

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION**



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ORTHOPEDIATRICS CORP.,

Plaintiff,

v.

WISHBONE MEDICAL, INC.,

Defendant.

Case No. 3:23-cv-491

COMPLAINT

Plaintiff OrthoPediatics Corp. (“OP”), by and through its undersigned counsel, for its Complaint against Defendant WishBone Medical, Inc. (“WishBone”), alleges as follows:

INTRODUCTION

1. This case is about OP’s game-changing innovation in orthopedic surgery, particularly a patented orthopedic plate system used to support or stabilize long bones in pediatric patients that resolved the difficulties and dangers in the field of trying to adapt implants for adults to pediatric cases. WishBone has copied the patented technology.

2. The inventors of the patent in issue, U.S. Patent No. 8,777,998 (the “’998 Patent”) are four innovators in the field of orthopedics: David Daniels, Dave Bailey, Chris Bremer, and Dr. Daniel Hoernschemeyer. David Daniels is a Principal Engineer at OP. Dave Bailey is President and CEO of OP. Chris Bremer is a former employee of OrthoPediatics. Dr. Daniel Hoernschemeyer is a Pediatric Orthopedic Surgeon that has been practicing for more than 20 years.

3. Mr. Daniels, Mr. Bailey, Mr. Bremer, and Dr. Hoernschemeyer developed the invention in the ’998 Patent, which was specifically designed for pediatric patients to avoid the risks associated with adapting adult implants, such as damaging the epiphyseal plate or arresting the growth of the femoral bone.

More specifically, and as discussed later in the Complaint, by using a plate system specifically designed for pediatrics, rather than adapting an adult implant plate which was the norm in the industry, the patented apparatus avoids the risk of screwing through and violating the distal femoral growth plate, such violations of which could lead to partial growth arrest in the pediatric bone and other deformities.

4. OP is the assignee of the '998 Patent. OP is a leader in pediatric orthopedics. Through its work, OP has helped to set the standard of pediatric care in the field of orthopedics by developing products that meet the unique needs of pediatric patients. It is a leading supporter of pediatric orthopedic societies and clinical education in pediatric orthopedics. OP has a worldwide distribution reach and extraordinary brand equity with pediatric orthopedic surgeons.

5. Wishbone announced that on or about March 31, 2023, it received "510(k) clearance" from the United States Food and Drug Administration ("FDA") for its "PRIMA™ Femoral Locking Plate System," discussed in further detail below.

6. As discussed in greater detail and specificity below, WishBone's PRIMA™ Distal Femur Locking Plate System infringes the '998 Patent. WishBone's manufacture, use, sale, offer to sell, or importation of the PRIMA™ Distal Femur Locking Plate System is ongoing or at least imminent.

7. In sum, Plaintiff is an innovator in the field and the patent-at-issue is groundbreaking. Defendant cannot compete fairly, so instead it has resorted to intentionally infringing Plaintiff's patent. Defendant's conduct has caused damage to Plaintiff, thereby necessitating this lawsuit.

NATURE OF THE ACTION

8. This is an action under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* for patent infringement by WishBone of U.S. Patent No. 8,777,998 (the "'998 Patent").

THE PARTIES

9. Plaintiff OP is a Delaware corporation with a principal place of business at 2850 Frontier

Drive, Warsaw, Indiana 46582.

10. Upon information and belief, Defendant WishBone is an Indiana corporation with a principal place of business at 100 Capital Drive, Warsaw, Indiana 46582.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, over Plaintiff's claim of patent infringement. Jurisdiction is also based on the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 based on an actual and continuing controversy as detailed below.

12. This Court may exercise jurisdiction over Defendant because WishBone has a principal place of business in Indiana and a substantial part of the events giving rise to this action occurred within Indiana.

13. Venue is proper in this district because WishBone maintains an office and employees in this district and WishBone has committed acts of infringement in this district. *See, e.g., WISHBONE MEDICAL, Contact, available at* <https://www.wishbonemedical.com/contact/> (last visited May 24, 2023). Moreover, upon information and belief, WishBone, directly and/or through intermediaries, sells, distributes, makes, uses, imports, offers for sale, and/or advertises infringing products or services within this District, and has many customers within this District and the State of Indiana.

