IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
_____ DIVISION

BIEDERMANN TECHNOLOGIES GMBH & CO. KG, *PLAINTIFF*, VS. K2M, INC. AND K2M GROUP HOLDINGS, INC., *DEFENDANTS.*	JURY TRIAL DEMANDED Civil Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Biedermann Technologies GmbH & Co. KG ("Biedermann Technologies"), for its Complaint against K2M, Inc. and K2M Group Holdings, Inc. (collectively, "K2M"), hereby alleges as follows:

THE PARTIES

1. Plaintiff Biedermann Technologies is an entity that exists under the laws of Germany and is headquartered in Donaueschingen, Germany. Biedermann Technologies focuses on innovating and developing medical device technology for use in the human spine.

2. Defendant K2M, Inc. is a Delaware corporation with its principal place of business in Leesburg, Virginia. Defendant K2M Group Holdings, Inc. is a Delaware corporation that owns and controls K2M, Inc. and also has its principal place of business in Leesburg, Virginia. K2M's corporate headquarters are located at 600 Hope Parkway SE, Leesburg, Virginia 20175.

3. Biedermann Technologies previously filed ongoing Civil Action No. 2:18-CV-00585 (MSD-DEM) ("First Action") against K2M on November 2, 2018. The First Action involves the same parties and accused products described herein.

4. K2M regularly conducts and transacts business in Virginia, throughout the United States, and within the Eastern District of Virginia, and as set forth below, has committed and continues to commit, tortious acts of patent infringement within and outside of Virginia and within the Eastern District of Virginia. K2M maintains a regular and established place of business in this District through a permanent physical facility located at 600 Hope Parkway SE, Leesburg, Virginia 20175. Further, K2M directly or indirectly uses, distributes, markets, sells, and/or offers to sell throughout the United States, including in this judicial district, spinal implant systems and devices that infringe Biedermann Technologies' U.S. Patent No. 9,597,121 (the '121 patent).

5. K2M's infringement of the '121 patent has been willful and deliberate because K2M knew of or was willfully blind to the '121 patent and its infringement of the '121 patent. K2M's willfulness is demonstrated by its subjective bad-faith, its wanton, malicious, deliberate, flagrant and consciously wrongful actions; including for example continued infringement despite an objectively high likelihood that its acts would infringe the asserted patent. For example, K2M regularly files patent applications in the same area of technology as Biedermann Technologies' patents, and Biedermann Technologies' patents are often cited during prosecution of K2M's patent applications. Further, Biedermann Technologies recently filed suit against K2M for infringement of numerous of its patents, including the infringing YUKON Device. Additionally, K2M attended trade shows and conferences also attended by Biedermann Technologies where Biedermann Technologies and associated companies displayed technology covered by the asserted patent. K2M's 2016 Annual report also exemplifies its willfulness. In the Annual Report, K2M explains

that it regularly compares its products to its competitors, "[i]n order for us to sell our products, we must continue to successfully demonstrate to spine surgeons the merits of our technologies and techniques compared to those of our competitors for use in treating patients with spinal pathologies." *See* K2M, 2016 Annual Report, http://investors.k2m.com/static-files/9e7aaba3-95f8-4336-a62a-c317d3a9a1c4. These examples demonstrate that K2M knew of, or was willfully blind to, Biedermann Technologies' asserted patent. Despite this knowledge and/or willful blindness, K2M continued and continues to infringe Biedermann Technologies' asserted patent willfully and in bad-faith.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This Court has exclusive subject matter jurisdiction over this case for patent infringement under 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over K2M. K2M has conducted and does conduct business within the State of Virginia. K2M maintains a regular and established place of business in this District through a permanent physical facility located at 600 Hope Parkway SE, Leesburg, Virginia 20175. K2M, directly or through subsidiaries or intermediaries (including distributors, retailers, and others), ships, distributes, offers for sale, sells, and advertises its products in the United States, the State of Virginia, and the Eastern District of Virginia. K2M, directly and through subsidiaries or intermediaries (including distributors, retailers, and others), has purposefully and voluntarily placed one or more of its infringing products, as described below, into the stream of commerce with the expectation that they will be purchased and used by consumers in the Eastern District of Virginia. These infringing products have been and continue to be purchased and used by consumers in the Eastern District of Virginia. K2M has committed

acts of patent infringement within the State of Virginia and, more particularly, within the Eastern District of Virginia.

