AMENDED THIS AUG 2 9 2017 PURSUANT TO
MODIFIÉ CE CONFORMÉMENT À
☒ RULE/LA RÈGLE 26.02 (A)
☐ THE ORDER OF
L'ORDONNANCE DU
DATED / FAIT LE

REGISTRAR
SUPERIOR COURT OF JUSTICE
GREFFIER
COUR SUPÉRIEURE DE JUSTICE

Court File No.: CV- 17- 577209-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

TAMMY CURRIE

Plaintiff

- and -

DAVOL, INC., C.R. BARD, INC., BARD CANADA INC., GENZYME CORPORATION, and SANOFI S.A.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date June 15, 2017

Issued by "D. RHODEN"
Local registrar

Address of court office: 10th Floor, 393 University Avenue, Toronto, Ontario

TO: **DAVOL, INC.**

100 Crossings Blvd.
Warwick, Rhode Island
02886

AND TO: **C.R. BARD, INC.**

730 Central Avenue
Murray Hill, New Jersey
07974

AND TO: **BARD CANADA INC.**

2715 Bristol Circle
Unit #1
Oakville, Ontario
L6H 6X5

AND TO: **GENZYME CORPORATION**

76 New York Ave,
Framingham, Massachusetts
01701

AND TO: **SANOFI S.A.**

54, rue La Boétie
75008 Paris
France

CLAIM

1. The Plaintiff, Tammy Currie, claims on behalf of herself and others similarly situated in Canada:

(a) an Order certifying this proceeding as a class proceeding and appointing her as Representative Plaintiff for the class(es), to be further defined on the motion for certification;

(b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Sepramesh Products (as defined in paragraph 25);

(c) a declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives;

(d) pecuniary and special damages in the amount of $500,000 for each person implanted with one of the Defendants' Sepramesh Products or as aggregated following a trial on the common issues;

(e) non-pecuniary damages in an amount to be assessed for each person who was implanted with one of the Defendants' Sepramesh Products;

(f) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sales of their Sepramesh Products;

(g) damages pursuant to the *Family Law Act*, RSO 1990, c F.3 s.61 and similar legislation and common law in other provinces, where applicable, in the amount of $100,000 for each such plaintiff;

(h) punitive, aggravated, and exemplary damages in the amount of $20,000,000;

(i) the costs of distributing all monies received to class members;

(j) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;

(k) costs on a substantial indemnity basis, plus applicable taxes; and

(l) such further and other relief as this Honourable Court may deem just.

NATURE OF THE ACTION

2. This proposed class proceeding involves Sepramesh Products – Sepramesh is a coated surgical mesh that is intended for hernia repair. This action arises out of the Defendants' unlawful, negligent, inadequate, improper, unfair, and deceptive practices and misrepresentations related to, *inter alia*, their design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Sepramesh Products.

3. The Defendants misrepresented that their Sepramesh Products are safe and effective, when in fact these devices cause serious Injuries, Conditions, and Complications (as defined in paragraph 27).

4. Patients implanted with the Defendants' Sepramesh Products were misled as to the devices' safety and efficacy, and as a result have suffered serious Injuries, Conditions, and Complications.

THE PLAINTIFF

5. The Plaintiff Tammy Currie resides in Tiny, Ontario.

6. On September 26, 2012, Ms. Currie was implanted with one of the Defendants' Sepramesh Products, specifically Sepramesh IP, to surgically repair an incisional hernia.

THE DEFENDANTS

7. The Defendant Davol, Inc. is a corporation, headquartered in Warwick, Rhode Island. Davol, Inc. is a subsidiary of the Defendant C.R. Bard, Inc.

8. The Defendant C.R. Bard, Inc. is a Delaware corporation with its head office located in Murray Hill, New Jersey.

9. The Defendant Bard Canada Inc. is an Ontario corporation, with its head office located in Oakville, Ontario.

10. The Defendant Genzyme Corporation is a Massachusetts corporation, with its head office located in Framingham, Massachusetts. Genzyme Corporation is a fully owned subsidiary of the Defendant Sanofi S.A.

11. The Defendant Sanofi S.A. is a multinational pharmaceutical company headquartered in Gentilly, France.

12. Hereinafter, each of the above Defendants shall be collectively referred to as the "Defendants".

13. The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Sepramesh Products in Canada. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Sepramesh Products in Canada. The development of Sepramesh Products for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Sepramesh Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Ontario and elsewhere.

