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CRANIAL TECHNOLOGIES, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

CRANIAL TECHNOLOGIES, INC,

Plaintiff,

vs.

OTTOBOCK SE & CO. KGAA and ACTIVE LIFE LLC,

Defendants.

Case No. 2:23-CV-02320

COMPLAINT FOR PATENT INFRINGEMENT

DEMAND FOR JURY TRIAL

Plaintiff Cranial Technologies, Inc. ("Cranial"), by and through its undersigned counsel, seeks a declaration and judgment that Defendants Ottobock SE & Co. KGAA ("Ottobock SE") and Active Life LLC ("Active Life") (collectively, "Ottobock") infringe U.S. Patent Nos. 7,242,798 ("the '798 patent"); 7,227,979 ("the '979 patent"); 10,846,925 ("the '925 patent"); 10,726,617 ("the '617 patent"); and 10,603,203 ("the '203 patent) (collectively, the "Asserted Patents"), which are each owned by and assigned to Cranial, invoking the Court's jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because the claims set forth herein arise under the patent laws of the United States, 35 U.S.C. § 1 *et. seq*.

NATURE OF THE ACTION

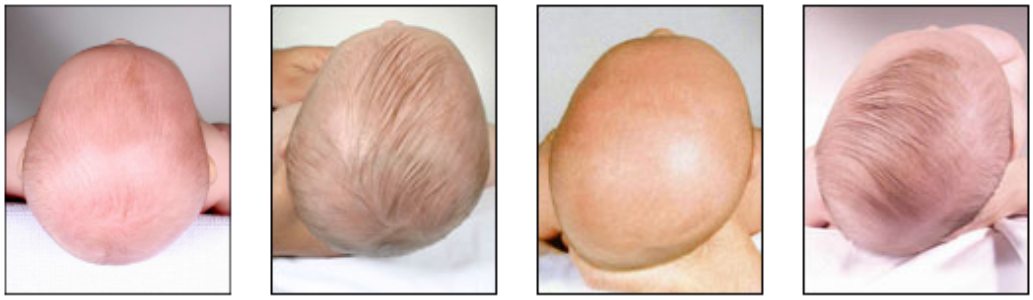
1. This case arises out of Ottobock's use, without authorization or license, of Cranial's intellectual property.

2. Cranial is an innovator and pioneer in the cranial orthotic helmet industry. Founded in 1986, Cranial was the first company to obtain approval from the U.S. Food and Drug Administration ("FDA") for a cranial helmet to treat cranial deformations.

3. Cranial deformation is a common condition in infants that causes abnormal or deformed head shapes. Babies' skulls are soft and malleable and external forces, even if gentle, can cause misshaping. Cranial deformations may be the result of an infant sleeping on its back or extended use of car seats and bouncy seats. Cranial deformations may also be caused by congenital muscular torticollis (CMT), a condition in which the baby's neck muscles are abnormally tight on one side and cause the baby's head to tilt and/or turn. Premature births, the baby's position in the womb, and multiple births (*e.g.*, twins) may also cause cranial deformations.

4. There are generally three types of cranial deformations: plagiocephaly, brachycephaly, and scaphocephaly. Plagiocephaly, also known as "flat head syndrome," is where an infant develops a flat spot on the back or backside of the head.

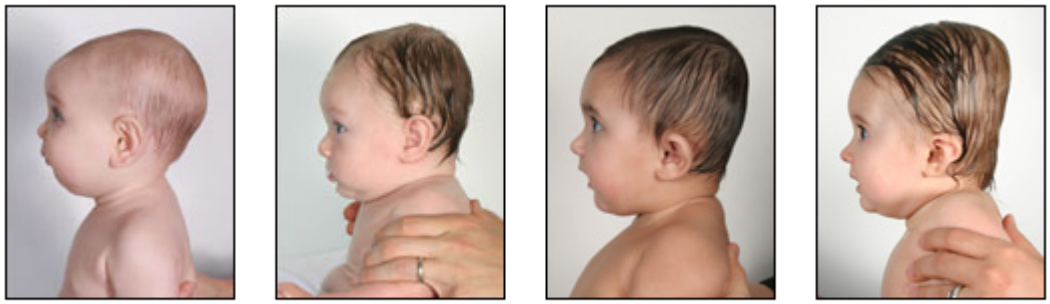
Plagiocephaly affects about 50% of children.[1] The head shape of an infant with plagiocephaly resembles a parallelogram from above. Other characteristics of plagiocephaly may include: one ear more forward than the other, one eye smaller than the other, one cheek fuller than the other, and the top of the head not being level.



Plagiocephaly head shapes, ranging from normal to severe.

Source: https://www.cranialtech.com/plagiocephaly/

5. A brachycephaly head shape is where the back of the infant's head becomes flat and causes the head to be wider than normal and flat rather than curved. Other characteristics of brachycephaly may include: an abnormally tall head, a face that appears small relative to head size, the widest part of patient's head being just above the ears, protruding ear tips, and a head shape that resembles a trapezoid from above.

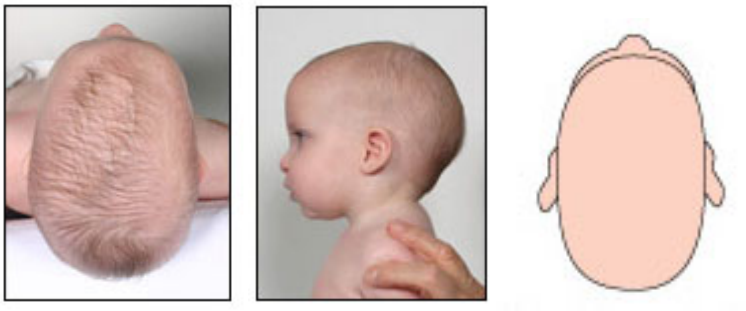


Brachycephaly head shapes, ranging from normal to severe.

Source: https://www.cranialtech.com/plagiocephaly/

6. A scaphocephaly head shape is where the infant's head is longer, narrower, and taller than normal.

[1] https://www.healthline.com/health/parenting/flat-head-baby#types

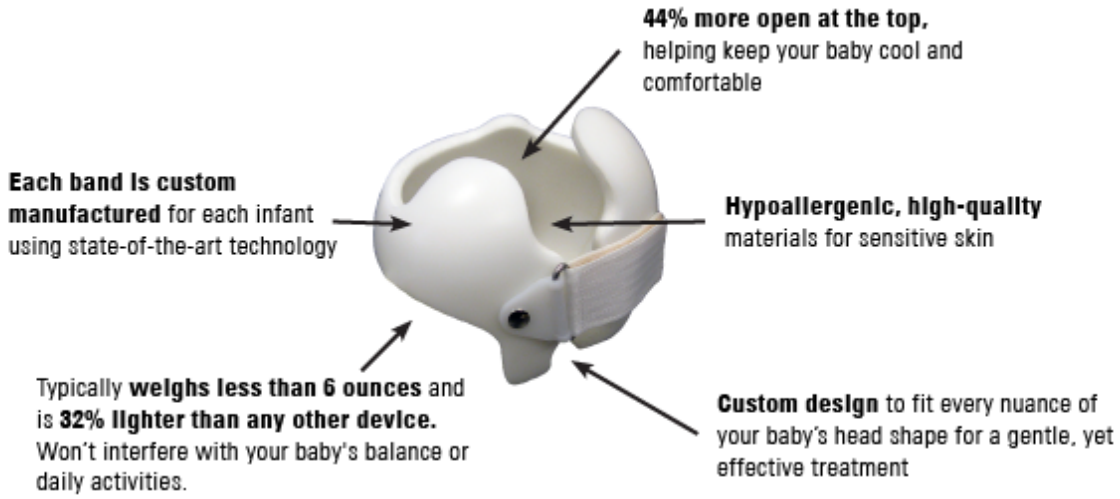


Source: https://www.cranialtech.com/plagiocephaly/what-is-plagiocephaly/; https://www.cranialtech.com/how-to-assess/

7. Before Cranial, the only viable approach for correcting these types of cranial deformities was through surgical correction of the cranium. Cranial, however, invented a treatment solution that is far less risky, does not require surgery, and with which parents can feel more comfortable.

