IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HEXAGON HEALTH, INC. and SHIRIN TOWFIGH, Plaintiffs, v. MEDTRONIC PLC, MEDTRONIC, INC., COVIDIEN LLC, COVIDIEN LP, COVIDIEN SALES LLC, and SOFRADIM PRODUCTION SAS, Defendants.	)	C.A. No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Hexagon Health, Inc. ("Hexagon Health") and Dr. Shirin Towfigh ("Dr. Towfigh") (collectively, the "Plaintiffs"), by and through their attorneys, for their Complaint against Defendants Medtronic plc, Medtronic, Inc., Covidien LLC, Covidien LP, Covidien Sales LLC, and Sofradim Production SAS ("Sofradim") (collectively, "Medtronic"), allege as follows:

PRELIMINARY STATEMENT

1. Medtronic, one of the world's largest medical device companies, knowingly copied Dr. Towfigh's patent-pending design for an innovative hernia treatment device that improves hernia repair outcomes for patients. Even after Dr. Towfigh was formally awarded patents for her inventions, Medtronic continued to manufacture, market, and sell the Dextile Anatomical Mesh, its version of Dr. Towfigh's device, without regard for Dr. Towfigh's rights. Medtronic's unlawful behavior has not only denied Dr. Towfigh and Hexagon Health of the full value of her inventions but also set back the field of hernia health, a critical but understudied medical specialty in need of treatment options that innovative specialist-physicians like Dr. Towfigh are uniquely positioned to address.

2. Hexagon Health and Dr. Towfigh now bring this an action for patent infringement and correction of inventorship arising under the patent laws of the United States, Title 35, United States Code, including §§ 256 and 271, and the Declaratory Judgment Act, Title 28, United States Code, including §§ 2201, 2202.

3. Hexagon Health brings suit against Medtronic for infringement of its patents, U.S. Patent No. 11,207,169 (the "'169 Patent"), U.S. Patent No. 11,219,516 (the "'516 Patent"), and U.S. Patent No. 11,324,579 (the "'579 Patent") (collectively, the "Asserted Patents"), by Medtronic's inguinal hernia mesh products, including the hernia mesh product sold as the Dextile Anatomical Mesh ("Dextile" or the "Dextile mesh").

4. Hexagon Health and Dr. Towfigh, the inventor of the Asserted Patents and founder of Hexagon Health, also seek declaratory judgment to have Dr. Towfigh be properly named as an inventor on Medtronic's patents through Sofradim, U.S. Patent Nos. 10,657,137 and 11,672,636, which copy the innovative mesh designs that Dr. Towfigh had disclosed to Medtronic when Dr. Towfigh and Medtronic were evaluating a potential business collaboration regarding the implementation of Dr. Towfigh's inventions to reduce hernia-mesh related complications in patients undergoing inguinal hernia repair.

BACKGROUND

Dr. Towfigh and Her Inventions

5. Dr. Towfigh is a distinguished surgeon whose practice exclusively focuses on the treatment of all types of hernias and hernia-related complications. Board-certified, and with over 22 years of experience, Dr. Towfigh has performed more than 6,000 hernia repairs, using tailored surgical techniques to achieve optimal outcomes. Over 80% of Dr. Towfigh's practice is dedicated to the treatment of complex hernias, especially complications related to hernia mesh. Dr. Towfigh's unique expertise in inguinal hernias and treating chronic pain related to inguinal hernia

repairs places her amongst a handful of hernia experts worldwide. In recognition of her achievements in patient care, Dr. Towfigh has been awarded the Top Doctor recognition by Castle Connolly annually for over a decade and was awarded an honorary certificate in Abdominal Wall Surgery by the European Board of Surgery in 2022.

6. Dr. Towfigh is also internationally recognized as a key opinion leader ("KOL") in hernia repair. She has held major leadership positions within local and national surgical societies, including the American Hernia Society, American College of Surgeons, and the International Hernia Collaboration. Dr. Towfigh also leads an academic practice that actively researches topics in hernia surgery. She is widely published and her textbook, *The SAGES Manual of Groin Pain*, is considered the preeminent reference for the evaluation and treatment of groin and pelvic pain.

7. Through the years, Dr. Towfigh has been a fierce advocate for hernia patients. She is often invited as a speaker on patient concerns and perspectives. She also hosts several patient support groups and a weekly podcast, HerniaTalk LIVE, to help answer patient questions. Additionally, Dr. Towfigh developed HerniaTalk.com, a free online patient education and discussion forum.

8. Because of her reputation for deep expertise and compassionate care, patients seek out Dr. Towfigh to treat their post-operative complications. After an inguinal hernia repair, these complications can include severe groin pain, chronic pelvic pain, nerve damage, testicular pain, vaginal pain, and sexual dysfunction, sometimes requiring another invasive surgery to remove the mesh. As there are few specialists in this field, patients can be incorrectly diagnosed and routed through several ineffective treatment options before the real problem is corrected. Dr. Towfigh has witnessed this patient journey many times over and understands how these complications greatly affect a patient's quality of life.

9. Over the course of removing many inguinal hernia meshes in her surgical practice, Dr. Towfigh came to realize that the then-available meshes suffered from significant design flaws that were leading to the post-operative complications that she was correcting. For example, Dr. Towfigh observed that the meshes did not provide optimal coverage of the femoral space, which is important in improving outcomes in hernia repair and avoiding recurrence, especially in females. Meanwhile, the meshes were designed in such a way as to overlap with several critical anatomical structures upon implantation, such as the femoral artery, femoral vein, spermatic cord, psoas muscle, and genital nerves, thus increasing the risk of chronic pain and other mesh-related complications. Dr. Towfigh recognized a need for an inguinal hernia mesh design that could securely cover the inguinal hernia defects and femoral space without increasing the risk of interfering with surrounding key anatomical features.

10. Using the insight gained from her unmatched surgical experience and seeking to address this patient need, Dr. Towfigh conceived of the innovative mesh reflected in the Asserted Patents. Among other benefits, her re-designed inguinal hernia mesh ensures broad coverage of the medial direct groin area with a fin that thoroughly covers the femoral space. This feature helps prevent future hernia recurrences in this location, which is beneficial for all patients, but can be particularly important, indeed even life-saving, for female patients. The mesh design with the fin is also designed to maintain the position of the mesh while minimizing overlap with critical anatomical structures, such as the femoral vein, spermatic cord, or genital nerve, which helps prevent the severe chronic pain and sexual dysfunction that can result if a hernia mesh adheres to the structures in male patients. Lateral to the fin, the mesh is designed to cover the indirect inguinal hernia space while also avoiding overlap with critical structures. This combination of benefits—maximized mesh coverage of the hernia and minimized mesh contact with sensitive non-hernia

areas—had never existed prior to Dr. Towfigh's re-design, offering an industry breakthrough for improved patient outcomes to all patients.

11. In 2015, Dr. Towfigh founded Hexagon Health to further her mission of patient-first innovation in hernia treatments, and to improve abdominal wall and pelvic floor healthcare, including by leveraging her inventions to help protect future hernia patients from the mesh-related complications she has had to correct in her surgical practice. In March 2016, seeking to protect her inventions from being copied without her permission, Dr. Towfigh filed an international patent application (or PCT application) to cover her inventive mesh designs. That application was published as WO 2016/154478, which gave rise to the Asserted Patents that Hexagon Health now owns.

History of Dealings Between the Parties

12. In late 2015, prompted by an outreach from Medtronic's representatives seeking to collaborate on potential projects with Dr. Towfigh as a KOL, Dr. Towfigh shared with them that she had a provisional patent application for a new mesh design that could complement Medtronic's product development efforts. Soon thereafter, Medtronic arranged for Dr. Towfigh to speak about her mesh ideas with Michel Thérin, the then-Global Vice President and General Manager of Medtronic, Inc.

