

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ROCHE DIABETES CARE, INC.,

Plaintiff,

v.

VALERITAS, INC. and VALERITAS
HOLDINGS, INC.,

Defendants.

C. A. No. _____

JURY TRIAL DEMANDED

**ROCHE DIABETES CARE, INC.’S COMPLAINT FOR PATENT INFRINGEMENT
AGAINST VALERITAS, INC. AND VALERITAS HOLDINGS, INC.**

Plaintiff Roche Diabetes Care, Inc. (“Roche”) files this Complaint for Patent Infringement against Defendants Valeritas, Inc. and Valeritas Holdings, Inc. (collectively, “Valeritas”) and alleges as follows:

NATURE OF THE ACTION

1. Roche is a pioneer, innovating in diabetes technology and services for more than 40 years to help people with diabetes live their lives as active and unrestricted as possible. Roche is a global leader in diabetes management, with more than 5,000 employees in over 150 markets worldwide working every day to support people with diabetes and those at risk for diabetes, caregivers and healthcare providers to manage diabetes. Under the brand Accu-Chek® and in collaboration with partners, Roche creates value by providing integrated diabetes management solutions to monitor glucose levels, deliver insulin, and track relevant data points for successful glucose management. The Accu-Chek® brand encompasses blood glucose meters, insulin delivery systems, lancing devices, digital health solutions as well as coaching and education—contributing to improved outcomes. Accu-Chek® brand products are number one in

blood glucose monitoring systems worldwide, helping people in over 100 countries around the globe.

2. This is an action for infringement of Roche's United States Patent No. 6,736,795 ("the '795 Patent") relating to devices for administering an injectable product.

3. On April 20, 2018, Roche sent a letter to Valeritas offering a license for the '795 Patent.

4. Instead, Valeritas continued willfully using Roche's patented technology without a license, including Valeritas's manufacture, importing, use, offers for sale, and sales of a product marketed as V-Go® ("V-Go" or "Accused Product").

5. Because of Valeritas's refusal and continued infringement, Roche was forced to bring this action to protect its intellectual property, including recovering damages for Valeritas's unlicensed use of Roche patented technology in the Accused Product and stopping Valeritas from infringing the '795 Patent.

THE PARTIES

6. Plaintiff Roche Diabetes Care, Inc. is a Delaware corporation, with a principal place of business at 9115 Hague Road, Indianapolis, Indiana 46250. Roche Diabetes Care, Inc. is a subsidiary of Roche Diagnostics Corp. and Roche Diagnostics Operations, Inc. Roche Diabetes Care, Inc.'s ultimate parent, Roche Holding Ltd., is a publicly traded company.

7. On information and belief, Defendant Valeritas Holdings, Inc. is a company organized under the laws of Delaware, having a principal place of business at 750 Route 202 South, Suite 600, Bridgewater, New Jersey 08807.

8. On information and belief, Defendant Valeritas, Inc., a wholly owned subsidiary of Valeritas Holdings, Inc., is organized under the laws of Delaware, having a principal place of business at 750 Route 202 South, Suite 600, Bridgewater, New Jersey 08807.

9. On information and belief, Valeritas is in the business of selling diabetes related medical technology throughout the United States, including in the District of Delaware.

JURISDICTION AND VENUE

10. This action for patent infringement arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*, including § 271. This Court has subject matter jurisdiction over the action pursuant to 28 U.S.C. §§ 1331 and 1338.

11. This Court has personal jurisdiction over Valeritas, Inc. and Valeritas Holdings, Inc. because Valeritas, Inc. and Valeritas Holdings, Inc. are organized under the laws of the State of Delaware. Each of the Valeritas Defendants have committed the acts of infringement complained of by Roche in this District.

12. Venue is proper in this District under 28 U.S.C. § 1400(b) because, among other reasons, Delaware is the judicial district in which Valeritas, Inc. and Valeritas Holdings, Inc. are incorporated.

FACTUAL BACKGROUND

The '795 Patent

13. The United States Patent and Trademark Office duly and properly issued the '795 Patent, entitled "Device for Administering an Injectable Product," on May 18, 2004. The '795 Patent names Peter Michel as the inventor. A true and correct copy of the '795 Patent is attached as Exhibit A to this Complaint.

14. The '795 Patent was duly assigned to Roche, which is the assignee of all right, title, and interest in and to the '795 Patent and possesses the exclusive right of recovery for past, present, and future infringement. The '795 Patent is valid and enforceable.