FACTUAL ALLEGATIONS

A. The Parties

14. OP was founded in 2006 to focus on the field of orthopedic implants for children. At that time, implantable orthopedic devices in adults were becoming the norm, but too often, adult implants were modified in the operating room so they could be used in children. OP asked why a more appropriate standard of pediatric care should not be available, too. The company's vision was to address the problem of off-label use of adult implants by building a different kind of orthopedic company: a company focused exclusively on pediatric orthopedics and committed to the cause of improving the lives of children with orthopedic conditions.

15. A key premise at OP is to account for a child's growing anatomy during a surgical procedure. Accordingly, all of its products are designed and developed to ensure they are anatomically appropriate for pediatric patients. In addition to OP's own engineering team, OP has a track record of collaborating with engineers and other industry experts around the world. OP has also assembled a board of eminent pediatric orthopedic surgeons to assist in developing products that meet the unique needs of pediatric patients. These factors have made OP the innovation leader in pediatric orthopedics.

16. OP has developed and received regulatory clearance for 47 surgical systems for trauma and deformity, scoliosis, and sports medicine and other procedures. In the hands of skilled surgeons, OP's products can relieve the pain of children who are confined to a wheelchair, while enabling others to walk for the first time. OP's global sales organization is focused exclusively on pediatric orthopedics and distributes its products in the United States and more than 70 countries outside the United States.

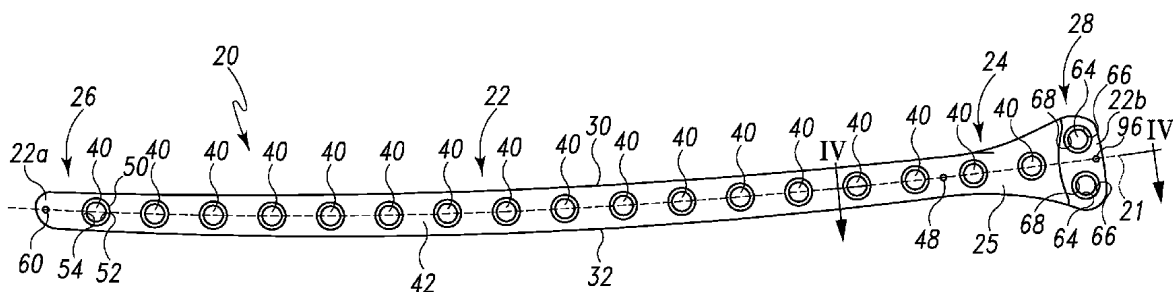
17. Upon information and belief, WishBone is a pediatric orthopedic company with operations in Istanbul and Singapore as well as Warsaw, Indiana.

B. The Asserted Patent

18. The '998 Patent, titled "Pediatric Long Bone Support or Fixation Plate," issued on July 15, 2014. A true and correct copy of the '998 Patent is attached hereto as Exhibit A.

19. The '998 Patent is assigned to OP, which has the right to bring suit for patent infringement. The named inventors for the '998 Patent are David Daniels, Dave Bailey, Chris Bremer, and Dr. Daniel Hoernschemeyer.

20. The '998 patent relates to bone support or fixation plate systems for use in pediatric orthopedic cases. For illustration purposes only, a picture of a bone plate shown in the '998 Patent is reproduced below:



21. Unlike adult support and fixation plate systems, the pediatric long bone support or fixation plate systems was specifically designed for pediatric patients to avoid the risks associated with adapting adult implants. Prior to the '998 Patent, pediatric orthopedic surgeons were challenged for years when it came to having implants for use in children or young adults. Many tried to modify small adult implants by various means, as such modification were necessary to try to accommodate the variability in shape and size of the growing skeleton, even though they can potentially compromise the mechanical properties of the implant. ('998 Patent at 1:23-31).

22. Further difficulties and risks to the patient can arise when trying to adapt implants for adults to pediatric cases. For example, in the case of femoral plates used for the fixation of distal femoral fractures and osteotomies, there is an additional and very significant problem involving the distal femoral growth plate of a pediatric bone. If a surgeon takes a plate that is straight and tries to contour it to fit on the distal femoral metaphysis, such contouring also re-directs the distal screw holes such that screws through those distal holes run the risk of entering and violating the distal femoral growth plate. If not recognized, such a violation could lead to a partial growth arrest in the pediatric bone with the development of deformity of the distal femur depending on which part of the growth plate is violated. ('998 Patent at 1:35-49).

