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7 Cross Innovations, LLC

8 **UNITED STATES DISTRICT COURT**  
9 **SOUTHERN DISTRICT OF NEW YORK**

10 CROSS INNOVATIONS, LLC

11 Plaintiff,

12 v.

13 JUAN FELIPE VELEZ WIESNER  
14 WIESNER HEALTHCARE INNOVATION LLC  
15 and  
16 WIESNER HEALTHCARE SAS

17 Defendants.

Case No. 1:23-cv-04614

**COMPLAINT**

**JURY TRIAL DEMANDED**  
(PLAINTIFF DEMANDS A JURY TRIAL FOR ALL CLAIMS SO TRIABLE)

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20 Complaint Filed: May 30, 2023

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22 Plaintiff, Cross Innovations, LLC, by and through its undersigned attorney, as and  
23 for its Complaint against Defendants, Juan Felipe Velez Wiesner, Wiesner Healthcare  
24 Innovation LLC, and Wiesner Healthcare SAS, alleges as follows:

25 **PARTIES**

26 1. Plaintiff Cross Innovations, LLC (“Plaintiff” or “Cross Innovations”) is a limited  
27 liability company organized and existing under the laws of the State of Wyoming.

1 2. Cross Innovations creates and sells medical products under the LUNDERG brand,  
2 including the LUNDERG Confidence Clamp product for male patients with urinary  
3 incontinence available on Amazon.com (<https://www.amazon.com/dp/B081N6ZSGV/>).

4 3. Upon information and belief, Defendant Wiesner Healthcare Innovation LLC  
5 (“Wiesner Healthcare LLC”) is a limited liability company existing under the laws of the  
6 State of Delaware.

7 4. Upon information and belief, Defendant Wiesner Healthcare Innovation LLC sells  
8 the WIESNER Incontinence Clamp product available on Amazon.com  
9 (<https://www.amazon.com/dp/B00F3HZJ74/>).

10 5. Upon information and belief, Juan Felipe Velez Wiesner (“Mr. Wiesner”) is a  
11 resident of Colombia and the sole member of Defendant Wiesner Healthcare Innovation  
12 LLC.

13 6. Defendant Wiesner Healthcare SAS is an entity formed in Colombia that purports to  
14 be the manufacturer of the WIESNER Incontinence Clamp.

15 7. Upon information and belief, Wiesner Healthcare SAS has only one shareholder, Mr.  
16 Wiesner.

17 **JURISDICTION AND VENUE**

18 8. This Court has subject matter jurisdiction pursuant to at least 28 U.S.C. §§ 1331,  
19 1338, and 1367.

20 9. This court has personal jurisdiction over the Defendants. Defendants have  
21 purposefully availed themselves of the benefits of this forum. Defendants have intentionally  
22 established regular distribution channels whereby they advertise and sell products to  
23 individuals located in this district. Defendants’ regular distribution channels include  
24 appointing Amazon.com as a distributor of Defendants’ products in this state. Defendants  
25 have also initiated patent enforcement and enlisted Amazon.com to remove Plaintiff’s  
26 products from being sold to consumers, including preventing sale of Plaintiff’s products to  
27 consumers in this district. Upon information and belief, Amazon.com is acting on such  
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1 request on behalf of Defendants by and through Amazon.com, Inc. and/or its affiliates, which  
2 are believed to have places of business and are registered to conduct business in this district.

