



The company has grown into America's largest privately held national manufacturer and distributor of health care supplies and services.

4. Headquartered in Mundelein, IL since 1984, Medline manufactures and distributes more than 350,000 health care supplies and services across the continuum of care. Medline's customers include hospitals, nursing homes, surgery centers, physician offices, home care providers, home health agencies and retail outlets.

5. To serve its customers, Medline has 40 distribution centers in North America and 50 throughout the world. In addition, it has 17 manufacturing facilities worldwide.

6. In 2012, Forbes Magazine ranked Medline in the top 100 list of largest privately held companies in America. Medline employs more than 12,000 colleagues worldwide, with operations in more than 25 countries.

7. Medline leads the market in more than a dozen major medical product categories, including exam gloves, textiles, durable medical equipment, plastic patient utensils, skin care, disposable incontinence care, OR kits, protective apparel, gauze, packs and gowns, bathing systems, surgical trays and advanced wound care.

8. On information and belief, Defendant C.R. Bard, Inc. ("Bard") is a corporation organized under the laws of the State of New Jersey, and having a principal place of business at 730 Central Avenue, Murray Hill, New Jersey 07974.

### **JURISDICTION AND VENUE**

9. This is a civil action for patent infringement arising under the United States patent statutes, 35 U.S.C. § 1 et seq.

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Defendant Bard is subject to this Court's personal jurisdiction because it does and has done substantial business in this judicial district, including upon information and belief offering to sell in this judicial district the following products:

- SureStep™ Foley Tray System, Bardex® I.C. Complete Care® Infection Control Foley Catheter Tray with Bard® Hydrogel and Bacti-Guard® Silver Alloy Coating (the "Bardex® I System"), and
- Bardex® I.C. Complete Care® Infection Control Foley Catheter Tray with Bard® Hydrogel and Bacti-Guard® Silver Alloy Coating with StatLock® Stabilization Device (the "Bardex® II System")

12. In addition, upon information and belief, Bard directly and/or through its distribution network regularly places the Bardex® I System and the Bardex® II System in the stream of commerce with the knowledge and/or understanding that such products will be sold and used in Illinois and within this judicial district. Finally, Bard is subject to the general jurisdiction of this Court because it has regular and systematic contacts with this forum such that the exercise of jurisdiction over it would not offend traditional notions of fair play and substantial justice.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

#### **THE PATENTS-IN-SUIT**

14. A urinary catheter is a thin tube placed in the bladder to drain urine. The urine drains through a tube into a collection bag. If sterility of the catheter is compromised prior to insertion, it is possible for germs to travel along the catheter, which results in catheter-associated urinary tract infection (a.k.a. "CAUTI").

15. In 2009, Medline designed the industry's first one-layer proprietary Foley-catheter tray (the "Medline Tray") to reduce the risk of CAUTI. Medline further developed methods using catheter tray assemblies in a manner that reduces the risks of CAUTI.

16. In recognition of the innovative features of the Medline Tray, the U.S. Patent and Trademark Office awarded three patents to Medline. In addition, Medline has other patents pending that protect the Medline Tray and related methods.

17. On May 28, 2013, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,448,786 ("the '786 Patent", a copy of which is attached as Exhibit A hereto), entitled "Catheter Tray, Packaging System, Instruction Insert, and Associated Methods," to Medline in the names of inventors Jennifer E. Tomes and Sarah Zyburt.

18. On January 21, 2014, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,631,935 ("the '935 Patent", a copy of which is attached as Exhibit B hereto), entitled "Catheter Tray, Packaging System, and Associated Methods," to Medline in the names of inventors Jennifer E. Tomes, Deborah B. Adler, Jack E. Maze, Alberto Cc. Savage, Kenneth S. Chua, Earl D. Wilson and John H. Kutsch.

19. On March 25, 2014, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,678,190 ("the '190 Patent", a copy of which is attached as Exhibit C hereto), entitled "Catheter Tray, Packaging System, Instruction Insert, and Associated Methods," to Medline in the names of inventors Jennifer E. Tomes and Sarah Zyburt.