15. The '795 Patent relates generally to a device for administering an injectable product. As the '795 Patent notes, the patented injection devices generally include a casing that accommodates a container with the product to be injected, a means for delivering the product out of the container, a drive means, and a transmission link or coupling means. The patented devices can be designed so that the working stroke of the delivering means is greater than the working stroke of the drive means. The patent devices can also be designed so that the drive piston's area is larger than the driven piston's area.

16. Without the patented technology, other injection devices – like injection syringes or pens – have a piston that pushes the injectable product via drive springs or user muscle power. Such devices have the disadvantage that the drive force or energy applied by a user or spring is subject to changes throughout the course of release, resulting in an undesirable variable delivery rate.

17. The '795 Patent claims a device for administering an injectable product, where the injectable product, for example insulin, is evenly delivered in the course of an injection or infusion—an improvement over other injection devices.

18. Claim 1 of the '795 Patent recites:

1. A device for administering an injectable product, comprising:
 - a) a casing;
 - b) a container for the product accommodated by said casing;
 - c) a delivering means for delivering product out of said container;
 - d) a drive means; and
 - e) a transmission link via which said drive means drives said delivering means, said transmission link comprising a fluid space for an incompressible fluid and a pressure reducing means, wherein said fluid

space can be impinged on a drive side by pressure from said drive means and said pressure reducing means reduces a fluid pressure generated by said drive means toward a driven side of said fluid space.

19. Dependent from claim 1, claim 2 further specifies “a working stroke of said drive means is transmitted in said fluid space into a working stroke of said delivering means which is greater than the working stroke of said drive means.” Also dependent from claim 1, claim 4 of the '795 Patent claims the “device as set forth in claim 1, wherein said drive side of said fluid space is formed by a piston area of a drive piston which is larger than a piston area of a driven piston which forms the driven side of said fluid space.”

Valeritas’s Infringing Activities and Products

20. On information and belief, the Valeritas Defendants are in the business of developing, testing, manufacturing, importing, selling, offering to sell, and/or distributing insulin delivery devices, including the Accused Product, in this District and elsewhere in the United States, without the consent or authorization of Roche.

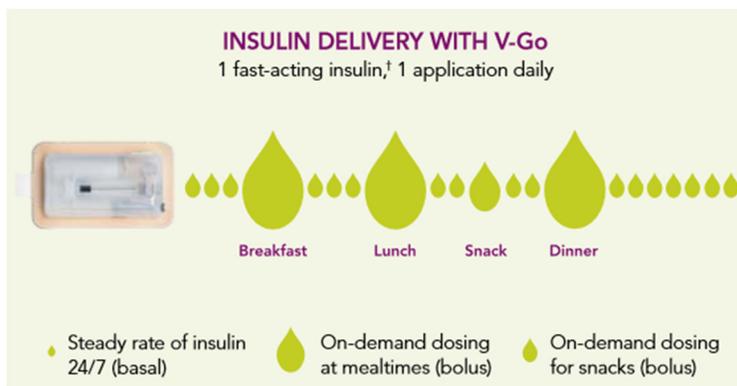
21. On information and belief, Valeritas has induced others to make, use, sell, offer to sell, and/or import the Accused Product in the United States, including in this District, individually and in concert.

22. On information, belief, and publicly available information, the Accused Product is a disposable insulin delivery device, “indicated for continuous subcutaneous infusion of insulin over 24 hours and on-demand bolus dosing” for adult patients requiring insulin. *See* Valeritas’s 2017 SEC Form 10-K Annual Report (available at https://www.sec.gov/Archives/edgar/data/1619250/000119312517056731/d334340ds1a.htm#toc334340_22).

23. Valeritas markets the structure, operation, and use of the Accused Product to the public. By way of example, Valeritas provides instructions to the public on the structure,

function, use and purchasing of the Accused Product on its website, including marketing materials, sales materials, purchasing information, videos, catalogues, specification sheets, user instructions, and guides. As an additional example, Valeritas provides instructions to the public on the structure, function, and use of the Accused Product in the product packaging, including user instructions. Example instructions and other materials can be found at <https://www.go-vgo.com/>, including the customer care and other portions, and the V-Go YouTube Channel at https://www.youtube.com/channel/UCHc_QTRAJqreHm35vAkBaYA.

24. By way of example, on its website, Valeritas markets the use of the Accused product for insulin delivery.



COUNT 1:

(Infringement under 35 U.S.C. § 271 of the '795 Patent)

25. Roche re-alleges and incorporates by reference Paragraphs 1 through 24 above, as if fully set forth herein.

26. Based on at least Roche's notice, Valeritas's infringement of the '795 Patent identified below occurred with knowledge of Roche's patent rights.