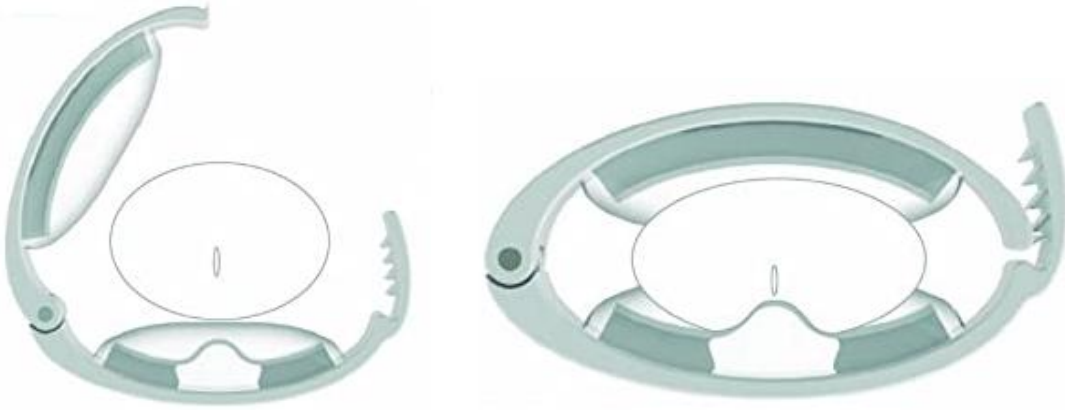
3 10. Venue is proper in this judicial district pursuant to at least 28 U.S.C. § 1391(b) &  
4 (c)(3).

5 **BACKGROUND**

6 11. In February 2012, Mr. Wiesner began selling the WIESNER Incontinence Clamp in  
7 the United States.

8 12. By September 2013, Mr. Wiesner was offering the WIESNER Incontinence Clamp  
9 for sale on Amazon.com.

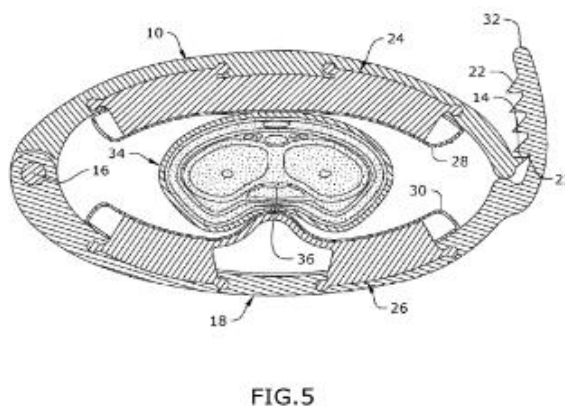
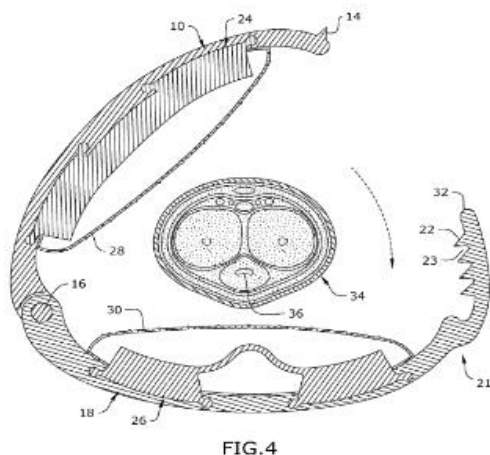
10 13. At least as early as 2014 and more than one year prior to the filing of any patent  
11 application by one or more of the Defendants, the following images (collectively the  
12 “Advertising Images”) were disclosed to the public in advertising materials:



20 14. Defendant Wiesner Healthcare Innovation LLC was created on April 24, 2015.

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1 15. On August 31, 2016, Mr. Wiesner filed U.S. Patent Application Serial No.  
2 15/253,051, which included the following figures:



11 16. In U.S. Patent Application Serial No. 15/253,051, Mr. Wiesner did not disclose to the  
12 USPTO that he had been selling the WIESNER Incontinence Clamp since February 2012.

13 17. In U.S. Patent Application Serial No. 15/253,051, Mr. Wiesner did not disclose the  
14 existence of the Advertising Images to the USPTO.

15 18. On April 21, 2020, the United States Patent and Trademark Office issued U.S. Patent  
16 Application Serial No. 15/253,051 as U.S. Patent No. 10,624,728 to Mr. Wiesner.

17 19. Mr. Wiesner purports to have assigned U.S. Patent No. 10,624,728 to Wiesner  
18 Healthcare Innovations LLC on August 12, 2020.