8. In 1998, Cranial's Dynamic Orthotic Cranioplasty®, also known as the DOC Band®, became the first ever FDA-cleared cranial orthotic for plagiocephaly treatment.[2] The DOC Band® is a helmet, typically worn by the baby for 23 hours a day, that applies corrective pressure to the baby's head to redirect the baby's natural head growth into a normal head shape. Because each baby's head is unique, each DOC Band® is custom designed and manufactured to fit and gently shape the baby's head.

[2] https://www.cranialtech.com/about/



Source: https://www.cranialtech.com/treatment/the-doc-band/

9. To this day, the DOC Band® is the only cranial orthotic device supported by clinical studies and over 35 years of documented outcomes. Since 1998, over 300,000 babies have been treated with the DOC Band®. Due to Cranial's pioneering technology, treating infants with plagiocephaly using cranial remodeling bands, such as the DOC Band®, is the standard of care in the United States today.

10. When the DOC Band® was first introduced into the market, it and follow-on cranial helmets offered by other companies, were produced by first obtaining a full size cast (*e.g.*, using plaster) of the infant's head. This process involved pulling a stocking over the infant's head, applying the plaster, and waiting for the plaster to sufficiently harden. The resulting cast would then be filled with plaster to create a positive model of the infant's actual head shape. That first model would then be manually modified—by filing down certain portions and adding materials to others—to produce a second model of the desired head shape. The second model was then used to form the cranial helmet.

11. Historically, the cranial helmet was manufactured by vacuum thermo-forming a foam liner over the second model, vacuum thermo-forming a hard plastic over the foam liner, cutting the edges of the helmet, and then further grinding the foam liner to fine tune the helmet to the final desired shape.

12. After the introduction of the DOC Band®, Cranial continued to innovate to further improve these processes for designing and manufacturing cranial orthotic helmets. For example, Cranial developed its Digital Surface Imaging® ("DSi®") system, which is capable of capturing highly accurate 3-D images of the entirety of a baby's head. These digital images can be used to create a custom and precise-fitting cranial helmet for each baby. The U.S. Patent Office awarded Cranial with patents for its innovations including those implemented in the DSi® system.

13. Cranial also developed its Sentient3D® and Contour3D™ systems. These systems take information from digital images of an infant's deformed head to automatically calculate configuration information (*e.g.*, trim/contour lines, suspension to maintain band in proper orientation, location and magnitude of corrective forces) for the cranial orthotic device to treat that particular infant's condition. That information is then used to manufacture the cranial orthotic device. The U.S. Patent Office awarded Cranial with patents for its innovations including those implemented in the Sentient3D® and Contour3D™ systems, including the '798 patent and '979 patent.

14. Cranial's improvements eliminated the need to cast the infant's head with plaster to produce a cranial helmet that precisely fits that infant's head and can treat that infant's particular cranial deformities. Cranial's improvements thus eliminated the discomfort to the infant caused by requiring the infant to have plaster applied to the infant's head and to wait with the plaster on his/her head until the plaster sufficiently dried.

15. Cranial further improved the process of manufacturing cranial helmets by using additive manufacturing to improve the accuracy and ease with which cranial helmets are manufactured. Rather than fabricating a life size model of the desired head shape, vacuum thermo-forming a hard plastic onto the foam liner, generating trim lines for the device, projecting the trim lines onto the hard plastic, cutting the trim lines, and manually finishing the trimmed cranial modeling device, as was previously

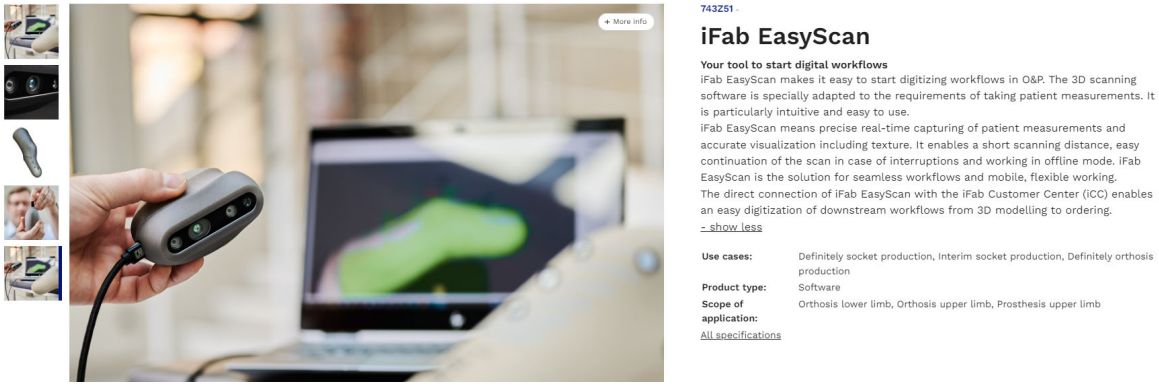
done, Cranial invented a manufacturing process by which the inner and outer layers of the cranial helmet are manufactured by additive manufacture (*e.g.*, 3-D printing) based on automated data that defines the proper shape and contour lines of the cranial helmet. Cranial's improvements reduced the number of steps required in the process for manufacturing cranial helmets increasing the efficiency of manufacture and reducing the possibility of error. The U.S. Patent Office awarded Cranial with patents for its innovations, including the '203 patent, '925 patent, and '617 patent.

16. Ottobock makes, uses, sells, offers for sale, and/or imports into the United States the infringing MyCRO Band and iFab system (collectively, "Accused Products") and distributes them to and through various clinics and subsidiaries including, *inter alia*, Active Life. Ottobock's MyCRO Band is a 3-D printed cranial orthotic helmet for treating cranial head deformities, such as plagiocephaly, brachycephaly, and scaphocephaly using Cranial's patented and inventive methods and systems.

Source: https://www.ottobock.com/en-us/product/24H1

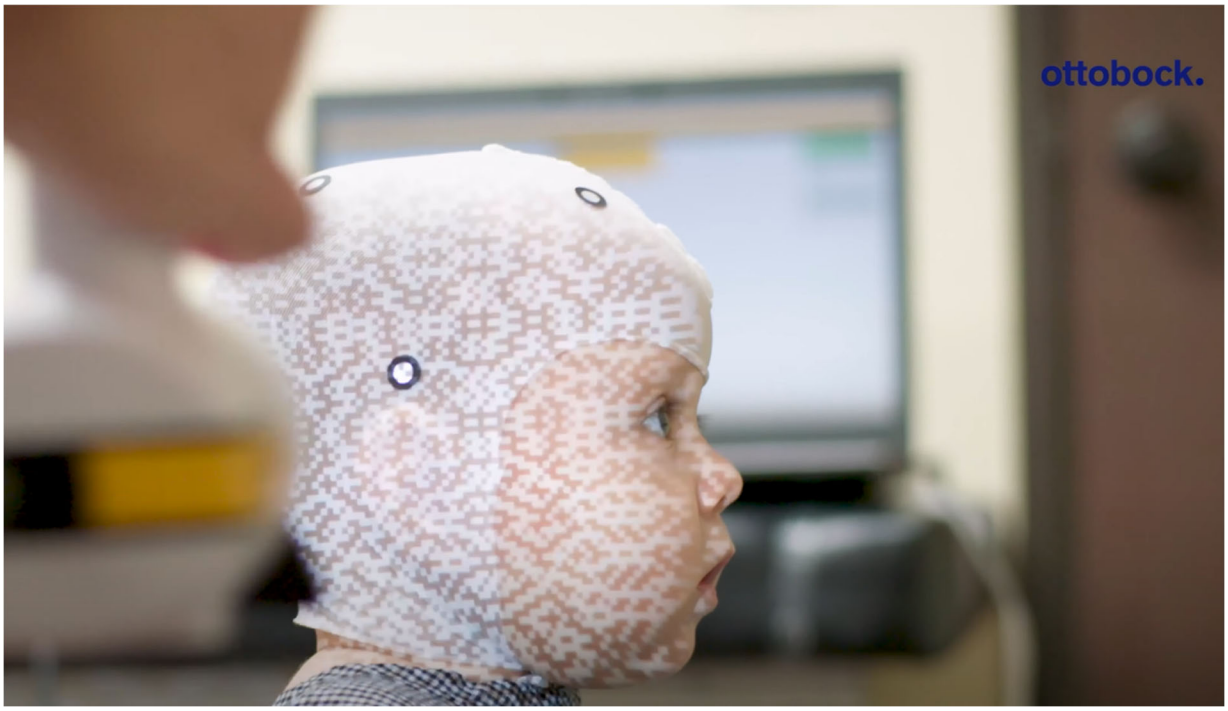
Source: https://www.youtube.com/watch?v=qu6OxfA05lI (posted Oct. 27, 2022)

