IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BAXTER INTERNATIONAL, INC., Plaintiff, v. BECTON, DICKINSON AND COMPANY, Defendant.	No. 1:17-cv-07576 Judge Joan H. Lefkow Mag. Judge Heather K. McShain (Jury Trial Demanded)

THIRD AMENDED COMPLAINT

Baxter International, Inc. ("Baxter") brings this Third Amended Complaint against Becton, Dickinson and Company ("BD") and alleges as follows:

Nature of Action

1. This action, brought under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, seeks relief arising out of BD's infringement of U.S. Patent Nos. 5,989,237 (the "'237 Patent"), 6,159,192 (the "'192 Patent"), and 6,852,103 (the "'103 Patent") (collectively, the "Patents-in-Suit"). Baxter owns the Patents-in-Suit.

2. True and correct copies of the '237 Patent, '192 Patent and '103 Patent are attached hereto as Exhibits A, B and C, respectively.

Parties

3. Baxter is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Baxter Parkway, Deerfield, Illinois, 60015.

4. Upon information and belief, BD is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey, 07417.

Jurisdiction and Venue

5. This Court has subject matter jurisdiction over the asserted claims pursuant to 28 U.S.C. §§ 1331 and 1338, and 35 U.S.C. § 281.

6. This Court has personal jurisdiction over BD, who, upon information and belief, has regular and established places of business in the State of Illinois and in this District, including at 75 North Fairway Drive, Vernon Hills, Illinois, and/or regularly engage in extensive business transactions and solicitations in the State of Illinois and within this District, have contracted to supply goods and services within this District, and/or have committed acts of patent infringement in this District by making, using, selling, offering to sell, and/or importing, directly and/or through its agents or distributors, products that infringe one or more of the claims of one or more of the Patents-in-Suit. BD is also registered to do business in Illinois and has appointed an agent for service of process that is located at 208 South LaSalle Street, Suite 814, Chicago, Illinois.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and/or 1400, because, upon information and belief, a substantial part of the events or omissions giving rise to the claims occurred in this District and/or because BD has committed acts of infringement in this District and has a regular and established place of business in this District, including at 75 North Fairway Drive, Vernon Hills, Illinois.

Factual Allegations

8. From its headquarters in Deerfield, Illinois, Baxter is a recognized innovator and leader in the research, development, manufacture and distribution of medical products in the United States and around the world. Baxter manufactures, among other things, products used in the delivery of fluids and drugs to patients across the continuum of care.

9. BD manufactures, uses, sells, offers for sale, and/or imports a closed system drug transfer device, known as the BD PhaSeal™ System (hereinafter referred to as the "Accused Product"), in the United States.

10. As described by BD, the Accused Product "is an airtight, leakproof system that utilizes a membrane-to-membrane technology. It mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor aerosols and spills." (*See* http://www.bd.com/en-us/offerings/capabilities/hazardous-drug-safety/bd-phaseal-system (visited October 10, 2017).)

11. The Accused Product consists of various components that include a combination of at least: (1) a product that BD calls "Protector™," which it describes as a "drug vial adapter for closed reconstitution and pressure equalization;" and (2) a product that BD calls "Injector™," which it describes as an "encapsulated cannula that attaches permanently to a disposable syringe or IV tubing." Moreover, the Accused Product drives the sale of additional administration and application products.

12. The components of the Accused Product, alone or in combination with other components, constitute a connector device for establishing fluid communication between a first container and a second container. The Accused Product is comprised of (1) a first sleeve member having a first end and a second end and a sidewall defining a chamber, the first sleeve member having at the first end a first attaching member adapted to attach to the first container; (2) a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and is movable axially with respect thereto from an inactivated position to an activated position; (3) a second attaching member on the second end of the second

sleeve and adapted to attach the second sleeve member to the second container; (4) a piercing member positioned in the chamber and projecting from one of the first and second sleeve members for providing a fluid flow path from the first container to the second container; (5) means positioned on the first sleeve member for preventing the first sleeve member from becoming disassociated from the second sleeve member and which comprises a stop at the first end of the first sleeve member; and (6) means for visually indicating that the connector is in the activated position comprising a color indicator, the other sleeve member has a second color, wherein only one color is visible when the connector is in the activated position.

The ’237 Patent

13. Baxter is the sole owner of, and has the sole right to sue upon, the ’237 Patent, which is entitled “Sliding Reconstitution Device With Seal” and was duly and legally issued on November 23, 1999. The ’237 Patent is assigned to Baxter.