19 20. On August 13, 2020, Mr. Wiesner submitted an intellectual property infringement  
20 claim through Amazon.com, alleging that the LUNDERG Confidence Clamp infringed upon  
21 U.S. Patent No. 10,624,728.

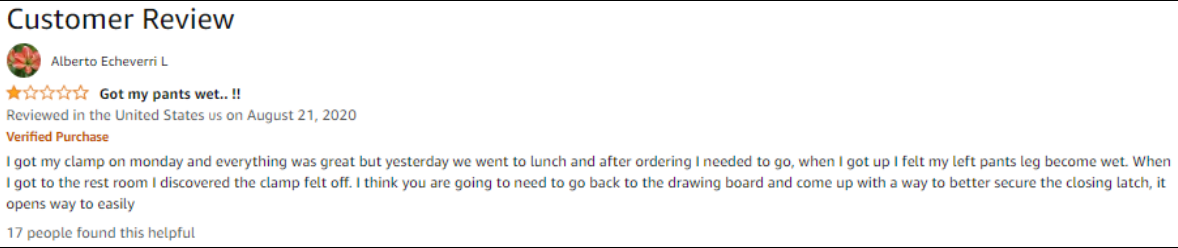
22 21. On August 20, 2020, Cross Innovations, by and through undersigned counsel,  
23 identified to Mr. Wiesner and his counsel at least four (4) missing elements from the claims  
24 patented in U.S. Patent No. 10,624,728.

25 22. Mr. Wiesner had no reason in fact or law to believe that Cross Innovations infringed  
26 upon U.S. Patent No. 10,624,728, at least because the LUNDERG Confidence Clamp did  
27 not have at least the above referenced claim limitations.

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23. With the August 20, 2020 correspondence, Cross Innovations kindly requested that Mr. Wiesner retract his willfully improper allegation of patent infringement of U.S. Patent No. 10,624,728.

24. On information and belief, on August 21, 2020, Mr. Wiesner submitted the following fake negative review of the LUNDERG Confidence Clamp product, purporting to be “Alberto Echeverri L.”:



25. Mr. Wiesner withdrew his complaint of patent infringement with Amazon.com, but only after the harm to Cross Innovations’ Amazon.com account was done.

26. In October 2020, Wiesner Healthcare expressed interest in acquiring the LUNDERG Confidence Clamp product line and requested that Cross Innovations exit the incontinence clamp marketplace.

27. In October 2020, Mr. Wiesner, Wiesner Healthcare LLC, Wiesner Healthcare SAS, and Cross Innovations entered into a non-disclosure agreement, effective October 19, 2020, to discuss the purchase of the LUNDERG Confidence Clamp product line and related assets. Cross Innovations provided information to Mr. Wiesner, Wiesner Healthcare LLC, and Wiesner Healthcare SAS, but an acquisition agreement was not reached.

28. Prior to the issuance of U.S. Patent No. 10,624,728, specifically on March 5, 2020, Mr. Wiesner filed U.S. Patent Application Serial No. 16/810,148, as a continuation of U.S. Patent Application Serial No. 15/253,051 that later became U.S. Patent No. 10,624,728.

29. Years later, the USPTO allowed U.S. Patent Application Serial No. 16/810,148, based on the opinion that the claimed “upper guide” limitations were not present in the prior art.

30. In U.S. Patent Application Serial No. 16/810,148, Mr. Wiesner did not disclose to the USPTO that he had been selling the WIESNER Incontinence Clamp since February 2012.

1 31. In U.S. Patent Application Serial No. 16/810,148, Mr. Wiesner did not disclose the  
2 existence of the Advertising Images to the USPTO.

3 32. In U.S. Patent Application Serial No. 16/810,148, Mr. Wiesner did not disclose the  
4 existence of other relevant prior art products, including the BioDerm Kind Klamp.

5 33. Mr. Wiesner purports to have assigned U.S. Patent Application Serial No. 16/810,148  
6 to Wiesner Healthcare Innovations LLC.