23. In pediatric patients, the epiphyseal plate (or "growth plate") in each long bone remains active. Responsible for longitudinal growth of the long bones, the epiphyseal plate is a cartilaginous region that generates new bone cells which stack facing the epiphysis of the bone, with older cells being pushed

toward the diaphysis. Those older cells ossify to form new bone. As one approaches the mid-twenties, the epiphyseal plate's cartilaginous cells cease their activity and slowly ossify, and the bones cannot grow any further. With the activity of the epiphyseal plates, implant plates may be contraindicated for fear of impinging on the epiphyseal plate and consequent retarding, arresting, or changing the growth of the bone. If used, such plates require great care in order not to damage the epiphyseal plate or arrest the growth of the bone. Plates that are made for adults, with a curved end to extend into the epiphysis of the bone, rely on screws placed into both the diaphysis and the epiphysis. In many cases, screws through the end of the plate extend through the epiphyseal plate and into the epiphysis. The screws keep the bone from lengthening, which may result in impeding or blocking generation of new cells by the epiphyseal plate, or in forcing newly generated cells to the side of the long bone. In either case, further growth of the bone is halted or limited, and/or continued growth may dislodge screws or otherwise cause the implant to fail. In an effort to avoid intersection of screws with an epiphyseal plate, shorter screws have been used in these situations. However, the shorter screws potentially compromise the rigidity and stability of the plate and the fixation of the bone (e.g., a distal femoral fragment). ('998 Patent at 1:50-2:11).

24. There have also been cases where a surgeon uses an adult plate to fix a pediatric long bone where the surgeon purposely re-orient a screw in a plate hole, cross threading the head of the screw in it to try to avoid interference with the epiphyseal plate, but this method also has several drawbacks. ('998 Patent at 2:12-25).

25. The invention claimed in the '998 Patent avoids all the issues with using adult implants described in ¶ 21-24 because it is specifically designed for pediatric patients. For example, the configuration shown and described in the illustrated embodiment is particularly useful in pediatric cases. The disclosed configuration does not interfere with growth of the long bones. Many long bone plates wrap around and fix to the epiphysis or end of the bone, or insert one or more screws through the metaphysis and into the epiphysis, as may be appropriate for adult patients. The plate in the illustrated embodiment does not extend

on the metaphysis past the epiphyseal or “growth” plate of the bone. The screws do not enter or pass through the epiphyseal plate, so that addition and ossification of bone tissue in the epiphyseal plate is not impeded. Rather, in the illustrated embodiment, the screws in the plate have an orientation generally parallel to the epiphyseal plate, and generally perpendicular to the longitudinal axis of the bone. Use of such a plate eliminates impingement on the growth structure of a bone, as well as problems facing surgeons in trying to alter plates developed for adults to provide compatibility with a pediatric patient. ('998 Patent at 7:29-45).

26. The claims of the '998 Patent set forth a unique and specific apparatus that results in a great improvement in efficiency, ease of use, safety, and accuracy in pediatric orthopedic bone support and stabilization using a bone plate.

27. OP is not subject to any marking requirements under 35 U.S.C. § 287 and/or has complied with any such requirements

C. WishBone's Patent Infringing System

28. On information and belief, WishBone recently sought and obtained FDA clearance for its PRIMA™ Distal Femur Locking Plate System (“the Accused System”). See WISHBONE MEDICAL, *FDA Clearance Granted to WishBone Medical's Pediatric PRIMA™ Femoral Locking Plate System*, available at <https://wishbonemedical.com/2023/03/31/prima-femoral-locking-plate-system-fda-clearance/> (last visited May 24, 2023).

29. WishBone markets and promotes the Accused System on its website, where it describes the Accused System as “help[ing] surgeons better address proximal and distal deformities and trauma applications of the femur in pediatric patients.” See WISHBONE MEDICAL, *Femoral Locking Plate System PRIMA™*, available at <https://wishbonemedical.com/product/prima-femoral-locking-plate-system/#toggle-id-4> (last visited May 24, 2023).

30. WishBone provides a brochure describing the Accused System (“Brochure”) on its website. A true and correct copy of the Brochure is attached hereto as Exhibit B.

31. WishBone also provides on its website Instructions for Use and Surgical Technique documents. A true and correct copy of each document is attached hereto as Exhibits C and D, respectively.

