

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

QFIX SYSTEMS, LLC and	:	
ANHOLT TECHNOLOGIES, INC.	:	
d/b/a QFIX,	:	
	:	
Plaintiffs	:	
	:	
v.	:	Civil Action No.
	:	
KLARITY MEDICAL PRODUCTS, LLC,	:	JURY TRIAL DEMANDED
	:	
Defendant	:	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Qfix Systems, LLC and Anholt Technologies, Inc. d/b/a Qfix (“Plaintiffs” or “Qfix”), by and through their undersigned counsel, file this Complaint and Jury Demand against Defendant Klarity Medical Products, LLC (“Defendant” or “Klarity”), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 11,364,088 arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

THE PARTIES

2. Plaintiff Qfix Systems, LLC is a corporation organized and existing under the laws of the State of Delaware, having a primary place of business of 440 Church Rd, Avondale, PA 19311.

3. Plaintiff Anholt Technologies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a primary place of business of 440 Church Rd, Avondale, PA 19311.

4. On information and belief, Klarity is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Klarity has a principal place of business at 600 Industrial Parkway, Heath, Ohio 43056.

JURISDICTION AND VENUE

5. This court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that this action arises under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

6. This Court has personal jurisdiction over Klarity. Klarity is a corporation organized and existing under the laws of the State of Delaware and, therefore, subject to this Court's jurisdiction. Furthermore, on information and belief, Klarity has regularly and systematically transacted business in and with residents of the State of Delaware, directly and/or through intermediaries, and/or committed acts of infringement in the State of Delaware as alleged more particularly below. In particular, on information and belief, Klarity sells and/or offers for sale products throughout the United States, including in Delaware, for infringing use under such circumstances that Klarity reasonably should have anticipated being subject to suit in this judicial district.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b).

BACKGROUND

8. Qfix is a medical device company that has long been an industry leader in developing and commercializing innovative medical products such as patient positioning and transfer systems for use in conjunction with treatments such as radiotherapy.

9. Qfix has developed a number of improvements in patient positioning and transfer systems which are incorporated into the products designed, manufactured, and sold by Qfix.

10. As one example, Qfix has developed an innovative patient immobilization system, called the Integrated Shim™ system, for use in stereotactic radiosurgery and other procedures.

The Integrated Shim™ system allows independent height adjustment at each pin location.

11. United States Patent No. 11,364,088 (“the ‘088 patent”), entitled “ADJUSTABLE IMMOBILIZER APPARATUS AND METHOD FOR IMMOBILIZING A PATIENT,” was duly and lawfully issued to Qfix on June 21, 2022. A true and correct copy of the ‘088 patent is attached hereto as **Exhibit 1** and is incorporated by reference herein.

12. The ‘088 patent has been in full force and effect since its issuance. Qfix owns by assignment the entire right, title, and interest in and to the ‘088 patent, including the right to seek damages for past, current, and future infringement thereof.

13. The Integrated Shim™ system of Qfix is covered by at least one claim of the ‘088 patent.

14. Klarity is a competitor of Qfix in a number of markets, including in the marketing and sale of products designed for stereotactic radiosurgery.

15. Klarity imports, sells, offers to sell, and distributes within the United States at least one product in the stereotactic radiosurgery market, namely, Klarity SRS Masks employing Klarity’s Simple Shim System.

16. Klarity SRS Masks employing Klarity’s Simple Shim System are marketed in the same markets and in competition with Qfix’s marketing and sale of its Integrated Shim™ system.

17. As set forth in greater detail below, Klarity’s import, sale, offer for sale, and/or distribution in the United States of Klarity SRS Masks employing Klarity’s Simple Shim System directly infringes one or more claims of the ‘088 patent.

18. On information and belief, Klarity's customers that use Klarity SRS Masks employing Klarity's Simple Shim System in the United States directly infringe one or more claims of the '088 patent.

19. On information and belief, Klarity owns and operates www.klaritymedical.com/srs, which offers for sale within the United States Klarity SRS Masks employing Klarity's Simple Shim System.

20. On information and belief, Klarity induces and/or contributes to infringement of the '088 patent by selling, offering for sale, and/or distributing in the United States Klarity SRS Masks employing Klarity's Simple Shim System, in conjunction with Klarity's marketing of these products and/or the instructions provided by Klarity in association with these products. A true and correct copy of Klarity's Simple Shim SRS Instructions for Use inducing and/or contributing to infringement of the '088 patent is attached hereto as **Exhibit 2** and is incorporated by reference herein.