17. Upon information and belief, the MyCRO Band is produced using Ottobock's iFab system. The iFab system comprises the iFab EasyScan, which includes a scanner and software that digitally captures 3-D images of the patient.



Source: https://www.ottobock.com/en-us/product/743Z51

Source: https://www.youtube.com/watch?v=qu6OxfA05lI (posted Oct. 27, 2022)



Source: https://www.youtube.com/watch?v=qu6OxfA05lI (posted Oct. 27, 2022)

18. The iFab EasyScan works in conjunction with the iFab Customer Center.[3] The iFab Customer Center allows users (*e.g.*, clinicians and orthotists) to upload digital images taken by iFab EasyScan and processes that data to automatically model the desired product for fabrication (*e.g.*, MyCRO Band). The information from the iFab Customer Center is then used to additively manufacture the desired product (*e.g.*, MyCRO Band).


iFab

How 3D scanners and printers are revolutionising fitting for patients

To this day, plaster casts are made in order to fit prostheses as effectively as possible. However, 3D scanners are a faster option that is more comfortable for the patient. Our iFab – short for "individual fabrication" – enables us to produce custom orthoses and prostheses quickly. O&P professionals scan a residual limb and process the data directly on a computer. Time that was once spent on manual work on the plaster cast – often a complex task – can now be channeled into the fitting process. The processed data are tested in a computer simulation and transferred directly to the milling machine and 3D printer. This minimises error sources. iFab digitalises the entire fitting and manufacturing process.

Source: https://corporate.ottobock.com/en/futuring/digitalisation

19. Cranial has invested significant time and resources researching and developing its patented technology. Cranial will be irreparably harmed if Ottobock is permitted to continue to manufacture, use, offer to sell, and sell devices that infringe Cranial's patents. Cranial will be forced to compete against the very technology that it spent significant time and resources researching and developing.

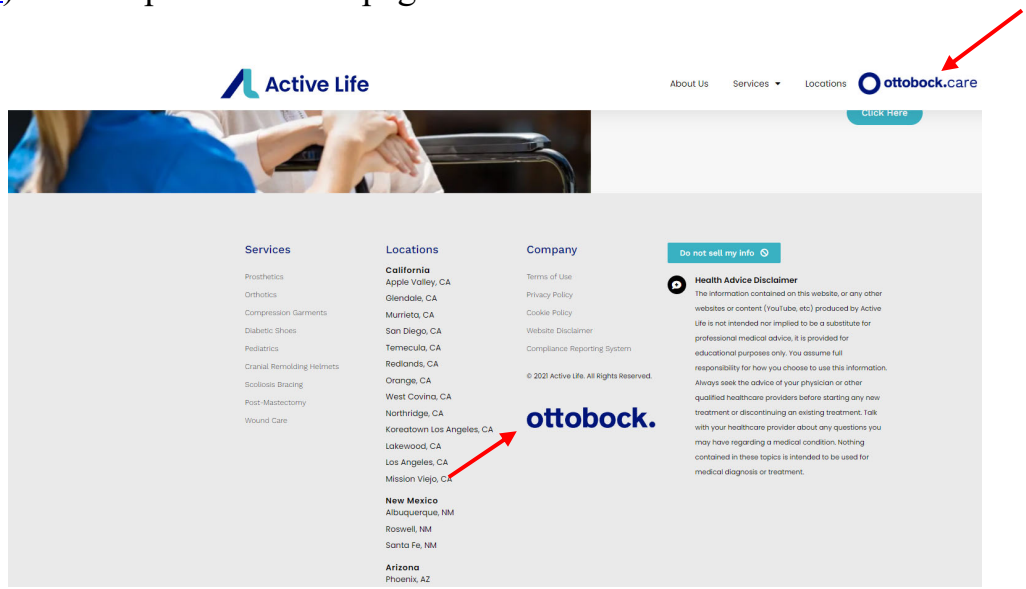
THE PARTIES

20. Plaintiff Cranial is an Arizona corporation with its principal place of business at 1405 W Auto Drive, Fl. 2, Tempe, Arizona 85284.

21. Defendant Ottobock SE is a German corporation with its principal place of business at 15 Max-näder-straße, Duderstadt, Lower Saxony, 37115, Germany. Defendant Active Life LLC is a Delaware company with its principal place of business at 1577 E Chevy Chase Drive #210, Glendale, CA 91206. Upon information and belief, Active Life operates under Ottobock SE's direction and control and for

[3] https://www.ifab-customer-center.com

Ottobock SE's direct benefit, and is controlled by Ottobock SE. For example, Active Life's website explains that Ottobock SE "entered the patient care market in North America through strategic partnership[s] with select best-in-class patient care providers through the United States," and that Active Life "joined Ottobock Patient Care" in 2021.[4] Active Life's website also includes Ottobock SE's logo on the bottom of each web page and a link to Ottobock SE's website (https://www.ottobock.com/en-us/Home) at the top of each web page.[5]



JURISDICTION AND VENUE

22. Cranial realleges and incorporates by reference the allegations contained in paragraphs 1-21 as though fully set forth herein.

23. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271 et seq.

24. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

25. This Court has personal jurisdiction over Ottobock SE and Active Life. Upon information and belief, Ottobock SE and Active Life have systematic and continuous contacts in California, regularly transact business within California, and

[4] https://goactivelife.com/about-us/.
[5] https://goactivelife.com/.

regularly avail themselves of the benefits of California. Upon information and belief, Ottobock SE offers for use and sale and sells the Accused Products in California, including in this District, to and/or through Active Life, which has at least 12 offices throughout California, including in this District.[6] For example, Active Life advertises the accused MyCRO Band Cranial Helmet as a pediatric orthotic[7] on its website and identifies locations in California, including in this District, that offer pediatric orthotic services.[8]

26. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b). Ottobock SE is subject to personal jurisdiction in this District. In addition, Active Life has committed acts of infringement and has multiple regular and established places of business in this District.[9]

FIRST CAUSE OF ACTION

(Infringement of U.S. Patent No. 7,242,798)

27. Cranial realleges and incorporates by reference the allegations contained in paragraphs 1-26 as though fully set forth herein.

28. Cranial is the owner of all rights, title, and interest in and to the '798 patent.[10] The '798 patent issued on July 10, 2007, and is titled "Automatic Selection of Cranial Remodeling Device Configuration."