8. Venue is proper in the Eastern District of Virginia under 28 U.S.C. §§ 1391 and 1400(b). K2M has transacted business in this District, and has directly committed acts of patent infringement in this District, and has a regular and established place of business in this District. K2M maintains a regular and established place of business in this District through a permanent physical facility located at 600 Hope Parkway SE, Leesburg, Virginia 20175. Upon information and belief, K2M employs a number of personnel in this District, including personnel involved in K2M's infringement by at least through the testing, demonstration, use, offer for sale, and sale of the accused products within Virginia.

THE PATENT IN SUIT

9. On March 21, 2017, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,597,121 ("the '121 patent" or "asserted patent"), entitled "Bone Anchoring Device." A true and correct copy of the '121 patent is attached hereto as Exhibit A.

10. Biedermann Technologies owns by assignment the entire right, title, and interest in and to the '121 patent.

11. The '121 patent is valid and enforceable.

12. K2M has infringed and continues to infringe one or more claims of the '121 patent by engaging in acts that constitute infringement under 35 U.S.C. § 271, including but not necessarily limited to making, using, selling, and/or offering for sale, in this district and elsewhere in the United States, and/or importing into this district and elsewhere in the United States, certain spinal implant systems and devices ("the Accused Products").

ACCUSED PRODUCTS

13. Based on publicly-available information and product samples provided by K2M in the First Action, K2M advertises its YUKON product as a "newly designed top-loading polyaxial screw with high angulation and the ability to accommodate rods in two diameters" (hereinafter, "YUKON Device"). Based on publicly-available materials, the YUKON Device is used in at least one spinal system: the YUKON OCT Spinal System. Based on publicly-available materials, the YUKON Device can be ordered in different screw lengths, and to accommodate two different diameters of rods. Based on publicly-available information, K2M announced the commercial launch of the YUKON Device in the YUKON OCT Spinal System at the 34th Annual Meeting of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Section on Disorders of the Spine and Peripheral Nerves on March 14, 2018.

FIRST CAUSE OF ACTION

(Infringement of the '121 Patent)

14. Paragraphs 1 through 13 are incorporated by reference as if fully stated herein.

15. K2M has infringed and continues to literally infringe the '121 patent by making, using, selling, offering for sale within the United States, and/or importing into the United States, products that are covered by one or more claims of the '121 patent, such as K2M's YUKON Device.

16. In addition to directly infringing the '121 patent, K2M has indirectly infringed and continues to indirectly infringe one or more claims of the '121 patent, including at least claim 1, by actively inducing others to directly infringe the '121 patent in violation of 35 U.S.C. § 271(b). For example, K2M, with knowledge that the YUKON Device infringes the '121 patent at least as of the date of this Complaint and/or with willful blindness to the '121 patent, knowingly induced infringement of the '121 patent with specific intent to do so by their activities relating to the

marketing, distribution, and/or sale of the YUKON Device to their purchasers, and by instructing and encouraging purchasers (including through product documentation) to operate and use those products in an infringing manner with knowledge that these actions would infringe the ’121 patent. Further, as noted above, K2M knew of or was willfully blind to Biedermann Technologies’ patents. Moreover, as further detailed above, K2M provides and markets the YUKON Device to customers. K2M further instructs and directs their customers on how to infringe the ’121 patent by configuring the YUKON Device to be used in spinal or other orthopaedic surgeries in manners that infringe the ’121 patent.

