CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

N°: 500-06-000519-104

SUPERIOR COURT
(Class Action)

FRANCINE COURSOLLE, residing and domiciled at 6360, Côte-St-Luc, apartment 4, Montreal, Quebec, H4V 1E9

Petitioner

v.

BARD CANADA INC., having a place of business at 24, de la Concorde east, Laval (Québec) H7G 4X2

and

C. R. BARD, having a place of business at 730, Central Avenue, Murray Hill, New Jersey, USA, 07974

And

DAVOL INC., having a place of business at 100 Crossings Boulevard, Warwick, Rhode Island, USA, 02886

Respondents

MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION, AND TO OBTAIN THE STATUS OF REPRESENTATIVE (ARTICLE 1002 C.C.P.)

IN SUPPORT OF HER MOTION, PETITIONER, RESPECTFULLY SUBMITS THE FOLLOWING:

The Group

1. Petitioner intends to institute a class action on behalf of the persons forming part of the group hereinafter described and of which Petitioner is a member, namely:

Description of the Group

(a) All those natural persons who reside or have resided in the Province of Québec who had a Kugel Mesh (defined below subparagraph (b)) implanted in them at any time on or before the date of the trial and which was manufactured, marketed and/or sold or otherwise placed into the stream of commerce in the Province of Quebec by any or all of Bard Canada Inc., C.R. Bard Inc. and Davol Inc.;

(b) Kugel Mesh means any and all of the following products :

i. All nine (9) models of Bard Composix Kugel Hernia Patches (Product Codes 0010201 through 0010209);

ii. All other Davol Hernia patches with PET «memory recall rings», including the Bard Kugel Hernia Patch, Bard Ventralex Hernia Patch, Bard CK Parastomal Patch and Bard Modified Kugel Patch; and

iii. Other Davol hernia mesches composed of layers of polypropylene and polytetrafluoroethylene (ePTFE), including the Bard Composix E/X Mesh;

The Kugel Mesh

2. The Kugel Mesh is used to repair ventral hernias, or hernias of the abdominal region;

3. The Kugel Mesh is made of one layer of expanded polytetrafluoroethylene (ePTFE) attached to two layers of monofilament polypropylene, mesh that surround a flexible «memory recoil ring» made of polyethylene terephthalate (PET);

4. The intended purpose of the PET «memory recoil ring» is to aid in surgical placement;

5. After insertion, the PET «memory recoil ring» forces the patch to spring back to its original shape and to lie flat;

6. The monofilament polypropylene mesh serves as a substrate, enabling the hernia patient's own tissue to grow and assist in healing the hernia.

7. The layer of expanded polytetrafluoroethylene (ePTFE) is intended to act as a barrier preventing abdominal organs from adhering to the mesh layers;

Petitioner's Situation

8. Petitioner's personal claim against the Respondents is based on the following facts:

9. On June 16, 2006, the Petitioner had surgery to repair an abdominal incisional hernia and a Kugel Mesh was inserted in said repair, as it appears from the Operation Report dated June 16, 2006 and an extract of Petitioner's medical record, **Exhibit P-1**;

10. The particular Kugel Mesh product was a large elipse, 20.3 x 25.4 cm, product reference number 0123810, lot number 43APD459;

11. At the time of the surgery, the Petitioner was otherwise generally in good health;

12. In October 2008, Petitioner started to experience intense pain in the abdominal region and was admitted to St. Mary's Hospital Center's emergency on October 22, 2008, as described in St. Mary's Hospital Center medical's record for Petitioner from October 22, 2008 to October 24, 2008 (extracts), **Exhibit P-2**;

13. A recurrent incisional hernia was then diagnosed;

14. Petitioner was 21 weeks pregnant at the time;

15. Petitioner had to undergo an urgent surgery on October 24, 2008, as it appears from the Operation report, **Exhibit P-3**;

16. Petitioner was discharged from the hospital on October 29, 2008, as it appears from the Summary Sheet, **Exhibit P-4**;