29. Cranial significantly improved its own existing technology for producing a custom cranial remodeling device through the innovations of the '798 patent. The '798 patent explains, for example, that cranial remodeling devices were previously produced by casting the infant's head with a plaster, creating a first model of the

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[6] https://goactivelife.com/clinics/.
[7] https://goactivelife.com/mycro/.
[8] *See, e.g.*, https://goactivelife.com/clinics/koreatown-los-angeles-ca/ (location in Los Angeles offering "Pediatric Orthotics and Bracing").
[9] https://goactivelife.com/clinics/ (identifying locations in Apple Valley, Glendale, Lakewood, Los Angeles, Mission Viejo, Murrieta, Northridge, Orange, Redlands, and West Covina).
[10] A copy of the '798 patent is available at https://patentcenter.uspto.gov/applications/10753118.

infant's head shape from the cast, manually modifying the first model of the infant's misshaped head to form the desired head shape, and then forming the cranial remodeling device over the desired head shape. *See*, *e.g.*, '798 patent at 1:45-53, 2:31-36, 8:58-67. The '798 patent improves that prior art process by taking a digital capture of the child's actual head shape and processing that information to automatically calculate the unique configuration (*e.g.*, suspension, corrective forces, trim lines) of the cranial remodeling device that will treat that particular child's deformities. *See*, *e.g.*, *id*. at 14:4-25, 16:58-65, 17:4-7. The '798 patent, thus, "eliminate[s] the need to cast the children's head," "produces a cranial remodeling band of an appropriate configuration and having appropriate features, and appropriate trim lines all without any significant human intervention," and improves the efficiency and accuracy with which cranial remodeling devices are made. *See*, *e.g.*, *id*. at 14:4-5, 17:4-7.

30. Accordingly, the claims of the '798 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and systems for producing a cranial remodeling device. These advancements were neither well-known, routine, nor conventional. Upon information and belief, a person of ordinary skill in the art would have viewed the invention of the '798 patent as a patentable advancement over the prior art.

31. The claims of the '798 patent cover inventive methods and systems for producing cranial remodeling devices to correct for cranial shape abnormalities. Ottobock has infringed and continues to infringe one or more claims of the '798 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) at least by manufacturing, using, importing, selling, and/or offering to sell in the United States the iFab system, which, upon information and belief, is used to produce the MyCRO Band.

32. For example, claim 1 of the '798 patent recites:

(pre) A method for producing cranial remodeling devices to correct for cranial shape abnormalities comprising:

(a) capturing a three dimensional digital image of a deformed head to produce first digital data; and

(b) utilizing said first digital data to automatically provide cranial remodeling device information for use in fabricating a cranial remodeling device for said deformed head.

33. To the extent the preamble of claim 1 is considered a limitation, at least the iFab system comprises a method for producing cranial remodeling devices to correct for cranial shape abnormalities. Additional information is set forth in Exhibit 1 at claim 1(pre).

34. At least the iFab system captures a three dimensional digital image of a deformed head to produce first digital data. Additional information is set forth in Exhibit 1 at claim 1(a).

35. At least the iFab system utilizes said first digital data to automatically provide cranial remodeling device information for use in fabricating a cranial remodeling device for said deformed head. Additional information is set forth in Exhibit 1 at claim 1(b).

36. Ottobock has actively induced others to infringe the ’798 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including clinicians and orthotists, to directly infringe at least claim 1 of the ’798 patent. For example, Ottobock encourages clinicians and orthotists to use the iFab system to produce the MyCRO Band through marketing materials, manuals, and promotional demonstrations and videos.[11] Ottobock has actual knowledge of the ’798

[11] Exemplary materials: https://corporate.ottobock.com/en/futuring/ifab (“O&P professionals scan a residual limb and process the data directly on a computer. Time that was once spent on manual work on the plaster cast – often a complex task – can now be channeled into the fitting process.”); https://www.aopanet.org/2022-aopa-national-assembly/assembly-schedule/manufacturers-workshops-tier-b-5/ (“Ottobock is excited to demonstrate the first all-inclusive scanning, modelling, and 3D-printing

patent and that the actions of these third parties, including clinicians and orthotists, infringe the '798 patent since at least the filing of this Complaint.

37. Ottobock has contributed to the infringement by others of one or more claims of the '798 patent in violation of 35 U.S.C. § 271(c) by offering to sell or selling in the United States and/or importing into the United States its infringing iFab system and/or components of its infringing iFab system.[12] As described above, the iFab system and/or its components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '798 patent. Also, as described above, Ottobock has actual knowledge of the '798 patent and that the infringing iFab system and/or components are especially made or especially adapted for use in an infringement of the '798 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use since at least the filing of this Complaint. Ottobock has offered to sell, sold, and/or imported its infringing iFab system and components to clinicians and orthotists. These clinicians and orthotists then make, use, sell, or offer to sell products or systems that utilize the infringing iFab system and/or components. For example,

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technology specifically designed for the O&P industry."); https://www.ot-world.com/en/exhibitor-press-releases/ottobock-at-otworld-2022-technology-that-serves-people ("The third thematic focus at the trade show will present solutions that enable orthopaedic companies to enter the field of digital patient care. An example is 'iFab EasyScan.' … [P]roduct modeling, ordering and production – can also be carried out digitally including through Ottobock iFab (service centre for individual fabrication). The first 3D-printed products have been produced there since 2021, such as … MyCRO Band for helmet therapy for babies with skull deformities."); https://shop.ottobock.us/iFabSuite; https://www.youtube.com/watch?v=9NzuhpvkXrU ("iFab EasyScan – Discover digital solutions for taking your treatment offer to the next level"); https://shop.ottobock.us/Prosthetics/Materials-%26-Equipment/Equipment/Alignment-and-Measuring/iFab-EasyScan-%E2%80%93-hardware-kit/p/743Z51 (providing link to 743Z51 iFab EasyScan hardware kit); https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

[12] *See, e.g.*, https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2.

Ottobock has represented that its iFab system can be used with other manufacturers' 3-D imaging devices for capturing an image of the infant's head.[13]

38. Ottobock's continued infringement of the '798 patent is reckless, knowing, deliberate, and willful, and renders this an exceptional case under 35 U.S.C. § 285.

39. Ottobock's infringement is without the consent or other authority of Cranial.

40. Cranial has been damaged by Ottobock's acts in an amount as yet unknown. Cranial has no adequate legal remedy. Unless enjoined by this Court, Ottobock's continued acts of infringement will cause Cranial substantial and irreparable harm. Under 35 U.S.C. § 283, Cranial is entitled to an injunction barring Ottobock from further infringement of the '798 patent.

SECOND CAUSE OF ACTION

(Infringement of U.S. Patent No. 7,227,979)

41. Cranial realleges and incorporates by reference the allegations contained in paragraphs 1-40 as though fully set forth herein.

42. Cranial is the owner of all rights, title, and interest in and to the '979 patent.[14] The '979 patent issued on June 5, 2007, and is titled "Automatic Selection of Cranial Remodeling Device Trim Lines."

43. Cranial significantly improved its own existing technology for producing a custom cranial remodeling device through the innovations of the '979 patent. The '979 patent explains, for example, that cranial remodeling devices were previously

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[13] *See, e.g.*, 510(k) Approval (K201426) at 3 (identifying 3-D imaging devices by Creaform, Rodin4D, TechMed3D, Artec3D) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201426.pdf); 510(k) Approval (K213587) at 3 (same) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213587.pdf); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (identifying 3-D imaging devices by Creaform and Artec) (available at https://www.ottobock.com/en-us/product/24H1).

[14] A copy of the '979 patent is available at https://patentcenter.uspto.gov/applications/11584334.

produced by casting the infant's head with a plaster, creating a first model of the infant's head shape from the cast, manually modifying the first model of the infant's misshaped head to form the desired head shape, and then forming the cranial remodeling device over the desired head shape. *See*, *e.g.*, '979 patent at 1:48-56, 2:33-38, 9:5-14. The '979 patent improves that prior art process by taking a digital capture of the child's actual head shape and processing that information to automatically calculate the unique trim line information of the cranial remodeling device that will treat that particular child's deformities. *See*, *e.g.*, *id*. at 14:18-19, 17:5-12, 17:18-21. The '979 patent, thus, "eliminate[s] the need to cast the children's head," "produces a cranial remodeling band of an appropriate configuration and having appropriate features, and appropriate trim lines all without any significant human intervention," and improves the efficiency and accuracy with which cranial remodeling devices are made. *See*, *e.g.*, *id*. at 14:18-19, 17:18-21.