7 34. Wiesner Healthcare Innovations LLC never filed a statement in U.S. Patent  
8 Application Serial No. 16/810,148 under 37 C.F.R. § 3.73(c).

9 35. Wiesner Healthcare Innovations LLC was never the applicant in U.S. Patent  
10 Application Serial No. 16/810,148.

11 36. Wiesner Healthcare Innovations LLC never recorded a purported assignment of U.S.  
12 Patent Application Serial No. 16/810,148 with the USPTO.

13 37. On May 9, 2023, the United States Patent and Trademark Office issued U.S. Patent  
14 Application Serial No. 16/810,148 as U.S. Patent No. 11,642,205 to Wiesner Healthcare  
15 Innovation LLC.

16 38. Defendant Wiesner Healthcare Innovation LLC has represented that it owns and has  
17 the right to enforce U.S. Patent No. 11,642,205.

18 39. On or about May 15, 2023, Mr. Wiesner submitted an intellectual property  
19 infringement claim through Amazon.com, alleging that the LUNDERG Confidence Clamp  
20 infringes upon U.S. Patent No. 11,642,205 and requested that Amazon.com deactivate the  
21 product page for the LUNDERG Confidence Clamp.

22 40. In light of this background and context, the Defendants have forced action from Cross  
23 Innovations and required the filing of this action to put an end to the harassment, unlawful  
24 activities, and intellectual property abuse committed by the Defendants, including that on  
25 and through Amazon.com.

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**COUNT I  
DECLARATORY JUDGMENT  
INVALIDITY OF U.S. PATENT NO. 11,642,205**

41. Plaintiff incorporates by reference in their entirety each of the allegations set forth in paragraphs 1-40 of this Complaint.

42. Incontinence clamp devices date back to at least the 1950s and 1960s, as evidenced by U.S. Patent Nos. 2,756,753 and 3,203,421.

43. While innovation in this space lightened for several decades, with improved manufacturing techniques and increased customer need, innovations have been suggested in modern history, as evidenced by U.S. Patent Publication No. 2002/0111640, U.S. Patent Publication No. 2004/0129277, U.S. Patent No. 7,658,195, and at least the following products:



44. The FDA currently recognizes 70 registered establishments in the penile clamp product space.

45. As best understood, U.S. Patent No. 11,642,205 claims an incontinence clamp with features that are anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least (i) Mr. Wiesner’s product on sale since 2012; (ii) the Advertising Images; (iii) U.S. Patent Publication No. 2002/0111640; (iv) U.S. Patent Publication No. 2004/0129277; (v) U.S. Patent No. 7,658,195; (v) Bioderm Penile Clamp (also known as the Bioderm Kind Klamp); or (vi) a combination of two or more of the foregoing or other prior art.

46. The claims of U.S. Patent No. 11,642,205 are indefinite and invalid under 35 U.S.C. § 112 by claiming elements that do not precisely define the scope of the alleged invention,

1 including through the use of phrases including but not limited to: (i) “dimensioned to  
2 partially encircle”; (ii) “dimensioned to span a majority of the arcuate inner surface”; (iii)  
3 “spanning a majority of the arcuate inner surface”; (iv) “exclusive of the upper  
4 attachment”; and (v) “exclusive of the lower attachment”.

5 47. As best understood, the claims of U.S. Patent No. 11,642,205 are unsupported and  
6 invalid under 35 U.S.C. § 112 by claiming elements that do not have support in the  
7 disclosure, including but not limited to (i) “upper guide comprising a curved concave-inner  
8 surface, a convex outer surface, and an upper attachment coupling the upper guide with the  
9 upper clamp arm”;

10 (ii) “wherein the middle portion comprises a protrusion oriented towards the upper clamp  
11 arm and a lower attachment for removably coupling the removable lower guide with the  
12 lower clamp arm”; (iii) “connector is adjustable to define a different internal diameter  
13 between the upper clamp arm and the lower clamp arm”; (iv) “the upper guide having an  
14 upper attachment to couple the upper guide with the inner surface of the upper clamp arm”;  
15 and (v) “the removable lower guide having a convex outer face that underlies a majority of  
16 the arcuate inner surface of the lower clamp arm”.

