGMENT AND REPLY TO VISICU, INC.'S FIRST</u> AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Cerner Corporation hereby files its Fourth Amended Complaint and Request for Declaratory Judgment and Reply to VISICU, Inc's First Amended Answer, Affirmative Defenses, and Counterclaims (Doc. 114), as follows:

THE PARTIES

1. Plaintiff Cerner Corporation ("Cerner") is a Delaware corporation having

its principal place of business at 2800 Rockcreek Parkway, North Kansas City, Missouri 64117.

2. Defendant VISICU, Inc. ("VISICU") is a Delaware corporation having its

principal place of business at 217 E. Redwood Street, Suite 1900, Baltimore, Maryland 21202.

JURISDICTION AND VENUE

3. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201

and 2202, the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, the Lanham Act, 15 U.S.C. § 1051, *et seq.*, and the common law of the State of Missouri. There exists an actual and justiciable controversy between Cerner and VISICU.

4. This Court has subject matter jurisdiction over this action under 28 U.S.C.§§ 1331, 1338, 1367, and 2201.

5. This Court has personal jurisdiction over VISICU, as VISICU has purposefully directed its activities to the State of Missouri and this district and has transacted business in the State of Missouri and this district by, *inter alia*, selling and/or offering to sell products and services within this district.

6. Venue in this judicial district is proper under 28 U.S.C. §§ 1391 and 1400.

THE '656 PATENT

7. United States Patent No. 6,804,656 ("the '656 Patent") issued on October 12, 2004. The '656 Patent is entitled "System and Method for Providing Continuous, Expert Network Critical Care Services From a Remote Location(s)." A copy of the '656 Patent is attached as Exhibit A.

8. The '656 Patent indicates on its face that Dr. Brian A. Rosenfeld and Dr. Michael Breslow are the alleged inventors of the '656 Patent and that VISICU is the alleged assignee of the '656 Patent. *See* Exhibit A.

9. VISICU has represented to Cerner and others that VISICU is the recipient of the '656 Patent, that it "has certain exclusive rights under this patent," and that "[b]y receiving a grant of letters patent, VISICU now owns exclusive rights for a system providing and supporting 24/7 remote critical care." *See* Exhibits B-G.

THE '708 PATENT

10. United States Patent No. 7,256,708 ("the '708 Patent") issued on August
14, 2007. The '708 Patent is entitled "Telecommunications Network for Remote Patient
Monitoring." A copy of the '708 Patent is attached as Exhibit K.

11. The '708 Patent indicates on its face that the '708 Patent issued from U.S. Patent Application No. 10/946,548, which was a continuation-in-part application of U.S. Patent Application No. 09/443,072, filed on November 18, 1999, now the '656 Patent. *See* Exhibit K.

12. The '708 Patent indicates on its face that Dr. Brian Rosenfeld and Dr. Michael Breslow are the alleged inventors of the '708 Patent and that VISICU is the alleged assignee of the '708 Patent. *See* Exhibit K.

CERNER

13. Cerner is a leading supplier of healthcare information technology.

14. Cerner was founded in 1979 and employs over 3,000 physicians, engineers, scientists, and other associates in Kansas City alone.

15. Cerner's stated mission is to provide innovative software solutions and services that connect the appropriate persons, knowledge, and resources at the appropriate time and location to achieve optimal health outcomes.

16. In fulfilling its mission, Cerner has successfully developed and maintained valuable business relationships with more than 1,500 clients worldwide.

17. Cerner currently sells and offers to sell solutions related to the delivery of care to patients in intensive care units. These solutions will soon be implemented and used by

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Cerner's clients. Cerner intends to continue to lawfully sell and offer to sell those noninfringing solutions.

18. Cerner's and VISICU's solutions and services directly compete in the marketplace.

BACKGROUND

19. Since October 12, 2004, the day the '656 Patent issued, VISICU has subjected Cerner and its officers, directors, clients, prospective clients, and others to: (1) unfounded allegations that they are infringing the '656 Patent; (2) threats and warnings that VISICU will aggressively pursue and initiate legal action against any and all alleged infringers of the '656 Patent, including Cerner; and (3) baseless assertions that Cerner's solutions will not reach the market as a result of VISICU's alleged patent rights.

20. Since the day the '656 Patent issued, VISICU also has engaged in an aggressive and systematic campaign of patent misuse, unfair competition, and tortious interference with Cerner's existing and prospective clients.

21. Cerner has filed this declaratory judgment action to defend itself and its clients from VISICU's baseless charges of infringement and to prevent VISICU from further interfering with the valuable relationships between Cerner and its existing and prospective clients.

22. Because Cerner's unique solutions clearly fall outside the scope of the '656 and '708 Patents, Cerner also seeks the Court's declaration that Cerner and its solutions do not infringe any claim of the '656 and '708 Patents, either literally or under the doctrine of equivalents.

23. Further, Cerner seeks the Court's declaration that the claims of the '656 and '708 Patents are invalid in light of numerous prior art systems, methods, patents, and publications withheld from and/or not considered by the United States Patent and Trademark Office.

24. Cerner also seeks the Court's declaration that the '656 and '708 Patents are unenforceable as a result of the acts, omissions, and inequitable conduct of Drs. Michael Breslow and Brian Rosenfeld – the alleged inventors of the '656 and '708 Patents and VISICU's founders – and/or those acting in concert with Drs. Breslow and Rosenfeld.

25. Finally, Cerner seeks the Court's entry of preliminary and permanent injunctions against VISICU and an award of Cerner's damages resulting from VISICU's patent misuse, unfair competition, tortious interference, and other wrongful and anticompetitive acts.

VISICU'S ALLEGATIONS, THREATS, AND WARNINGS

26. On October 12, 2004, counsel for VISICU sent a letter by certified mail to Neal L. Patterson, the Chairman of the Board and CEO of Cerner. *See* Exhibit B.

27. On October 15, 2004, counsel for VISICU also sent letters by certified mail to current and recent members of Cerner's Board of Directors, including The Honorable John C. Danforth, Dr. William B. Neaves, Michael E. Herman, Nancy-Ann DeParle, and Dr. Gerald Bisbee, Jr. *See* Exhibits C-G.

28. The letters to Cerner's CEO and its current and recent Directors first assert that VISICU has engaged in a "review of [Cerner's] product offering." Exhibits B-G. The letters then assert, *inter alia*, that VISICU "has certain exclusive rights" in the '656 Patent and that "[u]nder U.S. patent law, 35 U.S.C. § 271, a patent entitles its owner to stop any entity from making, using, importing, selling or offering for sale a product that embodies any of the claims in the patent." *Id*.

29. VISICU's letters to Cerner's CEO and Directors threaten that "anyone in the distribution chain, including the manufacturer, distributor, and user *will be liable for infringement, for non-VISICU licensed products made after the patent issue date.*" Exhibits B-G (emphasis added).

30. The '656 Patent issued on October 12, 2004. The solutions currently made, sold, and offered for sale by Cerner are *not* licensed by VISICU to Cerner. Accordingly, VISICU has explicitly and unequivocally asserted in its letters that Cerner, its distributors, and its clients are currently liable for infringement of the '656 Patent and that VISICU will stop Cerner, its distributors, and its clients from making, using, selling, or offering to sell Cerner products. *See* Exhibits B-G (stating that VISICU has reviewed Cerner's products, warning that "the manufacturer, distributor, and user will be liable for infringement for non-VISICU licensed products made after the patent issue date," and emphasizing that VISICU is entitled "to stop any entity from making, using, importing, selling or offering for sale a product" that infringes the '656 Patent).