14. In bringing this action on behalf of all persons resident in Canada who were implanted with Sepramesh Products, at any time on or before the date of the certification order, which were manufactured, marketed and/or sold or otherwise placed into the stream of commerce in Canada, by one or more of the Defendants, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings Act, 1992*, SO 1992, c6, the *Negligence Act*, RSO 1990, c N-1, as amended and regulations thereunder, and the *Food and Drugs Act,* RSC 1985, c F.27 and regulations thereunder. The Plaintiff also brings this action on behalf of all persons resident in Canada entitled to claim by virtue of a personal or familial relationship to any one or more of the persons described above, and plead and rely upon the Ontario *Family Law Act,* RSO 1990, C F.3 and regulations thereunder, and any analogous provincial legislation.

THE DEFENDANTS' SEPRAMESH PRODUCTS

15. Sepramesh Products are designed for hernia repair and other soft tissue deficiencies. A hernia occurs when an organ pushes through an opening in the muscle or tissue that holds it in place. For example, the intestines may break through a weakened area in the abdominal wall. Hernias can occur in the abdomen (ventral hernias), the upper thigh (femoral hernias), the belly button (umbilical hernias), and the groin (inguinal hernias).

16. The use of a mesh in reconstruction of abdominal wall hernias is viewed by the medical community as an acceptable standard of care for hernia repair. Mesh is placed either under or over the defect in the abdominal wall and sutured in place. Mesh acts as "scaffolding" for new growth of a patient's own tissue, which eventually incorporates the mesh into the surrounding area.

17. Hernias can be surgically repaired using the conventional open method, or the less invasive laparoscopic method. In laparoscopic repair, a few small incisions are made through the abdominal wall to insert the laparoscope (a thin telescope with a light on the end) and surgical instruments into the abdomen. The hernia is then viewed from inside the abdomen, from the other side of the abdominal wall. The abdominal cavity is inflated with carbon dioxide gas to give the surgeon space to work inside the patient and the actual operating is done remotely with long instruments.

18. For laparoscopic hernia repairs, mesh must be suitable for intraperitoneal placement. Mesh adhesions, where the mesh rigidly attaches and integrates into the bowel or other viscera, is a frequently observed complication with intraperitoneal mesh placement. Accordingly, mesh materials have evolved to include "barrier" or "anti-adhesive"

products, which include a permanent or absorbable barrier layer to minimize adhesion of the abdominal viscera to the mesh when placed intraperitoneally.

19. Sepramesh Products are composed of a non-absorbable polypropylene mesh coated with an absorbable hydrogel coating on the posterior side of the mesh. The hydrogel coating is intended to minimize adhesion formation between the mesh and the viscera upon implantation and absorb within 30 days after surgical implantation. The permanent polypropylene mesh component is constructed of knitted filaments to facilitate tissue integration into the mesh pores.

20. Sepramesh Products entered the Canadian market in 2004.

21. Sepramesh IP was introduced into the Canadian market in 2004 by Genzyme Biosurgery, a division of the Defendant Genzyme Corporation. Genzyme Biosurgery terminated its Canadian Medical Device Licence for Sepramesh IP in 2010. In 2011, Genzyme Corporation was acquired by the Defendant Sanofi.

22. From 2010 to 2011, the Defendant, Davol, Inc., held the Canadian Medical Device Licence for Sepramesh IP. Sepramesh IP was no longer available in Canada after July of 2011.

23. In 2011, the Defendant, Davol, Inc., introduced Ventralight ST Mesh into the Canadian market. Ventralight ST Mesh is a low profile polypropylene mesh on the anterior side with an absorbable hydrogel barrier based on Sepra Technology on the posterior side, primarily intended for laparoscopic ventral hernia repairs.

24. In 2012, the Defendant, Davol, Inc., introduced Ventralex ST Hernia Patch into the Canadian market. Ventralex ST Hernia Patch is a low profile polypropylene mesh on the

anterior side with an absorbable hydrogel barrier based on Sepra Technology on the posterior side, primarily intended for umbilical hernia repairs.

25. In 2012, the Defendant, Davol, Inc., introduced Ventrio ST Hernia Patch into the Canadian market. Ventrio ST Hernia Patch is a self-expanding hernia mesh that is constructed of polypropylene on the anterior side with an absorbable hydrogel barrier based on Sepra Technology on the posterior side.

26. The Defendants' products listed in paragraphs 19 – 25 above, are collectively referenced herein as "Sepramesh Products".

THE RISKS

27. The Defendants knew or ought to have known that their Sepramesh Products are defective, and are not properly manufactured to withstand normal, foreseeable, and intended use. The Defendants' Sepramesh Products have high failure, injury, and complication rates, fail to perform as intended, have resulted in severe and irreversible injuries and conditions, and have caused damage to the Representative Plaintiff and other putative class members.

