

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

MASSACHUSETTS INSTITUTE OF
TECHNOLOGY,

and

CHILDREN'S MEDICAL CENTER
CORPORATION,

Plaintiffs,

v.

SHIRE PLC,

SHIRE PHARMACEUTICALS, INC.,

and

SHIRE REGENERATIVE
MEDICINE, INC.,

Defendants

Civil Action No. 13-cv-10020

COMPLAINT

Plaintiffs Massachusetts Institute of Technology (“MIT”) and Children’s Medical Center Corporation (“CMCC”) (collectively, “Plaintiffs”), by and through their undersigned counsel, bring this action for infringement of United States Patent Nos. 5,759,830, 5,770,417, and 5,770,193 (collectively, the “patents-in-suit”) against Defendants Shire Regenerative Medicine, Inc. (“SRM”), Shire plc (“Shire”), and Shire Pharmaceuticals, Inc. (“Shire Pharmaceuticals”) (collectively, “Defendants”).

PARTIES

1. MIT is a nonprofit educational corporation organized under the laws of the Commonwealth of Massachusetts and is located at 77 Massachusetts Avenue, Cambridge, Massachusetts 02139.
2. CMCC is a nonprofit corporation organized under the laws of the Commonwealth of Massachusetts and is located at 55 Shattuck Street, Boston, MA 02115.
3. Upon information and belief, defendant SRM is a corporation organized under the laws of the state of Delaware, with a principal place of business at 36 Church Lane, Westport, Connecticut 06880.
4. Upon information and belief, Shire Pharmaceuticals is a corporation organized under the laws of the state of Delaware, with a principal place of business at 725 Chesterbrook Boulevard, Wayne, PA 19007.
5. Upon information and belief, Shire is a public limited company organized under the laws of the Bailiwick of Jersey, with a principal place of business at 5 Riverwalk, Citywest Business Campus, Dublin 24, Republic of Ireland.

JURISDICTION AND VENUE

6. This action for patent infringement arises under the Patent Act, 35 U.S.C. § 1 *et seq.*
7. This Court has subject matter jurisdiction over these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).
8. This Court has personal jurisdiction over SRM. Upon information and belief, SRM has engaged and currently engages in continuous and systematic contacts with the Commonwealth of Massachusetts. Specifically, and upon information and belief, SRM has marketed, placed, and continues to market and place medical products, including the accused

product in this case, into the stream of commerce via established distribution channels, with the knowledge, intent, and/or understanding that such products are marketed and/or sold within this District. SRM has purposefully directed sales and marketing of Dermagraft and other products to Massachusetts residents. Furthermore, upon information and belief, SRM has caused and continues to cause injury to Plaintiffs in Massachusetts based on its infringement within and outside of Massachusetts while regularly doing business in Massachusetts and deriving substantial revenue from goods sold and used in Massachusetts.

9. This Court has personal jurisdiction over Shire. Upon information and belief, Shire engages in continuous and systematic contacts with the Commonwealth of Massachusetts at least through its subsidiary, Shire Human Genetic Therapies, a Delaware Corporation with its principal place of business at 300 Shire Way, Lexington, MA 02421. Upon information and belief Shire Human Genetic Therapies, Inc. is registered to conduct business in the Commonwealth of Massachusetts. Upon information and belief, Shire is an indirect parent company of Shire Pharmaceuticals and SRM and is involved in the manufacturing, marketing, and selling of the accused product in this case. Upon information and belief, Shire places products into the stream of commerce via established distribution channels, with the knowledge, intent, and/or understanding that such products are marketed and/or sold within this District. Shire has purposefully directed sales and marketing of its products to Massachusetts residents. Furthermore, upon information and belief, Shire has caused and continues to cause injury to Plaintiffs in Massachusetts based on its infringement within and outside of Massachusetts while regularly doing business in Massachusetts and deriving substantial revenue from goods sold and used in Massachusetts.

10. This Court has personal jurisdiction over Shire Pharmaceuticals. Upon information and belief, Shire Pharmaceuticals engages in continuous and systematic contacts with the Commonwealth of Massachusetts. Upon information and belief, Shire Pharmaceuticals is the parent company of SRM and is involved in the manufacturing, marketing, and selling of the accused product in this case. Upon information and belief, Shire Pharmaceuticals places products into the stream of commerce via established distribution channels, with the knowledge, intent, and/or understanding that such products are marketed and/or sold within this District. Shire Pharmaceuticals has purposefully directed sales and marketing of its products to Massachusetts residents. Furthermore, upon information and belief, Shire Pharmaceuticals has caused and continues to cause injury to Plaintiffs in Massachusetts based on its infringement within and outside of Massachusetts while regularly doing business in Massachusetts and deriving substantial revenue from goods sold and used in Massachusetts.