31. VISICU's letters to Cerner's Chairman and current and former Directors also threaten that "any company officer, or other individual, who participates in the decision to

manufacture, market or distribute can be *personally liable for damages*." Exhibits B-G (emphasis added).

32. Finally, VISICU's letters to Cerner's Chairman and current and former Directors assert that, as a result of Cerner's allegedly infringing activities, VISICU will seek injunctive relief and that Cerner will be liable for "monetary damages for lost profits, price erosion, convoyed sales, market spoilage, increased costs, accelerated market entry of competitors, reasonable royalties and costs of patent enforcement." *Id*.

33. On October 12, 2004, the day the '656 Patent issued, counsel for VISICU also sent a letter by certified mail to Randy Stasik, President of Borgess Health Alliance ("Borgess"). See Exhibit H.

34. Borgess is a ministry of Ascension Health, the largest nonprofit health system in the United States.

35. Borgess, Ascension Health, and Cerner have enjoyed a successful and mutually beneficial business relationship.

36. VISICU's letter to Mr. Stasik of Borgess states, *inter alia*, that "VISICU understands that you have installed, are currently installing, or have contracted to install a remote critical care system manufactured by Cerner." Exhibit H. The letter to Mr. Stasik further states that "[b]y receiving a grant of letters patent, VISICU now owns exclusive rights for a system providing and supporting 24/7 remote critical care." *Id*.

37. VISICU's letter to Mr. Stasik asserts that "[b]y having exclusive patent rights, *only VISICU licensed products may be freely utilized for providing remote critical care.*" Exhibit H (emphasis added).

38. The letter to Mr. Stasik also threatens that VISICU "*intends to aggressively pursue infringers* that continue selling or utilizing infringing products." *Id.* (emphasis added). As a result of VISICU's letter, assertions, and threats, Borgess expressed to Cerner its serious concern that VISICU will initiate a patent infringement lawsuit and obtain an injunction against Borgess and/or Cerner in the event Borgess uses Cerner's noninfringing solutions and services. Cerner shares Borgess's concerns and apprehensions.

39. On October 12, 2004, VISICU's Chairman and CEO, Frank T. Sample, sent a letter to Karen Barker, Vice President and Chief Information Officer of LifeBridge Health. *See* Exhibit I.

40. LifeBridge Health and Cerner have enjoyed a successful and mutually beneficial business relationship for several years.

41. VISICU's letter to Ms. Barker states, *inter alia*, that VISICU "has just received a United States patent on our eICU solution for remote care of the critically ill" and that "[b]y receiving a grant of letters patent, VISICU now owns exclusive rights for a system providing and supporting 24/7 remote critical care and only VISICU licensed products may be utilized to provide this innovative care delivery model." *See* Exhibit I.

42. VISICU's letter to Ms. Barker warns LifeBridge Health to "carefully consider the pursuit of technology that allegedly claims similar offerings to that of VISICU's

eICU solution" and threatens that "[t]o protect its interests, VISICU actively polices the market and *intends to aggressively pursue infringers* that continue selling or utilizing infringing products." *See* Exhibit I (emphasis added).

43. VISICU has sent letters, e-mails, and other communications regarding the '656 Patent to other existing and prospective clients of Cerner.

44. In addition to the repeated written threats and warnings that VISICU will aggressively pursue infringers, VISICU, its employees, and/or its agents also have, on information and belief, orally advised Cerner's prospective clients that the '656 Patent covers Cerner's solutions and that VISICU will use the '656 Patent to prevent Cerner's solutions from ever reaching the market.

45. As a direct result of VISICU's false statements, misrepresentations, threats, and warnings, at least one prospective client of Cerner suspended discussions with Cerner regarding the purchase of Cerner's noninfringing solutions and services and expressed a reluctance to purchase Cerner solutions and services in the future.

46. On November 9, 2004, Mr. Sample sent a letter to Mr. Patterson. *See* Exhibit J. The letter from Mr. Sample was a "follow up" to the letter sent to Mr. Patterson from VISICU's attorney in which Mr. Patterson and others were threatened with personal liability for infringement of the '656 Patent. *See* Exhibits B and J.

47. VISICU's written and oral assertions, threats, and warnings made it clear that VISICU intended to resort to litigation by filing a patent infringement lawsuit against

Cerner, its officers, its directors, and/or its existing and prospective clients if Cerner continued its lawful sales and marketing activities relating to Cerner's noninfringing solutions and services.

48. VISICU's threats and warnings created on the part of Cerner a reasonable apprehension that VISICU would initiate a patent infringement suit against Cerner, its officers, its directors, and/or its current or prospective clients if Cerner continued its lawful marketing and sales activities. Such conduct by VISICU included, but was not limited to: (a) VISICU's written and oral assertions, warnings, and threats to Cerner, its officers, its directors, and its current and prospective clients; (b) VISICU's false, unfounded, and baseless allegations that Cerner, its officers, its directors, and/or its existing or prospective clients were and are infringing the '656 Patent; (c) VISICU's false, unfounded, and baseless assertions that VISICU's officers and directors were and are personally liable for infringement and damages; (d) VISICU's threats, warnings, and assertions that VISICU would aggressively pursue any and all alleged infringers of the '656 Patent; (e) VISICU's threats, warnings, and assertions that the '656 Patent covers the Cerner solutions; and (f) VISICU's threats, warnings, and assertions that it would use the '656 Patent to prevent the Cerner solutions from ever reaching the market. See, e.g., Exhibits B-G. Also, on December 17, 2007, VISICU filed a First Amended Answer, Affirmative Defenses, and Counterclaims (Doc. 114) in which VISICU alleged, inter alia, that Cerner has infringed and continues to infringe one or more claims of the '656 and '708 Patents.

49. Accordingly, there exists an actual and justiciable controversy between Cerner and VISICU under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*.

VISICU'S INEQUITABLE CONDUCT

50. The '656 and '708 Patents also are unenforceable as a result of the inequitable conduct of VISICU, its founders, its employees, its principals, and/or its representatives.

51. During prosecution of the '656 and '708 Patents, on information and belief, Dr. Michael Breslow, Dr. Brian Rosenfeld, VISICU, and/or others substantively involved in the preparation or prosecution of the '656 and '708 Patents engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO").

52. iMDsoft, Ltd. is an Israeli corporation founded in 1996 that develops and sells critical care systems. Upon information and belief, since its founding in 1996, iMDsoft has provided a clinical information system for intensive care units under the MetaVision name.

53. Upon information and belief, iMDsoft's clinical information system was deployed in the United States at Massachusetts General Hospital (Boston, Massachusetts) in 1996.

54. Prior to forming VISICU, Drs. Breslow and Rosenfeld worked at Johns Hopkins.

55. In 1997 and 1998, iMDsoft held meetings at Johns Hopkins regarding, at a minimum, the potential deployment of iMDsoft's clinical information system at Johns Hopkins.