17 48. Due to the actions and omissions of Mr. Wiesner and Wiesner Healthcare Innovation  
18 LLC and the USPTO’s reliance on those actions and omissions, U.S. Patent No. 11,642,205  
19 was unlawfully issued to Wiesner Healthcare Innovation LLC, contrary to at least 35 U.S.C.  
20 § 152 and 37 C.F.R. §§ 3.73(c) & 3.81 and is therefore invalid and void.

21 49. Based on at least the above, Plaintiff is entitled to a declaratory judgment that U.S.  
22 Patent No. 11,642,205 is invalid under at least 35 U.S.C. §§ 102, 103, 112, & 152.

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**COUNT II  
DECLARATORY JUDGMENT  
NON-INFRINGEMENT OF U.S. PATENT NO. 11,642,205**

50. Plaintiff incorporates by reference in their entirety each of the allegations set forth in paragraphs 1-49 of this Complaint.

51. As best understood, the LUNDERG Confidence Clamp product lacks many of the elements of the independent claims of U.S. Patent No. 11,642,205, including those claim elements shared with U.S. Patent No. 10,624,728.

52. By way of one specific example, the LUNDERG Confidence Clamp does not possess the allegedly patentable “upper guide” set forth in each of the independent claims of U.S. Patent No. 11,642,205. The LUNDERG Confidence Clamp does not have a removable upper guide; the top stabilizer is not removable and therefore cannot have the claimed upper attachment. Additionally, even if the top stabilizer of the LUNDERG Confidence Clamp was removable and separable, it does not have the claimed curved concave inner surface or convex outer surface. See images below.



53. By way of a second specific example, the LUNDERG Confidence Clamp does not possess the claimed “removable lower guide comprising a concave inner face”. See images above.

54. By way of a third specific example, the LUNDERG Confidence Clamp does not have the claimed “cooperating connector”, which invokes the means plus function provisions of 35 U.S.C. § 112. The specification discloses a “connector 2” that includes

1 “interlocking teeth 14 and 22”. The LUNDERG Confidence Clamp lacks the described and  
2 claimed “cooperating connector” with interlocking teeth.

3 55. The LUNDERG Confidence Clamp product cannot infringe any dependent claim that  
4 depends from a non-infringed independent claim.

5 56. Based on at least the above, Plaintiff is entitled to a declaratory judgment that the  
6 LUNDERG Confidence Clamp product does not infringe any claim of U.S. Patent No.  
7 11,642,205.

8 **COUNT III**  
9 **DECLARATORY JUDGMENT**  
10 **UNENFORCEABILITY OF U.S. PATENT NO. 11,642,205**

11 57. Plaintiff incorporates by reference in their entirety each of the allegations set forth in  
12 paragraphs 1-56 of this Complaint.

13 58. During prosecution of U.S. Patent No. 10,624,728, Mr. Wiesner did not disclose at  
14 least (i) the product he had been selling since 2012; and (ii) the Advertising Images. The  
15 USPTO would not have allowed U.S. Patent No. 10,624,728 if Mr. Wiesner would have  
16 disclosed that he was selling the product since 2012 and publicly using the Advertising  
17 Images for more than one year prior to filing any patent application. The product on sale in  
18 2012 and the Advertising Images render the patented claims anticipated or obvious alone and  
19 in combination with other prior art. Mr. Wiesner thus committed inequitable conduct during  
20 prosecution of 10,624,728. 10,624,728 is unenforceable due to said inequitable conduct.

21 59. 11,642,205 is unenforceable due to infectious unenforceability.

22 60. During correspondence with Mr. Wiesner and his attorney in August 2020, Cross  
23 Innovations, by and through undersigned counsel, informed Mr. Wiesner of the existence of  
24 several other products similar to the Wiesner Incontinence Clamp, including at least the  
25 BioDerm Kind Klamp that was on sale since at least as early as 2015.