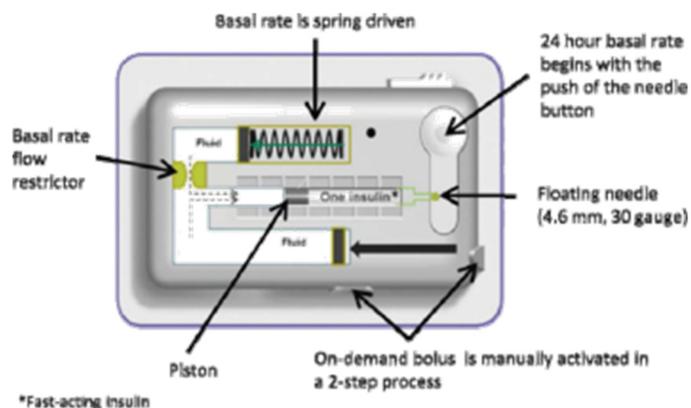
27. Each of the Valeritas Defendants directly infringe one or more claims of the '795 Patent, either literally or under the doctrine of equivalents, including at least claims 2 and 4.

Non-limiting examples of such infringement are provided below, based on the limited information currently available to Roche.

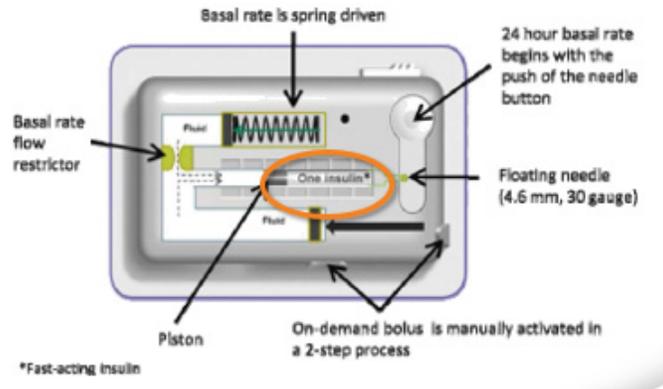
28. On information and belief, each of the Valeritas Defendants had actual knowledge of the '795 Patent since at least April 20, 2018. Specifically, on April 20, 2018, Roche sent a letter inviting Valeritas to engage in discussions regarding an opportunity to license the '795 Patent.

29. Despite knowledge of the '795 Patent, each of the Valeritas Defendants have been and actively continue to directly infringe the '795 Patent through manufacture, import, use, offer for sale, and/or sale of the Accused Product.

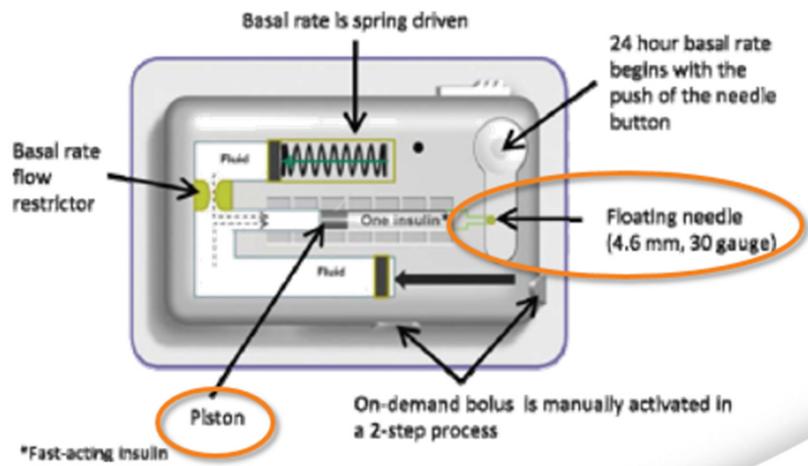
30. On information and belief, Valeritas uses Roche's patent features in its Accused Product in violation of Roche's patent rights. For example, the Accused Product is a device for administering an injectable product, namely insulin, which includes a casing (see schematic below).



31. The Accused Product incorporates a container for the insulin (indicated in circled orange, below). The Accused Product also incorporates a viscous fluid that, after passing through the Accused Product's flow restrictor, couples with and moves a piston in a container that contains active drug (i.e., insulin), as demonstrated in the below schematic.