56. Upon information and belief, Drs. Breslow and Rosenfeld attended at least one meeting at Johns Hopkins with iMDsoft during which iMDsoft shared information about

iMDsoft's MetaVision clinical information system, iMDsoft's deployment of the clinical information system at Massachusetts General Hospital, and the fact that iMDsoft had filed a patent application on the MetaVision system.

57. Upon information and belief, the information regarding the system and method developed and used by iMDsoft in Massachusetts General Hospital for providing critical care services to intensive care units was material information and not cumulative to information already before and/or considered by the PTO because, upon information and belief, the iMDsoft system was covered by iMDsoft's own patent application, Schoenberg et al. (WO 98/29790), which was used by the PTO in the first reexamination to reject all claims of the '656 Patent.

58. Drs. Breslow and Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents knowingly and intentionally withheld material information from the PTO including, but not limited to, information regarding the system and method developed and used by iMDsoft in Massachusetts General Hospital for providing critical care services to intensive care units.

59. On March 17, 2000, the alleged inventors of the '656 and '708 Patents, Drs. Breslow and Rosenfeld, conducted a telephone conference with Dr. M. Michael Shabot of Cedars-Sinai Medical Center in Los Angeles, California. During that conference, Drs. Rosenfeld, Breslow, and Shabot discussed a "rules engine" applied to multiple patient data elements stored in a database. The rules engine was developed and used by Dr. Shabot and Cedars-Sinai Medical Center in the early- and mid-1990s.

60. On March 22, 2000, Dr. Shabot sent Dr. Breslow a copy of a manuscript that Dr. Shabot submitted to the American Medical Informatics Association and subsequently

published as *Wireless Clincial Alerts for Physiologic, Laboratory and Medication Data*, Proceedings AMIA Annual Symposium: 7809–93, 2000. The manuscript provided the details of the rule set and system used by Dr. Shabot and Cedars-Sinai Medical Center in the 1990s. The manuscript also cited many related references that predated the priority date of the '656 Patent.

61. In April of 2000, Dr. Breslow and another VISICU representative met with Dr. Shabot at Cedars-Sinai Medical Center in Los Angeles, California. During that meeting, Dr. Breslow and Dr. Shabot discussed, among other things: (1) the rules engine developed and used by Dr. Shabot and Cedars-Sinai Medical Center in the early- to mid-1990s; and (2) a system and method developed and used by Cedars-Sinai Medical Center in Los Angeles, California for providing critical care services to multiple intensive care units and including the aforementioned rules engine.

62. The rule set and system used by Dr. Shabot and Cedars-Sinai Medical Center as well as Dr. Shabot's 2000 American Medical Informatics Association manuscript and incorporated references were highly material and not cumulative to the information already before and/or considered by the PTO.

63. Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents knowingly and intentionally withheld material information from the PTO including, but not limited to: (1) information regarding the system and method developed and used by Cedars-Sinai Medical Center in Los Angeles, California for providing critical care services to multiple intensive care units; (2) information regarding the rules engine developed and used by Dr. Shabot and Cedars-Sinai Medical Center as part of the aforementioned system; (3) U.S. Patent No. 5,942,986, entitled "System and Method for Automatic Critical Event Notification"; (4) the patents and publications cited in U.S. Patent No. 5,942,986 including, but not limited to, the publication entitled "Decision Support Systems in Critical Care" (M. Michael Shabot & Reed M. Gardner, eds., 1994); and (5) Dr. Shabot's 2000 American Medical Informatics Association manuscript and cited references.

64. In the spring of 2001, Drs. Breslow and/or Rosenfeld and other VISICU representatives engaged in a series of discussions with Cerner regarding Cerner's Millennium system, including the Cerner Discern solution, which included a multi-parameter rule set, and, on information and belief, the VISICU representatives were engaged in discussions with Cerner to investigate using at least portions of prior Cerner products instead of further developing aspects of Visicu's own system.

65. Indeed, on or about May 15-16, 2001, Dr. Breslow and other VISICU representatives attended a two-day meeting at Cerner, during which the functionality of the Cerner Millennium system and Discern solutions was discussed in detail.

66. During this meeting, Cerner presented a presentation to Dr. Breslow and other VISICU representatives that explained Cerner's products and cited an article, *A Computer Alert System to Prevent Injury from Adverse Drug Events*, published in the October 21, 1998 issue of the Journal of the American Medical Association (JAMA) and detailing the rules utilized in Discern. In addition, this same 1998 JAMA article was cited as a reference in Dr. Shabot's 2000 American Medical Informatics Association manuscript that he sent to Dr. Breslow.

67. Cerner's Discern solution and the 1998 JAMA article were material to the patentability of the '656 and '708 Patents.

68. Despite these meetings and Visicu's knowledge of Discern, Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents knowingly and intentionally withheld material information from the PTO including, but not limited to, Cerner's Discern solution and the 1998 JAMA article discussing Discern.

69. On or about June 23, 2000, VISICU's predecessor (IC-USA, Inc.) submitted a Section 510(k) notification of intent (the "510(k) Submission") to market the "ARGUS System – Continuous Expert Care Network" (the "ARGUS System") device to the United States Food and Drug Administration ("FDA"). *See* Exhibit L.

70. A 510(k) Submission is a premarket submission made to the FDA to demonstrate that a device to be marketed is at least as safe and effective (i.e., is "substantially equivalent") to a legally marketed device that is not subject to Premarket Approval (PMA) by the FDA. *See* <u>http://www.fda.gov/cdrh/devadvice/314.html#intro</u>. A 510(k) Submission submitter must compare their device to one or more similar legally marketed devices and must make and support their substantial equivalency claims. *See id*. For purposes of a 510(k) Submission, a device is "substantially equivalent" if, in comparison to a predicate device, the device has the same intended use and technological characteristics as the predicate device. *See id*.

71. The 510(k) Submission submitted to the FDA by VISICU's predecessor indicates that the ARGUS System was designed to support the delivery of clinical care to individual patients in intensive care units ("ICUs") and to provide care-givers with the ability to participate in patient management even when such care givers are not physically present in the hospital. *See* Exh. L at ¶ 18.4. The 510(k) Submission further indicates that the ARGUS System

allows a team of intensivists or physicians to monitor patients in an ICU network from a centralized, remote Telemedicine Center and is intended to provide patient information and surveillance of monitored patients at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated phone lines. *See id.* at \P 18.6. Moreover, the 510(k) Submission indicates that a "Decision Support System software program is also available." *See id.* at \P 18.7.

72. In the 510(k) Submission, VISICU's predecessor represented that Dr. Michael Breslow, an alleged inventor of the '656 and '708 Patents, was VISICU's "contact person" for purposes of processing VISICU's 510(k) Submission. *See* Exh. L. Upon information and belief, Dr. Michael Breslow was aware of the 510(k) Submission and its contents.

73. In the 510(k) Submission, VISICU's predecessor also represented that the ARGUS System was "substantially equivalent" to certain predicate devices, including the Hewlett-Packard (Agilent) Clinical Information System (CareVue/Device Link) and the VitalCom Networked Monitoring System. *See* Exh. L at ¶ 18.5. VISICU's predecessor also represented to the FDA that "the fundamental technical characteristics of the ARGUS System are similar to those of the predicate devices" and the "functionality and the indications for use for the ARGUS [System] are similar to the predicates." *See* Exh. L at ¶ 18.5.