17. Petitioner suffered pain and suffering, including the second operation, as a direct result of the implantation of the Kugel Mesh and the negligence of the Respondents described below;

18. Petitioner was never warned of the risks associated with the use of Kugel Mesh;

19. Has she been so advised she would have refused this medical product and would have insisted on a safer alternative treatment;

20. But for the Respondents' negligence she would not have suffered her injuries and incurred her damages;

21. Petitioner had to remain in the hospital for eight (8) days prior and after the second surgery;

22. These eight (8) days were saturated with pain and discomfort, requiring much pain medication, as it appears from extracts of Petitioner medical record (Medical Orders and Medication Administration Record Annex), **Exhibit P-5**;

23. After her release from hospital, Petitioner continued to experience pain and discomfort for several weeks;

24. Furthermore, Petitioner will require medical monitoring as a result of the implanted Kugel Mesh and Respondents' negligence;

25. Petitioner damages for personal injuries, pain, suffering, stress and inconveniences will be established at trial;

26. Petitioner lost a week of employment income while she stayed in the hospital;

27. In addition, Petitioner claims punitive damages from Respondents for their gross negligence and complete disregard for the health and lives of vulnerable patients, in an amount to be determined at trial;

28. In particular, the Respondents' conduct in continuing to market, sell and distribute Kugel Mesh after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award in punitive damages in such a sum which will serve to deter the Respondents from similar conduct in the future;

29. Petitioner's spouse has also suffered damages, including loss of income due to work absences required to attend to, care for and provide services to Petitioner, loss of care, guidance and companionship as well as expenses and special damages;

Respondent's Liability

30. The Respondent C. R. Bard inc. (Bard US) is incorporated in the State of New Jersey in the United States of America (USA), as it appears from its certificate of incorporation, **Exhibit P-6**;

31. Davol inc. (Davol) is incorporated in the State of Delaware in the USA, with its head office in the City of Warwick, in the State of Rhode Island, as it appears from its certificate of incorporation, **Exhibit P-7**;

32. Davol is a subsidiary of Bard US;

33. Bard US and Davol researched, developed, tested and manufactured Kugel Mesh and marketed, distributed and sold it throughout the USA and Canada since 2000;

34. The Respondent Bard Canada inc. (Bard Canada) is a Canadian corporation with a registered head office in the City of Toronto, in the Province of Ontario and other offices across Canada, including one in Quebec, as it appears from an extract of the *Registraire des entreprises*, **Exhibit P-8**;

35. Bard Canada is an affiliate or a subsidiary of Bard US;

36. Bard Canada has imported, marketed and distributed the medical products known collectively as Kugel Mesh throughout Canada since at least May 17, 2000;

37. At all material times Bard Canada, Bard US and Davol (collectively referred to as Bard) carried business jointly in and throughout Canada and Quebec;

38. Collectively, Bard researched, developed, tested, manufactured, marketed, distributed and sold Kugel Mesh as a medical product which was appropriate, cost effective and suitable for use in hernia repair surgery throughout Canada and Quebec;

39. On various dates starting on May 17, 2000, Kugel Mesh was approved by Health Canada to repair hernias in Canada;

40. The Respondents, however, failed to give Health Canada complete and accurate information concerning Kugel Mesh by failing to disclose the risks on a timely basis;

41. Furthermore, the Respondents continued to manufacture, distribute and sell Kugel Mesh notwithstanding the following;

42. On December 22, 2005, Davol recalled many sizes of Kugel Meshes pursuant to a U.S. Food and Drug Administration (FDA) Class I recall notice, as it appears from a copy of the notice of recall from the FDA, **Exhibit P-9**;

43. The reason given for that recall is that «*the «memory recoil ring» that opens the Composix Kugel Mesh Patch after it has been inserted into the intra-abdominal space can break. This can lead to bowel perforation and/or chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs)*».

