

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

L&R USA INC., )  
)  
Plaintiff, )  
)  
v. ) C.A. No. \_\_\_\_\_  
)  
CRAWFORD HEALTHCARE INC., )  
)  
Defendant. )

**VERIFIED COMPLAINT**

Plaintiff L&R USA Inc. for its Complaint in this action alleges:

**PARTIES AND JURISDICTION**

1. Plaintiff L&R USA Inc. (“L&R”) is a Wisconsin corporation having its principal place of business at 3880 West Wheelhouse Road, Milwaukee, Wisconsin 53208.
2. Defendant Crawford Healthcare Inc. (“Crawford”) is a Delaware corporation having its principal place of business at 2005 South Easton Road, Suite 203, Doylestown, Pennsylvania 18901.
3. This action arises under the federal Patent Act, 35 U.S.C. §§ 1–390.
4. This Court has jurisdiction to hear this action under 28 U.S.C. §§ 1331 and 1338(a).

**CLAIM FOR RELIEF**

5. Plaintiff L&R is the owner of U.S. Patent No. 9,713,553 issued July 25, 2017, for an invention entitled “Wound Cleaning Assembly” (the “’553 Patent”). A true copy of the ’553 Patent is annexed hereto as Exhibit 1.
6. The technology disclosed and claimed in the ’553 Patent gave birth to an entirely new category of wound cleaning products, which L&R markets and sells in the United

States under the registered trademark DEBRISOFT®.

7. As described in the product brochure annexed as Exhibit 2 to this complaint, DEBRISOFT® wound cleaning products are clinically proven to reduce 90–99% of slough, biofilm, and bacterial load from diverse wound types while protecting newly formed granulation tissue and being virtually painless. A specimen DEBRISOFT® wound cleaning product is depicted below:



8. DEBRISOFT® wound cleaning products embody the invention disclosed and claimed in the '553 Patent.

9. Defendant Crawford is a direct competitor of L&R in the field of wound cleaning products.

10. Crawford sells a line of wound cleaning products, exemplified by the KERRAPREP™ products depicted below (the “Accused Products”):

Two boxes of KerraPrep wound and skin preparation mitts. One box is blue and white, the other is white and blue. Next to them are two white, rectangular sterile mitts of different sizes.

Sizes	Sterile mitts per box	Product Code
4 x 4in (10 x 10cm)	5	CWL1021
5 x 8in (13.5 x 20cm)	5	CWL1022

To place an order please contact your medical supply distributor or call 855-522-2211

**KerraPrep™ - your partner in wound bed preparation**

Crawford has advertised and marketed the Accused Products as a direct substitute for DEBRISOFT® wound cleaning products.

11. The Accused Products embody the inventions defined by at least claims 1, 2, 4, 13, and 14 of the '533 Patent as set forth below.

12. Claim 1 of the '553 Patent reads as follows:

1. Wound cleaning assembly which comprises a wound cleansing cloth (1) having at least one supporting layer (2) and single-fiber threads (3) arranged on the supporting layer (2) and protruding from the supporting layer (2), at least some of the single-fiber threads comprising a synthetic fiber, wherein at least some of the single-fiber threads (3) have protruding ends (4) on the side thereof facing away from the supporting layer (2), at least some of the single-fiber threads further comprising end surfaces (4) which extend at an angle (23) neither orthogonal nor parallel with reference to the longitudinal axis (5) thereof, wherein the single-fiber threads form a pile arranged on and extending from the supporting layer and the pile having a pile height (13) of between about 3 millimeters and 12 millimeters, wherein the single-fiber threads have a dtex value of between about 0.5 and 20 and wherein the wound cleansing cloth is packed in a sterile manner in a sealed packaging.

13. Claim 2 of the '553 Patent reads as follows:

2. The wound cleaning assembly of claim 1, the synthetic fiber comprising a polyester fiber.

14. Claim 4 of the '553 Patent reads as follows:

4. The wound cleaning assembly of claim 1, wherein the angle is an acute angle with reference to the longitudinal axis thereof.

