

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO**

VITALTE LIFESCIENCES INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 4:23-cv-00887
)	
BONDS THERAPEUTICS LLC d/b/a)	JURY TRIAL DEMANDED
TROCAR SUPPLIES,)	
)	
Defendant.)	
)	

COMPLAINT FOR INFRINGEMENT OF U.S. PATENT NO. 11,406,806

Plaintiff Vitalte Lifesciences Inc. (“Plaintiff”), for its Complaint against Defendant Bonds Therapeutics LLC d/b/a Trocar Supplies (“Defendant”) for infringement of U.S. Patent No. 11,406,806 (“the ’806 patent”) alleges as follows:

THE PARTIES

1. Plaintiff Vitalte Lifesciences Inc. is a corporation organized under the laws of the State of Delaware and having a place of business at 960 Caughlin Crossing, Suite 100, Reno, Nevada 89519.
2. Plaintiff is owned by Charles P. Virden, M.D.
3. Dr. Virden is a dual Board-certified plastic surgeon and anti-aging physician.
4. Dr. Virden is an innovator in the field of pellet hormone therapy, having invented the VIRDEN METHOD™, an in-office procedure utilized during the hormone pellet implantation process. The VIRDEN METHOD™ uses an atraumatic trocar to simultaneously release multiple hormone pellets into a patient’s dermal layer. The VIRDEN METHOD™ eliminates the need for re-

entry and extensive tissue trauma, which was a common problem in prior hormone pellet implantation processes.

5. Dr. Virden is also the owner of TheraPellet, which is a hormone replacement therapy company in Reno, Nevada.

6. On information and belief, Defendant Bonds Therapeutics LLC d/b/a Trocar Supplies is a Kentucky limited liability corporation, having a principal place of business at 126 Nulf Dr., Columbiana, Ohio 44408.

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. 1331 and 1338(b).

8. Defendant is subject to this Court's specific and general personal jurisdiction pursuant to the Ohio Long Arm statute and/or in light of Defendant's systemic and continuous contact with Ohio, due at least to its substantial business in this State and judicial district. For example, on information and belief, Defendant's principal place of business is located at 126 Nulf Dr., Columbiana, Ohio 44408.

9. Venue is proper in this district as to Defendant under 28 U.S.C. § 1400(b) because, among other reasons, on information and belief, Defendant has committed acts of patent infringement and has a regular and established business in this Judicial District. On information and belief, Defendant makes, uses, offers to sell, sells, and imports atraumatic trocar apparatuses, which infringe the '806 patent, in the United States, including in this Judicial District. <https://trocarsupplies.com/collections/blunt-tipped-atraumatic-trocars>. In addition, Defendant has a regular and established place of business in this Judicial District, because, on information and belief,

Defendant's principal place of business is located at 126 Nulf Dr., Columbiana, Ohio 44408, which is in this Judicial District.

THE ASSERTED PATENT AND THE PATENTED TECHNOLOGY

10. The '806 patent is titled "Atraumatic Trocar Apparatus, System and Kit." A true and correct copy of the '806 patent is attached hereto as Exhibit 1. The '806 patent issued on August 9, 2022 from U.S. Patent Application No. 15/901,821, filed on February 21, 2018. Dr. Virden, the sole inventor of the '806 patent.

11. Plaintiff owns all rights, title, and interest in and to the '806 patent.

12. The '806 patent is valid, enforceable, and was duly issued by the U.S. Patent and Trademark office in full compliance with Title 35 of the United States Code.

13. The '806 patent is generally directed to "an atraumatic trocar apparatus, method, and kit that includes a cannula that receives an insertion obturator having an anterior rounded tip," which can be used in hormone pellet therapies. ('806 patent, 1:5-2:53.)

14. Hormone pellet therapy involves subcutaneously implanting pellets into a patient. After implantation, the pellets "provide a slow continuous release of hormone(s) into the bloodstream" "for a period of 3 to 6 months, depending on the size and composition of the pellets." ('806 patent, 1:30-53.) The pellets are typically implanted via a trocar into a patient's "lower abdomen or buttocks. The procedure is done in a physician's office with the use of a local anesthetic and a small incision for insertion of [the] trocar." (*Id.*)

15. Trocars are medical devices which include a hollow tubular cannula and a rod-like obturator that fits within the cannula. ('806 patent, 1:54-62.) Prior to the '806 patent, trocars for hormone pellet therapy included a beveled cutting edge. ('806 patent, FIGS. 1A-1B.) These trocars have known-negative effects on patients. For example, "insertion is painful and results in scarring"

and “traumatically inserted pellets may lead to infection and often pass outside the body, which requires replacement with an additional traumatic insertion.” (’806 patent, 2:29-44.)