44. Accordingly, the claims of the '979 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods and systems for producing a cranial remodeling device. These advancements were neither well-known, routine, nor conventional. Upon information and belief, a person of ordinary skill in the art would have viewed the invention of the '979 patent as a patentable advancement over the prior art.

45. The claims of the '979 patent cover inventive methods and systems for producing cranial remodeling devices to correct for cranial shape abnormalities. Ottobock has infringed and continues to infringe one or more claims of the '979 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) at least by manufacturing, using, importing, selling, and/or offering to sell in the United States the iFab system, which, upon information and belief, is used to produce the MyCRO Band.

46. For example, claim 1 of the '979 patent recites:

(pre) A method for producing cranial remodeling devices to correct for cranial shape abnormalities comprising:

(a) capturing a three dimensional digital image of a deformed head to produce first digital data; and

(b) utilizing said first digital data to automatically provide cranial remodeling device trim line information for use in fabricating a cranial remodeling device for said deformed head.

47. To the extent the preamble of claim 1 is considered a limitation, at least the iFab system comprises a method for producing cranial remodeling devices to correct for cranial shape abnormalities. Additional information is set forth in Exhibit 2 at claim 1(pre).

48. At least the iFab system captures a three dimensional digital image of a deformed head to produce first digital data. Additional information is set forth in Exhibit 2 at claim 1(a).

49. At least the iFab system utilizes said first digital data to automatically provide cranial remodeling device trim line information for use in fabricating a cranial remodeling device for said deformed head. Additional information is set forth in Exhibit 2 at claim 1(b).

50. Ottobock has actively induced others to infringe the ’979 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including clinicians and orthotists, to directly infringe at least claim 1 of the ’979 patent. For example, Ottobock encourages clinicians and orthotists to use the iFab system to produce the MyCRO Band through marketing materials, manuals, and promotional demonstrations and videos.[15] Ottobock has actual knowledge of the ’979

[15] Exemplary materials: https://corporate.ottobock.com/en/futuring/ifab (“O&P professionals scan a residual limb and process the data directly on a computer. Time that was once spent on manual work on the plaster cast – often a complex task – can now be channeled into the fitting process.”); https://www.aopanet.org/2022-aopa-national-assembly/assembly-schedule/manufacturers-workshops-tier-b-5/ (“Ottobock is excited to demonstrate the first all-inclusive scanning, modelling, and 3D-printing

patent and that the actions of these third parties, including clinicians and orthotists, infringe the '979 patent since at least the filing of this Complaint.

51. Ottobock has contributed to the infringement by others of one or more claims of the '979 patent in violation of 35 U.S.C. § 271(c) by offering to sell or selling in the United States and/or importing into the United States its infringing iFab system and/or components of its infringing iFab system.[16] As described above, the iFab system and/or its components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '979 patent. Also, as described above, Ottobock has actual knowledge of the '979 patent and that the infringing iFab system and/or components are especially made or especially adapted for use in an infringement of the '979 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use since at least the filing of this Complaint. Ottobock has offered to sell, sold, and/or imported its infringing iFab system and components to clinicians and orthotists. These clinicians and orthotists then make, use, sell, or offer to sell products

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technology specifically designed for the O&P industry."); https://www.ot-world.com/en/exhibitor-press-releases/ottobock-at-otworld-2022-technology-that-serves-people ("The third thematic focus at the trade show will present solutions that enable orthopaedic companies to enter the field of digital patient care. An example is 'iFab EasyScan.' … [P]roduct modeling, ordering and production – can also be carried out digitally including through Ottobock iFab (service centre for individual fabrication). The first 3D-printed products have been produced there since 2021, such as … MyCRO Band for helmet therapy for babies with skull deformities."); https://shop.ottobock.us/iFabSuite; https://www.youtube.com/watch?v=9NzuhpvkXrU ("iFab EasyScan – Discover digital solutions for taking your treatment offer to the next level"); https://shop.ottobock.us/Prosthetics/Materials-%26-Equipment/Equipment/Alignment-and-Measuring/iFab-EasyScan-%E2%80%93-hardware-kit/p/743Z51 (providing link to 743Z51 iFab EasyScan hardware kit); https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

[16] *See, e.g.*, https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

or systems that utilize the infringing iFab system and/or components. For example, Ottobock has represented that its iFab system can be used with other manufacturers' 3-D imaging devices for capturing an image of the infant's head.[17]

52. Ottobock's continued infringement of the '979 patent is reckless, knowing, deliberate, and willful, and renders this an exceptional case under 35 U.S.C. § 285.

53. Ottobock's infringement is without the consent or other authority of Cranial.

54. Cranial has been damaged by Ottobock's acts in an amount as yet unknown. Cranial has no adequate legal remedy. Unless enjoined by this Court, Ottobock's continued acts of infringement will cause Cranial substantial and irreparable harm. Under 35 U.S.C. § 283, Cranial is entitled to an injunction barring Ottobock from further infringement of the '979 patent.

THIRD CAUSE OF ACTION

(Infringement of U.S. Patent No. 10,603,203)

55. Cranial realleges and incorporates by reference the allegations contained in paragraphs 1-54 as though fully set forth herein.

56. Cranial is the owner of all rights, title, and interest in and to the '203 patent.[18] The '203 patent issued on March 31, 2020, and is titled "Custom Cranial Remodeling Devices Manufactured By Additive Manufacture."

57. Cranial significantly improved its own existing technology for manufacturing a custom cranial remodeling device through the innovations of the '203

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[17] *See, e.g.*, 510(k) Approval (K201426) at 3 (identifying 3-D imaging devices by Creaform, Rodin4D, TechMed3D, Artec3D) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201426.pdf); 510(k) Approval (K213587) at 3 (same) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213587.pdf) ; 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (identifying 3-D imaging devices by Creaform and Artec) (available at https://www.ottobock.com/en-us/product/24H1).

[18] A copy of the '203 patent is available at https://patentcenter.uspto.gov/applications/15475009.

patent. The '203 patent explains, for example, that even where a system uses digital images and automatically generates the desired head shape, traditional cranial remodeling devices are manufactured by first "fabricating a life size model of the desired head shape, vacuum thermo-forming a foam liner onto the life size model, vacuum thermo-forming a hard plastic onto the foam liner, generating trim lines for the device, projecting the trim lines onto the hard plastic, cutting the trim lines, and manually finishing the trimmed cranial remodeling device." '203 patent at 1:13-24. As the '203 patent explains, "[e]ach different step in a manufacturing process presents the possibility of introduction of error or inaccuracy." *Id*. at 1:25-26. The '203 patent improved the prior art by providing a custom cranial remodeling device that is manufactured by additively manufacturing (*e.g.*, 3-D printing) the inner and outer layers of the device according to configuration information, including contour lines, defining the proper shape of the device. *See*, *e.g.*, *id*. at 11:35-40, 13:37-64. The '203 patent automatically calculates contour lines for the cranial modeling device using predetermined reference points such that the contour lines are reflected in the additively manufactured device without the need for further trimming as in the prior art. *See*, *e.g.*, *id*. at 5:58-6:8. The '203 patent, thus, significantly reduces the number of steps required to manufacture the cranial remolding device and thereby minimizes the possibility of error and improves the accuracy of the final product. *See id*. at 1:25-26.

58. Accordingly, the claims of the '203 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed custom cranial remodeling device for correcting a deformed head. These advancements were neither well-known, routine, nor conventional. Upon information and belief, a person of ordinary skill in the art would have viewed the invention of the '203 patent as a patentable advancement over the prior art.

59. The claims of the '203 patent cover an inventive custom cranial remodeling device for correcting a deformed head. Ottobock has infringed and

continues to infringe one or more claims of the '203 patent, literally or under the doctrine of equivalents, including, without limitation, claim 1 in violation of 35 U.S.C. § 271(a) at least by manufacturing, using, importing, selling, and/or offering to sell in the United States its MyCRO Band product.