13. Under a mutual non-disclosure agreement, Dr. Towfigh spoke with Mr. Thérin about her mesh ideas on or about December 21, 2015. Mr. Thérin indicated that he recognized the potential in Dr. Towfigh's design and expressed interest in working with Dr. Towfigh. He invited her to visit Medtronic's manufacturing site in Trévoux, France, where Sofradim is located, to meet their R&D team and further discuss her ideas around hernia repair.

14. On or about September 14, 2016, Dr. Towfigh traveled to Trévoux and met with representatives of the Sofradim R&D team, including Mr. Thérin, Sébastien Ladet, and other personnel. On information and belief, Mr. Ladet was a Sofradim representative responsible for R&D portfolio management and investment for the company's hernia repair products at the time. Dr. Towfigh discussed with them the pending international patent application that she had filed in March 2016 and her clinical basis for developing the designs in that application, including a sublay inguinal hernia mesh with a fin shape. Dr. Towfigh also discussed with them the pending non-provisional U.S. patent application that she had filed in July 2016 that is based on her international patent application.

15. After the meeting, Mr. Ladet followed up with Dr. Towfigh, seeking to learn more about the clinical problems associated with hernia complications and postoperative chronic pain that she had raised during her visit. Dr. Towfigh shared with him her various writings and presentations on the subject, including one she had recently given to the Society of American Gastrointestinal and Endoscopic Surgeons.

16. Mr. Ladet subsequently introduced Dr. Towfigh to Kevin Ferguson, Medtronic's in-house intellectual property lawyer, for the purpose of reviewing her patent applications. Mr. Ferguson asked to review additional filings relating to the international application, which Dr. Towfigh's patent prosecuting attorney team duly provided on or about November 7, 2016.

17. Dr. Towfigh then heard nothing from Medtronic until, on or about February 1, 2017, Mr. Thérin informed Dr. Towfigh that Medtronic's legal department did not believe that Dr. Towfigh's patent applications would be granted. Mr. Thérin reiterated Medtronic's continuing interest in working with Dr. Towfigh on a re-design of inguinal hernia mesh products to address chronic pain complications, regardless of the outcome of her patent applications.

18. Yet, on information and belief, around that same time, Medtronic, without Dr. Towfigh's knowledge or involvement, began drafting its own patent application covering the inventive concepts conceived by Dr. Towfigh and communicated to at least Mr. Thérin and Mr. Ladet during Dr. Towfigh's September 2016 visit to Trévoux.

19. Medtronic, through Sofradim, filed that application as European Patent Application No. 17305489.1 on May 2, 2017. The application named as inventors three employees who, on information and belief, were members of Sofradim's R&D team at the time: Pierre Bailly, Mylene Desorme, and Suzelei Montanari. The application disclosed an inguinal hernia mesh design with broad hernial coverage of the medial inferior area of the inguinal region using, among others, a fin that incorporated the innovative mesh design described in Dr. Towfigh's international and U.S. patent applications that she had shared with Mr. Thérin, Mr. Ladet, Mr. Ferguson and other of Medtronic's employees.

20. All the while, Medtronic continued seeking Dr. Towfigh' s expertise for product development. For example, Mr. Ladet invited Dr. Towfigh to participate in an advisory board meeting and requested to meet with her in person at the annual American College of Surgeons ("ACS") Clinical Congress in October 2017. During these interactions, Medtronic never told Dr. Towfigh that Medtronic, through Sofradim, was pursuing its own patents on an inguinal hernia mesh that used her inventive design.

21. Medtronic also did not inform Dr. Towfigh that it was working on a commercial product that incorporated her mesh design. Instead, Dr. Towfigh first learned that Medtronic was copying her design when, at the October 2017 ACS meeting, Mr. Ladet invited Dr. Towfigh to visit Medtronic's private screening room for KOLs for pre-market evaluation of Medtronic's hernia products. There, Dr. Towfigh was taken aback to see that one of the products was her

patent-pending inguinal mesh re-design that she had introduced to Medtronic. Dr. Towfigh pointed out to Mr. Ladet that Medtronic's new product was copying her invention, but Mr. Ladet denied any knowledge of that. He expressed interest in continuing to collaborate with Dr. Towfigh, however, and stated that he would draw up a contract for such a collaboration.

22. On information and belief, after that meeting, Dr. Towfigh followed up with Mr. Ladet to confirm Medtronic's continuing interest in collaborating. Mr. Ladet responded that Medtronic remained interested in collaborating and that his team had started drawing up a contract to work with her. During the ensuing months, Mr. Ladet repeatedly reassured Dr. Towfigh of Medtronic's interest in working together on solving inguinal hernia pain and explained that he was doing his best to push things forward but that Medtronic's internal evaluation was ongoing.

23. After nearly a year of no progress by Medtronic, despite repeated follow-ups from Dr. Towfigh, Medtronic then informed Dr. Towfigh that, before any collaboration could take place, the parties would need to renew their prior non-disclosure agreement with an updated company template to reflect a new company structure. Ex. 7. The parties' discussions remained stalled while Medtronic continued to delay providing Dr. Towfigh with the updated non-disclosure agreement or the previously-discussed contract.

24. On or about January 9, 2019, Dr. Towfigh wrote to Mr. Ladet, expressing concern that it had been more than a year since she had seen Medtronic's prototype mesh design that "so exactly mirrored my pending patent." Ex. 7. On or about January 25, 2019, Mr. Ladet finally responded, "[w]e can have a discussion about the early exploration that we are doing currently but to reinsure [sic] you we are not going in the path of what you described to us in your patent" and "[t]he low frequency of our discussion is not because we [are] hiding something[.]" Ex. 7.

25. Two months later, on or about March 7, 2019, Medtronic finally presented Dr. Towfigh with a draft agreement, but it turned out to be merely a standard form one-way consulting agreement, under which Dr. Towfigh would provide unspecified services to Medtronic, rather than a two-way non-disclosure and collaboration agreement to facilitate mutual work on Dr. Towfigh's inguinal hernia mesh design. Dr. Towfigh explained again her concern to Mr. Ladet that Medtronic was developing an inguinal hernia mesh product using her ideas and patent-pending design while excluding her participation.

26. Shortly thereafter, Dr. Towfigh was introduced to Justin Roberts, who, on information and belief, had just started at Medtronic, Inc. as its new Vice President and General Manager. She updated Mr. Roberts on her communications with Medtronic regarding her inguinal hernia mesh design thus far, including her concern that Medtronic was exploiting her design without permission. Mr. Roberts informed Dr. Towfigh that he was still new but would gather more information from his team and then be ready to discuss the topic after mid-April 2019.

27. Accordingly, after mid-April 2019, Dr. Towfigh followed up with Mr. Roberts. She reiterated her strong belief that the medical device industry should move in the direction of her mesh re-designs that directly address patient complaints. Mr. Roberts responded that he had requested legal counsel to review her patent filings.

28. As Dr. Towfigh waited for Medtronic to evaluate her patent applications again, Dr. Towfigh learned that Medtronic was nonetheless proceeding with its copy of her mesh redesign. On or about June 11, 2019, Dr. Towfigh had a lunch meeting with Maria Bragg, who on information and belief was then Medtronic, Inc.'s Commercial Director, and Brian Buchanan, who on information and belief was then one of Medtronic, Inc.'s sales representatives. During the meeting Ms. Bragg and Mr. Buchanan mentioned a new inguinal hernia mesh product that

Medtronic would be launching soon. They were surprised to learn that Dr. Towfigh had not been invited to attend a pre-market demonstration of the product that had been held for local KOLs in the area, despite her being one of the most prominent KOLs in the state. They described the new product to her, which Dr. Towfigh immediately recognized as her own design. When Dr. Towfigh noted as such, Ms. Bragg assured her that if there were any resemblance to Dr. Towfigh's patent-pending design, Medtronic would honor her patent.