44. An FDA Class I recall is issued for problems related to medical devices that are potentially life-threatening or could cause a serious risk to the health of the patients implanted with the devices, as it appears from the FDA Recalls Background and Definitions Form, **Exhibit P-10**;

45. On February 6, 2006, Health Canada issued notice of recall effective January 9, 2006 for the same reasons, as it appears from a copy of the recall sheet, **Exhibit P-11**;

46. In January and February 2006, Health Canada and the FDA conducted investigations concerning the Kugel Mesh;

47. The results of these investigations determined, among other things, that the Respondents :

    a. Had excluded ring failure event which should have been included from their complication database reports and recall notices;

    b. Misidentified numerous Kugel Mesh complication events;

    c. Failed to apply the product quality hold and release procedure on a timely basis;

    d. Failed to properly follow the procedures for conducting design validation review;

    e. Failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Kugel Mesh complications, specifically, they provided no justification for including only the Extra Large Kugel Patch sizes in the December 2005 and February 2006 recalls;

    f. Failed to provide full information which they knew regarding numerous Kugel Mesh complaints;

    g. Failed to perform strength testing on memory recoil rings for all sizes of Kugel Mesh before putting them into stream of commerce;

    h. Failed to maintain appropriate sources for quality data to identify, track and trend existing and potential causes for the ring failures and Kugel Mesh complaints, resulting in numerous inconsistencies and errors;

48. On March 24, 2006 and again on January 10, 2007, the initial FDA Class I recall with respect to Kugel Mesh was expanded to include several more sizes of Kugel Mesh and numerous additional lots of defective hernia mesh product, as it appears from the FDA recall notice, **Exhibit P-12**;

49. This recall notice invites «*patients who have been implanted with one of the recalled devices [to] seek medical attention immediately if they experience symptoms that could be associated with ring breakage such as unexplained or persistent abdominal pain, fever, tenderness at the implant site or other unusual symptoms*»;

50. The Canadian recall was expanded pursuant to Health Canada's January 22, 2007 notice (effective December 22, 2006), as it appears from a copy of that notice, **Exhibit P-13**;

51. The Respondents were aware of the defect in manufacture and design prior to the recall of the Kugel Mesh, as it appears from a article titled «Kugel Mesh Hernia Patch Defects Put Patients at Risks, Yet Davol Waited Before Issuing Recall» dated November 14th, 2007, **Exhibit P-14**;

52. Bard, however, consistently failed to disclose or warn Canadian patients of the significant risk of ring migration, intestinal fistulae, bowel perforation and death;

53. Bard knew or ought to have known of the significant risks associated with the use of Kugel Mesh since inception;

54. Furthermore, the complications and failures associated with the Kugel Mesh are not limited to the sizes which the Respondents have recalled, as it appears, for example, from the Petitioner situation;

55. The Respondents were aware of the defects in the manufacture and design of the non-recalled Kugel Mesh and improperly chose not to issue a recall on all Kugel Mesh, notwithstanding the high degree of complication and failure rates;

56. More generally, the Respondents failed to conduct adequate tests and clinical trials initially and on an ongoing basis to determine the risks associated with the use of Kugel Mesh;

57. The Respondents failed to provide proper long term investigations of the effects and risks of continued use of Kugel Mesh;

58. The Respondents failed to adequately monitor, evaluate and act upon adverse reactions to Kugel Mesh in Canada and throughout the world;

59. As mentioned in the recall notices, the risks associated with using Kugel Mesh include bowel perforations and/or chronic intestinal fistulae (abnormal connections or passage ways between the intestines and other organs);

60. The Respondents with full knowledge that Kugel Mesh posed these significant risks continued to sell and distribute Kugel Mesh throughout Canada and Quebec;

61. Subsidiarily, the Respondents manufactured, marketed, distributed and sold Kugel Mesh without adequately disclosing those risks;