32. On information and belief, WishBone is currently using, manufacturing, selling, and/or importing the Accused System in the United States, including in this District, or plans to do so imminently.

33. As set forth in Counts I and II, Paragraphs 34-58, the Accused System infringes the '998 Patent.

COUNT I
INFRINGEMENT OF THE '998 PATENT
(by Plaintiff against Defendant WishBone)

34. Plaintiff re-alleges and incorporates by reference the allegations set forth in Paragraphs 1-33.

35. WishBone's manufacture, use, sale, offer for sale, and importation of the Accused System directly and/or indirectly infringes one or more Claims of the '998 Patent literally and/or under the doctrine of equivalents.

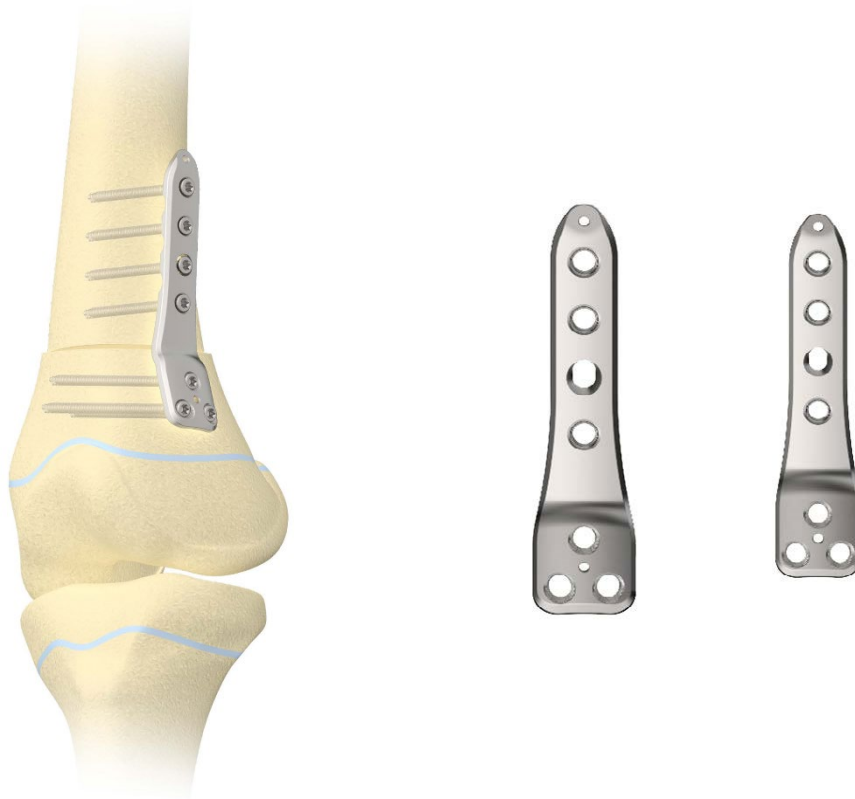
36. Independent Claim 1 of the '998 Patent reads as follows:

1. An apparatus for supporting a pediatric bone whereby the apparatus would not interfere with growth in the epiphyseal plate of the pediatric patient, comprising:
an elongated plate having a planar portion for attachment to a diaphysis of a pediatric bone, and a curved portion for attachment to a metaphysis of the pediatric bone, said plate having a top surface that faces away from the bone when said plate is implanted, said top surface being smoothly continuous between said planar portion and said curved portion and being in a plane in said planar portion and curved out of said plane in said curved portion;
wherein said plate has a set of holes, said set including a first plurality of holes in said planar portion, each of said first plurality of holes having a respective central longitudinal axis that is perpendicular to said top surface, and said set also including a second plurality of holes in said curved portion, each of said second plurality of holes having a respective central longitudinal axis that is not perpendicular to said top surface, and wherein said respective axes of said holes of said first plurality and said second plurality are parallel.