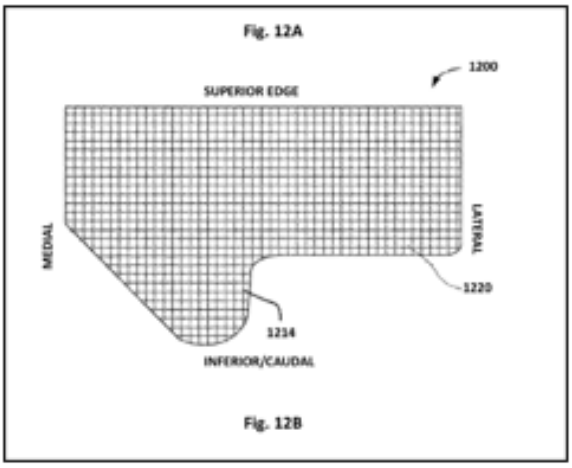
29. Dr. Towfigh followed up by writing to Mr. Roberts about the product launch she learned about from Ms. Bragg. She reminded him of the concern she had raised earlier about Medtronic's prototype design overlapping with the mesh redesign that she had shared with Medtronic in Trévoux and through her patent applications. She also informed Mr. Roberts that one of her mesh patents had been approved and thus would be granted soon. Dr. Towfigh asked for an update about the legal department's analysis of her patent applications, to which Mr. Roberts responded that they should meet in-person to discuss.

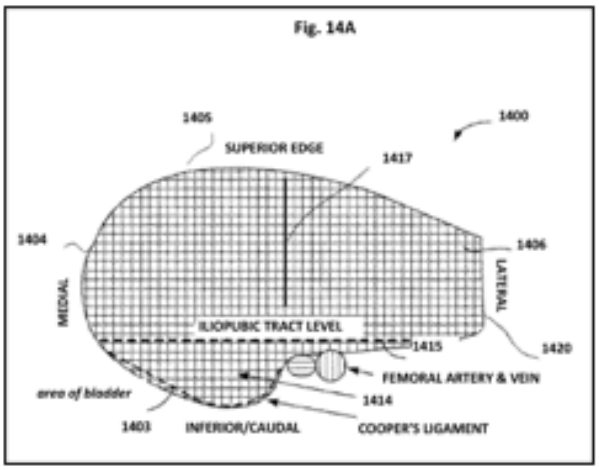
30. When Dr. Towfigh and Mr. Roberts met, however, Mr. Roberts informed Dr. Towfigh that his legal team had not granted him permission to discuss the patents. Mr. Roberts instead offered Dr. Towfigh a position as Chief Medical Officer of Medtronic's hernia division. Dr. Towfigh declined the offer, explaining that her primary goal was to partner with a company to produce her patent-pending mesh design.

31. After the grant of the first of Dr. Towfigh's patents from her March 2016 international patent application on October 8, 2019, Dr. Towfigh updated Mr. Roberts about the news. Mr. Roberts congratulated her, noting it "demonstrates the value of your thinking." Ex. 8. When Dr. Towfigh then followed up with Mr. Roberts in February 2020 to continue their

discussions about innovating hernia mesh designs, Mr. Roberts asked to meet at a conference in a few months to seek her input on "where to focus our early innovation." Ex. 8.

32. But just two weeks later, Dr. Towfigh learned from a sales representative for the first time that Medtronic was already poised to launch a new hernia mesh product named "Dextile" in May 2020. As a KOL, she was privately shown a pre-market packaged mesh labeled "Not for Human Use." Dr. Towfigh was dismayed to see that, despite Medtronic's representations about collaborating, Medtronic had instead utilized the mesh designs from her patent applications for its own commercial product.





Compare, e.g., WO 2016/154478, Figs. 12A, 14A *with* photo of Medtronic's mesh product.

33. On information and belief, in or around May 2020, Medtronic commercially launched the Dextile mesh with Dr. Towfigh's invention incorporated and without communicating further with Dr. Towfigh about the Dextile mesh or acknowledging her inventive contribution to the mesh product.

34. Following Medtronic's launch of the Dextile mesh, between May 2020 and December 2022, Dr. Towfigh repeatedly attempted to reach an agreement with Medtronic regarding its use of her inventions and updated Medtronic as her patents issued. In response, Medtronic repeatedly requested more time to review the patents, representing it needed the additional time before engaging in further discussions. For example, Medtronic's representatives, including Mr. Roberts, stated they were reviewing the patents with their internal lawyers and R&D team in Trévoux. Mr. Roberts then subsequently informed Dr. Towfigh that they had taken the additional step of engaging outside counsel for further review and thus would need yet more time. At their most recent meeting, on or around December 21, 2022, Mr. Roberts informed Dr. Towfigh that they needed eighteen more months to evaluate the patents before committing to further discussions. Nearly two years have elapsed since that meeting, but Medtronic has never provided Plaintiffs with an answer.

35. Medtronic has a history of trying to use its financial clout to outspend and out-maneuver physician-inventors like Dr. Towfigh when they seek damages for wrongful use of their intellectual property, including where that physician-inventor initially sought to collaborate with Medtronic. *See, e.g.*, https://www.reuters.com/legal/medtronic-hit-with-1065-mln-us-verdict-heart-valve-patent-case-2023-02-09/ (*Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal.)); *Speyside Med., LLC v. Medtronic, Inc.*, C.A. No. 20-00361-JLH-CJB

(D. Del. 2020); *see also* https://www.tigerbuford.com/texas-spine-surgeon-wins-patent-suit-against-medtronic-for-reckless-copying-designs/; https://www.reuters.com/legal/government/scotus-okays-medtronics-112-million-loss-patent-contract-case-2022-01-10/; https://www.nytimes.com/2005/04/23/business/medtronic-to-pay-135-billion-to-inventor.html. Medtronic's conduct with Dr. Towfigh is consistent with this past history. Allowing this misbehavior to go unchecked creates a disincentive for physicians to invest their expertise in the medical device marketplace, depriving patients of innovative products that could improve patient-focused care across a wide range of conditions.

36. Hexagon Health and Dr. Towfigh now have no other choice but to seek relief through litigation. Despite their efforts, Plaintiffs have been unable to reach agreement with or receive proper attribution from Medtronic regarding Medtronic's copying of Dr. Towfigh's mesh design. Meanwhile, Medtronic has continued to profit from its production and sale of Dextile—without renumeration or credit to Hexagon Health or Dr. Towfigh for her inventions—despite knowing that Medtronic's infringing products incorporate Dr. Towfigh's patented inventions without permission.

Medtronic's Infringing Activities and Products

37. Defendant Medtronic plc and its subsidiaries, including co-defendants Medtronic, Inc., Covidien LLC, Covidien LP, Covidien Sales LLC, and Sofradim, represent one of the world's largest medical device companies, having a market capitalization of over $110 billion. On information and belief, with Sofradim as its manufacturer, Medtronic plc and its subsidiaries together manufacture, market and sell, use, induce others to use, contribute to the use of by others, and/or import into the United States the Dextile Anatomical Mesh.