62. The Respondents failed to adequately warn the Petitioner, the members of the group and their physicians and surgeons of the risks then known or which were reasonably foreseeable in using Kugel Mesh;

63. Also, the Respondents failed to adequately warn the petitioner, the members of the group and their physicians and surgeons about the need for comprehensive regular medical monitoring to ensure early discovery of the potentially fatal health related complications from the use of Kugel Mesh set out above;

64. The Respondents failed to established any adequate procedures to educate their sales representatives and treating physicians and surgeons respecting the correct usage of Kugel Mesh and the risks associated with the medical device;

65. Those risks associated with Kugel Mesh were in Bard's exclusive knowledge and control;

66. The extent of the risks was not known and could not have been known to the Petitioner or the members of the group;

67. The injuries of the Petitioner and the members of the group would not have occurred but for the negligence of the Respondents in failing to ensure that Kugel Mesh was a safe for use or, in the alternative, for failing to provide adequate warning of the risks associated with Kugel Mesh to the petitioner, the members of the group and to their physicians;

The Situation of each Group Members

68. Every Group Member were implanted with a Kugel Mesh;

69. Several members of the group experience health problems directly caused by this implementation, including in several cases a second surgery;

70. All members of the group have to undergo close medical monitoring;

71. None of the group members were adequately warned about the risks associated with the use of Kugel Mesh;

72. All members of the group are entitled to claim from Respondents damages for personal injuries, pain, suffering, stress and inconveniences;

73. All members of the group are entitled to claim from Respondents damages for loss of employment income;

74. In addition, all members of the group are entitled to claim from Respondents punitive damages in an amount to be determined by the court for their gross negligence and complete disregard for their health and lives;

75. The Respondents' conduct in continuing to market, sell and distribute Kugel Mesh after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the

safety of members of the group justifying an award in punitive damages in such a sum which will serve to deter the Respondents from similar conduct in the future;

The Composition of the Group makes the application of articles 59 and 67 difficult or impractical

76. According to the information available on Bard's website, it appears that millions of patients worldwide have been treated with Kugel Mesh;

77. In 2008, the global market for Bard's hernia repair products was approximately US$ 825,000,000,00, as it appears from Bard's 2008 annual report, **exhibit P-14**;

78. As of January 2007, the total number of recalled Kugel Meshes that were distributed amounted to more than 100,000 units;

79. The group comprises numerous persons geographically dispersed throughout Quebec;

80. Thus, it is impossible for Petitioner to identify all such potential group members and/or obtain a mandate from each of them;

Identical, similar or related questions

81. The identical, similar, or related questions of fact and law between each Group Member and Respondents which Petitioner wishes to have decided by the class action are as follow :

a. Does Kugel Mesh cause intestinal fistulae, bowel perforation and secondary injuries and infection?

b. In the affirmative, is Kugel Mesh thereby defective or unfit for the purpose for which it was intended (including usages that ought reasonably to have been foreseen by defendants) as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Quebec by one or all the Respondents?

c. Were the Respondents negligent and/or in fault in distributing or otherwise dealing with Kugel Mesh in Quebec?

d. Did the Respondents failed in their duty to adequately warn the Petitioner and the members of the risks associated with the use of Kugel Mesh and/or did they knowingly and recklessly misrepresented to them any risk of harm from Kugel Mesh?

e. Are the Petitioner and Members of the group entitled to claim compensatory damages from the Respondent?

f. Are the Petitioner and Members of the group entitled to claim punitive damages from the Respondent?

g. Should the Respondent be required to implement a medical monitoring regime and, if so, what should that regime comprise and how should it be established?