60. For example, claim 1 of the '203 patent recites:

(pre) A custom cranial remodeling device to correct a deformed head of a subject, comprising:

(a) an inner layer shaped to contact the head of said subject at predetermined areas, said inner layer deposited by an additive manufacturing device;

(b) an outer layer deposited by said additive manufacturing device;

(c) said inner layer and said outer layer are each formed by said additive manufacture device utilizing a device data file derived from a subject data file, said subject data file representative of the shape of said deformed head, said device data file determining the shape of said cranial remodeling device to correct the shape of said deformed head; and

(d) each of said inner layer and said outer layer having a periphery defined by contour line data in said device data file, said contour line data determined by identifying predetermined anthropometric reference points on said shape of said deformed head represented by said subject data file and utilizing said predetermined anthropometric reference points to calculate said contour lines on said head represented by said subject data file for said cranial remodeling device.

61. To the extent the preamble of claim 1 is considered a limitation, at least the MyCRO Band comprises a custom cranial remodeling device to correct a deformed head of a subject. Additional information is set forth in Exhibit 3 at claim

1(pre).

62. At least the MyCRO Band comprises an inner layer shaped to contact the head of said subject at predetermined areas, said inner layer deposited by an additive manufacturing device. Additional information is set forth in Exhibit 3 at claim 1(a).

63. At least the MyCRO Band comprises an outer layer deposited by said additive manufacturing device. Additional information is set forth in Exhibit 3 at claim 1(b).

64. At least the MyCRO Band comprises said inner layer and said outer layer are each formed by said additive manufacture device utilizing a device data file derived from a subject data file, said subject data file representative of the shape of said deformed head, said device data file determining the shape of said cranial remodeling device to correct the shape of said deformed head. Additional information is set forth in Exhibit 3 at claim 1(c).

65. At least the MyCRO Band comprises each of said inner layer and said outer layer having a periphery defined by contour line data in said device data file, said contour line data determined by identifying predetermined anthropometric reference points on said shape of said deformed head represented by said subject data file and utilizing said predetermined anthropometric reference points to calculate said contour lines on said head represented by said subject data file for said cranial remodeling device. Additional information is set forth in Exhibit 3 at claim 1(d).

66. Ottobock has actively induced others to infringe the ’203 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including clinicians, orthotists, and patient customers, to directly infringe at least claim 1 of the ’203 patent. For example, Ottobock encourages clinicians, orthotists, and patient customers to use the MyCRO Band through marketing materials and manuals.[19] Ottobock has actual knowledge of the ’203 patent

[19] Exemplary materials: https://www.ottobock.com/en-us/product/24H1; https://shop.ottobock.us/Orthotics/Custom-Orthotics/Cranial-Orthotics/c/4097;

and that the actions of these third parties, including clinicians, orthotists, and patient customers, infringe the '203 patent since at least the filing of this Complaint.

67. Ottobock's continued infringement of the '203 patent is reckless, knowing, deliberate, and willful, and renders this an exceptional case under 35 U.S.C. § 285.

68. Ottobock's infringement is without the consent or other authority of Cranial.

69. Cranial has been damaged by Ottobock's acts in an amount as yet unknown. Cranial has no adequate legal remedy. Unless enjoined by this Court, Ottobock's continued acts of infringement will cause Cranial substantial and irreparable harm. Under 35 U.S.C. § 283, Cranial is entitled to an injunction barring Ottobock from further infringement of the '203 patent.

FOURTH CAUSE OF ACTION

(Infringement of U.S. Patent No. 10,846,925)

70. Cranial realleges and incorporates by reference the allegations contained in paragraphs 1-69 as though fully set forth herein.

71. Cranial is the owner of all rights, title, and interest in and to the '925 patent.[20] The '925 patent issued on November 24, 2020, and is titled "Method of Manufacture of Custom Cranial Remodeling Devices By Additive Manufacture."

72. Cranial significantly improved its own existing technology for fabricating a custom cranial remodeling device through the innovations of the '925 patent. The '925 patent explains, for example, that even where a system uses digital images and automatically generates the desired head shape, traditional cranial remodeling devices

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https://goactivelife.com/wp-content/uploads/2021/06/MyCRO-Band-Patient-Brochure.pdf; https://goactivelife.com/mycro/; https://www.youtube.com/watch?v=A_29jvv0DyU; 24H1 MyCro Band Instructions for Use (qualified personnel) (available at https://www.ottobock.com/en-us/product/24H1); 24H1 MyCro Band Instructions for Use (user) (available at https://www.ottobock.com/en-us/product/24H1).

[20] A copy of the '925 patent is available at https://patentcenter.uspto.gov/applications/15474092.

are formed by first "fabricating a life size model of the desired head shape, vacuum thermo-forming a foam liner onto the life size model, vacuum thermo-forming a hard plastic onto the foam liner, generating trim lines for the device, projecting the trim lines onto the hard plastic, cutting the trim lines, and manually finishing the trimmed cranial remodeling device." '925 patent at 1:13-24. As the '925 patent explains, "[e]ach different step in a manufacturing process presents the possibility of introduction of error or inaccuracy." *Id*. at 1:25-26. The '925 patent improved the prior art by providing a custom cranial remodeling device that is manufactured by creating a device data file that is used by a three-dimensional printer to additively manufacture (*e.g.*, 3-D printing) the inner and outer layers of the device according to configuration information defining the proper shape of the device. *See*, *e.g.*, *id*. at 10:42-45, 11:35-40, 13:37-64. The '925 patent's device data file automatically determines contour lines for the cranial modeling device using predetermined reference points such that the contour lines are reflected in the additively manufactured device without the need for further trimming as in the prior art. *See*, *e.g.*, *id*. at 5:58-6:8, 13:56-64, 14:19-22. The '925 patent, thus, significantly reduces the number of steps required to manufacture the cranial remolding device and thereby minimizes the possibility of error and improves the accuracy of the final product. *See id*. at 1:25-26.

73. Accordingly, the claims of the '925 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods for fabricating a custom cranial remodeling device. These advancements were neither well-known, routine, nor conventional. Upon information and belief, a person of ordinary skill in the art would have viewed the invention of the '925 patent as a patentable advancement over the prior art.

74. The claims of the '925 patent cover inventive methods for fabricating a custom cranial remodeling device for correction of cranial deformities in a subject's head and associated methods. Ottobock has infringed and continues to infringe one or

more claims of the '925 patent, literally or under the doctrine of equivalents, including, without limitation, claim 17 in violation of 35 U.S.C. § 271(a) at least by manufacturing, using, importing, selling, and/or offering to sell in the United States the iFab system, which, upon information and belief, is used to produce the MyCRO Band.

75. For example, claim 17 of the '925 patent recites:

(pre) A method for creating a device data file for use by a three-dimensional printer to print a custom cranial remodeling device for correction of a deformed head shape in an infant, said custom cranial remodeling device having a custom inner surface and a custom outer surface said method comprising:

(a) generating a three-dimensional data file of said deformed head shape;

(b) processing said three-dimensional data file to generate a three-dimensional modified data file for a modified head shape for said infant;

(c) utilizing said three-dimensional modified data file to generate a device data file for a shape for said custom cranial remodeling device;

(d) automatically determining predetermined reference points on said three-dimensional data file of said captured deformed head shape;

(e) automatically utilizing said predetermined reference points to calculate contour lines on said three-dimensional data file of said deformed head shape, said contour lines comprising peripheral edges for said custom cranial remodeling device;

(f) projecting lines outward from said contour lines to said outer surface of said custom cranial remodeling device; and

(g) utilizing said projected lines to establish peripheral edges for said

inner and outer surfaces of said custom cranial remodeling device in said device file.

76. To the extent the preamble of claim 17 is considered a limitation, at least the iFab system comprises a method for creating a device data file for use by a three-dimensional printer to print a custom cranial remodeling device for correction of a deformed head shape in an infant, said custom cranial remodeling device having a custom inner surface and a custom outer surface. Additional information is set forth in Exhibit 4 at claim 17(pre).

