

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
EASTERN DIVISION**

TRUDELL MEDICAL INTERNATIONAL,	)	
	)	
Plaintiff,	)	Case No.: 4:18-CV-00009
	)	
v.	)	DEMAND FOR JURY TRIAL
	)	
D R BURTON HEALTHCARE LLC,	)	
	)	
Defendant.	)	
	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

This is a civil action for infringement of U.S. Patent No. 9,808,588 under the patent laws of the United States, Title 35, United States Code, arising out of Defendant D R Burton Healthcare LLC’s manufacture, importation, use, sale, offer for sale, and/or sale of oscillating positive expiratory pressure devices in the United States. For its Complaint, Plaintiff Trudell Medical International alleges as follows:

**PARTIES**

1. Plaintiff Trudell Medical International (“TMI”) is a registered business name of a partnership existing under the laws of the province of Ontario, Canada, and has a place of business at 725 Third Street, London Ontario, Canada, N5V5G4.

2. Upon information and belief, Defendant D R Burton Healthcare LLC (“D R Burton”) is a company organized and existing under the laws of the State of Nevada, having its principal place of business at 3936 South Fields St. Farmville, North Carolina 27828.

## **FACTUAL BACKGROUND**

3. TMI is in the business of designing and manufacturing aerosol drug delivery and lung health devices for the management of respiratory conditions.

4. TMI's product line includes the Aerobika® (the "Aerobika® device"), which is a hand-held oscillating positive expiratory pressure ("OPEP") device. The Aerobika® device is described and shown at <https://www.trudellmed.com/aerobika>. An image of the Aerobika® device is reproduced below:



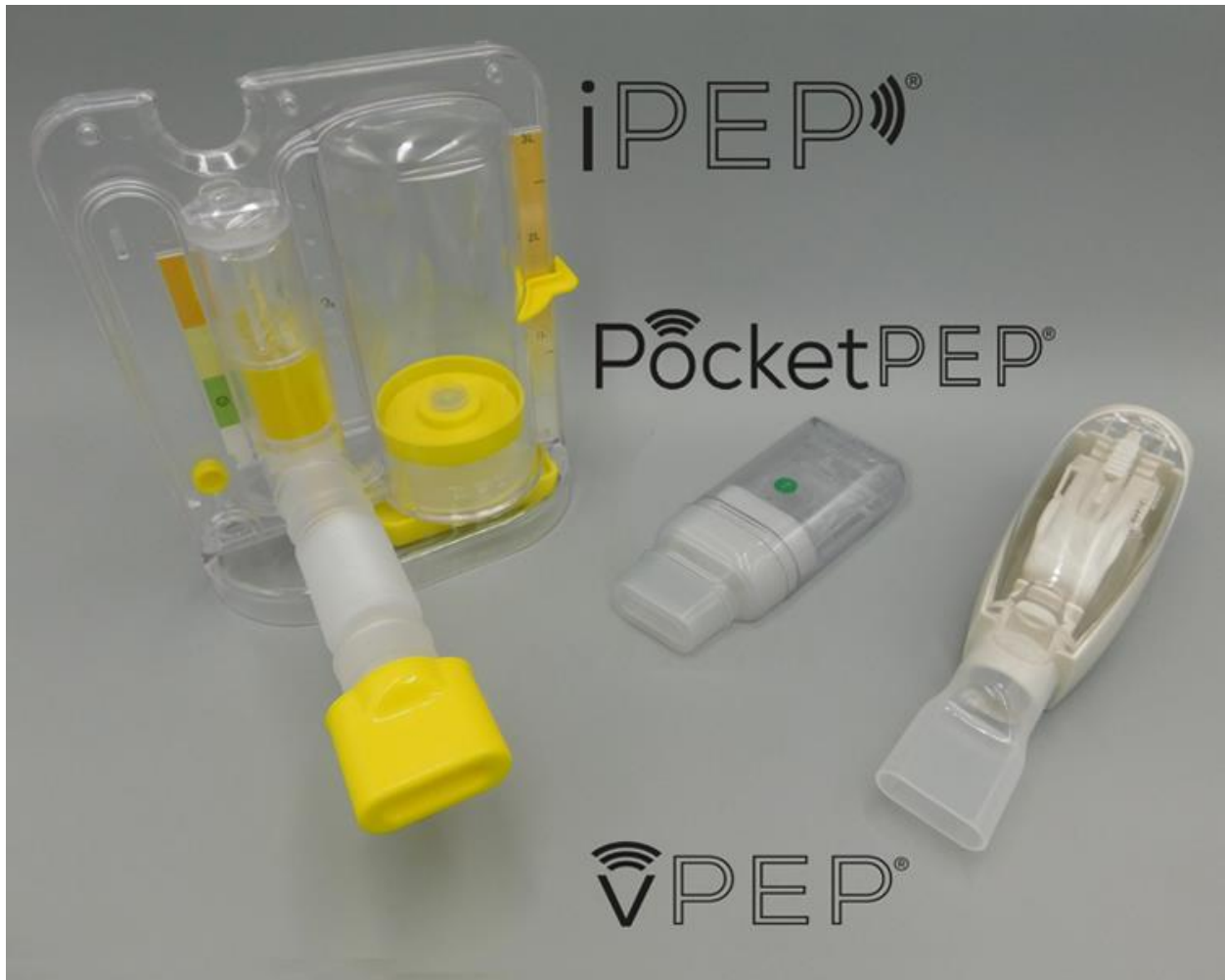
5. The Aerobika® device increases the natural process within the lungs to bring up mucus. The Aerobika® device achieves this result by providing intermittent resistance and creating positive pressure and oscillations simultaneously to open weak or collapsed airways to mobilize and assist mucociliary clearance in the upper airways, whereby mucus can be coughed out.