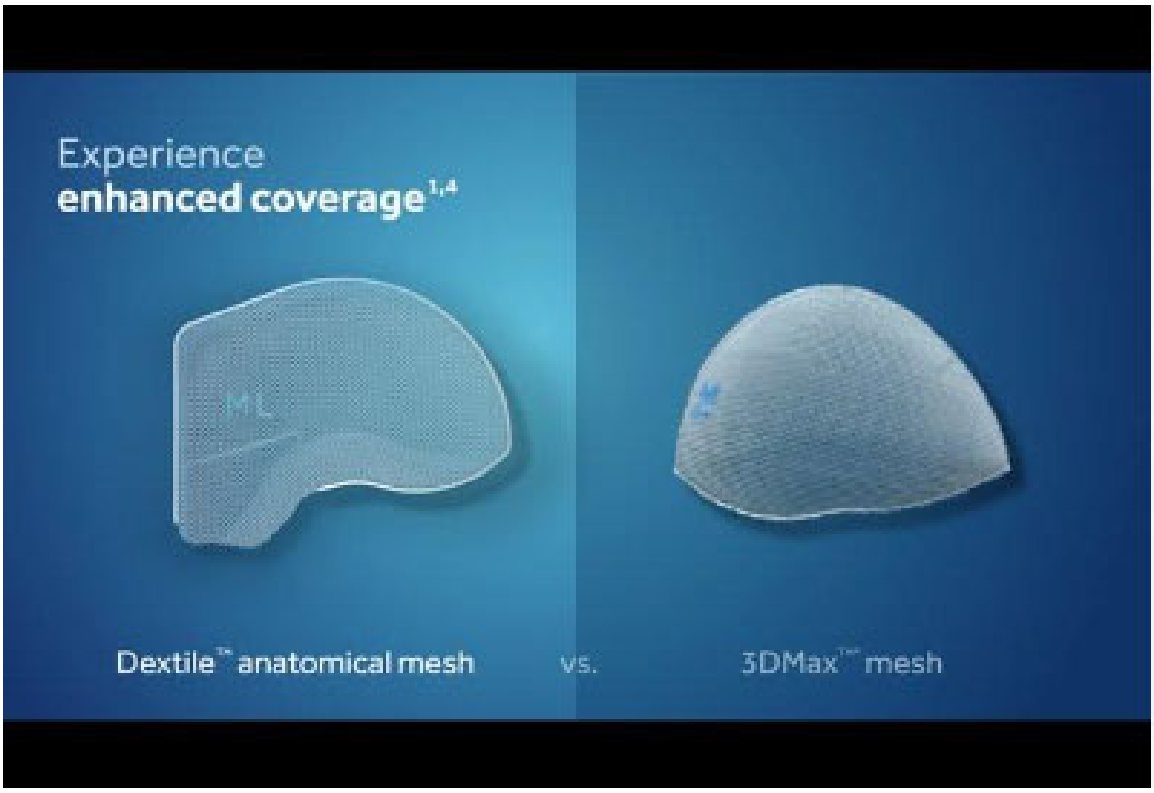
38. Medtronic's Dextile Anatomical Mesh is designed for use in inguinal hernia repair. Through its marketing materials, like Dr. Towfigh's invention and as claimed in the Asserted Patents, Medtronic touts the Dextile Anatomical Mesh as having, among other benefits, "[t]he benefits of anatomical design," highlighting the mesh's "conformance to the inguinal anatomy" that is "designed for a better coverage of the myopectineal orifice," that thereby "minimiz[es] the risk of recurrence." Medtronic additionally highlights that the Dextile Anatomical Mesh is made from a "macroporous monofilament polypropylene textile" where the "large pore size [] help[s] good tissue ingrowth." Medtronic also advertises an "inferior" portion and edge of the mesh that extends below the iliopubic tract for "optimal coverage." *See, e.g.*, Ex. 9; Ex. 10.

39. On information and belief, Medtronic instructs, recommends, and suggests to surgeons and other healthcare professionals how to implant the Dextile mesh in a manner that infringes the Asserted Patents, including implanting the mesh deep or posterior to the inguinal hernia defect so as to ensure broad coverage of the femoral space while avoiding obstruction of critical structures such as the femoral artery and vein, including through instructional videos provided on its website and YouTube channel, along with after-sales support and training. *See, e.g.*, Ex. 9; https://www.youtube.com/watch?v=EFT-X8PPnbc; https://www.youtube.com/watch?v=fRb08AXdH5c; https://www.youtube.com/watch?v=JA5SrCI7aXo.

40. On information and belief, Medtronic copied Dr. Towfigh's innovative mesh design for its Dextile product, including the fin shape and position, despite knowing that her design was covered by pending patent applications, which had been disclosed to it as early as September 2016. Moreover, after issuance of Dr. Towfigh's Asserted Patents from that application, Medtronic continued manufacturing, importing, marketing, selling, and using the Dextile mesh for

use in inguinal hernia repairs in the manner claimed in the Asserted Patents. On information and belief, Medtronic continued these activities, knowing of the Asserted Patents, which Medtronic knew or should have known it infringed, or deliberately did not find out whether it infringed, in willful disregard of the Asserted Patents, without any reasonable basis for believing that Medtronic had a right to engage in its infringing conduct.

41. On information and belief, Medtronic specifically introduced the Dextile mesh in order to compete directly with the then-leading inguinal hernia mesh product, the Bard 3DMax ("3DMax"), sold by its market-leading competitor Becton Dickinson and Co. ("Becton Dickinson"). In its FDA 510k application seeking FDA clearance to market and sell the Dextile mesh in the United States, Medtronic, via Sofradim as the applicant, claimed Dextile to be substantially equivalent to Becton Dickinson's 3DMax Light Mesh product. Dextile, like the 3DMax, is a three-dimensional mesh, but, unlike the 3DMax, Dextile additionally includes Dr. Towfigh's innovative fin design in combination with broad lateral coverage, which allows for full anatomical coverage and avoidance of key anatomical structures that could cause chronic pain or future complications. Medtronic advertises and markets its Dextile mesh directly against Becton Dickinson's 3DMax line, emphasizing the improved coverage and minimized hernia recurrence compared to the 3DMax. *See, e.g.*, https://www.youtube.com/watch?v=fRb08AXdH5c; Ex. 10; Ex. 9 ("Designed for a better coverage of the myopectineal orifice compared to Bard 3DMax™ and 3DMax™ light, minimizing the risk of recurrence.").



https://www.youtube.com/watch?v=fRb08AXdH5c.

42. On information and belief, with the benefit of Dr. Towfigh's innovations and contributions, Medtronic has been able to successfully compete with Becton Dickinson's 3DMax mesh line, enabling it to secure supply contracts with hospitals and other large purchasers that it otherwise would not have been able to secure. On information and belief, with these supply contracts obtained through Medtronic's infringement of the Asserted Patents, Medtronic is not only able to sell the Dextile mesh individually, but also as a bundle with others of Medtronic's hernia repair products, including its ProGrip mesh products, thereby enabling the sales of other products besides the Dextile mesh.