20. Medline is the owner by assignment of the entire right, title, and interest in each of the '786 Patent, the '935 Patent, and the '190 Patent (collectively, the "Medline Patents").

**COUNT I: INFRINGEMENT OF THE '786 PATENT**

21. With respect to the '786 Patent, at least as of the filing of this Complaint, Bard has and is now directly infringing, contributorily infringing and inducing others to infringe at least claim 2 of the '786 patent, either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling within the United States products, including but not limited to the Bardex® I System and the Bardex® II System.

**Notice of Infringement**

22. Bard, at least as of the filing of this Complaint, is aware of the '786 patent. Bard has been placed on notice of the '786 patent and of Medline's infringement claims at least as of the filing of this Complaint.

23. Upon information and belief, upon Bard's gaining knowledge of the '786 patent, it was, or has become, apparent to Bard that the use of the Bardex® I System and the Bardex® II System infringe the '786 patent.

**Direct Infringement of the '786 Patent**

24. With respect to direct infringement, upon information and belief, Bard itself is believed to have used the Bardex® I System and the Bardex® II System to practice the method claimed in the '786 patent.

**Indirect Infringement of the '786 Patent**

25. In addition to its liability for direct infringement of the '786 patent, Bard is also liable for indirectly infringing the '786 patent by inducing direct infringement in violation of 35 U.S.C. § 271(b) and contributing to direct infringement in violation of 35 U.S.C. § 271(c).

26. Upon information and belief, Bard has sold, offered for sale and/or marketed the Bardex® I System and the Bardex® II System to hospitals and other healthcare providers (collectively, “healthcare providers”).

27. Upon information and belief, the products sold, offered for sale and/or marketed to the healthcare providers, including the Bardex® I System and the Bardex® II System, are then used by the healthcare providers in a manner that directly infringe Medline’s patents, including the ‘786 Patent.

28. In connection with the use of the Bardex® I System and the Bardex® II System, Bard intends that healthcare providers place a layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.

29. Bard provides “Directions for Use” with the Bardex® I System. An exemplary copy of the “Directions for Use” for the Bardex® I System is attached as Exhibit D hereto.

30. The “Directions for Use” provided with the Bardex® I System include an instruction manual with a healthcare services portion and a patient portion detachably coupled thereto.

31. Bard also provides “Directions for Use” with the Bardex® II System. An exemplary copy of the “Directions for Use” for the Bardex® II System is attached as Exhibit E hereto.

32. The “Directions for Use” provided with the Bardex® II System include an instruction manual with a healthcare services portion and a patient portion detachably coupled thereto.

33. The “Directions of Use” provide a step-by-step explanation of the procedure for properly using the Bardex® I System and the Bardex® II System. The “Directions for Use” are

intended to direct healthcare providers in the proper technique for using the Bardex® I System and the Bardex® II System. By providing the “Directions of Use,” Bard specifically intends and encourages healthcare providers to directly infringe the ‘786 Patent.

34. In addition, Bard provides an instructional video (the “Bardex® I Instructional Video”) available on its website at:

<http://www.bardmedical.com/products/urological-drainage/foley-trays-and-kits/surestep-foley-tray/>

35. The Bardex® I Instructional Video provides a step-by-step demonstration of an aseptic technique to catheterize male and female patients using the Bardex® I System. By providing the Bardex® I Instructional Video, Bard specifically intends and encourages healthcare providers to directly infringe the ‘786 Patent.

36. The Bardex® I Instructional Video represents that, according to data published by the Department of Health and Human Services, CAUTIs are associated with increased morbidity, mortality, length of stay, antibiotic use and costs of more than \$500 million annually. In addition, according to the Bardex® I Instructional Video, aseptic procedures and proper catheter maintenance play an important role in helping mitigate the risk of CAUTI.

37. The Bardex® I System and the Bardex® II System each constitute a catheter package assembly.

38. Bard supplies the Bardex® I System and the Bardex® II System for use by healthcare providers in the provision of care for patients.