74. Based upon the 510(k) Submission, the FDA itself determined that the ARGUS System was "substantially equivalent . . . to legally marketed predicate devices," including the Hewlett-Packard (Agilent) Clinical Information System (CareVue/Device Link)

and the VitalCom Networked Monitoring System. See Exh. L (October 27, 2000 letter from FDA to IC-USA, Inc.).

75. Despite representations to the FDA that the ARGUS System was "substantially equivalent" to predicate devices, Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents failed to submit to the PTO information regarding the 510(k) Submission or the predicate devices, including the Hewlitt-Packard (Agilent) Clinical Information System (CareVue/Device Link) and the VitalCom Networked Monitoring System.

76. As evidenced by the 510(k) Submission, and upon information and belief, information regarding the aforementioned predicate devices and 510(k) Submission became available and known to Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 and '708 Patents at least as early as June of 2000, during prosecution of the '656 Patent, more than four years before the '656 Patent issued, and more than seven years before the '708 Patent issued.

77. The information disclosed to the FDA but withheld from the PTO by Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents was highly material and not cumulative to the information already before and/or considered by the PTO.

78. On information and belief, the material information withheld by Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents was withheld knowingly and with the intent to deceive the PTO.

79. Additionally, in the 510(k) Submission, VISICU's predecessor represented that the technical characteristics of the ARGUS System include a "Decision Support System software program" that provides "diagnostic and therapeutic information to the physician." *See* Exh. L. VISICU's predecessor also represented that the "fundamental technical characteristics of the ARGUS System are similar to those of the predicate devices." *See* Exhibit L.

80. Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent engaged in inequitable conduct during prosecution of the '656 Patent, and such inequitable conduct relates to the claims of the '708 Patent.

81. Cerner is entitled to declaratory judgment that Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent engaged in inequitable conduct during prosecution of the '656 Patent and that, as a result, the '656 and '708 Patents are unenforceable.

82. Cerner is entitled to declaratory judgment that Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '708 Patent engaged in inequitable conduct during prosecution of the '708 Patent and that, as a result, the '708 Patent is unenforceable.

83. In addition to the prior art and material information withheld from the PTO, there exist one or more prior art systems, methods, patents, and publications that render the claims of the '656 and '708 Patents invalid, including Cerner's own systems, methods, and publications.

COUNT I – DECLARATION OF NONINFRINGEMENT OF THE '656 PATENT

84. Cerner restates and alleges, as though fully set forth herein, the allegations contained in paragraphs 1 through 83 of this Complaint.

85. Cerner has not infringed and is not infringing any claim of the '656 Patent, either literally or under the doctrine of equivalents.

86. Cerner has not contributed to infringement by others, or actively induced others to infringe, any claim of the '656 Patent.

87. Cerner is entitled to declaratory judgment of noninfringement in its favor.

COUNT II – DECLARATION OF INVALIDITY OF THE '656 PATENT

88. Cerner restates and alleges, as though fully set forth herein, the allegations contained in paragraphs 1 through 87 of this Complaint.

89. The claims of the '656 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

90. Cerner is entitled to declaratory judgment that the claims of the '656 Patent are invalid.

COUNT III – DECLARATION OF NONINFRINGEMENT OF THE '708 PATENT

91. Cerner restates and alleges, as though fully set forth herein, the allegations contained in paragraphs 1 through 90 of this Complaint.

92. Cerner has not infringed and is not infringing any claim of the '708 Patent, either literally or under the doctrine of equivalents.

93. Cerner has not contributed to infringement by others, or actively induced others to infringe, any claim of the '708 Patent.

94. Cerner is entitled to declaratory judgment of noninfringement in its favor.

COUNT IV – DECLARATION OF INVALIDITY OF THE '708 PATENT

95. Cerner restates and alleges, as though fully set forth herein, the allegations contained in paragraphs 1 through 94 of this Complaint.

96. The claims of the '708 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

97. Cerner is entitled to declaratory judgment that the claims of the '708 Patent are invalid.

<u>COUNT V – DECLARATION OF INEQUITABLE CONDUCT AND</u> <u>UNENFORCEABILITY OF THE '656 AND '708 PATENTS</u>

98. Cerner restates and alleges, as though fully set forth herein, the allegations contained in paragraphs 1 through 97 of this Complaint.

99. During prosecution of the '656 and '708 Patents, on information and belief, Dr. Michael Breslow, Dr. Brian Rosenfeld, VISICU, and/or others substantively involved in the preparation or prosecution of the '656 and '708 Patents engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO").

100. iMDsoft, Ltd. is an Israeli corporation founded in 1996 that develops and sells critical care systems. Upon information and belief, since its founding in 1996, iMDsoft has provided a clinical information system for intensive care units under the MetaVision name.

101. Upon information and belief, iMDsoft's clinical information system was deployed in the United States at Massachusetts General Hospital (Boston, Massachusetts) in 1996.

102. Prior to forming VISICU, Drs. Breslow and Rosenfeld worked at Johns Hopkins.

103. In 1997 and 1998, iMDsoft held meetings at Johns Hopkins regarding, at a minimum, the potential deployment of iMDsoft's clinical information system at Johns Hopkins.

104. Upon information and belief, Drs. Breslow and Rosenfeld attended at least one meeting at Johns Hopkins with iMDsoft during which iMDsoft shared information about iMDsoft's MetaVision clinical information system, iMDsoft's deployment of the clinical information system at Massachusetts General Hospital, and the fact that iMDsoft had filed a patent application on the MetaVision system.

105. Upon information and belief, the information regarding the system and method developed and used by iMDsoft in Massachusetts General Hospital for providing critical care services to intensive care units was material information and not cumulative to information already before and/or considered by the PTO because, upon information and belief, the iMDsoft system was covered by iMDsoft's own patent application, Schoenberg et al. (WO 98/29790), which was used by the PTO in the first reexamination to reject all claims of the '656 Patent.

106. Drs. Breslow and Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents knowingly and intentionally withheld material information from the PTO including, but not limited to information regarding the system and method developed and used by iMDsoft in Massachusetts General Hospital for providing critical care services to intensive care units.

107. The aforementioned information became available to Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent at least as early as January of 1999, prior to filing of the '656 Patent.

108. On March 17, 2000, the alleged inventors of the '656 Patent, Drs. Rosenfeld and Breslow, conducted a telephone conference with Dr. M. Michael Shabot of Cedars-Sinai Medical Center in Los Angeles, California. During that conference, Drs. Rosenfeld, Breslow, and Shabot discussed a rules engine applied to multiple patient data elements stored in a database. The rules engine was developed and used by Dr. Shabot and Cedars-Sinai Medical Center in the early- and mid-1990s as part of a system and method for providing critical care services to multiple intensive care units and including the aforementioned rules engine.

109. On March 22, 2000, Dr. Shabot sent Dr. Breslow a copy of a manuscript that Dr. Shabot submitted to the American Medical Informatics Association and subsequently published as *Wireless Clincial Alerts for Physiologic, Laboratory and Medication Data*, Proceedings AMIA Annual Symposium: 7809–93, 2000. The manuscript provided the details of the rule set and system used by Dr. Shabot and Cedars-Sinai Medical Center in the 1990s. The manuscript also cited many related references that predated the '656 Patent.