26 61. During prosecution of U.S. Patent No. 11,642,205, Mr. Wiesner did not disclose at  
27 least (i) the product he had been selling since 2012; (ii) the material Advertising Images; and  
28 (iii) the BioDerm Kind Klamp. As best understood, The USPTO would not have allowed the

1 claims of U.S. Patent No. 11,642,205 if Mr. Wiesner had made these disclosures. The product  
2 on sale in 2012, the Advertising Images, and the BioDerm Kind Klamp render the patented  
3 claims anticipated or obvious alone and in combination with other prior art. Mr. Wiesner  
4 thus committed inequitable conduct during prosecution of U.S. Patent No. 11,642,205 and  
5 U.S. Patent No. 11,642,205 is unenforceable due to said inequitable conduct.

6 62. Based on at least the above, Plaintiff is entitled to a declaratory judgment that U.S.  
7 Patent No. 11,642,205 is unenforceable due to inequitable conduct.

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9 **COUNT IV**  
**FALSE ADVERTISING**  
**15 U.S.C. § 1125**

10 63. Plaintiff incorporates by reference in their entirety each of the allegations set forth in  
11 paragraphs 1-62 of this Complaint.

12 64. Wiesner Healthcare LLC has committed false advertising through a variety of false  
13 and misleading statements.

14 65. By way of a first example, Wiesner Healthcare LLC touts that it has “had the honor  
15 to work with some of the biggest institutions in the Country for the last 8 years and serve  
16 millions of patients!”.

17 66. Upon information and belief, best estimates indicate that only approximately 100,000  
18 WIESNER Incontinence Clamps have been sold to date, many of which were replacements  
19 for worn out products for the same customer, necessitating that only tens of thousands of  
20 patients were served by Defendants’ product, not millions.

21 67. By way of a second example, Wiesner Healthcare LLC advertises that “The Wiesner  
22 Incontinence Clamp product is FDA approved as a class I medical device, it is safe,  
23 comfortable and takes only seconds to put on!”.

24 68. The Wiesner Incontinence Clamp has not undergone any study of safety and  
25 effectiveness and is not FDA approved.

26 69. Upon information and belief, Wiesner Healthcare LLC is not registered with the FDA  
27 as required by 21 C.F.R. § 807.20.  
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1 70. Wiesner Healthcare LLC’s false advertising is misleading and amounts to  
2 misbranding. 21 C.F.R. § 807.39.

3 71. By way of a third example, one or more of the Defendants market and sell a product  
4 referred to as the “Virth Incontinence Clamp”, which is advertised as being sold by “Virth  
5 Healthcare”:



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15 See <https://www.amazon.com/dp/B0B3F6X9M4>.

16 72. There is no entity existing in the name of “Virth Healthcare”.

17 73. Furthermore, there is no FDA establishment registration for a Virth Incontinence  
18 Clamp and the Virth Incontinence Clamp should not be permitted import into the United  
19 States. 21 C.F.R. § 807.40(c).

20 74. Defendants have made false and misleading statements of fact in advertising, all in  
21 an attempt to increase volume of sales and lend credence to the notion that their products are  
22 somehow superior to other incontinence clamps.

23 75. Defendants actions and omissions have caused Plaintiff injury, including through  
24 harm to its goodwill and reputation, and through diversion of potential sales.

25 76. There is no basis in fact for the actions taken or statements made by Defendants.

26 77. Defendants’ statements are literally false and will mislead and confuse consumers.  
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1 78. As least as early as August 2020, Plaintiff, by and through undersigned counsel,  
2 requested that Defendants cease making false and misleading advertising statements,  
3 including the first two examples set forth herein.

4 79. Defendants have willfully continued to make false, misleading, and confusing  
5 advertising claims, all of which amount to false advertising under Section 43(a) of the  
6 Lanham Act.