21. On December 5, 2022, Qfix sent correspondence to Peter M. Larson, President of Klarity, regarding the '088 patent. A true and correct copy of the December 5 correspondence, as well as exhibits thereto, is attached hereto as **Exhibit 3** and is incorporated by reference herein.

22. The December 5 correspondence placed Klarity on notice that its importation, sale, offer for sale, and/or distribution of Klarity SRS Masks employing Klarity's Simple Shim System infringed one or more claims of the '088 patent.

COUNT I

Direct Infringement of U.S. Patent No. 11,364,088

23. Qfix restates and realleges each allegation contained in the preceding paragraphs of this Complaint as if fully set forth herein.

24. The '088 patent is valid and enforceable.

25. Claim 1 of the '088 patent recites:

[1.0] An immobilization apparatus configured to be coupled to a patient support, the immobilization apparatus comprising:

[1.1] a frame;

[1.2] a preform formed from a low melting temperature thermoplastic and configured to be formed to an anatomy of the patient, the preform being coupled to the frame;

[1.3] separate locks mounted to the frame each configured to lock the immobilization apparatus relative to the patient support, each of the separate locks having a plunger extending along a plunger axis, and each of the plungers being movable along the respective plunger axis between a locked position and an unlocked position;

[1.4] separate adjusters each configured to be associated with a corresponding one of the separate locks and each configured to selectively adjust a distance between the frame and the patient support along the plunger axis of the corresponding one of the separate locks;

[1.5] the separate adjusters being separate from one another such that the distance between the frame and the patient support along the plunger axis of the corresponding one of the separate locks is adjustable independent of the distance between the frame and the patient support along the plunger axis of another one of the separate locks, each of the separate adjusters being further configured to extend about the plunger axis of the corresponding one of the separate locks.

See **Exhibit 1**, column 19, lines 36-62.

26. Regarding element [1.0], the Klarity SRS mask is an immobilization apparatus configured to be coupled to a patient support. *See Exhibit 3*, p. 42.
27. Regarding element [1.1], the Klarity SRS mask includes a frame. *See Exhibit 3*, p. 43.
28. Regarding element [1.2], the Klarity SRS mask includes a preform formed from Klarity Blue™ thermoplastic, a low melting temperature thermoplastic. The SRS mask is configured to be formed to the anatomy of a patient, e.g., a patient's head. The preform is coupled to the frame. *See Exhibit 3*, pp. 44-45.
29. Regarding element [1.3], the Klarity SRS mask includes multiple separate locks which are mounted to the frame. Each lock is configured to lock the SRS mask to the patient support. Each of the locks of the Klarity SRS mask has a plunger extending along an axis. Each of the plungers is movable along the axis between locked and unlocked positions. *See Exhibit 3*, pp. 46-49.
30. Regarding element [1.4], the Klarity SRS Mask employing Klarity's Simple Shim System includes separate adjusters. The adjusters are configured to be provided at each lock. Each adjuster selectively adjusts a distance between the frame and the patient support along the plunger (or pin) axis (e.g., upward or downward). *See Exhibit 3*, p. 50.
31. Regarding element [1.5], the adjusters of the Klarity SRS Mask employing Klarity's Simple Shim System are separate from one another such that the distance between the frame and the patient support along the plunger axis is adjustable at each pin location independent of the distance between the frame and the patient support along the plunger axis of other pin locations. The adjusters of the Klarity SRS Mask employing Klarity's Simple Shim System extend about the plunger axis. *See Exhibit 3*, pp. 51-52.

32. On information and belief, Klarity has directly infringed and continues to directly infringe the '088 patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents, by importing, selling, offering to sell, and distributing within the United States one or more products, including Klarity SRS Masks employing Klarity's Simple Shim System.

33. Klarity does not have a license or other lawful right to practice the invention claimed in the '088 patent.

34. Klarity's infringement of the '088 patent has injured and continues to injure Qfix , causing irreparable harm for which damages are an inadequate remedy, such that a permanent injunction should be issued.

35. As a result of Klarity's infringement of the '088 patent, Qfix has suffered and continues to suffer monetary damages.