110. In April of 2000, Dr. Breslow and another VISICU representative met with Dr. Shabot at Cedars-Sinai Medical Center in Los Angeles, California. During that meeting, Dr. Breslow and Dr. Shabot discussed, among other things: (1) the aforementioned rules engine developed and used by Dr. Shabot and Cedars-Sinai Medical Center in the early- to mid-1990s; and (2) the system and method developed and used by Cedars-Sinai Medical Center in Los Angeles, California for providing critical care services to multiple intensive care units and including the aforementioned rules engine.

111. The rule set and system used by Dr. Shabot and Cedars-Sinai Medical Center as well as Dr. Shabot's 2000 American Medical Informatics Association manuscript and incorporated references were highly material and not cumulative to the information already before and/or considered by the PTO.

112. Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 Patent knowingly and intentionally withheld material information from the PTO including, but not limited to: (1) information regarding the aforementioned system and method developed and used by Cedars-Sinai Medical Center in Los Angeles, California for providing critical care services in the early- to mid-1990s; (2) information regarding the aforementioned rules engine developed and used by Dr. Shabot and Cedars-Sinai Medical Center; (3) U.S. Patent No. 5,942,986, entitled "System and Method for Automatic Critical Event Notification"; (4) the patents and publications cited in U.S. Patent No. 5,942,986 including, but not limited to, the publication entitled "Decision Support Systems in Critical Care" (M. Michael Shabot & Reed M. Gardner, eds., 1994); and (5) Dr. Shabot's 2000 American Medical Informatics Association manuscript and cited references.

113. The aforementioned information became available to Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of

the '656 Patent at least as early as April of 2000, during prosecution of the '656 Patent and more than four years before the '656 Patent issued.

114. In the spring of 2001, Drs. Breslow and Rosenfeld and other VISICU representatives engaged in a series of discussions with Cerner regarding Cerner's Millennium system, including the Discern solution, which included a multi-parameter rule set, and, on information and belief, the VISICU representatives were engaged in discussions with Cerner to investigate using at least portions of these prior Cerner products instead of developing aspects of Visicu's own system.

115. Indeed, on or about May 15-16, 2001, Dr. Breslow and other VISICU representatives attended a two-day meeting at Cerner, during which the functionality of the Cerner Millennium system and Discern solutions was discussed in detail.

116. During this conference, Cerner presented a presentation to Dr. Breslow and other VISICU representatives that explained Cerner's products and cited an article, *A Computer Alert System to Prevent Injury from Adverse Drug Events*, published in the October 21, 1998 issue of the Journal of the American Medical Association (JAMA) and detailing the rules utilized in Discern.

117. Cerner's Discern solution and the 1998 JAMA article were material to the patentability of the '656 and '708 Patents.

118. Despite these meetings and Visicu's knowledge of Discern, Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents knowingly and intentionally withheld material information from the PTO including, but not limited to, Cerner's Discern solution and the 1998 JAMA article discussing Discern.

119. The aforementioned information became available to Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent at least as early as May of 2001 or March of 2000, during prosecution of the '656 Patent and more than three years before the '656 Patent issued.

120. On or about June 23, 2000, VISICU's predecessor (IC-USA, Inc.) submitted a Section 510(k) notification of intent (the "510(k) Submission") to market the "ARGUS System – Continuous Expert Care Network" (the "ARGUS System") device to the United States Food and Drug Administration ("FDA"). *See* Exhibit L.

121. A 510(k) Submission is a premarket submission made to the FDA to demonstrate that a device to be marketed is at least as safe and effective (i.e., is "substantially equivalent") to a legally marketed device that is not subject to Premarket Approval (PMA) by the FDA. *See* <u>http://www.fda.gov/cdrh/devadvice/314.html#intro</u>. A 510(k) Submission submitter must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. *See id*. For purposes of a 510(k) Submission, a device is "substantially equivalent" if, in comparison to a predicate device, the device has the same intended use and technological characteristics as the predicate device. *See id*.

122. The 510(k) Submission submitted to the FDA by VISICU's predecessor indicates that the ARGUS System was designed to support the delivery of clinical care to individual patients in intensive care units ("ICUs") and to provide care-givers with the ability to participate in patient management even when such care-givers are not physically present in the

hospital. *See* Exh. L at \P 18.4. The 510(k) Submission further indicates that the ARGUS System allows a team of intensivists or physicians to monitor patients in an ICU network from a centralized, remote Telemedicine Center and is intended to provide patient information and surveillance of monitored patients at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated phone lines. *See id.* at \P 18.6. Moreover, the 510(k) Submission indicates that a "Decision Support System software program is also available." *See id.* at \P 18.7.

123. In the 510(k) Submission, VISICU's predecessor represented that Dr. Michael Breslow, an alleged inventor of the '656 and '708 Patents, was VISICU's "contact person" for purposes of processing VISICU's 510(k) Submission. *See* Exh. L. Upon information and belief, Dr. Michael Breslow was aware of the 510(k) Submission and its contents.

124. In the 510(k) Submission, VISICU's predecessor also represented that the ARGUS System was "substantially equivalent" to certain predicate devices, including the Hewlett-Packard (Agilent) Clinical Information System (CareVue/Device Link) and the VitalCom Networked Monitoring System. *See* Exh. L at ¶ 18.5. VISICU's predecessor also represented to the FDA that "the fundamental technical characteristics of the ARGUS System are similar to those of the 'predicate devices'" and the "functionality and the indications for use for the ARGUS [System] are similar to the predicates. *See* Exh. L at ¶ 18.5.

125. Based upon the 510(k) Submission, the FDA itself determined that the ARGUS System was "substantially equivalent . . . to legally marketed predicate devices," including the Hewlett-Packard (Agilent) Clinical Information System (CareVue/Device Link)

and the VitalCom Networked Monitoring System. See Exh. L (October 27, 2000 letter from FDA to IC-USA, Inc.).

126. Despite representations to the FDA that the ARGUS System was "substantially equivalent" to predicate devices, Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents failed to submit to the PTO information regarding the 510(k) Submission or the predicate devices, including the Hewlitt-Packard (Agilent) Clinical Information System (CareVue/Device Link) and the VitalCom Networked Monitoring System.

127. As evidenced by the 510(k) Submission, and upon information and belief, information regarding the aforementioned predicate devices and 510(k) Submission became available and known to Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 and '708 Patents at least as early as June of 2000, during prosecution of the '656 Patent, more than four years before the '656 Patent issued, and more than seven years before the '708 Patent issued.

128. The information disclosed to the FDA but withheld from the PTO by Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents was highly material and not cumulative to the information already before and/or considered by the PTO.

129. On information and belief, the material information withheld by Dr. Breslow, Dr. Rosenfeld, VISICU, and others substantively involved in the preparation and prosecution of the '656 and '708 Patents was withheld knowingly and with the intent to deceive the PTO.