39. Upon information and belief, Bard has continued to engage in activities constituting inducement of infringement, notwithstanding its knowledge (or willful blindness thereto) that the activities it was inducing would result in infringement of the ‘786 patent. Bard’s

inducement to infringe is evident at least from the Bardex® I Instructional Video and the “Directions for Use” it provides with its Bardex® I System and the Bardex® II System.

40. The “Directions for Use” provided with the Bardex® I and Bardex® II Systems each instruct healthcare providers to place a layer of wrap beneath the patient.

41. The Bardex® I Instructional Video likewise instructs healthcare providers that a layer of wrap should be placed beneath the patient.

42. Bard’s intention in providing the Bardex® I Instructional Video and “Directions for Use” as part of the Bardex® I and Bardex® II Systems is so that, when in use, an area beneath the patient will be transformed from a non-sterile field to a sterile field.

43. Upon information and belief, the healthcare providers, in accordance with Bard’s instructions provided on the Bardex® I Instructional Video and in the “Directions for Use,” have catheterized at least one patient within the United States using the Bardex® I System.

44. Upon information and belief, the healthcare providers, in accordance with Bard’s instructions provided in the “Directions of Use,” have catheterized at least one patient within the United States using the Bardex® II System.

45. Bard sells and offers for sale the Bardex® I System and the Bardex® II System within the United States.

46. The Bardex® I System and the Bardex® II System constitute a material part of the invention claimed in the ‘786 patent.

47. At least as of the filing of this Complaint, Bard knows that the Bardex® I System and the Bardex® II System are especially made for use in an infringement of Medline’s patents, including the ‘786 patent.

48. The Bardex® I System and the Bardex® II System are not staple articles or commodities of commerce.

49. The Bardex® I System and the Bardex® II System have no substantial uses except for use in conjunction with the methods claimed in the Medline Patents, including the '786 patent.

50. Medline has been irreparably harmed by Bard's infringement of the '786 patent. Moreover, Bard's infringement and inducement of others to infringe the '786 patent has threatened the value of the '786 patent because Bard's conduct results in Medline's loss of its lawful patent rights to exclude others from making, using, offering to sell, selling and/or importing the patented inventions.

51. Bard will derive a competitive advantage from using Medline's patented technology without paying compensation for such use. Accordingly, unless and until Bard's continued acts of infringement are enjoined, Medline will suffer further irreparable harm for which there is no adequate remedy at law.

## **COUNT II: INFRINGEMENT OF THE '935 PATENT**

### **Direct Infringement of the '935 Patent**

52. With respect to the '935 Patent, Bard has been and is directly infringing, either literally or under the doctrine of equivalents, at least claim 21 of the '935 Patent pursuant to 35 U.S.C. § 271(a) by making, using, offering to sell, selling, within the United States, and/or importing into the United States, infringing products, including but not limited to the Bardex® I System.

53. Medline has been irreparably harmed by Bard's infringement of the '935 patent. Moreover, Bard's unauthorized, infringing use of Medline's patented catheter tray has threatened

the value of the '935 patent because Bard's conduct results in Medline's loss of its lawful patent rights to exclude others from making, using, offering to sell, selling and/or importing the patented inventions.

54. Bard will derive a competitive advantage from using Medline's patented technology without paying compensation for such use. Accordingly, unless and until Bard's continued acts of infringement are enjoined, Medline will suffer further irreparable harm for which there is no adequate remedy at law.

**COUNT III: INFRINGEMENT OF THE '190 PATENT**

55. With respect to the '190 Patent, at least as of the filing of this Complaint, Bard has and is now directly infringing, contributorily infringing and inducing others to infringe at least claim 15 of the '190 patent, either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling within the United States products, including but not limited to the Bardex® I System. Bard is on notice of the '190 patent and of Medline's charge of infringement of the '190 patent at least as of the date of this Complaint.

**Notice of Infringement**

56. Bard, at least as of the filing of this Complaint, is aware of the '190 patent. Bard has been placed on notice of the '190 patent and of Medline's infringement claims at least as of the filing of this Complaint.

