

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

ZIMMER SURGICAL, INC. and
DORNOCH MEDICAL SYSTEMS, INC.,

Plaintiffs,

v.

STRYKER CORPORATION and
STRYKER SALES CORPORATION,

Defendants and
Counterclaim Plaintiffs,

v.

ZIMMER, INC., ZIMMER SURGICAL, INC. and
DORNOCH MEDICAL SYSTEMS, INC.,

Counterclaim
Defendants.

C. A. No. 16-679-RGA-MPT

DEMAND FOR JURY TRIAL

**REDACTED
PUBLIC VERSION**

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Zimmer Surgical, Inc. (“Zimmer”) and Dornoch Medical Systems, Inc. (“Dornoch Medical”) state the following as their amended complaint against Defendants Stryker Corporation (“Stryker”) and Stryker Sales Corporation (“Stryker Sales”):

NATURE OF THE ACTION

1. This is an action for patent infringement against Stryker and Stryker Sales for infringing U.S. Patent No. RE44,920 (“the ’920 patent”), titled “High Volume Liquid Waste Collection and Disposal System,” which was duly and legally issued to Dornoch Medical as assignee of inventors James L. Dunn and Lawrence E. Guerra. A certified copy of the ’920 patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff Zimmer is a Delaware corporation with a principal place of business at 200 West Ohio Ave., Dover, Ohio 44622. Zimmer is a worldwide leader in researching, designing, and manufacturing innovative and customizable surgical and operating room solutions. Zimmer is Dornoch Medical's exclusive licensee of the '920 patent for the manufacture, use, sale offer for sale, and import of all consumables and accessories covered by the '920 patent.

3. Plaintiff Dornoch Medical is a wholly-owned subsidiary of Zimmer. It is an Illinois corporation with a principal place of business at 200 NW Parkway Dr., Riverside, Missouri, 64150. Dornoch Medical specializes in designing and manufacturing safe, convenient, and environmentally considerate fluid waste management solutions for operating room environments. Among those solutions is the Transposal® UltrafleX Fluid Waste Management System, which simplifies fluid collection in operating rooms by safely using on-board regulated suction and class-leading fluid capacity. The Transposal® UltrafleX Fluid Waste Management System includes UltrafleX fluid carts, associated Ultra Evac Station fluid disposal units, and consumables used with UltrafleX fluid carts, such as single-use canister lids, single-use cart manifolds, manual IV poles, powered IV poles, smoke filters, specimen traps, and clot busters. Dornoch Medical manufactures and sells the UltrafleX fluid carts and associated Ultra Evac Station fluid disposal units, while Zimmer is responsible for making and exclusively distributing the consumables used with UltrafleX fluid carts, such as single-use lids and manifolds.

4. Upon information and belief, Defendant Stryker is a Michigan corporation having its principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

5. Upon information and belief, Defendant Stryker Sales is a Michigan corporation having its principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Stryker and Stryker Sales because Stryker and Stryker Sales have substantial contacts and conduct business in the State of Delaware, and have been infringing, contributing to the infringement of, and/or actively inducing others to infringe claims of the '920 patent in the State of Delaware and elsewhere.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b) because, on information and belief, a substantial part of the events giving rise to Zimmer and Dornoch Medical's claims occurred in the State of Delaware.

Stryker's and Stryker Sales' Acts of Infringement

9. Stryker and Stryker Sales have made, used, sold, imported, and/or offered for sale, and/or continue to make, use, sell, import, and/or offer for sale, products in the United States consisting of the Stryker Neptune 2 Waste Management System ("Neptune 2 System") and the Stryker Neptune 3 Waste Management System ("Neptune 3 System"). Stryker's and Stryker Sales' manufacture, use (e.g., through testing), sale, offer for sale, and/or importation of the Neptune 2 and Neptune 3 Systems in the United States constitute acts of direct infringement of the '920 patent.

10. The Neptune 2 and Neptune 3 Systems include a Rover, Docking Station, and consumables such as manifolds, filters, smoke tubing, detergent, and quick trap specimen collectors. Stryker and Stryker Sales have sold or offered to sell the Rover, Docking Station, and consumables to third parties who incorporate the Rover, Docking Station, and consumables into the Neptune 2 and Neptune 3 Systems. Those third parties in turn have made, used, sold, offered

for sale, and/or imported, and/or continue to make, use, sell, import, and/or offer for sale, the Neptune 2 and Neptune 3 Systems in the United States. These activities undertaken by third parties constitute acts of direct infringement of the '920 patent. The Rover, Docking Station, and consumables in the Neptune 2 and Neptune 3 Systems are known by Stryker and Stryker Sales to be especially made or especially adapted for use in infringement of the '920 patent and are not staple articles or commodities of commerce suitable for substantial noninfringing use. Stryker and Stryker Sales have therefore contributed to and continue to contribute to the infringement of the '920 patent.