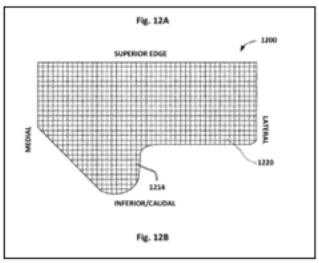
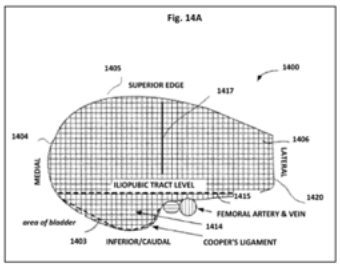
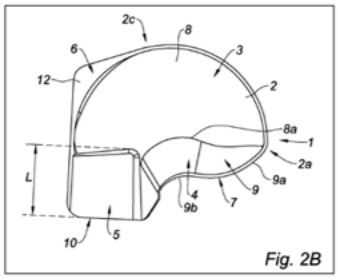
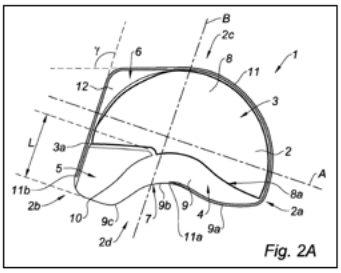
43. Medtronic's acts of infringement have inured to Medtronic's great benefit without renumeration to Hexagon Health. Hexagon Health has suffered and continues to suffer damages from Medtronic for its unlicensed use of the Asserted Patents.

Medtronic's Bailly Patents

44. Confirming the innovative nature of Dr. Towfigh's mesh re-design, Medtronic has continued to file patents relating to the Dextile mesh that claim priority to their May 2, 2017 European application, but without crediting Dr. Towfigh for the inventions that she shared when she met with them in September 2016 to discuss their possible collaboration.

45. For example, on April 27, 2018, Medtronic, through Sofradim, filed U.S. Patent Application No. 15/965,826, claiming priority to the European application and which was then published as U.S. Patent Publication No. 2018/0318057 (the "'057 Publication") and granted as U.S. Patent No. 10,675,137 (the "'137 Patent"). Medtronic, through Sofradim, also filed U.S. Patent Application No. 16/895,888, a continuation of U.S. Patent Application No. 15/965,826 that later issued as U.S. Patent No. 11,672,636 (the "'636 Patent") (collectively, the "Bailly Patents"). Medtronic has asserted the Dextile mesh is covered by these patents. *See, e.g.*, Ex. 10.

46. On information and belief, the '137 Patent and the '636 Patent incorporate inventive contributions conceived of by Dr. Towfigh. For example, the Bailly Patents include figures that incorporate her innovative fin design, mirroring figures in the patent applications that Dr. Towfigh shared with Medtronic, which also appear in Dr. Towfigh's asserted patents.

The Asserted Patents		
The Bailly Patents		

See, e.g., WO 2016/154478, Figs. 12A, 14A; U.S. Appl. No. 15/202,440, Figs. 12A, 14A; Ex. 1, Figs. 12A, 14A; Ex. 2, Figs. 12A, 14A; Ex. 3, Figs. 12A, 14A.

47. On information and belief, Dr. Towfigh's contributions were communicated to the named inventors of the '137 and '636 Patents, directly or indirectly, including by or through Messrs. Therin and Ladet, based on information that Dr. Towfigh provided during her September 2016 visit to Medtronic's R&D laboratories in Trévoux, and through the pending patent applications that she shared with them.

48. Medtronic, however, failed to disclose Dr. Towfigh's patent applications and patents to the United States Patent and Trademark Office in relation to the prosecution of the '137 and '636 Patents, or otherwise acknowledge her contribution to the subject matter claimed in those patents.

49. Furthermore, on information and belief, Medtronic knowingly and intentionally omitted Dr. Towfigh as a named inventor on the '137 and '636 Patents despite her inventive

contributions to these patents. Nor has Medtronic attributed to Dr. Towfigh any credit for the design of the Dextile Anatomical Mesh.

50. Medtronic's copying of Dr. Towfigh's inventions for its own patents and wrongful omission of Dr. Towfigh as an inventor of the '137 and '636 Patents has caused harm to Dr. Towfigh, including but not limited to injury to her reputation as an innovator in the field of hernia repair and thus loss of vocational and business opportunities to develop her inventions into commercial products that may be used for improved hernia treatments.

THE ASSERTED PATENTS

51. United States Patent Number 11,207,169 (the "'169 Patent"), entitled "Gender-Specific Mesh Implant with Barrier for Inguinal Hernia Repair," was duly and legally issued on December 28, 2021, and names Dr. Towfigh as the inventor. Attached as Exhibit 1 is a true and correct copy of the '169 Patent.

52. The '169 Patent claims, among other things, a method for a sublay inguinal hernia repair in a subject, the method comprising obtaining an implantable mesh comprising a fabric layer comprising a plurality of pores and a single fin having a fin edge and an inferior tip and positioning the mesh such that, e.g., the fin is inferior to an iliopubic tract and substantially covers a femoral space.

53. Hexagon Health is the owner and assignee of the entire right, title, and interest in the '169 Patent.

54. United States Patent Number 11,219,516 (the "'516 Patent"), entitled "Gender-Specific Mesh Implant with Barrier for Inguinal Hernia Repair," was duly and legally issued on January 11, 2022, and names Dr. Towfigh as the inventor. Attached as Exhibit 2 is a true and correct copy of the '516 Patent.

55. The ’516 Patent claims, among other things, a mesh for a sublay inguinal hernia repair in a subject, the mesh comprising a fabric layer comprising a plurality of pores and a single fin having a fin edge and an inferior tip, wherein upon implantation the mesh is located posterior to an inguinal hernia defect and posterior or deep to a genital nerve in the subject.

56. Hexagon Health is the owner and assignee of the entire right, title, and interest in the ’516 Patent.

57. United States Patent Number 11,324,579 (the “’579 Patent”), entitled “Gender-Specific Mesh Implant with Barrier for Inguinal Hernia Repair,” was duly and legally issued on May 10, 2022, and names Dr. Towfigh as the inventor. Attached as Exhibit 3 is a true and correct copy of the ’579 Patent.

58. The ’579 Patent claims, among other things, a method for inguinal hernia repair in a subject, the method comprising obtaining an implantable mesh comprising a fabric layer comprising a plurality of pores and a single fin having a fin edge extending inferiorly from the inferolateral quarter and positioning the mesh such that, e.g., the fin is posterior to the genital nerve, inferior to the iliopubic tracts, and substantially covers a femoral space without obstructing the femoral artery or femoral vein.

59. Hexagon Health is the owner and assignee of the entire right, title, and interest in the ’579 Patent.

THE PARTIES

60. Plaintiff Dr. Shirin Towfigh is a resident of California and the sole named inventor on the Asserted Patents.

61. Plaintiff Hexagon Health is a corporation organized and existing under the laws of California with its principal place of business at 450 N Roxbury Drive, Suite 224, Beverly Hills, California 90210, and is qualified to do business in the State of California. Dr. Towfigh founded

Hexagon Health in 2015 to further her mission of patient-first innovation in hernia treatments and overall abdominal wall and pelvic floor health. Dr. Towfigh assigned all rights to her invention to Hexagon Health.

62. Defendant Medtronic plc is a corporation that is incorporated in Ireland and has its principal place of business at 20 Lower Hatch Street, Dublin 2, Ireland. On information and belief, Medtronic plc sells, offers to sell, and/or imports into the United States the Dextile Mesh.

63. Defendant Medtronic, Inc. is incorporated in Minnesota and has its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432. Medtronic, Inc. markets, sells, offers to sell, and/or imports the Dextile mesh, including through its website.

64. Defendant Covidien LLC is a company that is organized under the laws of Delaware and has its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts. Covidien LLC is a subsidiary of Defendant Medtronic plc, having been acquired by and merged into the Medtronic organization in or around 2014 to 2015. On information and belief, Covidien LLC sells, offers to sell, and/or imports into the United States the Dextile Mesh.