130. Additionally, in the 510(k) Submission, VISICU's predecessor represented that the technical characteristics of the ARGUS System include a "Decision Support System software program" that provides "diagnostic and therapeutic information to the physician." *See* Exh. L. VISICU's predecessor also represented that the "fundamental technical characteristics of the ARGUS System are similar to those of the predicate devices." *See* Exhibit L.

131. The aforementioned information became available to Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent at least as early as October of 2000, during prosecution of the '656 Patent and four years before the '656 Patent issued.

132. Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent engaged in inequitable conduct during prosecution of the '656 Patent, and such inequitable conduct relates to the claims of the '708 Patent.

133. Cerner is entitled to declaratory judgment that Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '656 Patent engaged in inequitable conduct during prosecution of the '656 Patent and that, as a result, the '656 and '708 Patents are unenforceable.

134. Cerner is entitled to declaratory judgment that Dr. Breslow, Dr. Rosenfeld, VISICU, and/or others substantively involved in the preparation and prosecution of the '708 Patent engaged in inequitable conduct during prosecution of the '708 Patent and that, as a result, the '708 Patent is unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Cerner respectfully requests the following relief:

A. Entry of judgment declaring that Cerner has not directly infringed and is not directly infringing any claim of the '656 Patent, either literally or under the doctrine of equivalents.

B. Entry of judgment declaring that Cerner has not contributed to infringement by others, nor actively induced others to infringe, any claim of the '656 Patent.

C. Entry of judgment declaring that the claims of the '656 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

D. Entry of judgment declaring that the '656 Patent is unenforceable as a result of inequitable conduct.

E. Entry of judgment declaring that Cerner has not directly infringed and is not directly infringing any claim of the '708 Patent, either literally or under the doctrine of equivalents.

F. Entry of judgment declaring that Cerner has not contributed to infringement by others, nor actively induced others to infringe, any claim of the '708 Patent.

G. Entry of judgment declaring that the claims of the '708 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

H. Entry of judgment declaring that the '708 Patent is unenforceable as a result of inequitable conduct.

I. Entry of a preliminary and permanent injunction enjoining VISICU, its subsidiaries, affiliates, officers, directors, agents, employees, assignees, and attorneys, and those persons or entities in active concert or participation with them who receive actual notice thereof, from threatening or initiating infringement litigation under the '656 and/or '708 Patents against

any of Cerner's clients, prospective clients, customers, subsidiaries, affiliates, officers, directors, agents, or employees.

J. Entry of a preliminary and permanent injunction enjoining VISICU, its subsidiaries, affiliates, officers, directors, agents, employees, assignees, and attorneys, and those persons or entities in active concert or participation with them who receive actual notice thereof, from asserting, expressly or impliedly, that Cerner or any of its clients, prospective clients, customers, subsidiaries, affiliates, officers, directors, agents, or employees have infringed or are infringing the '656 and/or '708 Patents or any claim thereof.

K. A declaration that this is an exceptional case under 35 U.S.C. § 285.

L. An award to Cerner of its costs and reasonable attorney's fees incurred in this action.

M. Such other and further relief as the Court may deem just and proper.

CERNER CORPORATION'S REPLY TO VISICU, INC.'S COUNTERCLAIMS

Cerner hereby replies to VISICU's Counterclaims set forth in VISICU's First Amended Answer, Affirmative Defenses, and Counterclaims with Respect to Cerner's First Amended Complaint and Request for Declaratory Judgment (Doc. 114). Cerner answers the numbered paragraphs of VISICU's Counterclaims as follows:

THE PARTIES

- 1. Cerner admits the allegations of paragraph 1.
- 2. Cerner admits the allegations of paragraph 2.

JURISDICTION

3. Cerner admits that VISICU's counterclaims have been characterized by VISICU as arising under the Patent Laws of the United States, 35 U.S.C. §§ 1, et seq., the Lanham Act, 15 U.S.C. §§ 1051, et seq., and the statutory and common law of Missouri. Cerner admits that this Court has jurisdiction over meritorious causes of action arising under the Patent Laws of the United States and the Lanham Act. Cerner denies, however, that VISICU's Counterclaims set forth such meritorious causes of action.

4. Cerner admits so much of Paragraph 4 as alleges that this Court has subject matter jurisdiction over meritorious causes of action arising under the Patent Laws of the United States, 35 U.S.C. §§ 1, et seq., and the Lanham Act, 15 U.S.C. §§ 1051, et seq. Cerner further admits that, pursuant to 28 U.S.C. § 1367, this Court may choose to exercise supplemental jurisdiction over meritorious causes of action that are so related to meritorious claims arising under the Patent Laws of the United States, 35 U.S.C. § 1051, et seq., as to form a part of the same case or controversy. Cerner denies, however, that VISICU's Counterclaims sets forth such meritorious causes of action.

5. Cerner admits the allegations of paragraph 5.

6. Cerner admits so much of Paragraph 6 as alleges that Cerner has a principal place of business in this district and is doing business in this district. Cerner admits that, for the purposes of this action, Cerner is subject to personal jurisdiction in this district and that, therefore, Cerner resides in this district as defined by 35 U.S.C. § 1391(c). Accordingly, Cerner admits that venue is proper in this district.

GENERAL BACKGROUND AND ALLEGATIONS

7. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7, and therefore denies such allegations.

8. Cerner admits the allegations of paragraph 8.

9. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9, and therefore denies such allegations.

10. Cerner admits so much of Paragraph 10 as alleges that employees and officers of VISICU and Cerner have held discussions concerning the possibility of entering into a business arrangement. Cerner further admits that copies of two (2) documents that VISICU purports are non-disclosure agreements ("NDAs") executed by employees or officers of VISICU and Cerner are attached to VISICU's Answer and Counterclaims. Cerner further answers that such purported NDAs speak for themselves. Cerner admits that paragraph 1 of one document attached to VISICU's Counterclaims provides that "[VISICU] and [Cerner] wish to explore a business opportunity of mutual interest and in connection with this opportunity, [VISICU] may disclose to [Cerner] certain confidential technical and business information in the field of critical care management which [VISICU] desires [Cerner] to treat as confidential." Cerner further admits that paragraph 3 of one document attached to VISICU's Counterclaims is entitled "Nonuse and Non-disclosure" and provides in part that "[Cerner] agrees not to use any Confidential Information for any purpose except to evaluate and engage in discussions concerning a potential business relationship between [Cerner] and [VISICU]." Cerner is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10, and therefore denies such allegations.

11. Cerner admits so much of Paragraph 11 as alleges that Cerner and VISICU never reached a business arrangement. Cerner is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11, and therefore denies such allegations.

12. Cerner admits that United States Patent No. 6,804,656 ("the '656 patent") is entitled "SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)" and purports on its face to have issued on October 12, 2004. Cerner further admits that the '656 patent names on its face Brian A. Rosenfeld and Michael Breslow as the inventors and that the '656 patent names on its face VISICU, Inc. as the assignee. Cerner denies that the '656 patent was duly and legally issued. Cerner admits that the '656 patent and claims thereof are presumed valid under 35 U.S.C. § 282, but denies that the '656 patent and its claims are valid, enforceable, or "in effect." Cerner is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 12, and therefore denies such allegations.

- 13. Cerner admits the allegations of paragraph 13.
- 14. Cerner admits the allegations of paragraph 14.