37. WishBone's Accused System provides "[a]n apparatus for supporting a pediatric bone whereby **the apparatus would not interfere with growth in the epiphyseal plate of the pediatric patient,**" as claimed in the '998 Patent. (emphasis added). In the Brochure, WishBone describes the Accused System as being "[s]pecifically designed for pediatric patients...[and including] condylar screws [that] are angled 5° away from the physis [to] help[] prevent penetrating the growth plate." (Brochure at 1). WishBone describes the Accused System as one that "helps surgeons better address proximal and distal deformities and trauma applications of the femur in pediatric patients." *Id.*

38. Wishbone's Accused System comprises at least the features of Claim 1 of the '998 Patent. Wishbone's Accused System includes "an elongated plate having a planar portion for attachment to a diaphysis of a pediatric bone, and a curved portion for attachment to a metaphysis of the pediatric bone, said plate having a top surface that faces away from the bone when said plate is implanted, said top surface being smoothly continuous between said planar portion and said curved portion and being in a plane in said planar portion and curved out of said plane in said curved portion," as claimed. Further, the plate in the Accused System "has a set of holes, said set including a first plurality of holes in said planar portion, each of said first plurality of holes having a respective central longitudinal axis that is perpendicular to said top surface, and said set also including a second plurality of holes in said curved portion, each of said second plurality of holes having a respective central longitudinal axis that is not perpendicular to said top surface, and wherein said respective axes of said holes of said first plurality and said second plurality are parallel," as claimed. As evidenced from the screenshots reproduced below from the Surgical Technique document, WishBone's Accused System has an "elongated plate" that has a "planar portion" attached to a "diaphysis of a pediatric bone" and a "curved portion" attached to a metaphysis of the pediatric bone." The top surface of the Accused System's plate faces away from the bone when implanted and is "smoothly continuous between said planar portion and said curved portion." Further, as seen below, the plate of the Accused system has a "set of holes," the first plurality of which is in the planar portion and has a "respective central

longitudinal axis that is perpendicular to said top surface” and a second plurality of holes in the curved portion that have a “respective central longitudinal axis that is not perpendicular to said top surface.” Finally, upon information and belief, the respective axes of the holes of the first and second plurality of holes in the plate are parallel in the Accused System.



39. On information and belief, WishBone uses the Accused System for multiple purposes including, without limitation, testing, demonstrations, marketing, advertising, product development and training. WishBone also markets and/or sells the Accused System to third-party customers, including orthopedic professionals, and instructs such third-party customers to use the Accused System, which directly infringes at least Claim 1 of the '998 Patent. As set forth above, WishBone provides instructions to such third parties on how to use the Accused system in a manner that infringes the claims of the '998 Patent.

At least the Instructions for Use and Surgical Technique documents describe how to use the infringing Accused System.

40. Thus, WishBone directly infringes the claims of the '998 Patent because each step of the claims is either performed by or attributable to WishBone, as described in Paragraphs 28-39 above.

41. WishBone also indirectly infringes the '998 Patent under 35 U.S.C. § 271(b) by actively and knowingly inducing third parties, including orthopedic professionals, to commit acts that constitute infringement of the '998 Patent, as described in Paragraphs 28-39.

42. Thus, as alleged above, WishBone actively, knowingly, and intentionally aids, abets, directs, encourages, or otherwise instructs third parties via the sale, offer to sell, promotions, and advertising of the Accused System, and provision of instructions regarding using such Accused System in the manner described in the asserted claims of the '998 Patent, to infringe the '998 Patent by and through their use of the Accused System. Therefore, WishBone induces, has induced, and continues to induce, infringement of at least Claim 1 of the '998 Patent in violation of the patent laws of the United States, and in particular 35 U.S.C. §§ 271, *et seq.*

43. WishBone's conduct, as described herein, also constitutes contributory infringement of the '998 Patent under 35 U.S.C. § 271(c). WishBone has known that the Accused System was being made and distributed for the purpose of infringement of the '998 Patent by users or businesses. Moreover, the Accused System has no substantial non-infringing uses.

44. As a result of WishBone's infringement of the '998 Patent, Plaintiff has suffered and continues to suffer monetary damages, and seeks recovery in an amount to compensate Plaintiff for WishBone's infringement, in no event less than a reasonable royalty for WishBone's use of the patented invention, together with interest and costs as fixed by the Court.