77. At least the iFab system generates a three-dimensional data file of said deformed head shape. Additional information is set forth in Exhibit 4 at claim 17(a).

78. At least the iFab system processes said three-dimensional data file to generate a three-dimensional modified data file for a modified head shape for said infant. Additional information is set forth in Exhibit 4 at claim 17(b).

79. At least the iFab system utilizes said three-dimensional modified data file to generate a device data file for a shape for said custom cranial remodeling device. Additional information is set forth in Exhibit 4 at claim 17(c).

80. At least the iFab system automatically determines predetermined reference points on said three-dimensional data file of said captured deformed head shape. Additional information is set forth in Exhibit 4 at claim 17(d).

81. At least the iFab system automatically utilizes said predetermined reference points to calculate contour lines on said three-dimensional data file of said deformed head shape, said contour lines comprising peripheral edges for said custom cranial remodeling device. Additional information is set forth in Exhibit 4 at claim 17(e).

82. At least the iFab system projects lines outward from said contour lines to said outer surface of said custom cranial remodeling device. Additional information is set forth in Exhibit 4 at claim 17(f).

83. At least the iFab system utilizes said projected lines to establish

peripheral edges for said inner and outer surfaces of said custom cranial remodeling device in said device file. Additional information is set forth in Exhibit 4 at claim 17(g).

84. Ottobock has actively induced others to infringe the '925 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including clinicians and orthotists, to directly infringe at least claim 17 of the '925 patent. For example, Ottobock encourages clinicians and orthotists to use the iFab system to produce the MyCRO Band through marketing materials, manuals, and promotional demonstrations and videos.[21] Ottobock has actual knowledge of the '925 patent and that the actions of these third parties, including clinicians and orthotists, infringe the '925 patent since at least the filing of this Complaint.

85. Ottobock has contributed to the infringement by others of one or more claims of the '925 patent in violation of 35 U.S.C. § 271(c) by offering to sell or selling in the United States and/or importing into the United States its infringing iFab

[21] Exemplary materials: https://corporate.ottobock.com/en/futuring/ifab ("O&P professionals scan a residual limb and process the data directly on a computer. Time that was once spent on manual work on the plaster cast – often a complex task – can now be channeled into the fitting process."); https://www.aopanet.org/2022-aopa-national-assembly/assembly-schedule/manufacturers-workshops-tier-b-5/ ("Ottobock is excited to demonstrate the first all-inclusive scanning, modelling, and 3D-printing technology specifically designed for the O&P industry."); https://www.ot-world.com/en/exhibitor-press-releases/ottobock-at-otworld-2022-technology-that-serves-people ("The third thematic focus at the trade show will present solutions that enable orthopaedic companies to enter the field of digital patient care. An example is 'iFab EasyScan.' … [P]roduct modeling, ordering and production – can also be carried out digitally including through Ottobock iFab (service centre for individual fabrication). The first 3D-printed products have been produced there since 2021, such as … MyCRO Band for helmet therapy for babies with skull deformities."); https://shop.ottobock.us/iFabSuite; https://www.youtube.com/watch?v=9NzuhpvkXrU ("iFab EasyScan – Discover digital solutions for taking your treatment offer to the next level"); https://shop.ottobock.us/Prosthetics/Materials-%26-Equipment/Equipment/Alignment-and-Measuring/iFab-EasyScan-%E2%80%93-hardware-kit/p/743Z51 (providing link to 743Z51 iFab EasyScan hardware kit); https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

system and/or components of its infringing iFab system.[22] As described above, the iFab system and/or its components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '925 patent. Also, as described above, Ottobock has actual knowledge of the '925 patent and that the infringing iFab system and/or components are especially made or especially adapted for use in an infringement of the '925 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use since at least the filing of this Complaint. Ottobock has offered to sell, sold, and/or imported its infringing iFab system and components to clinicians and orthotists. These clinicians and orthotists then make, use, sell, or offer to sell products or systems that utilize the infringing iFab system and/or components. For example, Ottobock has represented that its iFab system can be used with other manufacturers' 3-D imaging devices for capturing an image of the infant's head.[23]

86. Ottobock's continued infringement of the '925 patent is reckless, knowing, deliberate, and willful, and renders this an exceptional case under 35 U.S.C. § 285.

87. Ottobock's infringement is without the consent or other authority of Cranial.

88. Cranial has been damaged by Ottobock's acts in an amount as yet unknown. Cranial has no adequate legal remedy. Unless enjoined by this Court, Ottobock's continued acts of infringement will cause Cranial substantial and

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[22] *See, e.g.*, https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

[23] *See, e.g.*, 510(k) Approval (K201426) at 3 (identifying 3-D imaging devices by Creaform, Rodin4D, TechMed3D, Artec3D) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201426.pdf); 510(k) Approval (K213587) at 3 (same) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213587.pdf); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (identifying 3-D imaging devices by Creaform and Artec) (available at https://www.ottobock.com/en-us/product/24H1).

irreparable harm. Under 35 U.S.C. § 283, Cranial is entitled to an injunction barring Ottobock from further infringement of the '925 patent.

FIFTH CAUSE OF ACTION

(Infringement of U.S. Patent No. 10,726,617)

89. Cranial realleges and incorporates by reference the allegations contained in paragraphs 1-88 as though fully set forth herein.

90. Cranial is the owner of all rights, title, and interest in and to the '617 patent.[24] The '617 patent issued on July 28, 2020, and is titled "Method of Manufacture of Custom Headwear By Additive Manufacture."

91. Cranial significantly improved its own existing technology for fabricating custom headwear, including cranial remodeling devices through the innovations of the '617 patent. The '617 patent explains, for example, that even where a system uses digital images and automatically generates the desired head shape for custom headwear, such as cranial remodeling devices, such headwear were traditionally formed by first "fabricating a life size model of the desired head shape, vacuum thermo-forming a foam liner onto the life size model, vacuum thermo-forming a hard plastic onto the foam liner, generating trim lines for the device, projecting the trim lines onto the hard plastic, cutting the trim lines, and manually finishing the trimmed cranial remodeling device." '617 patent at 1:15-26. As the '617 patent explains, "[e]ach different step in a manufacturing process presents the possibility of introduction of error or inaccuracy." *Id*. at 1:27-28. The '617 patent improved the prior art by providing custom headwear, such as cranial remodeling devices, that is manufactured by additively manufacturing (*e.g.*, 3-D printing) the inner and outer layers of the device according to configuration information defining the proper shape of the device. *See*, *e.g.*, *id*. at 11:35-40, 13:37-64. The '617 patent automatically calculates contour lines for the headwear using predetermined reference points such

[24] A copy of the '617 patent is available at https://patentcenter.uspto.gov/applications/15474316.

that the contour lines are reflected in the additively manufactured device without the need for further trimming as in the prior art. *See*, *e.g.*, *id*. at 5:58-6:8. The '617 patent, thus, significantly reduces the number of steps required to manufacture the headwear and thereby minimizes the possibility of error and improves the accuracy of the final product. *See*, *e.g.*, *id*. at 1:52-55.

92. Accordingly, the claims of the '617 patent provide a significant advancement over the prior art. For example, the prior art neither teaches nor suggests the claimed methods for fabricating a custom headwear. These advancements were neither well-known, routine, nor conventional. Upon information and belief, a person of ordinary skill in the art would have viewed the invention of the '617 patent as a patentable advancement over the prior art.

93. The claims of the '617 patent cover inventive methods of fabricating custom headwear and associated methods. Ottobock has infringed and continues to infringe one or more claims of the '617 patent, literally or under the doctrine of equivalents, including, without limitation, claim 17 in violation of 35 U.S.C. § 271(a) at least by manufacturing, using, importing, selling, and/or offering to sell in the United States the iFab system, which, upon information and belief, is used to produce the MyCRO Band.