11. Stryker and Stryker Sales have also induced and continue to induce acts by third parties that Stryker and Stryker Sales know or should know constitute direct infringement of the '920 patent. Stryker and Stryker Sales actively induce infringement of the '920 patent by designing the Neptune 2 and Neptune 3 Systems such that they infringe the '920 patent and by directing, promoting, and encouraging the use of its Neptune 2 and Neptune 3 Systems by third parties in ways that infringe the '920 patent.

12. Dornoch Medical and Zimmer, as Dornoch Medical's exclusive licensee, are entitled to recover from Stryker and Stryker Sales the actual damages they sustained as a result of Stryker's and Stryker Sales' wrongful acts alleged herein under 35 U.S.C. § 284 in an amount to be proven at trial, together with interest and costs.

13. Stryker's and Stryker Sales' infringement of the '920 patent has been and is willful, deliberate, and in disregard of Zimmer's and Dornoch Medical's patent rights, and Zimmer and Dornoch Medical are therefore entitled to increased damages up to three times the amount of actual damages and attorneys' fees pursuant to 35 U.S.C. §§ 284, 285.

CLAIM FOR RELIEF

Infringement of the '920 Patent

14. Stryker and Stryker Sales have and continue to directly infringe one or more claims of the '920 patent by making, using (e.g., through testing), offering for sale, and/or selling at least the Neptune 2 and Neptune 3 Systems. For example, and without limitation, upon information and belief the Neptune 2 and Neptune 3 Systems meet every limitation of at least independent claims 15 and 29 of the '920 patent, and thus the Neptune 2 and Neptune 3 Systems infringe at least independent claims 15 and 29 of the '920 patent.

15. The Neptune 2 System is “intended to be used in the operating room, pathology, surgical centers, and doctor’s offices to collect and dispose of surgical fluid waste as well as collect smoke generated from electrocautery or laser devices.” (Exhibit B, Neptune 2 Instructions for Use, at 6 (“Neptune 2 Manual”).)

16. The Neptune 2 System includes a Rover, which “is a mobile unit used to suction and collect fluid waste and surgical smoke from a surgical site in an operating room.” (*Id.* at 7.) The Rover is supported by “four swivel casters,” which also allow for mobility. (*Id.* at 10.) The Neptune 2 System also includes a Docking Station. (Exhibit C, Neptune 2 510(k) Summary, at 005-2.) The Docking Station “is a stationary device for automated rover cleaning and waste offloading. It provides a fixed connection to the hospital’s water supply, sewer, and electricity.” (*Id.*)

17. The Rover includes a “two canister design,” which “allows separate suction limit settings.” (Neptune 2 Manual at 7.) Each canister is configured to provide at least two different levels of suction, and the level of suction at one of the suction ports is independently adjustable from the level of suction at the other suction port. (*See, e.g., id.* at 12; Fig. 7.) Each canister is configured to collect fluid waste from a patient via its respective suction port when a vacuum is

applied to the container. (*See, e.g., id.* at 7.)

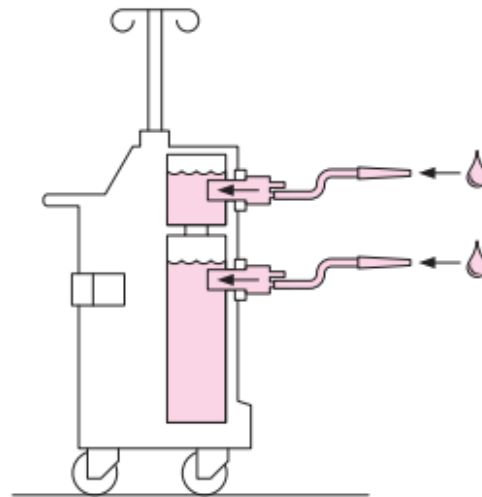


Figure 1 To Collect Fluid Waste

18. An outlet from each canister is also operatively connected to a drain system, and an inlet to each canister is operatively connected to a flushing system. (*Id.* at 7.) After collecting fluid waste, the Rover “is relocated and mated to the Stryker Docking Station (docker). Once the rover is connected to the docker, the emptying of the fluid waste and cleaning of the canisters occurs automatically.” (*Id.*) The canisters in the Rover are drained and “are rinsed with clean water and Neptune Docking Detergent REF 0700-001-026 to clean the canisters of any residual fluid waste.” (*Id.*)