15. Cerner admits that United States Patent No. 7,256,708 ("the '708 patent") is entitled "TELECOMMUNICATIONS NETWORK FOR REMOTE PATIENT MONITORING" and purports on its face to have issued on August 14, 2007. Cerner further admits that the '708 patent names on its face Brian A. Rosenfeld and Michael Breslow as the inventors and that the '708 patent names on its face VISICU, Inc. as the assignee. Cerner denies that the '708 patent was duly and legally issued. Cerner admits that the '708 patent and claims

thereof are presumed valid under 35 U.S.C. § 282, but denies that the '708 patent and its claims are valid, enforceable, or "in effect." Cerner is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 15, and therefore denies such allegations.

16. Cerner answers that the claims, specification, and "technical description" of the '656 and '708 patents speak for themselves, and further answers that the claims of the '656 and '708 patents have not been construed as a matter of law to determine their meaning and scope. Cerner is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 16, and therefore denies such allegations.

17. Cerner admits so much of Paragraph 17 as alleges that on or around October 12, 2004, VISICU sent to Cerner a certified letter stating that the '656 patent had issued and that a copy of the '656 patent was attached to the letter. Cerner further admits that it knew of the existence of the '656 patent on or shortly after October 12, 2004. Cerner denies the remaining allegations of paragraph 17.

18. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegation of Paragraph 18 that VISICU received a document prepared by Cerner directly from the Chief Medical Officer of a prospective business partner on or around August 22, 2005, accompanied by a request that VISICU respond to the statements in the document, and therefore denies this allegation. Cerner denies that such document, if any, included false or misleading statements concerning VISICU's remote care systems. Cerner denies the remaining allegations of Paragraph 18. 19. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegation of Paragraph 19 that VISICU received a Cerner-authored document from a prospective business partner on or around August 30, 2005, and therefore denies this allegation. Cerner denies that such document, if any, included false or misleading statements concerning VISICU's remote care systems. Cerner denies the remaining allegations of Paragraph 19.

20. Cerner admits that Borgess Health Alliance ("Borgess") has purchased products from Cerner. Cerner further admits that it became aware, at some point in time, that VISICU had an agreement with Borgess regarding the sale of certain products and/or services. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20 that Borgess had agreed to purchase a VISICU remote care system and that after being contacted by Cerner, Borgess breached a contract with VISICU, and therefore denies these allegations. Cerner denies the remaining allegations of Paragraph 20.

21. Cerner admits that it filed its original complaint against VISICU in this Court on November 12, 2004. Cerner is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 21, and therefore denies such allegations.

FIRST COUNTERCLAIM

ALLEGATIONS OF '656 PATENT INFRINGEMENT, 35 U.S.C. § 271(A)

22. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–21 above.

23. Cerner denies the allegations of paragraph 23.

24. Cerner denies the allegations of paragraph 24.

25. Cerner admits that on or around October 12, 2004, VISICU sent a letter by certified mail to Neil [sic] L. Patterson, Cerner's Chairman of the Board and CEO, notifying Cerner, and attaching a copy, of the '656 patent. Cerner admits that on or around October 15, 2005, VISICU sent letters by certified mail to current and recent members of Cerner's Board of Directors notifying them, and attaching a copy, of the '656 patent. Cerner further admits that it had knowledge of the '656 patent on or around October 12, 2004. Cerner denies the remaining allegations of paragraph 25.

- 26. Cerner denies the allegations of paragraph 26.
- 27. Cerner denies the allegations of paragraph 27.
- 28. Cerner denies the allegations of paragraph 28.
- 29. Cerner denies the allegations of paragraph 29.

SECOND COUNTERCLAIM

ALLEGATIONS OF INDUCEMENT OF '656 PATENT INFRINGEMENT, 35 U.S.C. § 271(B)

30. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–29 above.

- 31. Cerner denies the allegations of paragraph 31.
- 32. Cerner denies the allegations of paragraph 32.
- 33. Cerner denies the allegations of paragraph 33.

- 34. Cerner denies the allegations of paragraph 34.
- 35. Cerner denies the allegations of paragraph 35.
- 36. Cerner denies the allegations of paragraph 36.
- 37. Cerner denies the allegations of paragraph 37.
- 38. Cerner denies the allegations of paragraph 38.

THIRD COUNTERCLAIM

ALLEGATIONS OF CONTRIBUTORY INFRINGEMENT OF '656 PATENT, 35 U.S.C. § 271(C)

39. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–38 above.

- 40. Cerner denies the allegations of paragraph 40.
- 41. Cerner denies the allegations of paragraph 41.
- 42. Cerner denies the allegations of paragraph 42.
- 43. Cerner denies the allegations of paragraph 43.
- 44. Cerner denies the allegations of paragraph 44.
- 45. Cerner denies the allegations of paragraph 45.
- 46. Cerner denies the allegations of paragraph 46.
- 47. Cerner denies the allegations of paragraph 47.

FOURTH COUNTERCLAIM

ALLEGATIONS OF '708 PATENT INFRINGEMENT, 35 U.S.C. § 271(A)

48. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–47 above.

- 49. Cerner denies the allegations of paragraph 49.
- 50. Cerner denies the allegations of paragraph 50.
- 51. Cerner denies the allegations of paragraph 51.
- 52. Cerner denies the allegations of paragraph 52.
- 53. Cerner denies the allegations of paragraph 53.
- 54. Cerner denies the allegations of paragraph 54.

FIFTH COUNTERCLAIM

ALLEGATIONS OF CONTRIBUTORY INFRINGEMENT OF '708 PATENT, 35 U.S.C. § 271(C)

55. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–54 above.

- 56. Cerner denies the allegations of paragraph 56.
- 57. Cerner denies the allegations of paragraph 57.
- 58. Cerner denies the allegations of paragraph 58.
- 59. Cerner denies the allegations of paragraph 59.
- 60. Cerner denies the allegations of paragraph 60.

- 61. Cerner denies the allegations of paragraph 61.
- 62. Cerner denies the allegations of paragraph 62.
- 63. Cerner denies the allegations of paragraph 63.

SIXTH COUNTERCLAIM

ALLEGATIONS OF TRADE SECRET MISAPPROPRIATION UNDER

Mo. Rev. Stat. §§ 417.450 ET SEQ.

64. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–63 above.

65. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 65, and therefore denies such allegations.

66. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66, and therefore denies such allegations.

67. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 67, and therefore denies such allegations.

68. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 68, and therefore denies such allegations.

- 69. Cerner denies the allegations of paragraph 69.
- 70. Cerner denies the allegations of paragraph 70.
- 71. Cerner denies the allegations of paragraph 71.

72. Cerner denies the allegations of paragraph 72.

73. Cerner answers that the NDAs purportedly entered into by Cerner and VISICU speak for themselves. Cerner denies the remaining allegations of paragraph 73.

74. Cerner denies the allegations of paragraph 74.

SEVENTH COUNTERCLAIM

ALLEGATIONS OF BREACH OF CONTRACT

75. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–74 above.

76. Cerner admits that copies of two (2) documents that VISICU alleges are non-disclosure agreements ("NDAs") purportedly executed by employees or officers of VISICU and Cerner are attached to VISICU's Answer and Counterclaims. Cerner further answers that such purported NDAs speak for themselves. Cerner incorporates by reference its response to Paragraph 10 of VISICU's Counterclaims.