57. Upon information and belief, upon Bard's gaining knowledge of the '190 patent, it was, or became, apparent to Bard that its Bardex® I System infringes the '190 patent.

### **Direct Infringement of the '190 Patent**

58. With respect to direct infringement, upon information and belief and as evidenced at least by the Bardex® I Instructional Video, Bard itself is believed to have used the Bardex® I System to practice the method claimed in the '190 patent.

### **Indirect Infringement of the '190 Patent**

59. In addition to its liability for direct infringement of the '190 Patent, Bard is also liable for indirectly infringing the '190 by inducing direct infringement in violation of 35 U.S.C. § 271(b) and contributing to direct infringement in violation of 35 U.S.C. § 271(c).

60. Upon information and belief, Bard has sold, offered for sale and/or marketed the Bardex® I System to healthcare providers who in turn use the Bardex® I System in the provision of medical services to patients in the hospital setting, the use of which directly infringes Medline's patents, including the '190 patent.

61. Upon information and belief, Bard has continued to engage in activities constituting inducement of infringement, notwithstanding its knowledge (or willful blindness thereto) that the activities it was inducing would result in the direct infringement of the '190 patent. Bard's inducement to infringe is evident at least from the Bardex® I Instructional Video and the "Directions for Use" it provides with its Bardex® I System.

62. For example, the Bardex® I Instructional Video and the "Directions of Use" for the Bardex® I instruct healthcare providers to pass at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment, thereby passing the catheter assembly through the lubricating jelly.

63. In addition, the catheter tray itself for the Bardex® I System provides indicia instructing healthcare providers to dispense lubricating jelly into the first compartment of the tray.

64. In connection with healthcare providers' use of the Bardex® I System, as evidenced by the Bardex® I Instructional Video and "Directions of Use," Bard intends, and in fact instructs and specifically encourages, that healthcare providers perform each step of the method recited in at least claim 15 of the '190 Patent, including:

- unsealing the sealed bag;
- unfolding the one or more layers of wrap to create a sterile field about the tray;
- removing at least one syringe from a first compartment;
- injecting lubricating jelly from the syringe into the first compartment of the tray; and
- passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in the first barrier separating the first compartment from the second compartment, thereby lubricating the catheter assembly.

65. The Bardex® I System includes components within the catheter packaging assembly that constitutes a material part of the invention claimed in the '190 patent.

66. At least as of the filing of this Complaint, Bard knows that the Bardex® I System is especially made for use such that it would infringe Medline's patents, including the '190 Patent.

67. The Bardex® I System is not a staple article or commodity of commerce.

68. The Bardex® I System has no substantial uses except for use in conjunction with Medline's patents, including the '190 patent.

69. Medline has been irreparably harmed by Bard's infringement of the '190 patent. Moreover, Bard's unauthorized, infringing use of Medline's patented catheter tray has threatened the value of the '190 patent because Bard's conduct results in Medline's loss of its lawful patent rights to exclude others from making, using, offering to sell, selling and/or importing the patented inventions.

70. Bard will derive a competitive advantage from using Medline's patented technology without paying compensation for such use. Accordingly, unless and until Bard's continued acts of infringement are enjoined, Medline will suffer further irreparable harm for which there is no adequate remedy at law.

**REQUEST FOR RELIEF**

WHEREFORE, Medline respectfully requests the following relief:

- A. A judgment holding Bard liable for infringement of the '786 Patent, the '935 Patent and the '190 Patent;
- B. A permanent injunction against Bard, its officers, agents, servants, employees, attorneys, parent and subsidiary corporations, assigns and successors in interest, and those persons in active concert or participation with them, enjoining them from continued acts of infringement of the '786 Patent, the '935 Patent and the '190 Patent;
- C. Damages to compensate Medline for injuries resulting from Bard's infringement of the '786 Patent, the '935 Patent and the '190 Patent, together with pre-judgment and post-judgment interest;
- D. A judgment holding this Action an exceptional case, and an award to Medline for its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and
- E. Such other relief as the Court deems just and equitable.

Dated: May 16, 2014

Respectfully submitted,

/s/ Allen E. Hoover

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