14. As identified in the Abstract of the ’237 Patent:

> The present invention provides a connector device for establishing fluid communication between a first container and a second container. The device has a first sleeve member having a first end and a second end and a sidewall defining a chamber, the first sleeve member having at the first end a first attaching member adapted to attach to the first container. The device further has a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and is movable axially with respect thereto from an inactivated position to an activated position. A second attaching member is positioned on the second end of the second sleeve and adapted to attach the second sleeve member to the second container. A piercing member positioned in the chamber and projecting from one of the first and second sleeve members is provided for establishing a fluid flow path from the first container to the second container. The piercing member is hermetically sealed.

15. Baxter has not licensed or authorized BD to practice the ’237 Patent, and BD has no right or authority to license others to practice the ’237 Patent.

16. BD has known of, or reasonably should have known of, the '237 Patent since at least 2011.

The '192 Patent

17. Baxter is the sole owner of, and has the sole right to sue upon, the '192 Patent, which is entitled "Sliding Reconstitution Device With Seal" and was duly and legally issued on December 12, 2000. The '192 Patent was assigned to Baxter.

18. As identified in the Abstract of the '192 Patent:

> The present invention provides a method of connecting a reconstitution device to a drug container having a top and a closure. The method includes the steps of:
>
> providing a reconstitution device having first and second ends, the second end having a receiving chamber dimensioned to receive the top of the container for fixedly attaching the device to the container, the device having a central channel housing a piercing member, the device further having first and second sleeve members capable of sliding axially with respect to one another from an inactivated position where the piercing member is outside the receiving chamber to an activated position where a portion of the piercing member is positioned inside the receiving chamber; and
>
> inserting the top of the container into the receiving chamber of the device and fixedly attaching the container therein when the device is in the inactivated position.

19. Baxter has not licensed or authorized BD to practice the '192 Patent, and BD has no right or authority to license others to practice the '192 Patent.

20. BD has known of the '192 Patent since at least 2000.

The '103 Patent

21. Baxter is the sole owner of, and has the sole right to sue upon, the '103 Patent, which is entitled "Sliding Reconstitution Device With Seal" and was duly and legally issued on February 8, 2005. The '103 Patent was assigned to Baxter.

22. As identified in the Abstract of the '103 Patent:

> The present invention provides a connector device for establishing fluid communication between a first container and a second container. The device has a first sleeve member having a first and a second end, the first sleeve member having at the first end a first attaching member adapted to attach to the first container. The device further has a second sleeve member having a first end and a second end, the second sleeve member being associated with the first sleeve member and movable with respect thereto from an inactivated position to an activated position, the second sleeve member having at the second end a second attaching member adapted to attach the second sleeve member to the second container. First and second piercing members project from one of the first and second sleeve members for providing a fluid flow path from the first container to the second container, and the first and second piercing members are independently hermetically sealed.

23. Baxter has not licensed or authorized BD to practice the '103 Patent, and BD has no right or authority to license others to practice the '103 Patent.

24. BD has known of the '103 Patent since at least 2013.

Count I
(*Infringement of the '237 Patent*)

25. Baxter repeats and reasserts all of the foregoing allegations as if they were stated in full herein.

26. As set forth in Baxter's Final Infringement Contentions in this case, which are incorporated herein by reference, BD has directly infringed one or more claims of the '237 Patent, within the meaning of 35 U.S.C. § 271(a) and either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and or importing the Accused Product in the United States, without license or authorization by Baxter.

27. In particular, BD has directly infringed at least Claims 1 and 15 of the '237 Patent by the manufacture, use, sale, offer for sale, and/or importation of the Accused Product in the United States. Specific components of the Accused Product that are known to be involved in the infringement of these Claims include (1) a product that BD calls "Protector™," which it describes

as a "drug vial adapter for closed reconstitution and pressure equalization;" and (2) a product that BD calls "Injector™," which it describes as an "encapsulated cannula that attaches permanently to a disposable syringe or IV tubing."

28. BD's infringement of the '237 Patent has caused Baxter damages in an amount to be proven at trial.

29. As also set forth in Baxter's Final Infringement Contentions in this case, which are incorporated herein by reference, BD has engaged in egregious misconduct and has willfully infringed the '237 Patent.

30. BD knew, or reasonably should have known, of the '237 Patent since at least 2011 when it acquired Carmel Pharma.

31. Since at least 2011, BD knew, or reasonably should have known, that the Accused Product infringes one or more valid claims in the '237 Patent, and despite this knowledge BD continued to make, use, offer for sale, import and/or sell the Accused Product despite an objectively high likelihood that its actions constituted infringement of the '237 Patent. BD knew and/or should have known that its actions would cause direct and indirect infringement of the '237 Patent.

32. BD's infringement of the '237 Patent has caused Baxter damages, and entitle Baxter to recover, among other things, treble damages, attorney's fees, and costs.