17. For example, K2M has infringed, and continues to infringe, at least claim 1 of the ’121 patent:

> 1. A polyaxial bone anchoring device comprising:
>
> a bone anchoring element having a head and a shaft for anchoring to a bone;
>
> a receiving part for coupling the bone anchoring element to a rod, the receiving part having a first end and a second end, a head receiving portion at the second end with an accommodation space for accommodating the head, and a rod receiving portion at the first end, the rod receiving portion having an inner wall defining a bore, the bore having a bore axis; and
>
> a pressure member movable in the bore and comprising a first section defining a first surface for engaging the head, and a one-piece second section that is axially connected to the first section and that defines both a second surface for engaging the rod and an outer surface;
>
> wherein when the bone anchoring element and the pressure member are in the receiving part, the pressure member is configured to assume and be held at a first position where friction between the first surface and the head generates a preload on the head to maintain the shaft at a temporary angular position relative to the receiving part, and a second position different from the first position where the head is locked relative to the receiving part; and
>
> wherein when the pressure member is at the first position, a portion of the inner wall of the receiving part that is directed towards the bore axis exerts a holding force on the outer surface of the pressure member to restrict movement of the pressure member towards the first end of the receiving part, and wherein the pressure member is movable out of the first position towards

the first end of the receiving part by applying a sufficient axial force on the pressure member.

18. K2M's YUKON Device comprises "[a] polyaxial bone anchoring device comprising: a bone anchoring element having a head and a shaft for anchoring to a bone":

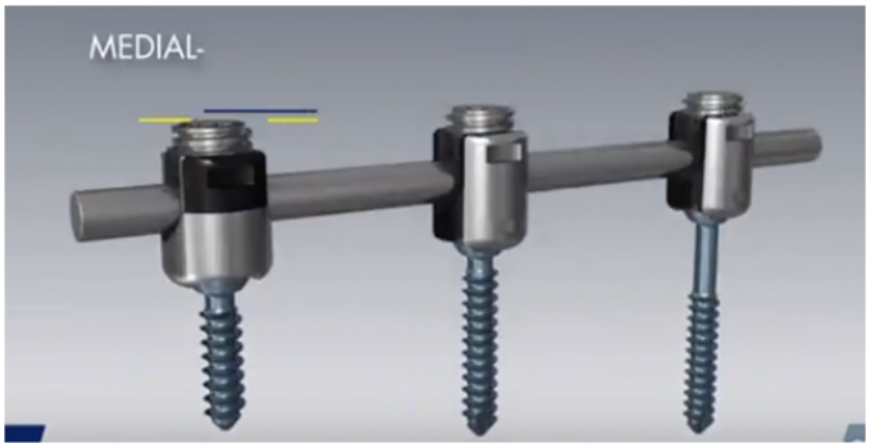
YUKON™ OCT Spinal System

The YUKON™ OCT Spinal System features a newly designed top-loading polyaxial screw with high angulation and the ability to accommodate rods in two diameters. The system offers a comprehensive selection of polyaxial screws, hooks, rods, connectors, and occipital plates.

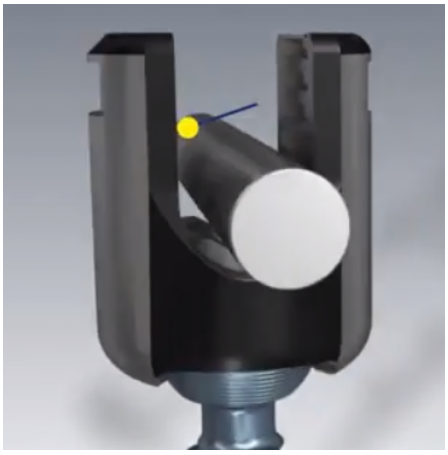
See YUKON OCT Spinal System, https://www.k2m.com/products/product/yukon-oct/; YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:27, 0:32, 0:38). It can be seen in the images above that K2M's YUKON device is a bone anchoring device that is polyaxial and has a head and a shaft for anchoring to a bone.