28. The Injuries, Conditions, and Complications suffered due to the Defendants' Sepramesh Products include but are not limited to: hernia recurrence, chronic pain, mesh contraction, mesh migration, scarring, adhesions, infection, abscess formation, bleeding, intestinal blockage, fistulas, hematomas, seromas, perforations, allergic reactions, rashes, and the need for further surgeries (collectively the "Injuries, Conditions, and Complications").

29. The failure of Defendants' Sepramesh Products is attributable, in part, to the fact that all of the Defendants' Sepramesh Products suffer from a common design defect, the

absorbable hydrogel coating, which, *inter alia*, incites high levels of inflammation once implanted. Chronic inflammation caused by Sepramesh Products slows wound healing and contributes to chronic infection, which causes or materially contributes to the Injuries, Conditions, and Complications outlined above.

30. The Defendants' Sepramesh Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

31. At all material times, the Defendants knew or ought to have known that the risks of using their Sepramesh Products included severe Injuries, Conditions, and Complications.

32. The Defendants' Sepramesh Products create risks to the health and safety of patients that are far more significant than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of their Sepramesh Products.

33. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiff and putative class members, of the risk of Injuries, Conditions, and Complications caused by their Sepramesh Products.

34. The Defendants did not provide adequate safety data to Health Canada with respect to their Sepramesh Products. The Defendants knew or ought to have known that their Sepramesh Products were unsafe, defective, unreasonably dangerous, and not fit for their intended purposes.

35. At all material times, the Defendants, through their servants and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold their Sepramesh Products without adequate warnings of the products' serious side effects and unreasonably dangerous risks.

THE PLAINTIFF'S EXPERIENCE

36. In September of 2012, Ms. Currie underwent a surgical repair of a large infraumbilical incisional hernia using one of the Defendants' Sepramesh Products, at Royal Victoria Regional Health Centre in Barrie, Ontario. Ms. Currie did not suffer any intraoperative complications during implantation of the mesh.

37. Shortly after her surgery, Ms. Currie began to experience concerning complications. She suffered a significant reaction to the mesh and developed an infection. She required a tube to be inserted near the mesh to assist with drainage and inflammation.

38. Shortly after her surgery, Ms. Currie developed significant abdominal pain and indigestion. She describes her abdomen as "hard" and reports that she "feels sick" after eating.

39. Since being implanted with the Defendnats' Sepramesh Product, Ms. Currie's symptoms have become severe and intolerable, such that she experiences ongoing pain and suffering, which impacts her activities of daily living and has rendered her unable to perform her employment duties.

40. Ms. Currie has been advised by her healthcare providers that, despite the severity of her symptoms, surgical removal of her mesh is too dangerous.

41. Ms. Currie continues to experience pain and discomfort on a daily basis.

42. Prior to and at the time when Ms. Currie was implanted with the Defendants' Sepramesh Product, she received no or inadequate warning about the risk of developing Injuries, Conditions, and Complications.

43. Had Ms. Currie been aware of the magnitude of risks of developing Injuries, Conditions, and Complications, she would never have agreed to being implanted with the Defendants' Sepramesh Product. But for the Defendants' wrongful conduct, the Plaintiff would not have incurred damages.

44. The Plaintiff, and other class members, have suffered and continue to suffer damages including loss of care, guidance, companionship and consortium, as well as financial expenses and special damages due to the wrongful conduct of the Defendants.

CAUSES OF ACTION

45. The Defendants at all material times owed a duty of care to the Plaintiff to:

(a) ensure that their Sepramesh Products were fit for their intended and/or reasonably foreseeable use;

(b) conduct appropriate testing to determine whether and to what extent use of their Sepramesh Products posed serious health risks, including the magnitude of risk of developing Injuries, Conditions, and Complications;

(c) properly, adequately, and fairly warn the Plaintiff and physicians of the magnitude of the risk of developing Injuries, Conditions, and Complications with use of their Sepramesh Products compared to alternative treatments;

(d) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their Sepramesh Products;

(e) monitor, investigate, evaluate and follow up on adverse reactions to the use of their Sepramesh Products; and

(f) properly inform Health Canada and other regulatory agencies of all risks associated with their Sepramesh Products.