77. Cerner denies the allegations of paragraph 77.

78. Cerner denies the allegations of paragraph 78.

79. Cerner answers that the NDAs purportedly entered into by Cerner and VISICU speak for themselves. Cerner denies the remaining allegations of paragraph 79.

80. Cerner denies the allegations of paragraph 80.

EIGHTH COUNTERCLAIM

ALLEGATIONS OF UNFAIR COMPETITION UNDER THE LANHAM ACT, 15 U.S.C. § 1125(A)

81. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–80 above.

- 82. Cerner denies the allegations of paragraph 82.
- 83. Cerner denies the allegations of paragraph 83.
- 84. Cerner denies the allegations of paragraph 84.
- 85. Cerner denies the allegations of paragraph 85.
- 86. Cerner denies the allegations of paragraph 86.
- 87. Cerner denies the allegations of paragraph 87.

NINTH COUNTERCLAIM

ALLEGATIONS OF MISSOURI COMMON LAW—UNFAIR COMPETITION

88. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–87 above.

- 89. Cerner denies the allegations of paragraph 89.
- 90. Cerner denies the allegations of paragraph 90.
- 91. Cerner denies the allegations of paragraph 91.
- 92. Cerner denies the allegations of paragraph 92.
- 93. Cerner denies the allegations of paragraph 93.
- 94. Cerner denies the allegations of paragraph 94.

TENTH COUNTERCLAIM

ALLEGATIONS OF MISSOURI COMMON LAW—INJURIOUS FALSEHOOD

95. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–94 above.

- 96. Cerner denies the allegations of paragraph 96.
- 97. Cerner denies the allegations of paragraph 97.
- 98. Cerner denies the allegations of paragraph 98.
- 99. Cerner denies the allegations of paragraph 99.

ELEVENTH COUNTERCLAIM

ALLEGATIONS OF MISSOURI COMMON LAW—TORTIOUS INTERFERENCE WITH CONTRACT AND BUSINESS EXPECTANCY

100. Cerner repeats and incorporates each of the responses set forth in paragraphs 1–99 above.

101. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 101, and therefore denies such allegations.

102. Cerner admits only so much of Paragraph 102 as alleges that Cerner became aware, at some point in time, that VISICU had an agreement with Borgess regarding the sale of certain products and/or services. Cerner is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 102, and therefore denies such allegations.

- 103. Cerner denies the allegations of paragraph 103.
- 104. Cerner denies the allegations of paragraph 104.
- 105. Cerner denies the allegations of paragraph 105.
- 106. Cerner denies the allegations of paragraph 106.
- 107. Cerner denies the allegations of paragraph 107.
- 108. Cerner denies the allegations of paragraph 108.

VISICU'S PRAYER FOR RELIEF

Cerner denies that VISICU is entitled to any relief in connection with its Counterclaims including, without limitation, the relief requested in VISICU's Prayer for Relief:

A. Cerner denies that VISICU is entitled to the relief requested in paragraph A of VISICU'S Prayer for Relief.

B. Cerner denies that VISICU is entitled to the relief requested in paragraphB of VISICU'S Prayer for Relief..

C. Cerner denies that VISICU is entitled to the relief requested in paragraph C of VISICU'S Prayer for Relief.

D. Cerner denies that VISICU is entitled to the relief requested in either of paragraphs D, or any subparagraphs thereof, of VISICU'S Prayer for Relief.

E. Cerner denies that VISICU is entitled to the relief requested in paragraph E of VISICU'S Prayer for Relief. F. Cerner denies that VISICU is entitled to the relief requested in paragraph F of VISICU'S Prayer for Relief.

G. Cerner denies that VISICU is entitled to the relief requested in paragraph G of VISICU'S Prayer for Relief.

H. Cerner denies that VISICU is entitled to the relief requested in paragraphH of VISICU'S Prayer for Relief.

I. Cerner denies that VISICU is entitled to the relief requested in paragraph I of VISICU'S Prayer for Relief.

J. Cerner denies that VISICU is entitled to the relief requested in paragraph J of VISICU'S Prayer for Relief.

K. Cerner denies that VISICU is entitled to the relief requested in paragraph K of VISICU'S Prayer for Relief.

L. Cerner denies that VISICU is entitled to the relief requested in paragraph L of VISICU'S Prayer for Relief.

To the extent any allegation contained in VISICU's Counterclaims has not been specifically admitted herein, it is hereby denied. Cerner further denies any allegation that may be implied by or inferred from the headings contained in VISICU's Counterclaims.

AFFIRMATIVE DEFENSES TO VISICU'S COUNTERCLAIMS

FIRST AFFIRMATIVE DEFENSE

1. Cerner incorporates by reference Cerner's claims for declaratory relief contained in its Third Amended Complaint and Request for Declaratory Judgment, including, without limitation, the noninfringement, invalidity, and unenforceability of the '656 and '708 patents.

SECOND AFFIRMATIVE DEFENSE

2. VISICU's Counterclaims fail to state a claim upon which relief can be

granted.

THIRD AFFIRMATIVE DEFENSE

3. VISICU's Counterclaims may be barred in whole or in part by the doctrine

of unclean hands.

FOURTH AFFIRMATIVE DEFENSE

4. VISICU's Counterclaims may be barred in whole or in part by the doctrine

of laches.

FIFTH AFFIRMATIVE DEFENSE

5. VISICU's Counterclaims may be barred in whole or in part by the doctrines of estoppel and/or waiver.

SIXTH AFFIRMATIVE DEFENSE

6. VISICU's Counterclaims may be barred by applicable statutes of

limitation.

SEVENTH AFFIRMATIVE DEFENSE

7. VISICU's claims for punitive, treble, and/or enhanced damages are barred due to the lack of any recoverable compensatory damages by VISICU in connection with its counterclaims.

EIGHTH AFFIRMATIVE DEFENSE

8. VISICU's claims for punitive and/or exemplary damages are excessive, disproportionate, and violate Cerner's procedural and substantive rights under the due process clause of the Fourteenth Amendment to the United States Constitution and other applicable law.

NINTH AFFIRMATIVE DEFENSE

9. VISICU's Counterclaims may be barred in whole or part based on a contractual release in the Settlement Agreement between VISICU and Borgess Health Alliance dated December 6, 2007.

TENTH AFFIRMATIVE DEFENSE

10. VISICU's Counterclaims may be barred in whole or part based on the principles of free competition and legitimate business interest.

Cerner reserves the right to raise additional affirmative defenses as they become known through further investigations and discovery.

WHEREFORE, Cerner requests that judgment be entered against VISICU in connection with its Counterclaims, that judgment be entered in favor of Cerner in connection with its Third Amended Complaint and Request for Declaratory Judgment, that Cerner be awarded its costs, fees, and other expenses incurred in defending VISICU's Counterclaims, and for such other relief deemed appropriate by the Court. Dated: July 28, 2009

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By /s/ Bart A. Starr_

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ATTORNEYS FOR CERNER CORPORATION

CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2009 I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system which sent notification of such filing to counsel for VISICU, Inc.

<u>/s/ Bart A. Starr</u> Attorney for Cerner Corporation