94. For example, claim 17 of the '617 patent recites:

(pre) A method for creating a device data file for use by a three-dimensional printer to print a custom headwear for a head of a subject, said custom headwear having a custom inner surface and a custom outer surface, said method comprising:

(a) generating a three-dimensional data file of a shape of said head;

(b) processing said three-dimensional data file to generate a shape for said custom headwear;

(c) processing said three-dimensional data file to generate a three-dimensional device data file comprising said shape for said custom

headwear;

(d) automatically determining predetermined reference points in said three-dimensional data file;

(e) automatically utilizing said predetermined reference points to calculate contour lines in said three-dimensional data file representing said head shape; said contour lines defining one or more peripheral edges of said custom headwear;

(f) projecting lines outward from said contour lines to an outer surface of said custom headwear represented by said three-dimensional device data file; and

(g) processing said three-dimensional device data file by utilizing said projected lines to establish contour lines defining one or more edges for said inner surface and corresponding one or more edges for said outer surface of said custom headwear in said three-dimensional device data file.

95. To the extent the preamble of claim 17 is considered a limitation, at least the iFab system comprises a method for creating a device data file for use by a three-dimensional printer to print a custom headwear for a head of a subject, said custom headwear having a custom inner surface and a custom outer surface. Additional information is set forth in Exhibit 5 at claim 17(pre).

96. At least the iFab system generates a three-dimensional data file of a shape of said head. Additional information is set forth in Exhibit 5 at claim 17(a).

97. At least the iFab system processes said three-dimensional data file to generate a shape for said custom headwear. Additional information is set forth in Exhibit 5 at claim 17(b).

98. At least the iFab system processes said three-dimensional data file to generate a three-dimensional device data file comprising said shape for said custom headwear. Additional information is set forth in Exhibit 5 at claim 17(c).

99. At least the iFab system automatically determines predetermined reference points in said three-dimensional data file. Additional information is set forth in Exhibit 5 at claim 17(d).

100. At least the iFab system automatically utilizes said predetermined reference points to calculate contour lines in said three-dimensional data file representing said head shape where said contour lines define one or more peripheral edges of said custom headwear. Additional information is set forth in Exhibit 5 at claim 17(e).

101. At least the iFab system projects lines outward from said contour lines to an outer surface of said custom headwear represented by said three-dimensional device data file. Additional information is set forth in Exhibit 5 at claim 17(f).

102. At least the iFab system processes said three-dimensional device data file by utilizing said projected lines to establish contour lines defining one or more edges for said inner surface and corresponding one or more edges for said outer surface of said custom headwear in said three-dimensional device data file. Additional information is set forth in Exhibit 5 at claim 17(g).

103. Ottobock has actively induced others to infringe the '617 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including clinicians and orthotists, to directly infringe at least claim 17 of the '617 patent. For example, Ottobock encourages clinicians and orthotists to use the iFab system to produce the MyCRO Band through marketing materials, manuals, and promotional videos.[25] Ottobock has actual knowledge of the '617 patent and that

[25] Exemplary materials: https://corporate.ottobock.com/en/futuring/ifab ("O&P professionals scan a residual limb and process the data directly on a computer. Time that was once spent on manual work on the plaster cast – often a complex task – can now be channeled into the fitting process."); https://www.aopanet.org/2022-aopa-national-assembly/assembly-schedule/manufacturers-workshops-tier-b-5/ ("Ottobock is excited to demonstrate the first all-inclusive scanning, modelling, and 3D-printing technology specifically designed for the O&P industry."); https://www.ot-world.com/en/exhibitor-press-releases/ottobock-at-otworld-2022-technology-that-serves-people ("The third thematic focus at the trade show will present solutions that enable orthopaedic companies to enter the field of digital patient care. An example is

the actions of these third parties, including clinicians and orthotists, infringe the '617 patent since at least the filing of this Complaint. Ottobock's continued infringement of the '617 patent is reckless, knowing, deliberate, and willful, and render this an exceptional case under 35 U.S.C. § 285.

104. Ottobock has contributed to the infringement by others of one or more claims of the '617 patent in violation of 35 U.S.C. § 271(c) by offering to sell or selling in the United States and/or importing into the United States its infringing iFab system and/or components of its infringing iFab system.[26] As described above, the iFab system and/or its components are components of a patented machine, manufacture, combination or composition and constitute a material part of the inventions claimed in the '617 patent. Also, as described above, Ottobock has actual knowledge of the '617 patent and that the infringing iFab system and/or components are especially made or especially adapted for use in an infringement of the '617 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use since at least the filing of this Complaint. Ottobock has offered to sell, sold, and/or imported its infringing iFab system and components to clinicians and orthotists. These clinicians and orthotists then make, use, sell, or offer to sell products

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'iFab EasyScan.' … [P]roduct modeling, ordering and production – can also be carried out digitally including through Ottobock iFab (service centre for individual fabrication). The first 3D-printed products have been produced there since 2021, such as … MyCRO Band for helmet therapy for babies with skull deformities."); https://shop.ottobock.us/iFabSuite; https://www.youtube.com/watch?v=9NzuhpvkXrU ("iFab EasyScan – Discover digital solutions for taking your treatment offer to the next level"); https://shop.ottobock.us/Prosthetics/Materials-%26-Equipment/Equipment/Alignment-and-Measuring/iFab-EasyScan-%E2%80%93-hardware-kit/p/743Z51 (providing link to 743Z51 iFab EasyScan hardware kit); https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

[26] *See, e.g.*, https://shop.ottobock.us/c/iFab-EasyScan-basic-license/p/119A2 and https://shop.ottobock.us/c/iFab-EasyScan-Data-export-license/p/119A3 (offering for sale iFab EasyScan Basic License and iFab EasyScan Data Export License); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (available at https://www.ottobock.com/en-us/product/24H1).

or systems that utilize the infringing iFab system and/or components. For example, Ottobock has represented that its iFab system can be used with other manufacturers' 3-D imaging devices for capturing an image of the infant's head.[27]

105. Ottobock's infringement is without the consent or other authority of Cranial.

106. Cranial has been damaged by Ottobock's acts in an amount as yet unknown. Cranial has no adequate legal remedy. Unless enjoined by this Court, Ottobock's continued acts of infringement will cause Cranial substantial and irreparable harm. Under 35 U.S.C. § 283, Cranial is entitled to an injunction barring Ottobock from further infringement of the '617 patent.

PRAYER FOR RELIEF

WHEREFORE, Cranial respectfully requests judgment from this Court as follows:

A. The entry of judgment that Ottobock has directly infringed, literally or under the doctrine of equivalents, contributed to infringement of, and/or induced infringement of one or more claims of the Asserted Patents;

B. The entry of judgment that Ottobock has willfully infringed one or more claims of the Asserted Patents;

C. A judgment against Ottobock preliminarily and/or permanently enjoining Ottobock and its officers, employees, agents, attorneys, affiliates, successors, assigns, and others acting in privity or concert with them, and their parents, subsidiaries, divisions, successors and assigns, from further acts of infringement of the Asserted Patents;

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[27] *See, e.g.*, 510(k) Approval (K201426) at 3 (identifying 3-D imaging devices by Creaform, Rodin4D, TechMed3D, Artec3D) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201426.pdf); 510(k) Approval (K213587) at 3 (same) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213587.pdf); 24H1 MyCro Band Instructions for Use (qualified personnel) at 2 (identifying 3-D imaging devices by Creaform and Artec) (available at https://www.ottobock.com/en-us/product/24H1).

D. A judgment awarding Cranial damages resulting from Ottobock's infringement in an amount no less than a reasonable royalty;

E. A judgment declaring that this is an exceptional case and awarding Cranial attorneys' fees pursuant to 35 U.S.C. § 285;

F. A judgment against Ottobock that interest, costs, and expenses be awarded in favor of Cranial; and

G. Such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Cranial hereby demands trial by jury for all causes of action, claims, or issues that are triable as a matter of right to a jury.

Date: March 29, 2023

By: */s/ Douglas A. Axel*
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