COUNT II

Willful Infringement of U.S. Patent No. 11,364,088

36. Qfix restates and realleges each allegation contained in the preceding paragraphs of this Complaint as if fully set forth herein.

37. Klarity first learned of the '088 patent at least as early as its receipt of the December 5 correspondence. *See Exhibit 3.*

38. Klarity has been on notice that its importing, selling, offering to sell, and distributing within the United States of the Klarity SRS Masks employing Klarity's Simple Shim System infringes at least one claim of the '088 Patent since at least as early as its receipt of the December 5 correspondence. *See Exhibit 3.*

39. On information and belief, Klarity has continued to import, sell, offer for sale, and distribute within the United States the Klarity SRS Masks employing Klarity's Simple Shim

System since first learning of the '088 patent, and since being on notice of infringement from Qfix.

40. On information and belief, Klarity acted despite an objectively high likelihood that the actions set forth above constituted infringement of at least one claim of a valid patent, the '088 patent.

41. On information and belief, Klarity actually knew, or it was so obvious that Klarity should have known, that its actions constituted infringement of a valid patent, the '088 patent.

42. Klarity's infringement is therefore willful.

COUNT III

Indirect Infringement of U.S. Patent No. 11,364,088

43. Qfix restates and realleges each allegation contained in the preceding paragraphs of this Complaint as if fully set forth herein.

44. On information and belief, users of Klarity's SRS Masks employing Klarity's Simple Shim System have directly infringed and continue to directly infringe the '088 patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of equivalents.

45. Klarity had actual knowledge of the '088 patent at least as early as its receipt of the December 5 correspondence.

46. On information and belief, Klarity has induced and/or contributed to the infringement of the '088 patent under 35 U.S.C. §§ 271(b) and (c) by selling, offering for sale, and/or distributing in the United States Klarity SRS Masks employing Klarity's Simple Shim System, in conjunction with Klarity's marketing of these products and/or the instructions provided by Klarity in association with these products.

47. On information and belief, Klarity induces infringement of at least one claim of the '088 patent at least by instructing users to use Klarity's Simple Shim System with Klarity's

SRS Masks in a manner resulting in direct infringement by the user with the knowledge and intent that doing so would result in the infringement of one or more claims of the '088 patent by those users.

48. On information and belief, Klarity contributes to infringement of at least one claim of the '088 patent at least by selling, offering to sell, and/or distributing Klarity's SRS Masks along with Klarity's Simple Shim System, knowing the same to be especially made or especially adapted for use in a manner infringing the '088 patent, without the same being a staple article or commodity of commerce suitable for substantial noninfringing use.

49. Klarity's indirect infringement of the '088 patent has injured and continues to injure Qfix, causing irreparable harm for which damages are an inadequate remedy, such that a permanent injunction should be issued.

50. As a result of Klarity's indirect infringement of the '088 patent, Qfix has suffered monetary damages.

PRAYER FOR RELIEF

WHEREFORE, Qfix respectfully requests that the Court grant the following relief:

- A. Enter judgement that Klarity has directly infringed the '088 patent;
- B. Enter judgment that Klarity has induced infringement of the '088 patent by selling, offering to sell, and/or distributing Klarity's SRS Masks employing Klarity's Simple Shim System in the United States and instructing users to use Klarity's Simple Shim System with Klarity's SRS Masks;
- C. Enter judgment that Klarity has contributed to infringement of the '088 patent by selling, offering to sell, and/or distributing Klarity's SRS Masks employing Klarity's Simple Shim System in the United States;

D. Enter an order enjoining Klarity and its affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, from infringing the '088 patent;

E. Award Qfix damages in an amount sufficient to compensate it for Klarity's infringement of the '088 patent, including lost profits but in no event less than a reasonable royalty, together with prejudgment and post-judgment interest at the maximum rate allowed by law and costs under 35 U.S.C. § 284;

F. Find that Klarity's infringement has been willful, and treble the damages awarded to Qfix under 35 U.S.C. § 284;

G. Declare this case to be exceptional under 35 U.S.C. § 285 and award Qfix its attorney fees, expenses, and costs incurred in this action; and

H. Award Qfix such other and further relief as this Court deems just and proper.

JURY DEMAND

Qfix demands a jury trial on all issues so triable.

Date: 1/23/23

Respectfully submitted,

/s/Andrew J. Koopman

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