15. Claim 13 of the '553 Patent reads as follows:

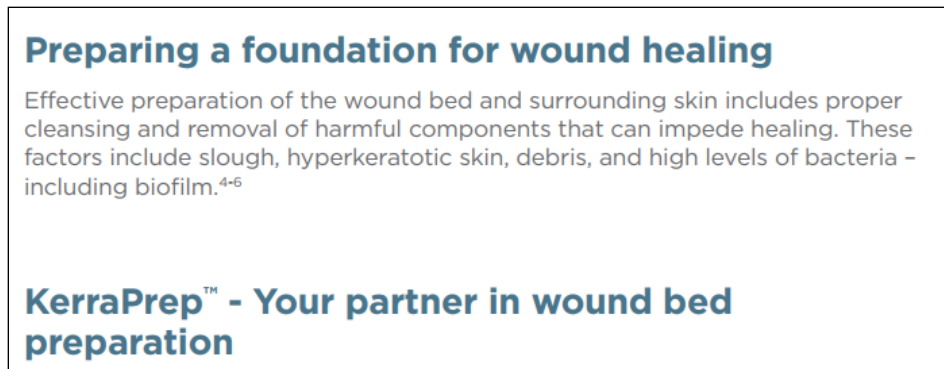
13. The wound cleaning assembly of claim 1, wherein said wound cleansing cloth has four edges, and each edge is from 5 to 20 cm in length.

16. Claim 14 of the '553 Patent reads as follows:

14. The wound cleaning assembly of claim 1, further comprising a pocket formed on a surface of the supporting layer facing away

from the threads, wherein said pocket is adapted to engage a hand of a person using the wound cleaning assembly.

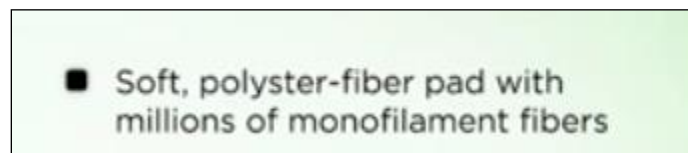
17. Each of the Accused Products is a “wound cleaning assembly” within the meaning of claims 1, 2, 4, 13, and 14 of the ’533 Patent. Crawford’s own advertising for the Accused Products characterizes them as such as shown in paragraph 10, above, and in the product description reproduced below:



See [http://crawfordhealthcare.us/wp-content/uploads/2017/06/CH17036-US\\_KPREP\\_4P\\_062217-21.pdf](http://crawfordhealthcare.us/wp-content/uploads/2017/06/CH17036-US_KPREP_4P_062217-21.pdf) (last visited July 27, 2017).

18. Each of the Accused Products also comprises a polyester cloth pad that consists of a supporting layer and millions of single-fiber (monofilament) threads arranged on and protruding from the supporting layer.

19. A video on Crawford’s website describes the Accused Products as follows:



See <http://crawfordhealthcare.us/in-service-debrimitt/> (last visited July 27, 2017).

20. Each of the Accused Products comprises a wound cleansing cloth that has a supporting layer.

21. The wound cleansing cloth of the Accused Products comprises single-fiber

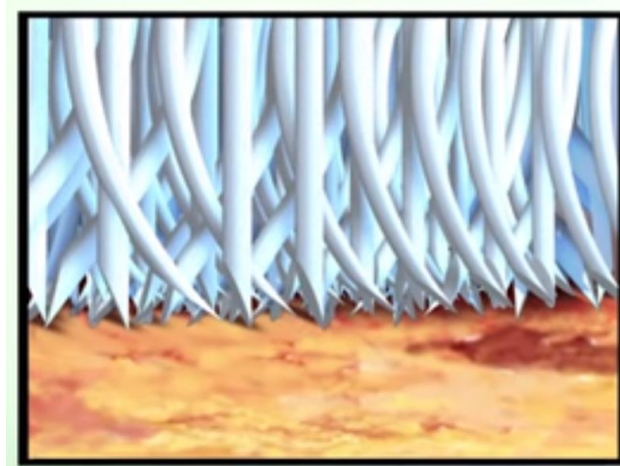
threads arranged on the supporting layer.

22. The single-fiber threads of the Accused Products protrude from a supporting layer.

23. At least some of the threads of the Accused Products are made of polyester, which is a synthetic fiber.

24. In the Accused Products, single-fiber threads protrude from the supporting layer and end in surfaces disposed at an acute angle to the longitudinal axis of the threads.

25. A video on the website of defendant website of defendant Crawford Healthcare Inc. illustrates the Accused Products as follows:



See <http://crawfordhealthcare.us/in-service-debrimitt/> (last visited July 27, 2017), depicting threads with protruding ends whose surfaces make an acute angle with reference to the longitudinal axis of the threads.