45. WishBone's actions further make this an exceptional case supporting an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

46. Plaintiff has suffered and will continue to suffer irreparable harm in the future unless WishBone's infringing activities are enjoined by this Court.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '998 PATENT
(by Plaintiff against Defendant WishBone)

47. Plaintiff re-alleges and incorporates by reference the allegations set forth in Paragraphs 1-46.

48. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271(a), (b), or (c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

50. Upon information and belief, the FDA's approval of WishBone's Accused System coupled with WishBone's commercial activities in support of importation and launch of the Accused System, including (i) WishBone's application to the FDA for permission to market the Accused System, (ii) WishBone's announcement of the FDA's approval, (iii) WishBone's advertising of and making available the Accused System on its website, (iv) and WishBone's provision of the instructions pertaining to the use of Accused System such as those provided in its Brochure, Instructions for Use, and Surgical Technique documents create an actual, immediate, and real controversy under the Declaratory Judgment Act that WishBone will directly infringe, actively induce, and/or contribute to the infringement of valid and enforceable claims of the '998 Patent before its expiration in violation of 35 U.S.C. § 271(a), (b), and (c), as alleged in Paragraphs 28-43 incorporated by reference herein.

51. WishBone's manufacture, use, sale, offer for sale, and importation of the Accused System directly and/or indirectly infringes one or more Claims of the '998 Patent literally and/or under the doctrine

of equivalents, as alleged in Paragraphs 28-43 above incorporated by reference herein. WishBone's infringement has caused significant damages to Plaintiff, as alleged in Paragraphs 44-46 incorporated by reference herein.

52. Upon information and belief, WishBone is currently manufacturing and/or imminently will manufacture and supply the Accused System, and WishBone is marketing the Accused System, intends to market the Accused System and will market the Accused System, within this District and elsewhere in the United States.

53. Upon information and belief, WishBone and/or a third party acting in concert with WishBone are importing and/or imminently will import the Accused System in the United States.

54. Upon information and belief, WishBone has engaged in and will continue to engage in substantial activities in preparation to market the Accused System in the United States.

55. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

56. Plaintiff will be substantially and irreparably harmed if WishBone is not enjoined from infringing the '998 Patent.

57. Plaintiff has no adequate remedy at law.

58. This case is exceptional, and Plaintiff is entitled to an award of attorney fees under 35 U.S.C. § 285.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury on all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully pray for the following relief:

A. That the Court enter judgment that the '998 Patent is enforceable and infringed by

WishBone, literally and/or under the doctrine of equivalents.

B. That the Court enter judgment that WishBone has engaged in induced infringement of one or more claims of the '998 Patent.

C. That the Court enter judgment that WishBone has engaged in contributory infringement of one or more claims of the '998 Patent.

D. That the Court declare that WishBone's manufacture, use, sale, offer to sell, and/or importation of the Accused System will constitute direct infringement of the '998 Patent.

E. That the Court declare that WishBone's manufacture, use, sale, offer to sell, and/or importation of the Accused System will constitute indirect infringement of the '998 Patent.

F. That the Court enter a judgment and order against WishBone and awarding to Plaintiff all damages adequate to compensate Plaintiff for WishBone's direct or indirect infringement of the '998 Patent, together with interests, costs, and disbursements.

G. That the Court enter a judgment and order requiring WishBone to provide accountings and to pay additional and/or supplemental damages to Plaintiff, including without limitation: (i) with respect to any sales or revenues not presented at trial, (ii) post-judgment reasonable royalty damages, (iii) prejudgment interest, and (iv) post-judgment interest.

H. That the Court enter a permanent injunction to prevent WishBone and its subsidiaries, parents, divisions, directors, officers, agents, servants, employees and all other persons in active concert or privity or in participation with them, from making, using, selling, offering for sale, importing or distributing, or inducing others to make, use, sell, offer for sale, import or distribute, the Accused System and any other product or service that infringes the '998 Patent.

I. That the Court enter a judgment that this case is exceptional, and to award Plaintiff all of its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate; and

J. That Plaintiff be awarded such other and further relief as this Court may deem just and proper under the circumstance.

Dated: May 26, 2023

VENABLE, LLP

By: /s/ Timothy J. Carroll

Timothy J. Carroll (*pro hac vice* application forthcoming)

227 W. Monroe Street, Suite 1900

Chicago IL 60606

Telephone: (312) 820-3414

Fax: (312) 820-3401

tjcarroll@venable.com

Elizabeth M. Manno (*pro hac vice* application forthcoming)

600 Massachusetts Avenue, NW

Washington, District of Columbia 20001

Telephone: (202) 344-4253

Fax: (202) 344-8300

emmanno@venable.com

Attorneys for Plaintiff