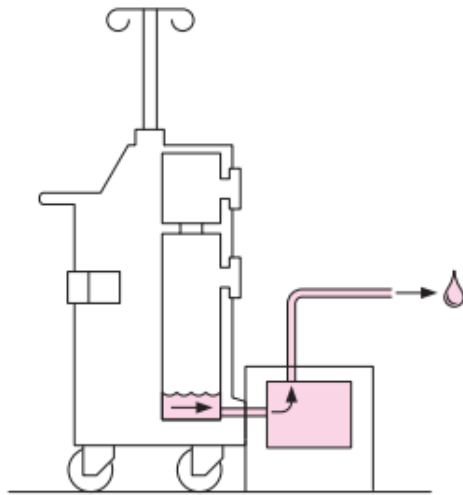


Figure 3 To Empty the Canisters

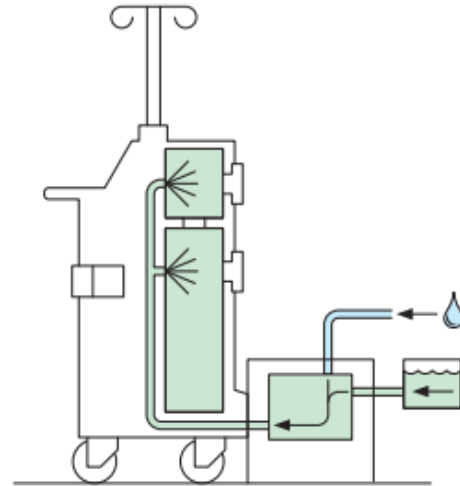


Figure 4 To Clean the Canisters

19. The Docking Station has a first portion coupled to the flushing portion of the Rover. (*Id.* at 7; Fig. 4.) The Docking Station includes a “Wash” option, which “applies detergent to the interior walls of both canisters, and rinses the detergent with water.” (*Id.* at 26.)

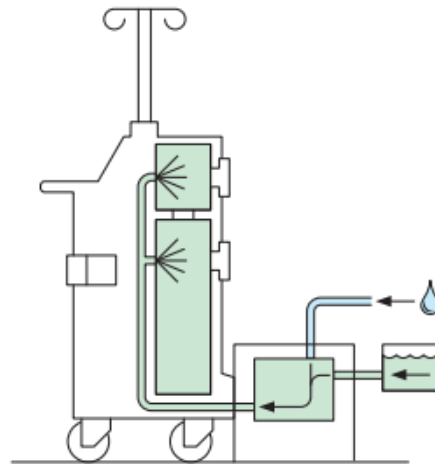


Figure 4 To Clean the Canisters

20. The Docking Station also has a second portion coupled to the drain portion of the Rover. (*Id.* at 7; Fig. 3.) The Docking Station includes a “Quick Drain” option to drain the contents of both canisters. (*Id.* at 26.) Upon information and belief, the drain process is facilitated by a drain pump in the Docking Station.