65. Defendant Covidien LP is a limited partnership organized and existing under the laws of Delaware and has its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. Covidien LP is a subsidiary of Defendant Medtronic plc, having been acquired by and merged into the Medtronic organization in or around 2014 to 2015. On information and belief, Covidien LLC sells, offers to sell, and/or imports into the United States the Dextile Mesh.

66. Defendant Covidien Sales LLC is a company that is organized under the laws of Delaware and has its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. Covidien LLC is a subsidiary of Defendant Medtronic plc, having been acquired by and

merged into the Medtronic organization in or around 2014 to 2015. On information and belief, Covidien Sales LLC sells, offers to sell, and/or imports into the United States the Dextile mesh.

67. Defendant Sofradim is a corporation that is incorporated in France and has its principal place of business at 116 Avenue Du Fromans, Trevoux, France 01600. Sofradim is a subsidiary of Defendant Medtronic plc and Defendant Covidien LLC. On information and belief, Sofradim makes, sells, offers to sell, and/or imports into the United States the Dextile mesh.

JURISDICTION AND VENUE

68. Plaintiffs repeat and reallege all of the allegations of the preceding paragraphs, as if fully set forth herein.

69. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., including in particular 35 U.S.C. § 271. This Court has subject matter and personal jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

70. On information and belief, Medtronic holds itself out as a single entity and its subsidiaries and affiliates are agents of each other and/or work in concert with each other with respect to the manufacture, regulatory approval, marketing, sale, importation, and distribution of the Dextile Mesh throughout the United States, including in Delaware.

71. On information and belief, Medtronic has substantial, continuous, and systematic contacts with Delaware.

72. On information and belief, Medtronic is in the business of, among other things, manufacturing and selling medical devices and medical products. On information and belief, Medtronic itself, and through its subsidiaries, affiliates, and agents, manufacture, import, market, distribute and/or sell medical devices and medical products, including the Dextile Mesh, throughout the United States, including in Delaware.

73. On information and belief, Medtronic has distribution channels throughout the United States, including in Delaware. By advertising the Dextile Mesh on the Medtronic website and without restriction to a particular geographic area, Medtronic has made clear that it intends to use Medtronic's national distribution channels to distribute and sell the Dextile Mesh throughout the United States, including in Delaware, which would have a substantial effect on Delaware. Medtronic has introduced the Dextile Mesh into the stream of commerce with the knowledge, or reasonable expectation, that actual or potential users of such products and methods are located within Delaware.

74. This Court has both general and specific personal jurisdiction over Covidien LLC, Covidien LP, and Covidien Sales LLC, consistent with the requirements of the Due Process Clause of the United States Constitution and the Delaware Long Arm Statute as each are Delaware entities. This Court has personal jurisdiction over Medtronic, Inc., by virtue of, for example, its continuous and systematic contacts with Delaware, its registered agent for service of process in Delaware, its acts of tortious patent infringement in Delaware, and its sale of a substantial volume of medical devices and products in Delaware, including the Dextile mesh. This court has personal jurisdiction over Medtronic plc by virtue of, for example, its continuous and systematic contacts with Delaware, its acts of tortious patent infringement in Delaware, its sale of a substantial volume of medical devices and products in Delaware, and its conduct by, through and in concert with Medtronic, Inc. In the alternative, this Court has personal jurisdiction over Medtronic plc under Federal Rule of Civil Procedure 4(k)(2).

75. This Court further has personal jurisdiction over each Defendant because each, directly or through subsidiaries or intermediaries (including distributors, general purchasing organizations, retailers, and others), ships, distributes, offers for sale, sells, and/or advertises

(including the provision of an interactive web page) its products, such as the Dextile mesh, in the United States and the District of Delaware. By shipping into, selling, offering to sell, and/or using products, such as the Dextile mesh, that infringe the Asserted Patents in this District, or by inducing or causing those acts to occur, Medtronic has transacted and continue to transact business and perform work and services in this District, have supplied and continue to supply services and things in this District, have caused and continue to cause injury and damages in this District by acts and omissions in this District, and have caused and continue to cause injury and damages in this District by acts or omissions outside of this District while deriving revenue from services or things used or consumed within this District.

76. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b). Covidien LLC, Covidien LP, and Covidien Sales LLC are each Delaware entities that reside in this District. Sofradim and Medtronic plc are foreign entities and therefore may be sued in any District. Medtronic, Inc. has committed acts of infringement in this District by shipping into, selling, or offering to sell products, such as the Dextile mesh, that infringe the Asserted Patents, or by encouraging, instructing, and/or contributing to the infringement of others within this District. On information and belief, Medtronic, Inc. has a regular and established place of business in this District, including by and through the presence of its agents, Covidien LLC, Covidien LP, and Covidien Sales LLC. Further, on information and belief, Medtronic, Inc. has authorized sales/customer service agents in the District of Delaware, who hold themselves out as Medtronic sales and customer service representatives. Exs. 11-13. By and through these representatives acting as its agents, Medtronic, Inc. has a regular and established place of business in the District of Delaware.

FIRST CAUSE OF ACTION
(PATENT INFRINGEMENT – '169 PATENT)

77. Hexagon Health repeats and realleges all of the allegations of the preceding paragraphs, as if fully set forth herein.

78. On information and belief, Medtronic has been and is inducing infringement of at least claim 1 of the '169 Patent by actively and knowingly inducing others to make, use, sell, offer for sale, or import hernia repair mesh products with a fin design to practice the invention claimed in the '169 Patent, including the Dextile mesh, in violation of 35 U.S.C. § 271(b). For example, through Medtronic's website and Medtronic's marketing and sales personnel, Medtronic provides videos, instructions for use, and other sales support that instruct and encourage its customers and end users, such as surgeons and other healthcare professionals, to practice the methods of the '169 Patent using the Dextile mesh, knowing of the patent and that such acts would constitute infringement of the patent.

79. On information and belief, Medtronic has been and is contributing to the infringement of at least claim 1 of the '169 Patent by selling or offering to sell hernia repair mesh products with a fin design for use with the invention claimed in the '169 Patent, including the Dextile mesh, knowing it to be especially made or especially adapted for practicing the invention of the '169 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, in violation of 35 U.S.C. § 271(c). For example, Medtronic specifically designed and markets the Dextile Anatomical Mesh for use in inguinal hernia repairs in a manner that Medtronic has known, or should have known, infringes the '169 Patent and has no substantial non-infringing uses.

80. Attached as Exhibit 4 is an element-by-element claim chart with non-limiting examples showing how the use of the Dextile mesh infringes the '169 Patent.

81. On information and belief, Medtronic has known of the '169 Patent since at or around the time it issued, including because Medtronic had received copies of the patent application that gave rise to the patent from Dr. Towfigh at least by November 2016 and would have monitored the application for patents issuing therefrom. Further, Plaintiffs disclosed the patent to Medtronic soon after its issuance.

82. Medtronic's infringement of the '169 Patent has been, and continues to be knowing, intentional, and willful. Having known of the pending patent applications that led to the '169 Patent and the '169 Patent itself, Medtronic has known or should have known that its making, using, selling, or offering for sale in the United States, or importing into the United States the Dextile mesh has been and is infringing.

83. Alternatively, on information and belief, Medtronic has been willfully blind to the existence of the '169 Patent, its own infringement, and the infringement by others. On information and belief, Medtronic has no reasonable basis for believing that the '169 Patent is not infringed.

84. Medtronic's infringement of the '169 Patent has been without the permission, consent, authorization or license of Hexagon Health.

85. Medtronic's infringement of the '169 Patent has caused and will continue to cause Hexagon Health damages for which Hexagon Health is entitled to compensation pursuant to 35 U.S.C. § 284, including treble damages for Medtronic's willful infringement.