6. The Aerobika® device received 510(k) clearance from the United States Food and Drug Administration on May 16, 2013. Since then, the Aerobika® device has been and continues to be sold in the United States.

7. In June 2014, the Aerobika® device earned the Gold award at the Medical Design Excellence Awards® held in New York, NY, which awards recognize significant achievements in medical product design and engineering that improve the quality of healthcare delivery and accessibility.

8. TMI is the owner of many issued patents and pending patent applications in the United States and abroad relating to OPEP devices, including U.S. Patent No. 9,808,588 (“the ’588 patent”). A true and correct copy of the ’588 patent is attached as Exhibit A. The ’588 patent was legally issued on Nov. 7, 2017, and is entitled “Oscillating Positive Respiratory Pressure Device.”

9. On information and belief, D R Burton is in the business of manufacturing, importing, marketing, and selling several OPEP devices in the United States, including the vPEP®, iPEP®, and PocketPEP® devices. These devices are described and shown at <http://www.drburtonhpi.com/product-OPEP.php>. An image of these devices is reproduced below:



<http://www.drburtonhpi.com/product-OPEP.php> (last visited January 8, 2018)

### **JURISDICTION AND VENUE**

10. This is a civil action for patent infringement arising under Title 35 of the United States Code, and in particular 35 U.S.C. §§ 271, 282, 283, 284, and 285.

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

12. This Court has personal jurisdiction over D R Burton pursuant to provisions of the North Carolina Long Arm Statute, N.C. Gen. Stat. § 1-75.4, and the laws of the United States based at least on D R Burton's substantial activity in this judicial district, including: (i) the fact

that at least a portion of the infringement alleged herein occurred in this judicial district, and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided from and to individuals in North Carolina and in this judicial district.

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

**COUNT 1: DIRECT INFRINGEMENT OF THE '588 PATENT**  
**UNDER 35 U.S.C. § 271(a)**

14. TMI incorporates by reference each of the preceding allegations of paragraphs 1-13 above as though stated herein.

15. D R Burton has directly infringed the '588 Patent in violation of at least 35 U.S.C. § 271(a) by, through itself and/or through its agents, unlawfully and wrongfully making, importing, using, offering to sell, and/or selling OPEP devices covered by one or more claims of the '588 Patent within the United States without permission or license from TMI, and will continue to do so unless enjoined by this Court.

16. An example of an OPEP device that directly infringes the '588 Patent includes, but is not limited to, the vPEP® device.