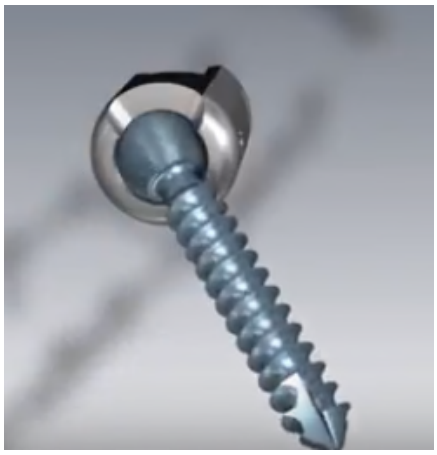
19. K2M's YUKON Device comprises "a receiving part for coupling the bone anchoring element to a rod, the receiving part having a first end and a second end, a head receiving portion at the second end with an accommodation space for accommodating the head, and a rod

receiving portion at the first end, the rod receiving portion having an inner wall defining a bore, the bore having a bore axis":



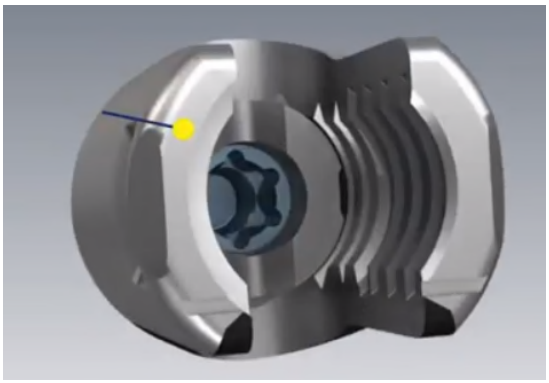
See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:32). The image above depicts that the receiving part couples the anchoring element to a rod.





See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:32, 0:39). Further, the receiving part has a rod receiving portion at a first end that has an inner wall that defines a bore having a bore axis. The receiving part also has a head receiving portion at a second end that accommodates the head of the anchoring element.

20. Based on product samples provided by K2M in the First Action, K2M's YUKON Device comprises "a pressure member movable in the bore and comprising a first section defining a first surface for engaging the head, and a one-piece second section that is axially connected to the first section and that defines both a second surface for engaging the rod and an outer surface":

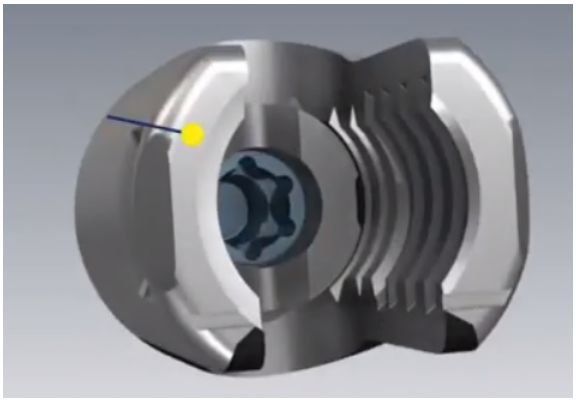


See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 1:08). The image above depicts a pressure member that is movable in the bore of the receiving part. Further, the pressure member has a first section for engaging the head and a second section axially connected to the first section.

See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting

YUKON Device at 0:48). The second section has both an outer surface and a second surface that engages the rod.

21. Based on product samples provided by K2M in the First Action, K2M's YUKON Device comprises "when the bone anchoring element and the pressure member are in the receiving part, the pressure member is configured to assume and be held at a first position where friction between the first surface and the head generates a preload on the head to maintain the shaft at a temporary angular position relative to the receiving part, and a second position different from the first position where the head is locked relative to the receiving part":