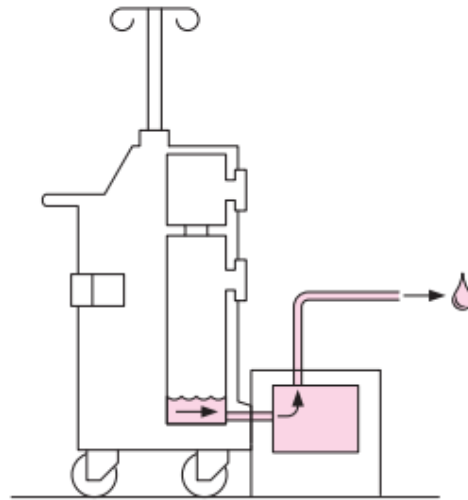


Figure 3 To Empty the Canisters

21. The Neptune 3 System operates in the same manner as the Neptune 2 System with respect to infringement of the claims of the '920 patent. The Food and Drug Administration's Section 510(k) approval for the Neptune 3 System lists the Neptune 2 System as the predicate device and states that "[t]he results of non-clinical performance testing demonstrate that the Neptune 3 Rover will perform as intended and is substantially equivalent to the [Neptune 2 System]." (Exhibit D, Neptune 3 510(k) Approval, at 5-5.) The Section 510(k) approval states that the Neptune 3 System contains "[t]wo independently operated suction levels" and "2 canisters," and is also "compatib[le] with the Neptune 2 Docking Station" for purposes of "waste off-load." (*Id.* at 5-3, 5-4.) Stryker Neptune 3 Waste Management System sales brochures confirm that it includes "Dual canisters" and performs "Hands-free docking and self cleaning" by using "seamless integration; backwards compatib[ility] with Neptune 2 manifolds, filters, and docking station[s]." (Exhibit E, Neptune 3 Sales Brochure, at pp. 2, 4 ("Neptune 3 Brochure").)

22. Stryker and Stryker Sales maintain offices or facilities throughout the United States. Upon information and belief, Stryker and/or Stryker Sales manufacture, make, and have made, the Neptune 2 and Neptune 3 Systems in the United States.

23. Upon information and belief, Stryker and Stryker Sales also conduct product and system research and development activities for its products in the United States. Upon information and belief, Stryker and/or Stryker Sales test and use their products in the United States when they conduct product and system research and development activities in their domestic offices.

24. Stryker and Stryker Sales give demonstrations of the Neptune 2 and Neptune 3 Systems, including at annual trade shows, such as at the Association of periOperative Registered Nurses Surgical Conference & Expo. (*See, e.g.*, http://www.stryker.com/en-us/products/SurgicalEquipment/WasteManagement/Neptune2/BOOK_DEMO.) Upon information and belief, Stryker and Stryker Sales also test the Neptune 2 and Neptune 3 Systems, including at their facilities and at the facilities of their end users during installation.

25. Stryker and Stryker Sales have indirectly infringed and continue to indirectly infringe at least independent claims 15 and 29 of the '920 patent, via both contributory and induced infringement.

26. Stryker and Stryker Sales knew or should have known of the '920 patent. For example, the '920 patent claims priority to U.S. Patent No. 6,893,425 ("the '425 patent"). Stryker's U.S. Patent Nos. 7,621,898, 7,615,037, and 8,518,002, which are all directed to medical waste disposal systems, list the '425 patent under the "References Cited." Additionally, Stryker and Zimmer are direct and active competitors in the two-competitor field of fluid waste management.

27. Stryker and Stryker Sales have also been monitoring and tracking the development of Zimmer's and Dornoch Medical's medical waste disposal systems, FDA submissions, and the patents that cover those systems, and collected documents relating to the same. For example, Stryker and Stryker Sales have established a timeline from when Dornoch

Medical was founded in 1995 to present, tracking the progress of Zimmer's and Dornoch Medical's products over the years. This timeline includes the dates in which important patents related to Zimmer's and Dornoch Medical's medical waste disposal systems were filed and granted. The timeline includes the dates in which the '425 patent, to which the '920 patent claims priority, was filed and granted

28. Stryker and Stryker Sales also tracked the development of Zimmer's and Dornoch Medical's medical waste disposal systems by requesting 510(k) information related to the Transposal® Ultraflex Fluid Waste Management System on March 21, 2014. The information provided by the Food and Drug Administration included an owner's manual for Ultraflex fluid carts that describes in detail how the fluid carts are made and how they operate. The owner's manual specifically mentions the '425 patent and also noted that there were "[o]ther patents pending". By the time the 510(k) request had been received by Stryker and Stryker Sales, the '920 patent had been allowed and issued later that year in 2014. This same owner's manual had been distributed internally at Stryker and/or Stryker Sales at least as early as April 27, 2010.

29. On information and belief Stryker and Stryker Sales monitored and tracked the patents that cover those systems, including the '920 patent. On information and belief, Stryker and Stryker Sales were aware of the '920 patent around the time of its issuance, prior to the filing of this lawsuit. On information and belief, Stryker anticipated litigation regarding the '920 patent prior to Plaintiffs' filing of this lawsuit. Stryker's privilege log includes two entries dated June 3, 2014, the date the '920 patent issued. Those entries are marked as containing attorney-client privileged communications and litigation work product and are directed to documents relevant to this litigation. The description for those entries is, "[e]mail with history containing information related to a confidential communication made for the purpose of providing legal advice between in-house counsel and Stryker personnel [REDACTED]"

regarding patent.” On information and belief, Stryker anticipated litigation regarding the ’920 patent, at least as early as June 3, 2014, the date the ’920 patent issued.