17. The photographs of the vPEP® device set forth below accurately show the features of the product.

18. The vPEP® device infringes the '588 Patent literally and/or under the doctrine of equivalents.

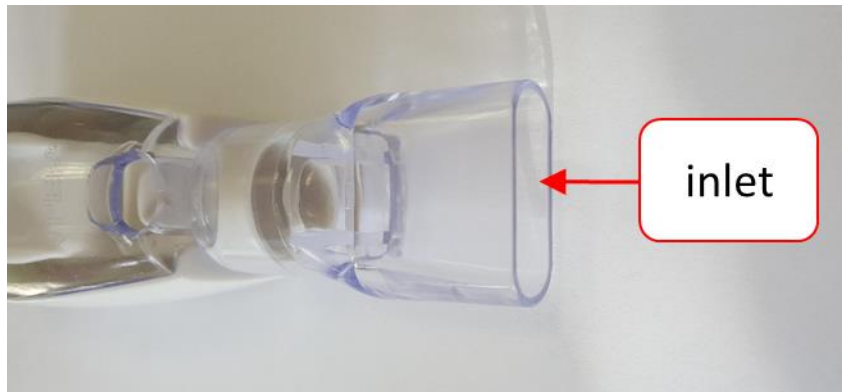
19. The vPEP® device infringes at least claims 1-18 and 20-26 of the '588 Patent.

20. Solely by way of example, as shown in the annotated photographs of paragraphs 21 through 27 below, the vPEP® device meets every limitation recited in claim 1 of the '588 Patent.

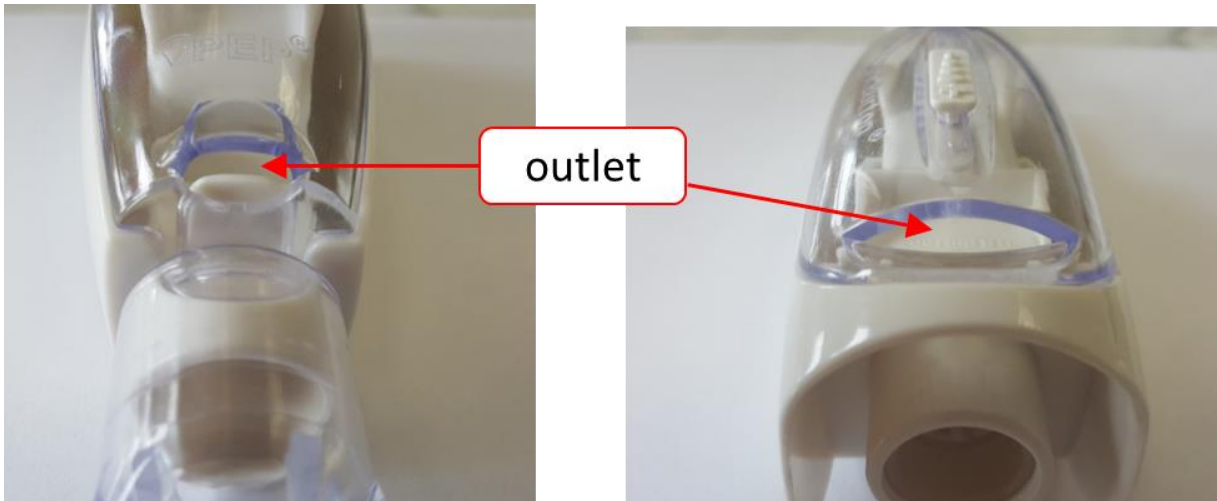
21. The vPEP® device is a respiratory treatment device as recited in the preamble of claim 1 of the '588 Patent.