11. Upon information and belief, venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and (c) because this is the judicial District where (i) a substantial part of the events or omissions giving rise to the claims has occurred and is currently occurring; and (ii) where Defendants are subject to personal jurisdiction.

FACTUAL BACKGROUND

Plaintiffs

12. Plaintiff MIT is a world-renowned education and research institution. The mission of MIT is to advance knowledge and educate students in science, technology, and other areas of scholarship that will best serve the nation and the world. For more than 150 years, MIT has produced an unending stream of engineering and scientific advancements, many of them world changing.

13. Plaintiff CMCC is the parent organization for The Children's Hospital Corporation which operates Boston Children's Hospital, a comprehensive center for pediatric health care and one of the largest pediatric medical centers in the United States. Boston Children's Hospital is home to the world's largest research enterprise based at a pediatric hospital, with more than 1,000 scientists working at or affiliated with the institution.

The Patents-in-Suit

14. United States Patent No. 5,759,830 (the "'830 patent") entitled "Three-dimensional fibrous scaffold containing attached cells for producing vascularized tissue in vivo" was duly and legally issued to Plaintiffs as assignees by the United States Patent and Trademark Office on June 2, 1998. A true and correct copy of the '830 patent is attached as Exhibit A. Since its date of issue, Plaintiffs have been and still are the owners of the '830 patent.

15. United States Patent No. 5,770,417 (the "'417 patent") entitled "Three-dimensional fibrous scaffold containing attached cells for producing vascularized tissue in vivo" was duly and legally issued to Plaintiffs as assignees by the United States Patent and Trademark Office on June 23, 1998. A true and correct copy of the '417 patent is attached as Exhibit B. Since its date of issue, Plaintiffs have been and still are the owners of the '417 patent.

16. United States Patent No. 5,770,193 (the "'193 patent" and, collectively with the '820 and the '417 patents, "the patents-in-suit") entitled "Preparation of three-dimensional fibrous scaffold for attaching cells to produce vascularized tissue in vivo" was duly and legally issued to Plaintiffs as assignees by the United States Patent and Trademark Office on June 23, 1998. A true and correct copy of the '193 patent is attached as Exhibit C. Since its date of issue, Plaintiffs have been and still are the owners of the '193 patent.

17. The patents-in-suit all name Dr. Robert Langer and Dr. Joseph Vacanti as inventors. Dr. Langer is an Institute Professor at MIT, and runs one of the world's leading research laboratories studying tissue regeneration. Dr. Vacanti is currently the John Homans Professor of Surgery at Harvard Medical School and a Director of the Laboratory for Tissue Engineering and Organ Fabrication at Massachusetts General Hospital. Previously Dr. Vacanti served on the surgery staff at Boston Children's Hospital.

The Accused Product

18. Upon information and belief, Defendant SRM manufactures, markets, and sells Dermagraft, a human fibroblast-derived dermal substitute indicated for use in treatment of full-thickness diabetic foot ulcers. Upon information and belief, Dermagraft is manufactured from human fibroblast cells derived from newborn foreskin tissue. Upon information and belief, during the manufacturing process, the human fibroblasts are seeded onto a bioabsorbable polyglactin three-dimensional mesh scaffold. Upon information and belief, the fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors, and cytokines to create a three-dimensional human dermal substitute containing metabolically active, living cells.

19. In 2001 the FDA approved Dermagraft for use in connection with treatment of full-thickness diabetic foot ulcers of greater than six weeks duration that extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.

20. In 2006, upon information and belief, SRM (then known as Advanced BioHealing, Inc.) acquired rights to Dermagraft. Upon information and belief, SRM began manufacturing and selling Dermagraft in the United States in 2007.

21. Upon information and belief, in 2011 Shire Pharmaceuticals acquired Advanced BioHealing, Inc., and in 2012 renamed the company Shire Regenerative Medicine.

22. On June 22, 2011 and July 27, 2011, MIT sent correspondence to both SRM and Shire Pharmaceuticals respectively, informing them of the patents-in-suit and inviting them to engage in discussions with MIT regarding the patents-in-suit. MIT received no response to its letters.