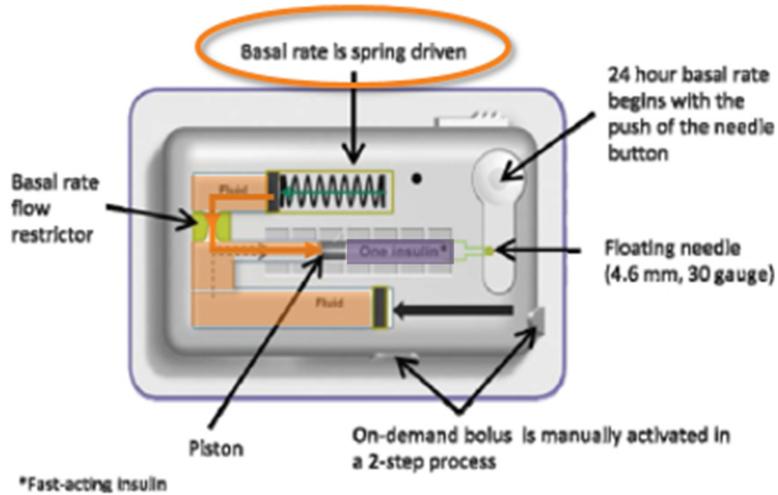


32. The Accused Product has a means for delivering insulin out of the insulin container. The Accused Product incorporates a viscous fluid that continually pushes a piston, dispensing insulin at the prescribed preset basal rate through a needle into the patient’s subcutaneous tissue, as highlighted in the below schematic.

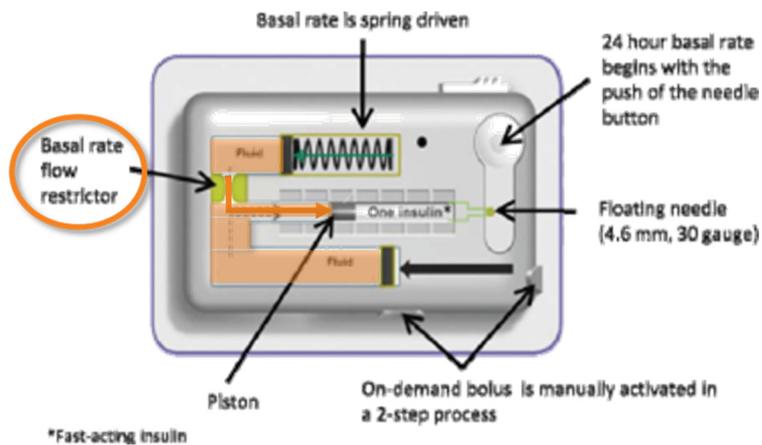


33. The Accused Product also incorporates a drive means and a transmission link via which the drive means drives the delivering means, whereby the transmission link includes a fluid space for an incompressible fluid. Once activated, the Accused Product’s system places a viscous fluid under pressure with a spring (indicated in circled orange, below). The viscous fluid is separately compartmentalized and therefore designed not to encounter the insulin, as

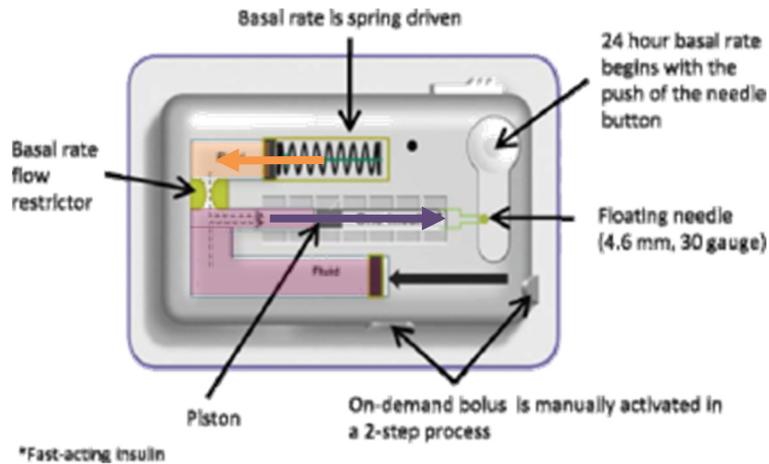
highlighted in the below schematic (viscous fluid space marked orange, insulin space marked purple).