30. Zimmer issued an interrogatory to Stryker and Stryker Sales requesting that they identify the date each Stryker entity “first became aware of the ’920 patent.” Stryker and Stryker Sales responded that “Stryker Corporation and Stryker Sales Corporation became aware of the RE920 Patent at least as early as the filing date of, and through the filing of, the Complaint.” Stryker and Stryker Sales did not deny pre-suit knowledge of the ’920 patent or affirmatively state that the earliest knowledge was through the filing of the original Complaint.

31. Notwithstanding Stryker’s and Stryker Sales’ earlier knowledge of the ’920 patent and related patents and applications, Stryker and Stryker Sales have had knowledge of the ’920 patent at least as early as filing of the initial complaint in this case on August 8, 2016.

32. Upon information and belief, others also infringe the ’920 patent. For example, the use by Stryker’s and Stryker Sales’ customers of the products accused of infringing the ’920 patent also constitutes infringement of at least independent claims 15 and 29 of the ’920 patent. The Neptune 2 and Neptune 3 Systems meet every limitation of at least independent claims 15 and 29 of the ’920 patent. When the Neptune 2 and Neptune 3 Systems are sold to and used by end users, those end users infringe at least independent claims 15 and 29 of the ’920 patent through the use of the Neptune 2 System or the Neptune 3 System.

33. Stryker and Stryker Sales specifically intend that third parties will infringe the ’920 patent. Stryker and Stryker Sales encourage infringement by end users at least by providing product support that instructs users on how to use the Neptune 2 and Neptune 3 Systems in an infringing manner. For example, Stryker and Stryker Sales provide an “Installation, Operation, and Maintenance Guide” manual for providing product information for the Neptune 2 to end users. (*See Neptune 2 Manual.*) The manual gives detailed instructions for use of the Neptune 2

System. (*Id.*) Stryker also advertises training and support for use of the Neptune 2 System. (<http://www.neptunewastemanagement.com/support/training.php>.) Stryker also sought and received Section 510(k) premarket approval to market the Neptune 3 System based on its substantial equivalence to the Neptune 2 System. (*See* Exhibit D, Neptune 3 510(k) Approval.) Upon information and belief, Stryker and Stryker Sales provide manuals and instructions similar to the Neptune 2 to users of the Neptune 3 System. Despite Stryker's and Stryker Sales' knowledge that users will necessarily infringe the '920 patent when the Neptune 2 and Neptune 3 Systems are used as instructed, Stryker and Stryker Sales continue to encourage infringement by third parties. (*See, e.g.*, Neptune 3 Brochure at p. 4 ("For more information or to schedule a product trial, please contact your Surgical sales representatives").) Stryker and Stryker Sales also encourage infringement by end users through the sale of consumables designed and intended to be used in the Neptune 2 and 3 Systems. Despite Stryker's and Stryker Sales' knowledge that users will necessarily infringe the '920 patent when the Neptune 2 and Neptune 3 Systems are used as instructed, Stryker and Stryker Sales continue to encourage infringement by third parties through the sale of consumables.

34. At least as early as the filing of the complaint in this case on August 8, 2016, Stryker and Stryker Sales have known how the Neptune 2 and Neptune 3 Systems infringe the '920 patent. Despite their knowledge, Stryker and Stryker Sales have not made any effort to recall the Neptune 2 and Neptune 3 Systems currently being used by Stryker's and Stryker Sales' customers of the products. Thus, at least as early as August 8, 2016, Stryker and Stryker Sales have been and are actively inducing infringement of the '920 patent by actively and knowingly inducing third parties such as customers to commit acts that Stryker and Stryker Sales know constitute infringement of the '920 patent.

35. Stryker and Stryker Sales also sell and/or offer to sell products that contributorily infringe the '920 patent. For example, Stryker and Stryker Sales sell products, such as at least the Rover, Docking Station, and consumables that have no substantial noninfringing uses. Upon information and belief, the Stryker Rover and Docking Station are especially made and/or adapted for use in an infringing manner because they cannot be used in a noninfringing manner. Thus, upon information and belief, the Rover, Docking Station, and associated consumables are not staple articles or commodities of commerce suitable for substantial noninfringing use. The Neptune 2 and 3 Rover and Docking Station are also a material part of the invention, as they infringe at least independent claims 15 and 29 of the '920 patent.