26. At least some of the threads of the Accused Products have protruding ends on the side of the threads facing away from the supporting layer.

27. At least some of the threads of the Accused Products comprise end surfaces which extend at an angle that is neither orthogonal nor parallel with reference to the longitudinal axis of the threads.

28. At least some of the threads of the Accused Products comprise end surfaces which extend at an acute angle with reference to the longitudinal axis of the threads.

29. The threads of the Accused Products form a pile with a height of approximately 5 millimeters, arranged on and extending from one side of the supporting layer; the opposite surface of the supporting layer provides a pocket into which fits the hand of a person using the product.

30. The pocket feature of the Accused Products is depicted in the below images reproduced from Crawford's website:



See <http://crawfordhealthcare.us/wound-care-products/kerraprep/> (last visited July 27, 2017), demonstrating that the threads form a pile that is arranged on and extends from one side of the supporting layer, with the other side of the supporting layer providing a pocket for engaging the hand of a person using the product.

31. The threads of the Accused Product form a pile arranged on and extending from the supporting layer.

32. Each of the Accused Products comprises a pocket that is formed on the surface of the supporting layer facing away from the threads and that is adapted to engage a hand of a person using the Accused Product.

33. The pile of the Accused Products has a pile height of approximately

9 millimeters, which is between 3 millimeters and 12 millimeters.

34. The threads of the Accused Product weigh approximately 5 grams per 10,000 meters.

35. As explained in the '553 Patent, a measurement of 1 dtex equals 1 gram per 10,000 meters. *See* '553 Patent, column 6, line 25.

36. The threads of the Accused Products have a dtex value of between about 0.5 and 20.

37. The Accused Products are packed in a sterile manner in a sealed packaging, as illustrated by the below images:



38. The Information for Use supplied with the Accused Products includes the following description.

### **Product Description**

KerraPrep™ is a mitt consisting of polyester fibers. The sterile mitt has been developed to aid in wound and peri-wound preparation where removal of non-viable tissue is required. It is available in 2 sizes: 10x10cm/4x4in and 13.5x20cm/5x8in available in packs of 5.

39. Crawford's website describes and illustrates the Accused Products as sold in packages of five "sterile mitts per box." See [http://crawfordhealthcare.us/wp-content/uploads/2017/06/CH17036-US\\_KPREP\\_4P\\_062217-21.pdf](http://crawfordhealthcare.us/wp-content/uploads/2017/06/CH17036-US_KPREP_4P_062217-21.pdf) (last visited July 27, 2017).

40. The description in the immediately preceding paragraph confirms that the wound cleansing cloth in the Accused Products is packed in a sterile manner in a sealed packaging.

41. Crawford's selling, offering for sale, importation, and use of the Accused Products since July 25, 2017, has been unauthorized by L&R.

42. Crawford's selling, offering for sale, importation, and use of the Accused Products since July 25, 2017, has infringed and is infringing the '553 Patent.

43. Crawford's infringement of the '553 Patent has been committed knowingly, willfully, and deliberately as set forth below.

44. The Accused Products were previously the subject of a civil action in the UK High Court for infringement of European patent EP2365794 ("EP '794").

45. The invention defined by claim 1 of the '553 Patent is virtually identical to the invention defined by claim 1 of the EP '794 Patent.

46. On February 10, 2016, the Opposition Division of the European Patent Office



(“EPO”) rejected a challenge by Crawford Healthcare Ltd. to the validity of claim 1 of the EP ’794 Patent.

47. L&R and Crawford thereafter entered into a Confidential Settlement Agreement dated December 22, 2016 (the “December 2016 Agreement”), under which Crawford Healthcare Ltd. and its affiliates, including Crawford, agreed not to commercialize the “KERRAPREP (formerly known as DEBRIMITT)” product or “any substantially similar product” in any country where the EP ’794 Patent was in force.

48. The December 2016 Agreement granted Crawford a non-exclusive license under any patent that resulted from then-pending U.S. Application Serial No. 14/790,398 (the “2015 U.S. Application”), but only with respect to provisional rights under 35 U.S.C. § 154(d).

49. Crawford’s license under the ’553 Patent and automatically terminated on July 25, 2017, when the 2015 U.S. Application issued as the ’553 Patent.

50. Despite the termination of its license under the ’553 Patent, and in willful and wanton infringement of L&R’s rights, Crawford has continued to market and sell the Accused Products in the United States in direct competition with DEBRISOFT<sup>®</sup> wound cleaning products marketed and sold by L&R.