16. In contrast to prior trocars for hormone pellet therapy, the trocar of the ’806 patent is atraumatic. (*e.g.*, ’806 patent, 2:57-4:18.) Specifically, the trocar of the ’806 patent includes a cannula with a blunt anterior end and an insertion obturator with an anterior rounded tip. (*e.g.*, ’806 patent, FIGS. 2A-2C, claim 1.) This innovative trocar “eliminates need for reentry and extensive trauma to the [patient’s] tissue,” which results in “fewer complication, minimal discomfort, and increased efficacy” in hormone pellet therapy. <https://therapellet.com/the-virden-method>.

**DEFENDANT’S KNOWLEDGE OF PLAINTIFF’S PATENTED
TECHNOLOGY AND DEFENDANT’S INFRINGING CONDUCT**

17. In or around February 2020, Mr. Matthew Virden, the business development director of Dr. Virden’s company, TheraPellet, contacted Melanie Parsons, the CEO of Trocar Supplies regarding the possibility of forming a manufacturing and distribution relationship with Trocar Supplies with respect to Dr. Virden’s atraumatic trocar. At this same time, Mr. Virden informed Ms. Parson of Dr. Virden’s “patented blunt tip trocar technology.”

18. On February 18, 2020, TheraPellet, and Defendant entered into a Confidential Disclosure Agreement (“CDA”) for the purpose of the parties evaluating their potential business relationship. According to the CDA, TheraPellet agreed to provide Defendant, on a confidential basis, “Proprietary Information” related to Dr. Virden’s atraumatic trocar apparatus, system, and method.

19. Less than one year after the CDA terminated, Defendant began making, using, offering to sell, sell, and importing into the United States atraumatic trocars (“Accused Products”). For example, on information and belief, Defendant owns and operates the website www.trocarsupplies.com. Through the Product Catalog section on Defendant’s website, Defendant has and continues to market, offer for sale, and sell “Blunt Tip Atraumatic Trocars,” i.e., Accused

Products. A true and correct screenshot from Defendant's website, showing these Accused Products, is attached hereto as Exhibit 2.

20. On information and belief, Defendant has and continues to import the Accused Products into the United States.

21. Claim 1 of the '806 patent recites:

An atraumatic trocar apparatus for delivering one or more medication pellets to a subcutaneous insertion site, the atraumatic trocar apparatus comprising:

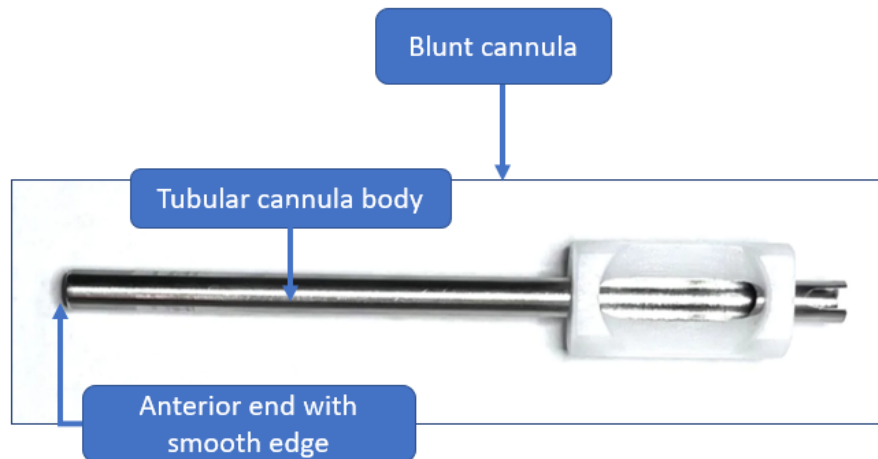
a blunt cannula with a tubular cannula body, wherein a surface of an anterior end of the tubular cannula body includes a smooth edge, wherein the blunt cannula is formed with a medication slot disposed along the tubular cannula body at a location more proximate to a posterior end of the tubular cannula body than the anterior end and a cannula handle fixedly coupled to the tubular cannula body, wherein the posterior end of the tubular cannula body includes a first coupling element disposed along a posterior portion of the tubular cannula body, wherein the first coupling element includes a notch, and wherein an inner diameter of the tubular cannula is at least 3 millimeters (mm);

an obturator that includes an anterior rounded tip, an obturator body that is inserted within the tubular cannula body, an obturator handle fixedly coupled to the obturator body proximate to a posterior end of the obturator, and a second coupling element that includes at least one tab; and