86. This case is exceptional and, therefore, Hexagon Health is entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

SECOND CAUSE OF ACTION
(PATENT INFRINGEMENT – '516 PATENT)

87. Hexagon Health repeats and realleges all of the allegations of the preceding paragraphs, as if fully set forth herein.

88. On information and belief, Medtronic has been and is infringing, literally or by equivalents, at least claim 1 of the ’516 Patent by making, using, selling, or offering for sale in the United States, or importing into the United States, including within this judicial district, hernia repair mesh products with a fin design, including the Dextile mesh, in violation of 35 U.S.C. § 271(a).

89. Attached as Exhibit 5 is an element-by-element claim chart with non-limiting examples showing how the Dextile mesh infringes the ’516 Patent.

90. On information and belief, Medtronic has known of the ’516 Patent since at or around the time it issued, including because Medtronic had received copies of the patent application that gave rise to the patent from Dr. Towfigh at least by November 2016 and would have monitored the application for patents issuing therefrom. Further, Plaintiffs disclosed the patent to Medtronic soon after its issuance.

91. Medtronic’s infringement of the ’516 Patent has been, and continues to be knowing, intentional, and willful. Having known of the pending patent applications that led to the ’516 Patent and the ’516 Patent itself, Medtronic has known or should have known that its making, using, selling, or offering for sale in the United States, or importing into the United States the Dextile mesh has been and is infringing.

92. Alternatively, on information and belief, Medtronic has been willfully blind to the existence of the ’516 Patent and its own infringement. On information and belief, Medtronic has no reasonable basis for believing that the ’516 Patent is not infringed.

93. Medtronic’s infringement of the ’516 Patent has been without the permission, consent, authorization or license of Hexagon Health.

94. Medtronic's infringement of the '516 Patent has caused and will continue to cause Hexagon Health damages for which Hexagon Health is entitled to compensation pursuant to 35 U.S.C. § 284, including treble damages for Medtronic's willful infringement.

95. This case is exceptional and, therefore, Hexagon Health is entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

THIRD CAUSE OF ACTION
(PATENT INFRINGEMENT – '579 PATENT)

96. Hexagon Health repeats and realleges all of the allegations of the preceding paragraphs, as if fully set forth herein.

97. On information and belief, Medtronic has been and is inducing infringement of at least claim 1 of the '579 Patent by actively and knowingly inducing others to make, use, sell, offer for sale, or import hernia repair mesh repair products with a fin design for use with the invention claimed in the '579 Patent, including the Dextile mesh, in violation of 35 U.S.C. § 271(b). For example, through Medtronic's website and Medtronic's marketing and sales personnel, Medtronic provides videos, instructions for use, and other sales support that instruct and encourage its customers and end users, such as surgeons and other healthcare professionals, to practice the methods of the '579 Patent using the Dextile mesh, knowing of the patent and that such acts would constitute infringement of the patent.

98. On information and belief, Medtronic has been and is contributing to the infringement of at least claim 1 of the '579 Patent by selling or offering to sell hernia repair mesh products with a fin design for use with the invention claimed in the '579 Patent, including the Dextile mesh, knowing it to be especially made or especially adapted for practicing the invention of the '579 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, in violation of 35 U.S.C. § 271(c). For example, Medtronic specifically designed

and markets the Dextile Anatomical Mesh for use in inguinal hernia repairs in a manner that Medtronic has known, or should have known, infringes the '579 Patent and has no substantial non-infringing uses.

99. Attached as Exhibit 6 is an element-by-element claim chart with non-limiting examples showing how the use of the Dextile mesh infringes the '579 Patent.

100. On information and belief, Medtronic has known of the '579 Patent since at or around the time it issued, including because Medtronic had received copies of the patent application that gave rise to the patent from Dr. Towfigh at least by November 2016 and would have monitored the application for patents issuing therefrom. Further, Plaintiffs disclosed the patent to Medtronic soon after its issuance.

101. Medtronic's infringement of the '579 Patent has been, and continues to be knowing, intentional, and willful. Having known of the pending patent applications that led to the '579 Patent and the '579 Patent itself, Medtronic has known or should have known that its making, using, selling, or offering for sale in the United States, or importing into the United States the Dextile mesh has been and is infringing.

102. Alternatively, on information and belief, Medtronic has been willfully blind to the existence of the '579 Patent, its own infringement, and the infringement by others. On information and belief, Medtronic has no reasonable basis for believing that the '579 Patent is not infringed.

103. Medtronic's infringement of the '579 Patent has been without the permission, consent, authorization or license of Hexagon Health.

104. Medtronic's infringement of the '579 Patent has caused and will continue to cause Hexagon Health damages for which Hexagon Health is entitled to compensation pursuant to 35 U.S.C. § 284.

105. This case is exceptional and, therefore, Hexagon Health is entitled to an award of attorney fees pursuant to 35 U.S.C. § 285.

FOURTH CAUSE OF ACTION
(CORRECTION OF INVENTORSHIP – '137 PATENT)

106. Plaintiffs repeat and reallege all of the allegations of the preceding paragraphs, as if fully set forth herein.

107. The '137 Patent is entitled "Prosthesis for Inguinal Hernia Repair." On its face, the '137 Patent names Pierre Bailly, Mylene Desorme, and Suzelei Montanari as inventors and Sofradim as applicant and assignee. The '137 Patent does not name Dr. Towfigh as an inventor. A copy of the '137 Patent is attached to this Complaint as Exhibit 14.

108. The '137 Patent issued from U.S. Patent Application No. 15/965,826, which was filed on April 27, 2018, and claims the benefit of and priority to European Patent Application No. 17305489.1, filed May 2, 2017, the disclosures of which are incorporated by reference in the '137 Patent. The '137 Patent issued on June 9, 2020.

109. The '137 Patent contains one independent claim, claim 1, which recites:

> 1. An implantable prosthesis for repairing a hernia defect in an inguinal region of a human body delimited by the anterior abdominal wall, the psoas muscle and a medial inferior area of the inguinal anatomy, the prosthesis comprising:
>
> a piece of biocompatible material having a preformed three-dimensional shape including a lateral side and a medial side extending along a medial-lateral axis and a superior side and inferior side extending along a superior-inferior axis, the piece including:
>
> a first portion, configured to face the anterior abdominal wall, said first portion forming a partial spherical cap surface shaped and dimensioned so as to substantially conform to the anterior abdominal wall and including an inferior edge extending between the lateral and medial sides,
>
> a second portion, configured to face the psoas muscle, said second portion extending in an inferior direction from at least a lateral portion of the inferior edge of said first portion and forming a wavy-shaped wall, shaped and dimensioned so as to substantially conform to the psoas muscle, and

> a third portion forming an arched part, said arched part extending longitudinally substantially in the inferior direction from at least a medial portion of the inferior edge of said first portion, said arched part extending radially substantially in a front direction, said third portion being configured to face the medial inferior area of the inguinal anatomy.

110. Dr. Towfigh significantly contributed to the conception of the subject matter claimed in the '137 Patent and is therefore a co-inventor of the '137 Patent.

111. Dr. Towfigh contributed to the conception of multiple claim elements, including elements of the claimed "third portion." This "third portion" corresponds to Dr. Towfigh's inventive fin design that she communicated to Sofradim representatives, including Mr. Thérin and Mr. Ladet, who, on information and belief, communicated with and worked with Sofradim's R&D team, directly or indirectly, including the named inventors of the '137 Patent.

112. Dr. Towfigh's invention provides maximum coverage for hernia repair, including in the femoral space, while avoiding anatomical features that would give rise to complications if obstructed by mesh. This innovative mesh design, including the fin, differentiates the patented subject matter of the '137 Patent from prior art meshes.