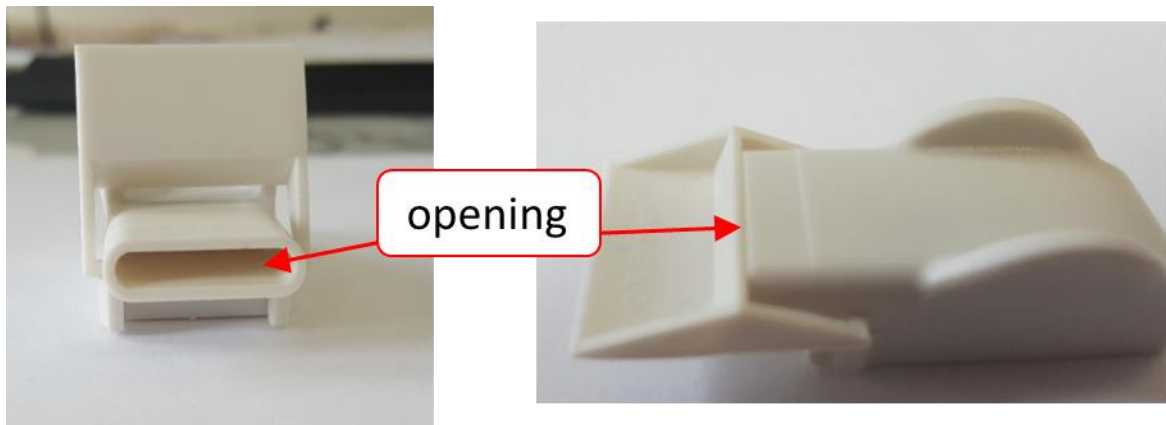
22. The vPEP® device includes an inlet (red arrow below) configured to receive exhaled air into the device.



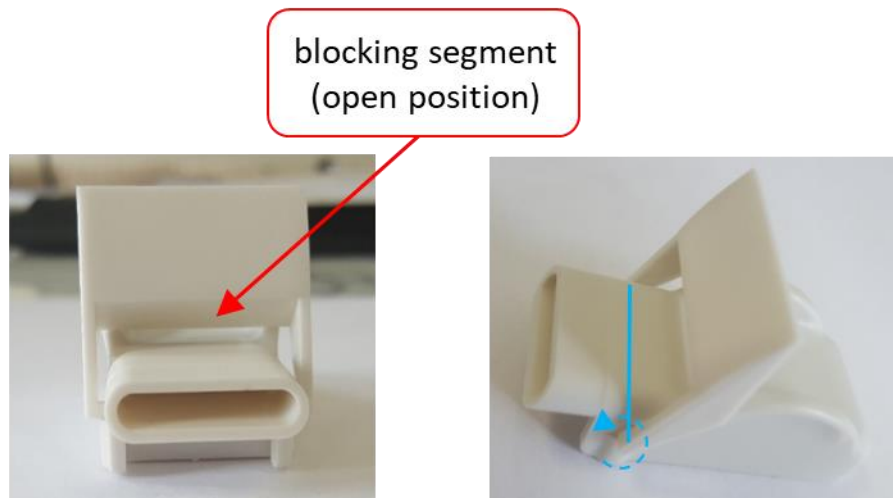
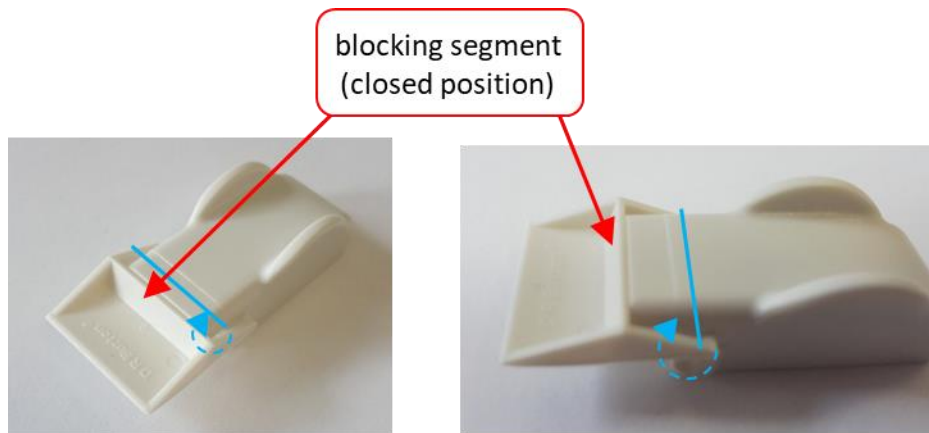
23. The vPEP® device includes an outlet (red arrows below) configured to permit air to exit the device.