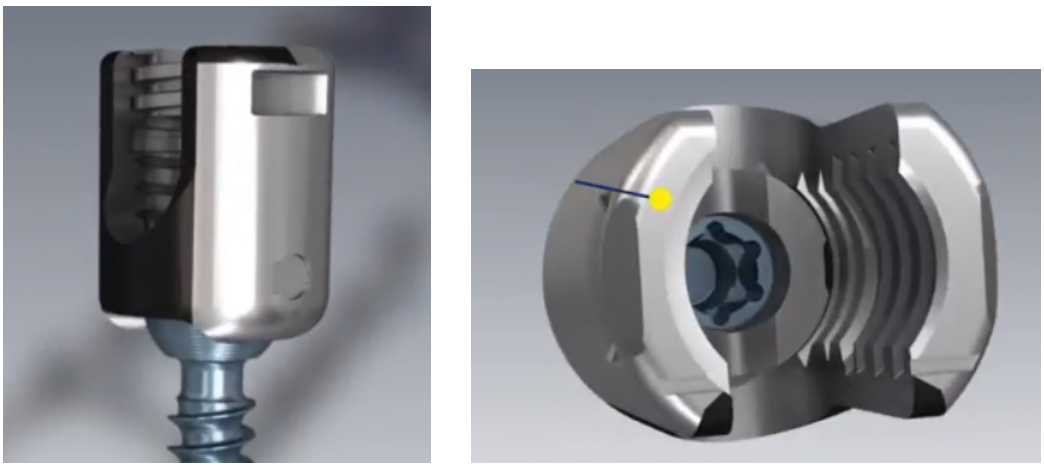
See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 1:08). As can be seen in the photo, the pressure member sits in the receiving part.

- Friction Head to Aid in Improved Rod Placement

See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:28); YUKON OCT Spinal System, https://www.k2m.com/products/product/yukon-oct/. The pressure member assumes and is held at a first position and generates a frictional preload force between the pressure member's first surface and the head of the anchoring element. The frictional preload force maintains the shaft of the anchoring element at a temporary angular position relative to the receiving part.

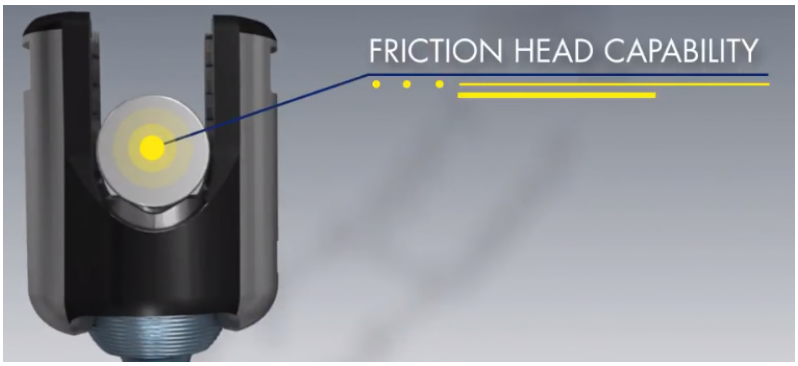
See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:19). As depicted above, the pressure member assumes a second position that is different from the first position where the head is locked relative to the receiving part.

22. Based on product samples provided by K2M in the First Action, K2M's YUKON Device comprises "when the pressure member is at the first position, a portion of the inner wall of the receiving part that is directed towards the bore axis exerts a holding force on the outer surface of the pressure member to restrict movement of the pressure member towards the first end of the receiving part, and wherein the pressure member is movable out of the first position towards the first end of the receiving part by applying a sufficient axial force on the pressure member":



See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:24, 1:08); YUKON OCT Spinal System, https://www.k2m.com/products/product/yukon-oct/. As shown in the images above, when the

pressure member is at a first position, a portion of the inner wall of the receiving part is directed toward the bore axis. This portion of the inner wall exerts a holding force on the outer surface of the pressure member, thus restricting movement of the pressure member toward the first end of the receiving part.



See YUKON OCT Spinal System Product Animation, https://www.youtube.com/watch?v=N98T3CfzlO0 (screenshot from video clip depicting YUKON Device at 0:39). Further, when sufficient axial force is applied to the pressure member, the pressure member is movable out of the first position toward the first end of the receiving part.