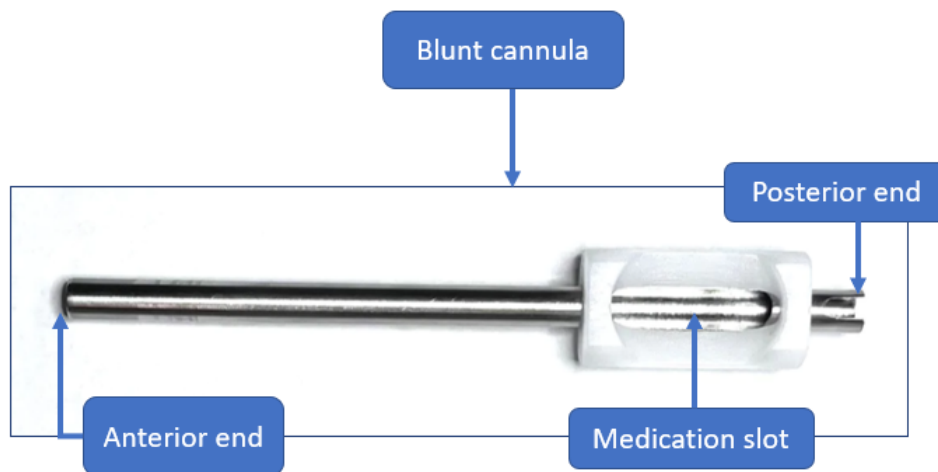
wherein the obturator extends through the tubular cannula body so that the anterior rounded tip of the obturator extends past the anterior end of the tubular cannula body when the notch and the at least one tab interface with one another.

22. The Accused Products include an atraumatic trocar apparatus for delivering or more medication pellets to a subcutaneous insertion site. (Exhibit 2; <https://trocarsupplies.com/collections/blunt-tipped-atraumatic-trocars/products/3-5mm-atraumatic-blunt-tip-trocar-combo-kit?variant=43535230271707>.)

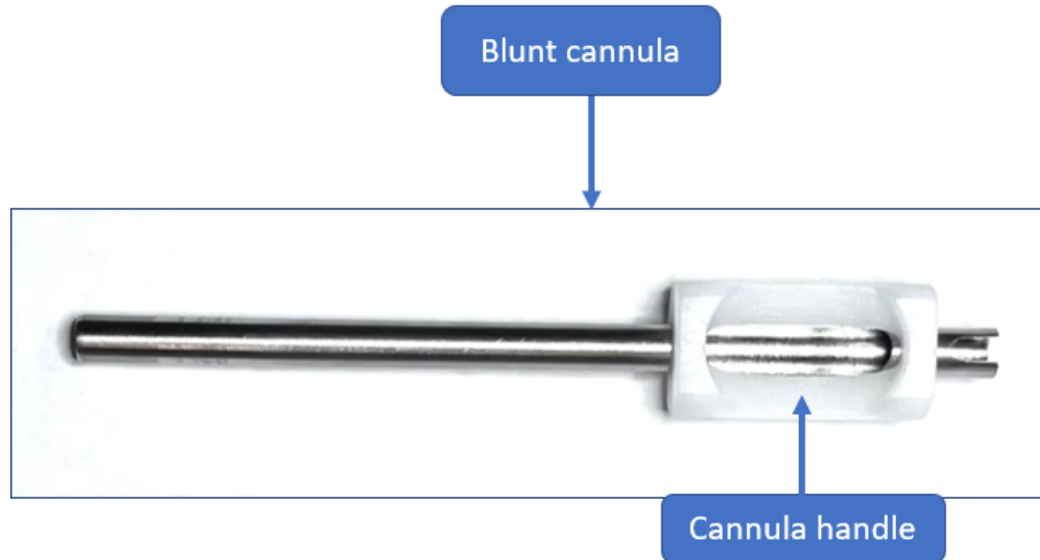
23. Defendant's atraumatic trocar apparatus comprises a blunt cannula with a tubular cannula body, wherein a surface of an anterior end of the tubular cannula body includes a smooth edge.