36. At least as early as the filing of the complaint in this case on August 8, 2016, Stryker and Stryker Sales have known that the Stryker Rover and Docking Station are especially made and/or adapted for use in an infringing manner. Also, at least as early as the filing of the complaint in this case on August 8, 2016, Stryker and Stryker Sales have known that the Rover, Docking Station, and associated consumables are not staple articles or commodities of commerce suitable for substantial noninfringing use. Despite their knowledge, Stryker and Stryker Sales have not made any effort to recall the Neptune 2 and Neptune 3 Systems currently being used by Stryker's and Stryker Sales' customers of the products. Thus, by continuing to provide the Neptune 2 and Neptune 3 Systems, Stryker and Stryker Sales continue to specifically intend to contributorily infringe the '920 patent.

37. In addition to independent claims 15 and 29, Stryker and Stryker Sales also directly and indirectly infringe at least claims 17–23, 25–28, 30, 32–38, 40, and 41 of the '920 patent, which depend from independent claims 15 and 29.

38. Stryker's and Stryker Sales' infringement has damaged and continues to damage and injure Zimmer and Dornoch Medical. Zimmer's and Dornoch Medical's injuries are

irreparable and will continue unless and until Stryker and Stryker Sales are enjoined by this Court from further infringement.

39. Stryker and Stryker Sales knew or should have known of the '920 patent and have acted, and continue to act, in an egregious and wanton manner by infringing '920 patent in the two-competitor field of fluid waste management. Their internal process of monitoring and tracking Zimmer's and Dornoch Medical's medical waste disposal products and patents made them aware or should have made them aware that they were infringing the '920 patent. Stryker and Stryker Sales nonetheless continued to copy, without authorization, the features of Zimmer and Dornoch Medical's medical waste disposal systems described in the '920 patent. Stryker and Stryker Sales' infringement of the '920 patent has been and continues to be willful and deliberate.

40. At least as early as the filing of the complaint in this case on August 8, 2016, Stryker and Stryker Sales knew of the '920 patent and their infringement of it. Despite their knowledge, Stryker and Stryker Sales have continued to make, use, sell, import, and/or offer for sale, the Neptune 2 and Neptune 3 Systems in the United States. In addition, Stryker and Stryker Sales have not made any effort to make any changes to the Neptune 2 and Neptune 3 Systems. Stryker and Stryker Sales have not made any attempts to license or request other authorization of the '920 patent despite their knowledge. As a result, their activity since August 8, 2016 and still ongoing has been and continues to be willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Zimmer and Dornoch Medical ask this Court to enter judgment in its favor against Stryker and Stryker Sales and grant the following relief:

A. a declaration that Stryker and Stryker Sales infringe the '920 patent under 35 U.S.C. § 271(a), (b), and/or (c) and a final judgment incorporating the same;

B. entry of an injunction enjoining Stryker and Stryker Sales, their subsidiaries, parents, divisions, agents, servants, and employees from making, using, selling, offering to sell, importing, or distributing any infringing fluid waste management systems, including the Neptune 2 and Neptune 3 Systems, and from infringing, contributing to the infringement of, and for inducing infringement of U.S. Patent No. RE44,920, and for all further and proper injunctive relief;

C. an award to Zimmer and Dornoch Medical of actual damages sufficient to compensate Zimmer and Dornoch Medical for Stryker's and Stryker Sales' acts of patent infringement, together with prejudgment and post-judgment interest under 35 U.S.C. § 284;

D. entry of an order compelling Stryker and Stryker Sales to compensate Zimmer and Dornoch Medical for any ongoing and/or future infringement of the '920 patent in an amount and under terms appropriate under the circumstances;

E. a declaration or order finding that Stryker's and Stryker Sales' infringement is willful and an award to Zimmer and Dornoch Medical of enhanced damages, up to and including trebling of Zimmer and Dornoch Medical's damages pursuant to 35 U.S.C. § 284, for Stryker's and Stryker Sales' willful infringement of the '920 patent;

F. a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding Zimmer and Dornoch Medical its reasonable attorney fees, costs, and expenses; and

G. any further relief that this Court deems just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, Zimmer and Dornoch Medical hereby demand trial by jury of all issues so triable by a jury in this action.

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