Count II
(*Infringement of the '192 Patent*)

33. Baxter repeats and reasserts all of the foregoing allegations as if they were stated in full herein.

34. As set forth in Baxter's Final Infringement Contentions in this case, which are incorporated herein by reference, BD has directly infringed one or more claims of the '192 Patent,

within the meaning of 35 U.S.C. § 271(a) and either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and or importing the Accused Product in the United States, without license or authorization by Baxter.

35. In particular, BD has directly infringed at least Claims 1 and 2 of the '192 Patent by the manufacture, use, sale, offer for sale, and/or importation of the Accused Product in the United States. Specific components of the Accused Product that are known to be involved in the infringement of these Claims include (1) a product that BD calls "Protector™," which it describes as a "drug vial adapter for closed reconstitution and pressure equalization;" and (2) a product that BD calls "Injector™," which it describes as an "encapsulated cannula that attaches permanently to a disposable syringe or IV tubing."

36. BD's infringement has been direct even though one or more of the steps of the methods claimed in the '192 Patent may have been performed by BD's customers and/or users of the Accused Product. BD provides to its customers and/or users of the Accused Product, the Accused Product, which is a reconstitution device having (1) first and second ends, the second end having a receiving chamber dimensioned to receive the top of a container for fixedly attaching the device to the container; (2) a central channel housing a piercing member; and (3) first and second sleeve members capable of sliding axially with respect to one another from an inactivated position where the piercing member is outside the receiving chamber to an activated position where a portion of the piercing member is positioned inside the receiving chamber. BD's customers and/or users of the Accused Product insert, either manually or through some other means, the top of a container into the receiving chamber of the device and fixedly attaching the container therein when the device is in the inactivated position.

37. Under similar circumstances, direct infringement has been found to occur where "a third party hoping to obtain access to certain benefits can only do so if it performs certain steps identify by the defendant, and does so under the terms prescribed by the defendant." *Travel Sentry, Inc. v. Tropp*, Appeal Nos. 2016-2386, 2016-2387, 2016-2714, 2017-1025, 2017 U.S. App. LEXIS 25548, *25 (Fed. Cir. Dec. 19, 2017). Here, the benefits BD's customers and/or users of the Accused Product hope to obtain include the ability to properly and safely mix, reconstitute and/or dilute a drug prior to administering it to a patient. This is of critical importance to BD's customers and/or users of the Accused Product because the product is designed to mix, reconstitute and/or dilute hazardous drugs, which, if done improperly could cause serious harm to both BD's customers and/or users of the Accused Product, and their patients. Indeed, this benefit is expressly marketed by BD on its website, on which BD asserts that the Accused Product will "[p]rotect healthcare workers from exposure to hazardous drugs with a closed system drug transfer device." (*See* https://www.bd.com/en-us/offerings/capabilities/hazardous-drug-safety/bd-phaseal-system (visited January 3, 2018).) BD goes on to say on its website that the Accused Product "is a closed system drug transfer device (CSTD) that has been demonstrated to prevent exposure to hazardous drugs, from drug preparation to IV administration. It is an airtight, leakproof system that utilizes a membrane-to-membrane technology. It mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor aerosols and spills. It also prevents microbial ingress within an ISO Class V environment with proper aseptic technique." (*See id.*) Yet, this benefit can only be obtained by BD's customers and/or users of the Accused Product if they follow BD's explicit, step-by-step instructions for use. Further, upon information and belief, BD warrants the Accused

Product. Upon further information and belief, BD's customers and/or users of the Accused Product purchase the Accused Product hoping to obtain the benefit BD's warranty, which, upon information and belief, BD will not honor if the Accused Product was not used in accordance with BD's instructions for use.

38. As such, under the applicable legal standard, BD directs and/or controls the performance of such customers and/or users because, among other things, it conditions receipt of the benefits associated with the claimed methods of the '192 Patent to its customers and/or users upon their performance of one or more steps of those methods, and establishes the manner of that performance by, among other things, providing detailed instructions concerning the use of the Accused Product, which, if they are not followed, will deprive BD's customers and/or users of the benefits they hope to obtain from the product and/or practicing the claimed methods of the '192 Patent. In other words, BD's customers and/or users of the Accused Product only receive something of value from BD when they follow BD's instructions, including the steps in the method claimed in the '192 Patent.

39. Alternatively, BD has indirectly infringed, and continues to indirectly infringe, one or more claims of the '192 Patent, within the meaning of 35 U.S.C. § 271(c), by making, using, selling, offering for sale, and or importing the Accused Product in the United States, knowing that the Accused Product is especially made or especially adapted for use in direct infringement of the '192 Patent by BD's customers and/or users of the Accused Product, and knowing that the Accused Product is not a staple article or commodity of commerce suitable for non-infringing use and it constitutes a material part of the methods claimed in the '192 Patent.