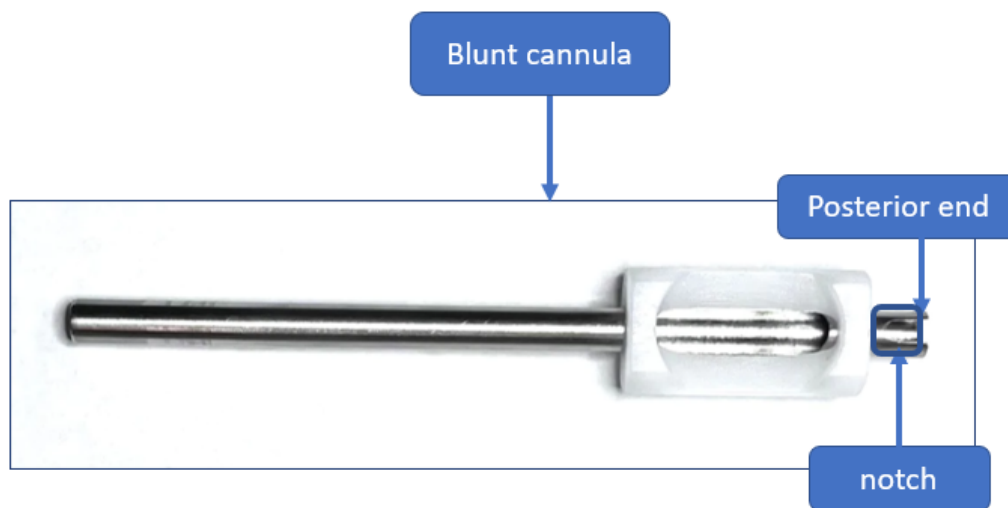
24. The blunt cannula is formed with a medication slot disposed along the tubular cannula body at a location more proximate to a posterior end of the tubular cannula body than the anterior end and a cannula handle fixedly coupled to the tubular cannula body at a location more proximate to a posterior end of the tubular cannula body than the anterior end.



25. The blunt cannula includes a cannula handle fixedly coupled to the tubular cannula body.

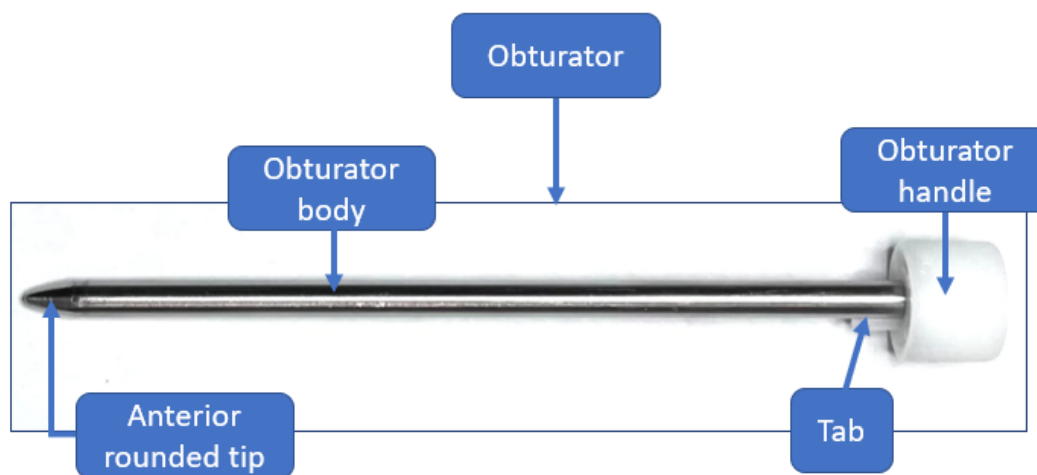


26. The posterior end of the tubular cannula body includes a first coupling element disposed along a posterior portion of the tubular cannula body, and the first coupling element includes a notch.