23. K2M's infringement has caused and is continuing to cause damage and irreparable injury to Biedermann Technologies, and Biedermann Technologies will continue to suffer damage and irreparable injury unless and until that infringement is enjoined by this Court.

24. Biedermann Technologies is entitled to injunctive relief, damages, and enhanced damages in accordance with 35 U.S.C. §§ 271, 281, 283, and 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Biedermann Technologies prays for relief and judgment as follows:

(A) that K2M has willfully infringed the Asserted Patent;

(B) that K2M, its officers, agents, employees, and those persons in active concert or participation with any of them, and its successors and assigns, be permanently enjoined from infringement of the Asserted Patent, including but not limited to an injunction against making, using, selling, and/or offering for sale within the United States, and/or importing into the United States, any products and/or services that infringe the Asserted Patent;

(C) that Biedermann Technologies be awarded all damages sufficient to compensate Biedermann Technologies for K2M's infringement of the Asserted Patent, in an amount not less than a reasonable royalty;

(D) for an award of increased damages in an amount not less than three times the damages assessed for K2M's infringement of the Asserted Patent, in accordance with 35 U.S.C. § 284;

(E) that this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that Biedermann Technologies be awarded attorneys' fees, costs, and expenses incurred in connection with this action;

(F) that Biedermann Technologies be awarded prejudgment and post-judgment interest; and

(G) that Biedermann Technologies be awarded such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

In accordance with Rule 38 of the Federal Rules of Civil Procedure, Plaintiff respectfully demands a jury trial of all issues triable to a jury in this action.

Dated: June 17, 2019

Respectfully submitted,

/s/ Stephen E. Noona

Stephen Edward Noona
Virginia State Bar No. 25367
KAUFMAN & CANOLES, P.C.
150 W Main St., Suite 2100
Norfolk, VA 23510
Telephone: (757) 624-3239
Facsimile: (888) 360-9092
senoona@kaufcan.com

Luke L. Dauchot (*pro hac vice* to be filed)
Sharre Lotfollahi (*pro hac vice* to be filed)
Yungmoon Chang (*pro hac vice* to be filed)
KIRKLAND & ELLIS LLP
333 South Hope Street
Los Angeles, CA 90071
Telephone: (213) 680-8400
Facsimile: (213) 680-8500
Luke.dauchot@kirkland.com
Sharre.lotfollahi@kirkland.com
Yungmoon.chang@kirkland.com

Counsel for Plaintiff, Biedermann Technologies GmbH & CO. KG

CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2019, as a courtesy, I will send the foregoing Complaint for Patent Infringement by electronic mail to the following:

Robert M. Tata
Virginia State Bar No. 30101
Wendy C. McGraw
Virginia State Bar No. 37880
HUNTON ANDREWS KURTH LLP
500 E. Main Street, Suite 1000
Norfolk, VA 23510
Telephone: (757) 640-5300
Facsimile: (757) 625-7720
btata@huntonak.com
wmcgraw@huntonak.com

Gregory S. Gewirtz (*pro hac vice* to be filed)
Alexander Solo (*pro hac vice* to be filed)
Russell W. Faegenburg (*pro hac vice* to be filed)
LERNER DAVID LITTENBERG KRUMOLZ
& MENTLIK LLP
600 South Avenue West
Westfield, NJ 07090
Telephone: (908) 518-6343
Facsimile: (908) 654-7866
ggewirtz@lernerdavid.com
asolo@lernerdavid.com
rfaegenburg@lernerdavid.com

Attorneys for Defendants, K2M, Inc and K2M Group Holdings, Inc.

/s/ Stephen E. Noona
Stephen E. Noona
Virginia State Bar No. 25367
KAUFMAN & CANOLES, P.C.
150 West Main Street, Suite 2100
Norfolk, VA 23510
Telephone: (757) 624-3239
Facsimile: (888) 360-9092
senoona@kaufcan.com

Attorneys for Plaintiff Biedermann Technologies GmbH & Co. KG