51. The Accused Products sold by Crawford are the only products sold in the United States which compete directly with DEBRISOFT<sup>®</sup> wound cleaning products.

52. Crawford advertises and markets the Accused Products in the United States as purportedly being direct substitutes for DEBRISOFT<sup>®</sup> wound treatment products marketed and sold by L&R.

53. Crawford advertises and markets the Accused Products to the same types of customers as potentially would purchase DEBRISOFT<sup>®</sup> wound treatment products from L&R.

54. Crawford advertises and markets the Accused Products in the same journals as L&R advertises DEBRISOFT<sup>®</sup> wound cleaning products.

55. Crawford advertises and markets the Accused Products at the same conferences where L&R advertises and markets DEBRISOFT<sup>®</sup> wound cleaning products.

56. Crawford has marketed and sold the Accused Products at prices below those charged by L&R for DEBRISOFT<sup>®</sup> wound treatment products.

57. Crawford's infringement of the '553 Patent is designed and intended to divert sales from L&R to Crawford.

58. If not preliminarily enjoined, Crawford's infringement of the '533 Patent will result in losses of market share and reduced use and purchases of DEBRISOFT<sup>®</sup> wound treatment products in amounts that cannot be adequately compensated for in money damages.

59. If not preliminarily enjoined, Crawford's infringement of the '533 Patent will injure L&R's reputation as an innovator and cause buyers to believe, falsely, that the benefits of DEBRISOFT<sup>®</sup> wound treatment products are legitimately available from wound treatment products sold by Crawford, when they are not. This adverse effect cannot be adequately compensated for in money damages.

60. If not preliminarily enjoined, Crawford's infringement of the '553 Patent will alter buyer perceptions of DEBRISOFT<sup>®</sup> wound treatment products in a manner that cannot be adequately compensated for in money damages.

61. If not preliminarily enjoined, Crawford's infringement of the '553 Patent will expose L&R to loss of pricing discretion for DEBRISOFT<sup>®</sup> wound treatment products and price erosion whose magnitude and adverse effects cannot be adequately compensated for in money damages.

62. If not preliminarily enjoined, Crawford's infringement of the '553 Patent will result in the formation of vendor-vendee relationships between Crawford and L&R customers whose adverse effects on L&R's business cannot be adequately compensated for in money damages.

63. If not preliminarily enjoined, Crawford's infringement of the '553 Patent will expose L&R to loss of goodwill associated with DEBRISOFT<sup>®</sup> wound treatment products and risk of negative effects of buyer dissatisfaction with infringing cheap imitation Accused Products sold by Crawford. These adverse effects cannot be adequately compensated for in money damages.

64. Crawford has breached, and is continuing to breach, the December 2016 Agreement.

65. The number of the '553 Patent has been applied to the packaging of substantially all DEBRISOFT<sup>®</sup> wound treatment products that were manufactured after the issuance of the '553 Patent and sold in the United States.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray that the Court:

- A. Declare, adjudge, and decree that Crawford is liable to Plaintiff for infringement of the '553 Patent;
- B. Issue preliminary and permanent injunctions against continued infringement of the '553 Patent by Crawford or persons in active concert or participation with Crawford;
- C. Award Plaintiff compensatory damages as provided by law;
- D. Award Plaintiff prejudgment interest as provided by law;
- E. Declare this case exceptional pursuant to 35 U.S.C. § 285 and award Plaintiff its reasonable attorneys' fees, costs, and expenses incurred in prosecuting its claim for in-

fringement; and

F. Award Plaintiff such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

L&R demands a trial by jury on all issues triable to a jury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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August 31, 2017

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L&R USA INC., )  
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 Plaintiff, )  
 )  
 v. ) C.A. No. \_\_\_\_\_  
 )  
 CRAWFORD HEALTHCARE, INC., )  
 )  
 Defendant. )

**VERIFICATION**

I, Gary Keytel, declare as follows:

1. I am the President of L&R USA Inc. ("L&R").
2. I have personal knowledge of L&R and its activities, including those set out in the

Verified Complaint in this action.

3. I verify under penalty of perjury under the laws of the United States of America that the factual statements in the Verified Complaint concerning L&R and its activities are true and correct to the best of my knowledge, information and belief.

Executed on August 30, 2017.

\_\_\_\_\_  
Gary Keytel  
L&R USA Inc.