40. Upon information and belief, BD's customers and/or users of the Accused Product directly infringe at least Claims 1 and 2 of the '192 Patent by their use of the Accused Product in

the United States. More specifically, BD's customers and/or users of the Accused Product (1) provide the Accused Product, which is a reconstitution device having (a) first and second ends, the second end having a receiving chamber dimensioned to receive the top of a container for fixedly attaching the device to the container; (b) a central channel housing a piercing member; and (c) first and second sleeve members capable of sliding axially with respect to one another from an inactivated position where the piercing member is outside the receiving chamber to an activated position where a portion of the piercing member is positioned inside the receiving chamber; and (2) insert, either manually or through some other means, the top of a container into the receiving chamber of the device and fixedly attaching the container therein when the device is in the inactivated position.

41. BD's infringement of the '192 Patent has caused Baxter damages in an amount to be proven at trial.

42. As also set forth in Baxter's Final Infringement Contentions in this case, which are incorporated herein by reference, BD has engaged in egregious misconduct and has willfully infringed the '192 Patent.

43. BD knew of the '192 Patent since at least 2000.

44. Since at least 2011, BD knew, or reasonably should have known, that the Accused Product infringes one or more valid claims in the '192 Patent, and despite this knowledge BD continued to make, use, offer for sale, import and/or sell the Accused Product despite an objectively high likelihood that its actions constituted infringement of the '192 Patent. BD knew and/or should have known that its actions would cause direct and indirect infringement of the '192 Patent.

45. BD's infringement has caused Baxter damages, and entitle Baxter to recover, among other things, treble damages, attorney's fees, and costs.

Count III[1]
(*Infringement of the '103 Patent*)

46. Baxter repeats and reasserts all of the foregoing allegations as if they were stated in full herein.

47. As set forth in Baxter's Final Infringement Contentions in this case, which are incorporated herein by reference, BD has directly infringed one or more claims of the '103 Patent, within the meaning of 35 U.S.C. § 271(a) and either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and or importing the Accused Product in the United States, without license or authorization by Baxter.

48. In particular, BD has directly infringed at least Claims 1 and 11 of the '103 Patent by the manufacture, use, sale, offer for sale, and/or importation of the Accused Product in the United States. Specific components of the Accused Product that are known to be involved in the infringement of these Claims include (1) a product that BD calls "Protector™," which it describes as a "drug vial adapter for closed reconstitution and pressure equalization;" and (2) a product that BD calls "Injector™," which it describes as an "encapsulated cannula that attaches permanently to a disposable syringe or IV tubing." Additional claims may be infringed.

49. As also set forth in Baxter's Final Infringement Contentions in this case, which are incorporated herein by reference, BD has engaged in egregious misconduct and has willfully infringed the '103 Patent.

50. BD knew of the '103 Patent since at least 2013.

[1] In view of the Court's Orders at Docket Nos. 275 and 310, Count III is included in this Third Amended Complaint so as not to waive any rights on appeal.

51. Since at least 2013, BD knew, or reasonably should have known, that the Accused Product infringes one or more valid claims in the '103 Patent, and despite this knowledge BD continued to make, use, offer for sale, import and/or sell the Accused Product despite an objectively high likelihood that its actions constituted infringement of the '103 Patent. BD knew and/or should have known that its actions would cause direct and indirect infringement of the '103 Patent.

52. BD's infringement has caused Baxter damages, and entitle Baxter to recover, among other things, treble damages, attorney's fees, and costs.

Request for Relief

WHEREFORE, Baxter urges the Court to grant the following relief:

A. Entry of judgment that BD has infringed one or more claims of the '237 Patent, '192 Patent, and the '103 Patent;

B. An award of compensatory damages for Baxter as a result of infringement, as provided in 35 U.S.C. § 284, the extent of which will be determined at trial, but in no event less than a reasonable royalty, together with interest and costs;

C. A determination that BD's acts of infringement of one or more claims of the '237 Patent, the '192 Patent, and/or the '103 Patent was willful along with an award of enhanced damages of up to three times the amount of actual damages pursuant to 35 U.S.C. § 284;

D. A determination that, pursuant to 35 U.S.C. § 285, this is an exceptional case and that Baxter be awarded its reasonable attorney's fees;

E. An award of interest on any judgment rendered in this action;

F. An award of Baxter's costs in this action; and

G. Such other and further relief as is just and proper.

Jury Demand

Baxter demands a trial by jury on all issues so triable.

Dated: June 8, 2020

Respectfully submitted,

BAXTER INTERNATIONAL, INC.,

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CERTIFICATE OF SERVICE

I, John E. Bucheit, certify, as counsel for plaintiff Baxter International, Inc., that on this 8th day of June 2020, a true and correct copy of Baxter International, Inc.'s Third Amended Complaint was served upon counsel via email to the addresses listed below, in accordance with the Federal Rules of Civil Procedure:

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