23. On November 7, 2012, MIT and CMCC sent correspondence to SRM once again notifying them of MIT and CMCC's belief that Dermagraft infringes the patents-in-suit.

COUNT I
(Infringement of United States Patent No. 5,759,830)

24. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 23 above as if fully set forth herein.

25. SRM infringes and has infringed, either literally or under the doctrine of equivalents, one or more claims of the '830 patent under 35 U.S.C. 271(a), by the manufacture, use, offer to sell, sale, or importation of Dermagraft, including the sale of Dermagraft in this District.

26. Upon information and belief, Shire and Shire Pharmaceuticals actively induce and have induced, under 35 U.S.C. 271(b), SRM's infringement of one or more claims of the '830 patent and knew or should have known that their actions would induce SRM to infringe.

27. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '830 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that objectively-defined risk was either known or so obvious that it should have been known to Defendants.

28. Plaintiffs have been and are continuing to be damaged by Defendants' infringement and/or inducement of infringement of the '830 patent.

COUNT II
(Infringement of United States Patent No. 5,770,193)

29. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 28 above as if fully set forth herein.

30. SRM infringes and has infringed, either literally or under the doctrine of equivalents, one or more claims of the '193 patent under 35 U.S.C. 271(a), by the manufacture of Dermagraft.

31. SRM induces and has actively induced infringement under 35 U.S.C. 271(b) and contributed to the infringement, under 35 U.S.C. 271(c), of one or more claims of the '193 patent, either literally or under the doctrine of equivalents.

32. SRM sells and offers to sell Dermagraft in the United States for treatment of diabetic foot ulcers, together with instructing, directing, and/or advising others how to carry out methods of treatment that infringe one or more claims of the '193 patent.

33. SRM sells Dermagraft with a package insert that includes instructions for treating diabetic foot ulcers in a manner that infringes one or more claims of the '193 patent. When physicians or others use Dermagraft according to the instructions set forth in the package insert provided by SRM, such acts constitute direct infringement of one or more claims of the '193 patent, either literally or under the doctrine of equivalents.

34. SRM knew or should have known that its actions would induce others to infringe the '193 patent and knew that Dermagraft was especially made or adapted for use in an infringing manner. Dermagraft is a material component of the inventions claimed in the '193 patent and is not a staple article of commerce capable of substantial noninfringing use.

35. Upon information and belief, Shire and Shire Pharmaceuticals actively induce and have induced, under 35 U.S.C. 271(b), SRM's infringement of one or more claims of the '193 patent and knew or should have known that their actions would induce SRM to infringe.

36. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '193 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that objectively-defined risk was either known or so obvious that it should have been known to Defendants.

37. Plaintiffs have been and are continuing to be damaged by Defendants' infringement or inducement of and/or contributory infringement of the '193 patent.

COUNT III
(Infringement of United States Patent No. 5,770,417)

38. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 37 above as if fully set forth herein.

39. SRM infringes and has infringed, either literally or under the doctrine of equivalents, one or more claims of the '417 patent under 35 U.S.C. 271(a), by the manufacture, use, offer to sell, sale, or importation of Dermagraft, including the sale of Dermagraft in this District.

40. Upon information and belief, Shire and Shire Pharmaceuticals actively induce and have induced, under 35 U.S.C. 271(b), SRM's infringement of one or more claims of the '417 patent and knew or should have known that their actions would induce SRM to infringe.

41. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '417 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that

objectively-defined risk was either known or so obvious that it should have been known to Defendants.

42. Plaintiffs have been and are continuing to be damaged by Defendants' infringement and/or inducement of infringement of the '417 patent.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

- a. That the Court award damages arising out of Defendants' direct and indirect infringement of the '830 patent, including enhanced damages, together with prejudgment and post-judgment interest;
- b. That the Court award damages arising out of Defendants' direct and indirect infringement of the '193 patent, including enhanced damages, together with prejudgment and post-judgment interest;
- c. That the Court award damages arising out of Defendants' direct and indirect infringement of the '417 patent, including enhanced damages, together with prejudgment and post-judgment interest;
- d. That this Court declare that this is an exceptional case and Plaintiffs be awarded their costs and reasonable attorneys' fees in this action as provided by 35 U.S.C. 285 or as otherwise permitted by law; and
- e. That this Court award Plaintiffs such other and further relief that this Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury of all claims so triable.

Dated: January 4, 2013

Respectfully submitted,

MASSACHUSETTS INSTITUTE OF
TECHNOLOGY and CHILDREN'S
MEDICAL CENTER CORPORATION

By their attorneys,

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