24. The vPEP® device includes an opening (red arrows below) positioned in an exhalation flow path defined between the inlet and the outlet.

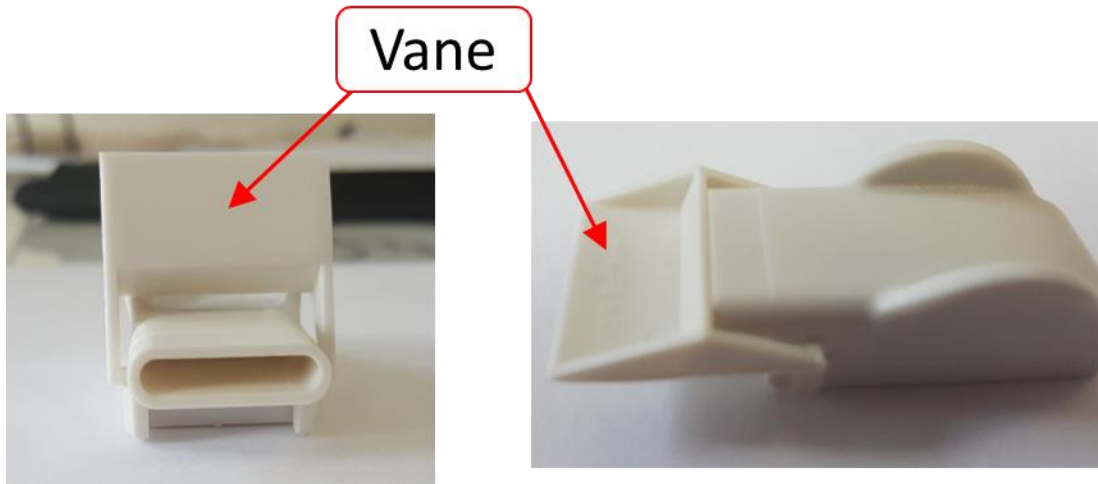


25. The vPEP® device includes a blocking segment (red arrows below) configured to rotate relative to the opening (about blue lines below) between a closed position where the flow of air through the opening is restricted, and an open position where the flow of air through the opening is less restricted.

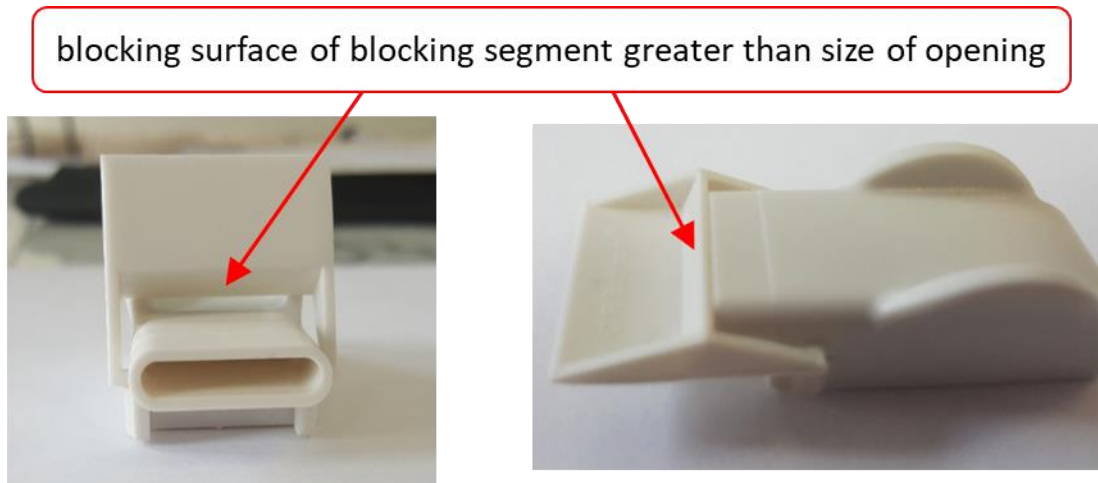


26. The vPEP® device includes a vane (red arrows below) configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening.