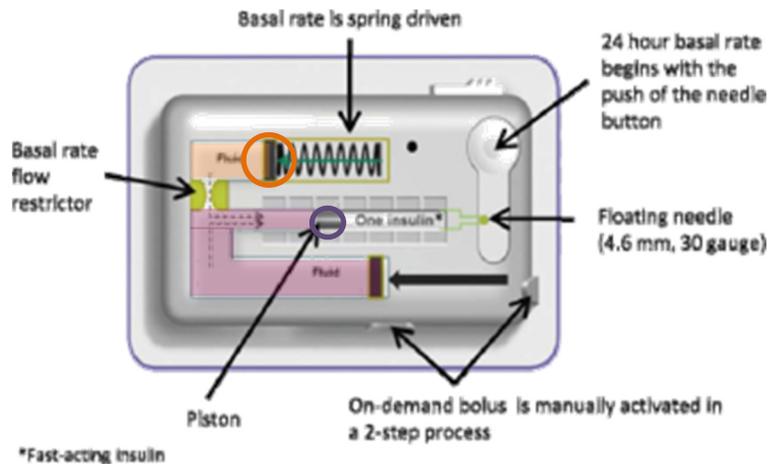
34. The Accused Product further incorporates a pressure reducing means by using a basal rate flow restrictor (indicated in circled orange, below) that reduces the fluid pressure generated by the drive means toward the driven side of the fluid space.



35. The Accused Product's drive means' working stroke (highlighted below by the orange arrow) is transmitted in the fluid space into the delivering means' work stroke (highlighted below by the purple arrow), which is greater than the drive means' working stroke.



36. The Accused Product's fluid space drive-side is formed by a piston area of a drive piston (indicated in circled orange, below) that is larger than a piston area of a driven piston (indicated in circled purple, below), forming the driven side of the fluid space.



37. As a result of Valeritas's direct infringement of the '795 Patent, Roche has suffered damages.

38. On information and belief, each of the Valeritas Defendants also actively induce infringement of the '795 Patent in violation of 35 U.S.C. § 271(b). Valeritas encourages and intends the use, importation, offer for sale, and/or sale of the Accused Product within this District and elsewhere in the United States by promoting the distribution of the Accused Product.

39. On information and belief, entities who use, import, offer to sell, or sell the Accused Product at Valeritas's request directly infringe the '795 Patent.

40. On information and belief, Valeritas possesses specific intent to encourage direct infringement of the '795 Patent. For example, as outlined above, Valeritas advertises the Accused Products for use within the United States and instructs customers on the use of the Accused Products.

41. Valeritas had knowledge of the '795 Patent since at least April 20, 2018 and likely before. Indeed, on information and belief, Valeritas knew – or at least should have known – that the use, importation, offer for sale, and sale of the Accused Product would be an act of direct infringement of the '795 Patent, and that Valeritas's activities would actively induce infringement of the '795 Patent. Despite such knowledge, Valeritas has been and actively continues to induce the infringement of the '795 Patent.

42. On information and belief, the induced infringement by Valeritas has been willful, intentional, and deliberate with full knowledge of the '795 Patent and in disregard of Roche's rights under the '795 Patent.

43. As a result of Valeritas's indirect infringement of the '795 Patent, Roche has suffered damages.

44. Valeritas will continue to infringe the '795 Patent unless and until they are enjoined by this Court.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Roche hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Roche respectfully prays that this Court enters judgment and provides relief as follows:

I. That each of the Valeritas Defendants is liable for infringement of the '795 Patent under 35 U.S.C. § 271 through the manufacture, use, importation, offer for sale, and/or sale of the Accused Product and/or any of the other acts prohibited by 35 U.S.C. § 271;

II. That each of the Valeritas Defendants and each of their affiliates, officers, agents, employees, parents, subsidiaries, representatives, successors and assigns, and those in active concert or participation with them directly or indirectly, be enjoined from further infringing in any manner the '795 Patent pursuant to 35 U.S.C. § 283;

III. That each of the Valeritas Defendants pay to Roche the damages resulting from Defendants' infringement of the '795 Patent, together with prejudgment and post-judgment interest and costs, and all other damages permitted by 35 U.S.C. § 284;

IV. That each of the Valeritas Defendants' infringement of the '795 Patent has been and continues to be willful, justifying an enhanced award of damages under 35 U.S.C. § 284;

V. That this action be declared exceptional and Roche be awarded reasonable attorneys' fees, costs and expenses under 35 U.S.C. § 285; and

VI. That Roche be awarded such other equitable or legal relief as this Court deems just and proper under the circumstances.

Dated: February 22, 2019

FISH & RICHARDSON P.C.

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