7 80. Defendants are liable for false advertising and unfair competition under 15 U.S.C. §  
8 1125(a) in connection with the manufacture, distribution, marketing and/or sales of male  
9 incontinence clamp devices, including by making literally false and unlawful claims, such as  
10 “serve millions of patients”, “FDA approved,” and other claims of superiority, and by  
11 facilitating the unregistered distribution of products within the United States.

12 81. Defendants’ false advertising and unfair competition are creating a real and present  
13 health and safety risk and causing, or likely causing, irreparable harm to Plaintiff.

14 82. Plaintiffs have no fully adequate remedy at law.

15 83. The public interest weighs in favor of an injunction against false advertising and  
16 unfair competition and in favor of the protection of the health and safety of consumers.

17 84. Defendants should be enjoined from making any of the above statements or other  
18 unsupported, false, and misleading statements of source or superiority.

19 85. Defendants’ false and misleading statements rise to the level of “exceptional” under  
20 15 U.S.C. § 1117(a) and justify that Plaintiff be awarded its attorney’s fees and treble  
21 damages.

22 **COUNT V**  
23 **FALSE ADVERTISING**  
24 **New York General Business Law §§ 349 and 350**

25 86. Plaintiff incorporates by reference in their entirety each of the allegations set forth in  
26 paragraphs 1-85 of this Complaint.

27 87. Defendants have orchestrated a misleading advertising campaign and have  
28 intentionally avoided required establishment registration with the FDA, which will cause

1 consumer injury and harm to the public at large. By way of one example, consumers are  
2 entitled to report claims of personal injury caused by an incontinence product, but consumers  
3 of the WIESNER or VIRTH incontinence clamps will not be able to locate and submit such  
4 claims to the responsible parties.

5 88. As a result of at least the above actions and omissions of Defendants, consumer injury  
6 will occur and thereafter repeat.

7 89. Defendants' actions and omissions will continue unless enjoined to force lawful  
8 activities and enjoin unlawful activities.

9 **COUNT VI**  
10 **FALSE ADVERTISING**  
11 **Unfair competition under New York common law**

12 90. Plaintiff incorporates by reference in their entirety each of the allegations set forth in  
13 paragraphs 1-89 of this Complaint.

14 91. Upon information and belief, Defendants have acted willfully and in bad faith to  
15 commit the unfair competition set forth herein.

16 92. For example, Defendants have refused to correct their actions and omissions after  
17 being given at least two years of time to do so, which evidences Defendants' continued bad  
18 faith and willful violations of law.

19 93. Upon information and belief, Plaintiff has lost sales of its product in New York due  
20 to Defendants' unfair competition.

21 94. Plaintiff has been and will continue to be injured as a direct and proximate result of  
22 Defendants' unfair competition.

23 95. Defendants have been and will be unjustly enriched by their unfair competition, by  
24 an amount to be proven at trial.

**DEMAND FOR RELIEF SOUGHT**

WHEREFORE, PLAINTIFF respectfully requests the following relief:

- A. That the Court declare that U.S. Patent No. 11,642,205 is invalid;
- B. That the Court declare that Plaintiff has not infringed U.S. Patent No. 11,642,205;
- C. That the Court declare that U.S. Patent No. 11,642,205 is unenforceable due to inequitable conduct;
- D. That the Court enjoin Defendants from committing unfair competition and from making false or misleading representations of source or superiority of the WIESNER incontinence clamp and VIRTH incontinence clamp;
- E. That the Court find that this case is “exceptional” within the meaning of at least 15 U.S.C. § 1117(a), and award treble damages, reasonable attorney’s fees, and expenses;
- F. That the Court award damages to Plaintiff, in an amount to be determined at trial, to the fullest extent permitted by applicable law; and
- G. That the Court award to the Plaintiff such further relief, in law or in equity, as this Court deems just and proper.

**JURY DEMAND**

Pursuant to Fed. R. Civ. P. 38, Plaintiff Cross Innovations, LLC demands a trial by jury on all issues properly so triable.

Respectfully submitted,

DATED: June 1, 2023

By: /s/ Daniel S. Bretzius  
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