27. The vPEP® device includes a size of a blocking surface (red arrows below) of the blocking segment that is greater than the size of the opening.



28. Paragraphs 21 through 27 demonstrate infringement of the '588 Patent by at least the vPEP® device. On information and belief, and subject to inspection of physical products, the iPEP® and PocketPEP® devices also may infringe the '588 Patent.

29. D R Burton's continued infringement of the '588 Patent following service of this Complaint is intentional, deliberate, and knowing.

30. Unless enjoined, D R Burton's acts will continue to cause TMI irreparable harm, loss, and injury.

**COUNT 2: INDUCED INFRINGEMENT OF THE '588 PATENT**  
**UNDER 35 U.S.C. § 271 (b)**

31. TMI incorporates by reference each of the preceding allegations of paragraphs 1-30 above as though stated herein.

32. D R Burton's continued infringement of the '588 Patent following service of this Complaint by making, importing, offering to sell, and selling the vPEP® device is intentional, deliberate, and knowing.

33. D R Burton induces infringement of the '588 Patent within this judicial district and elsewhere within the United States by its intentional acts which, among other things, encourage, instruct, enable, and otherwise cause others, such as physicians, medical institutions, pharmacies, and individuals, to use the vPEP® device. D R Burton provides the vPEP® device to said others for the primary purpose of causing infringing acts by said others. D R Burton has specifically intended that said others use the vPEP® device in such a way that the '588 Patent is infringed by, at a minimum, providing instructions to said others on how to use the vPEP® device.

34. Following service of this Complaint, D R Burton knows that its actions, including but not limited to providing such instructions, induce infringement by said others. Use of the vPEP® device in accordance with D R Burton's instructions infringes the '588 Patent.

35. Unless enjoined, D R Burton's acts will continue to cause TMI irreparable harm, loss, and injury.

**COUNT 3: CONTRIBUTORY INFRINGEMENT OF THE '588 PATENT**  
**UNDER 35 U.S.C. § 271 (c)**

36. TMI incorporates by reference each of the preceding allegations of paragraphs 1-35 above as though stated herein.

37. D R Burton's continued infringement of the '588 Patent following service of this Complaint by making, importing, offering to sell, and selling the vPEP® device is intentional, deliberate, and knowing.

38. Following service of this Complaint, D R Burton contributes to infringement of the '588 Patent within this judicial district and elsewhere in the United States by making, importing, offering to sell, and selling components of systems on which the '588 Patent read, constituting a material part of the invention, and knowing that the components are especially adapted for use in systems which infringe claims of the '588 Patent.

39. By making, importing, offering to sell, and selling the vPEP® device, D R Burton provides non-staple articles of commerce to others for use in infringing products. D R Burton provides instructions and directions for using the vPEP® device. These instructions and directions encourage users of the vPEP® device to directly infringe the claims of the '588 Patent.

40. Unless enjoined, D R Burton's acts will continue to cause TMI irreparable harm, loss, and injury.

**WHEREFORE**, TMI prays that:

A. U.S. Patent Nos. 9,808,588 be adjudged by this Court to be enforceable and not invalid;

B. D R Burton be adjudged by this Court to have infringed, induced others to infringe, and/or contributorily infringe U.S. Patent Nos. 9,808,588;

C. D R Burton be ordered by this Court to account for and pay TMI damages adequate to compensate TMI for the infringement of U.S. Patent No. 9,808,588, including interest, under 35 U.S.C. § 284;

D. A permanent injunction be issued preventing further infringement of U.S. Patent No. 9,808,588 by D R Burton, its officers, agents, servants, employees, attorneys, and those persons in active concert or participation with it;

E. This case be deemed exceptional and TMI be awarded interests, costs, expenses and reasonable attorney's fees for this suit as provided by 35 U.S.C. § 285; and,

F. TMI be awarded such other relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Fed. R. Civ. P. 38(b), TMI demands a trial by a jury in this action on all issues triable by jury.

Dated: January 29, 2018

Respectfully submitted,

/s/ David R. Boaz

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