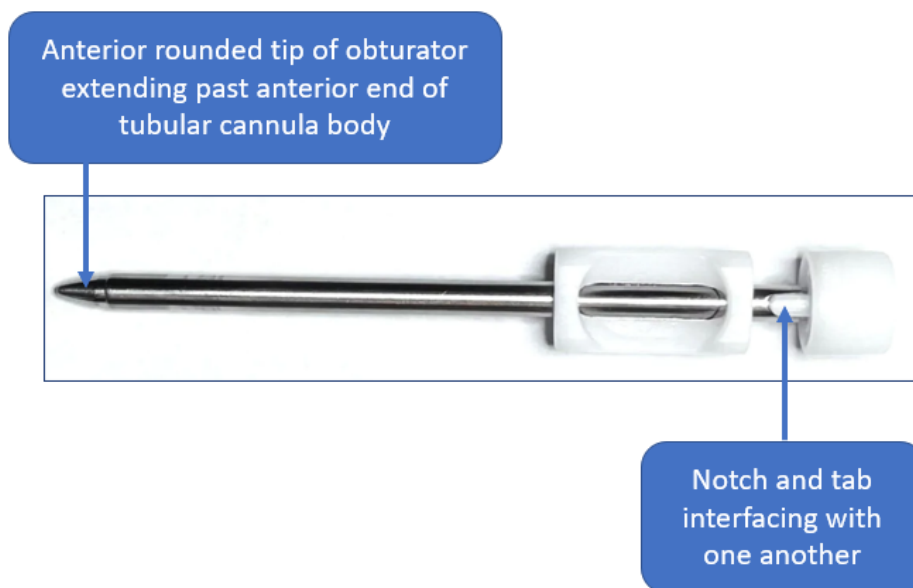


27. An inner diameter of the tubular cannula is at least 3 millimeters (mm). (Exhibit 2; <https://trocarsupplies.com/collections/blunt-tipped-atraumatic-trocars/products/3-5mm-atraumatic-blunt-tip-trocar-combo-kit?variant=43535230271707>.)

28. Defendant's atraumatic trocar apparatus also includes an obturator that includes an anterior rounded tip, an obturator body that is inserted within the tubular cannula body, an obturator handle fixedly coupled to the obturator body proximate to a posterior end of the obturator, and a second coupling element that includes at least one tab.



29. In addition, in Defendant's atraumatic trocar apparatus, the obturator extends through the tubular cannula body so that the anterior rounded tip of the obturator extends past the anterior end of the tubular cannula body when the notch and the at least one tab interface with one another.



FIRST CLAIM FOR RELIEF

(Infringement of the '806 patent)

30. Plaintiff repeats and realleges paragraphs 1-29 as if fully set forth herein.

31. Plaintiff has not licensed or otherwise authorized Defendant to make, use, offer for sell, sell or import into the United States any products that embody the inventions of the '806 patent.

32. Defendant has directly infringed and continues to directly infringe one or more claims of the '806 patent, including, but not limited to claim 1, by making, using, offering to sell, selling, and/or importing in the United States the Accused Products.

33. Defendant is liable, at a minimum, to Plaintiff in an amount that adequately compensates Plaintiff for Defendant's infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

34. Plaintiff has suffered, and will continue to suffer, irreparable harm for which there is no adequate remedy at law, unless Defendant's infringement is enjoined by this Court.

35. Defendant's conduct in infringing the '806 patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

36. Defendant's infringement has been and continues to be willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- A. That the Court enter judgment in favor of Defendant on all counts.
- B. An order and judgment permanently enjoining Defendant and its officers, directors, agents, servants, employees, affiliates, attorneys, and all others acting in privity or in concert with Defendant, and Defendant's parents, subsidiaries, divisions, successors, and assigns from:
 - a. Directly or indirectly infringing the '806 patent; and

b. Making, using, selling, offering for sale, or importing into the United States the Accused Products or any colorable variation thereof.

C. A judgment for an accounting of all damages, past and future, sustained by Plaintiff as a result of the acts of infringement by Defendant.

D. A judgment and order requiring Defendant to pay damages under 35 U.S.C. § 284, including up to treble damages as provided by 35 U.S.C. § 284, and any royalties determined to be appropriate.

E. A judgement requiring Defendant to pay Plaintiff's pre-judgment and post-judgment interest on the damages award.

F. A judgment and order finding this to be an exceptional case and requiring Defendant to pay the costs of this action (including all disbursements) and attorneys' fees as provided by 35 U.S.C. § 285.

G. Such other relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury on all issues and claims so triable.

DATED: April 28, 2023

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