46. The Defendants negligently breached their duty of care.

47. The Plaintiff states that her damages were caused by the negligence of the Defendants. Such negligence includes, but is not limited to, the following:

(a) the Defendants failed to ensure that their Sepramesh Products were not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

(b) the Defendants failed to adequately test their Sepramesh Products in a manner that would fully disclose the magnitude of the risks associated with their use, including but not limited to Injuries, Conditions, and Complications;

(c) the Defendants unreasonably and carelessly designed products that were insufficient to withstand the foreseeable use of normal placement within the human body;

(d) the Defendants failed to provide Health Canada complete and accurate information with respect to their Sepramesh Products as it became available;

(e) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and safety of their Sepramesh Products;

(f) the Defendants failed to conduct any or any adequate long-term studies of the risks of their Sepramesh Products;

(g) the Defendants failed to provide the Plaintiff, her physicians and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their Sepramesh Products, including, but not limited to, risk of Injuries, Conditions, and Complications;

(h) the Defendants failed to warn or adequately warn the Plaintiff or her physicians that in the event of failure, injury, or complications, it may be impossible to easily and safely remove the Defendants' Sepramesh Products, or to remove them at all;

(i) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to their Sepramesh Products in Canada and elsewhere;

(j) the Defendants failed to provide any or any adequate updated and/or current information to the Plaintiff, physicians and/or Health Canada respecting the risks of their Sepramesh Products as such information became available from time to time;

(k) the Defendants failed to provide adequate warnings of the risks associated with their Sepramesh Products, including the risk of Injuries, Conditions, and Complications in all persons receiving their Sepramesh Products on the patient information pamphlets in Canada;

(l) the Defendants, after noticing problems with their Sepramesh Products, failed to issue adequate warnings, timely recall their Sepramesh Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiff and her physicians of their Sepramesh Products' inherent dangers, including, but not limited to, the danger of Injuries, Conditions, and Complications;

(m) the Defendants failed to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Sepramesh Products;

(n) the Defendants represented that their Sepramesh Products were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(o) the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of their Sepramesh Products and their associated risks, including the risk of Injuries, Conditions, and Complications;

(p) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known by the Defendants;

(q) the Defendants failed to timely cease the manufacture, marketing and/or distribution of their Sepramesh Products when they knew or ought to have known that their Sepramesh Products caused Injuries, Conditions, and Complications;

(r) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

(s) the Defendants failed to properly supervise their employees, subsidiaries and affiliated corporations;

(t) the Defendants breached other duties of care to the Plaintiff and putative class members, details of which breaches are known only to the Defendants; and

(u) in all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Plaintiff and putative class members.

48. The Defendants' Sepramesh Products are defective because they are unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Plaintiff, putative class members, or their physicians. Any benefit from using the Defendants' Sepramesh Products was outweighed by the serious and undisclosed risks of their use when used as the Defendants intended. There are no individuals for whom the benefits of the Defendants' Sepramesh Products outweigh the risks, given that there are many alternative products and procedures that are at least as efficacious as the Defendants' Sepramesh Products and carry far less and/or less serious risks than the Sepramesh Products.

49. The risks associated with use of the Defendants' Sepramesh Products, including Injuries, Conditions, and Complications in all persons receiving their Sepramesh Products, were in the exclusive knowledge and control of the Defendants. The extent of the risks were not known to, and could not have been known by, the Plaintiff. The Plaintiff's injuries would

not have occurred but for the negligence of the Defendants in failing to ensure that their Sepramesh Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Sepramesh Products to the Plaintiff and putative class members, and to their physicians.

DAMAGES

50. The Plaintiff's and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.

51. As a result of the Defendants' negligence, the Plaintiff has suffered and continues to experience serious personal injuries and harm with resultant pain and suffering. It is more likely than not that the Plaintiff will require additional surgeries and/or procedures.

52. The Plaintiff and other putative class members have suffered special damages for medical costs incurred in the screening, diagnosis, and treatment of Injuries, Conditions, and Complications related to use of the Defendants' Sepramesh Products.

53. As a result of the conduct of the Defendants, the Plaintiff and other putative class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

54. Some of the expenses related to the medical treatment that the Plaintiff and class members have undergone, and will continue to undergo, have been borne by the various provincial health insurers.

55. The Plaintiff claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

56. The Plaintiff pleads and relies on sections 17.02 (g) and (p) of the *Rules of Civil Procedure*, allowing for service *ex juris* of the foreign defendants. Specifically, this originating process may be served without court order outside Ontario in that the claim is:

(a) in respect of a tort committed in Ontario (rule 17.02(g));

(b) against a person carrying on business in Ontario (rule 17.02(p)).

June 15, 2017

SISKINDS LLP
Barristers & Solicitors
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ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding commenced at Toronto
Proceeding under the *Class Proceedings Act, 1992*

AMENDED STATEMENT OF CLAIM

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