113. The contributions of Dr. Towfigh are not insignificant when measured against the dimension of the full invention.

114. The contributions of Dr. Towfigh amounted to more than merely explaining well-known concepts and/or the current state of the art.

115. As a result of being omitted as a named inventor on the '137 Patent, Dr. Towfigh has been harmed, including but not limited to injury to her reputation as a KOL and innovator in the field of hernia repair, which is founded on her recognition as a premier thought leader in solving hernia complications and patient pain caused by failed hernia repairs using old mesh designs and techniques. By depriving Dr. Towfigh of the professional credit that she should have received as an inventor of the '137 Patent, Dr. Towfigh's reputation has been materially harmed. And, with

her inventions being incorrectly recognized as belonging to others, Dr. Towfigh has lost vocational and business opportunities to develop her inventions into commercial products that may be used for improved hernia treatments.

116. As a result of Dr. Towfigh being omitted as a named inventor on the '137 Patent, Hexagon Health has also been harmed, including but not limited to being deprived of its ownership interest in the '137 Patent. As the sole owner of Hexagon Health, the financial harm to Hexagon Health has also harmed Dr. Towfigh.

117. Pursuant to 35 U.S.C. § 256(a), the '137 Patent should be corrected to include omitted inventor Dr. Towfigh as a named inventor.

118. Plaintiffs request that the Court order correction of the '137 Patent and that the Director of the U.S. Patent and Trademark Office issue a certificate, pursuant to 35 U.S.C. § 256(b), to include Dr. Towfigh as a named inventor of the '137 Patent.

FIFTH CAUSE OF ACTION
(CORRECTION OF INVENTORSHIP – '636 PATENT)

119. Plaintiffs repeat and reallege all of the allegations of the preceding paragraphs, as if fully set forth herein.

120. The '636 Patent is entitled "Prosthesis for Inguinal Hernia Repair." On its face, the '636 Patent names Pierre Bailly, Mylene Desorme, and Suzelei Montanari as inventors and Sofradim as applicant and assignee. The '636 Patent does not name Dr. Towfigh as an inventor. A copy of the '636 Patent is attached to this Complaint as Exhibit 15.

121. The '636 Patent issued from U.S. Patent Application No. 16/895,888, which was filed on June 8, 2020. U.S. Patent Application No. 16/895,888 is a continuation of U.S. Patent Application No. 15/965,826 filed April 27, 2018, and which claims the benefit of and priority to

European Patent Application No. 17305489.1, filed May 2, 2017, the disclosures of which are incorporated by reference in the '636 Patent. The '636 Patent issued on June 13, 2023.

122. The '636 Patent contains two independent claims, including claim 1, which recites:

> 1. A method of repairing a hernia in an inguinal region of a human body comprising:
>
> providing a prosthesis including a piece of biocompatible material having an initial preformed three-dimensional shape including a lateral side and a medial side extending along a medial-lateral axis and a superior side and inferior side extending along a superior-inferior axis, the piece including
>
> a first portion, configured to face an anterior abdominal wall, the first portion forming a partial spherical cap surface shaped and dimensioned to substantially conform to the anterior abdominal wall and including an inferior edge extending between the lateral and medial sides,
>
> a second portion, configured to face a psoas muscle, the second portion extending in an inferior direction from at least a lateral portion of the inferior edge of said first portion and forming a wavy-shaped wall, shaped and dimensioned to substantially conform to the psoas muscle, and
>
> a third portion forming an arched part, the arched part extending longitudinally substantially in the inferior direction from at least a medial portion of the inferior edge of the first portion, the arched part extending radially substantially in a front direction, the third portion configured to face the medial inferior area of an inguinal anatomy,
>
> applying pressure to the prosthesis to deform the prosthesis onto itself to form a deformed prosthesis, introducing the deformed prosthesis through a trocar to a site of implantation in the inguinal region of the human body, deploying the deformed prosthesis to return to the initial preformed three-dimensional shape, and positioning the prosthesis such that the third portion covers the medial inferior area of the inguinal anatomy.

123. Dr. Towfigh significantly contributed to the conception of the subject matter claimed in the '636 Patent and is therefore a co-inventor of the '636 Patent.

124. Dr. Towfigh contributed to the conception of multiple claim elements, including elements of the claimed "third portion." This "third portion" corresponds to Dr. Towfigh's inventive fin design that she communicated to Sofradim representatives, including Mr. Thérin and

Mr. Ladet, who, on information and belief, communicated with and worked with Sofradim's R&D team, directly or indirectly, including the named inventors of the '636 Patent.

125. Dr. Towfigh's invention provides maximum coverage for hernia repair, including in the femoral space, while avoiding anatomical features that would give rise to complications if obstructed by mesh. This innovative mesh design, including the fin, differentiates the patented subject matter of the '636 Patent from prior art meshes.

126. The contributions of Dr. Towfigh are not insignificant when measured against the dimension of the full invention.

127. The contributions of Dr. Towfigh amounted to more than merely explaining well-known concepts and/or the current state of the art.

128. As a result of being omitted as a named inventor on the '636 Patent, Dr. Towfigh has been harmed, including but not limited to injury to her reputation as a KOL and innovator in the field of hernia repair, which is founded on her recognition as a premier thought leader in solving hernia complications and patient pain caused by failed hernia repairs using old mesh designs and techniques. By depriving Dr. Towfigh of the professional credit that she should have received as an inventor of the '636 Patent, Dr. Towfigh's reputation has been materially harmed. And, with her inventions being incorrectly recognized as belonging to others, Dr. Towfigh has lost vocational leverage and business opportunities to develop her inventions into commercial products that may be used for improved hernia treatments.

129. As a result of Dr. Towfigh being omitted as a named inventor on the '636 Patent, Hexagon Health has been harmed, including but not limited to being deprived of its ownership interest in the '636 Patent. As the sole owner of Hexagon Health, the financial harm to Hexagon Health has also harmed Dr. Towfigh.

130. Pursuant to 35 U.S.C. § 256(a), the '636 Patent should be corrected to include omitted inventor Dr. Towfigh as a named inventor.

131. Plaintiffs request that the Court order correction of the '636 Patent and that the Director of the U.S. Patent and Trademark Office issue a certificate, pursuant to 35 U.S.C. § 256(b), to include Dr. Towfigh as a named inventor of the '636 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that the Court:

A. Enter judgment that Medtronic has infringed and is infringing at least one or more claims of the Asserted Patents, literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

B. Enter judgment that Medtronic's infringement of the Asserted Patents has been and is deliberate and willful;

C. Enter judgment awarding Hexagon Health all appropriate damages for the infringement that has occurred, and any continuing or future infringement of the Asserted Patents, up until the date such judgment is entered, including pre- and/or post-judgment interest, costs, and disbursements as justified under 35 U.S.C. § 284;

D. Order an accounting for any infringing sales not presented at trial and an award by the court of additional damages for any such infringing sales;

E. Order that the damages award be increased up to three times the actual amount assessed to account for Medtronic's willful infringement, pursuant to 35 U.S.C. § 284;

F. Enter judgment declaring correction of inventorship of the Bailly Patents to add Dr. Towfigh as an inventor;

G. Enter an order pursuant to 35 U.S.C. § 256 requiring the Director of the United States Patent and Trademark Office to issue a Certificate to correct the inventorship of the Bailly Patents to add Dr. Towfigh as an inventor;

H. Enter judgment declaring this case as exceptional and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. § 285;

I. Enter an order awarding costs and expenses to Plaintiffs in this action; and

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

REQUEST FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Brian P. Egan

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