Individual question

82. The only question of fact and law which is specific to each Group Member is the quantum of the damages;

The nature of the recourse

83. The nature of the recourse which the Petitioner wishes to exercise on behalf of the Members of the Group is a civil liability damages action;

The conclusions

84. The conclusions sought by Petitioner are :

GRANT Petitioner's action against Respondents

CONDEMN Respondents jointly and severally to pay Petitioner the total damages awarded by the court, the whole with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Quebec*, reckoned from the date of service of the present motion;

CONDEMN Respondents jointly and severally to pay each Group Member an amount corresponding to their loss, including damages personnal injury, for pain and suffering, troubles and inconveniences and for loss of income, the whole with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Quebec*, reckoned from the date of service of the present motion;

CONDEMN Respondents jointly and severally to pay each Group Member punitive damages in the amount determined by the court, the whole with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Quebec*, reckoned from the date of service of the present motion;

ORDER the collective recovery of the damage claims;

CONDEMN Respondents jointly and severally to pay such other amounts and grant Group Members such further relief as this Honourable Court may determine as being just and proper;

ORDER the Respondents to implement a medical monitoring regime, which will be more fully described and established during the hearing on the merit of the case;

THE WHOLE with cost, including the costs of all exhibits, experts, expertises and publication notices.

Representative status

85. Petitioner requests that he be ascribed the status of representative for the following reasons :

    a. She is a Group Member;

    b. She is well informed of the facts alleged in this motion;

    c. She has the required time, determination and energy to bring this matter to a conclusion and adequately represent the Group Members;

    d. She cooperates with her attorneys and responds diligently and articulately to request they make and he fully comprehends the nature of the class proceedings;

    e. She is not aware of any conflict of interest with other Group Members;

WHEREFORE PETITIONER PRAYS :

THAT the present motion be granted;

THAT the bringing of a class action be authorized as follows:

A civil liability action for damages

THAT the status of representative be granted to Francine Coursolle for bringing the said class action for the benefit of the Group described as follows, namely:

Description of the Group

a) All those natural persons who reside or have resided in the Province of Québec who had a Kugel Mesh (defined below subparagraph (b)) implanted in them at any time on or before the date of the trial and which was manufactured, marketed and/or sold or otherwise placed into the stream of commerce in the Province of Quebec by any or all of Bard Canada Inc., C.R. Bard Inc. and Davol Inc.;

b) Kugel Mesh means any and all of the following products :

i. *All nine (9) models of Bard Composix Kugel Hernia Patches (Product Codes 0010201 through 0010209);*

ii. *All other Davol Hernia patches with PET «memory recall rings», including the Bard Kugel Hernia Patch, Bard Ventralex Hernia Patch, Bard CK Parastomal Patch and Bard Modified Kugel Patch; and*

iii. *Other Davol hernia mesches composed of layers of polypropylene and polytetrafluoroethylene (ePTFE), including the Bard Composix E/X Mesh;*

THAT the principal questions of fact and law be dealt with collectively be identified as follows:

a. Does Kugel Mesh cause intestinal fistulae, bowel perforation and secondary injuries and infection?

b. In the affirmative, is Kugel Mesh thereby defective or unfit for the purpose for which it was intended (including usages that ought reasonably to have been foreseen by defendants) as designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Quebec by one or all the Respondents?

c. Were the Respondents negligent and/or in fault in distributing or otherwise dealing with Kugel Mesh in Quebec?

d. Did the Respondents failed in their duty to adequately warn the Petitioner and the members of the risks associated with the use of Kugel Mesh and/or did they knowingly and recklessly misrepresented to them any risk of harm from Kugel Mesh?

e. Are the Petitioner and Members of the group entitled to claim compensatory damages from the Respondent?

f. Are the Petitioner and Members of the group entitled to claim punitive damages from the Respondent?

g. Should the Respondent be required to implement a medical monitoring regime and, if so, what should that regime comprise and how should it be established?

THAT the conclusions sought with respect to such questions be identified as follows:

GRANT Petitioner's action against Respondents

CONDEMN Respondents jointly and severally to pay Petitioner the total damages awarded by the court, the whole with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Quebec*, reckoned from the date of service of the present motion;

CONDEMN Respondents jointly and severally to pay each Group Member an amount corresponding to their loss, including damages personnal injury, for pain and suffering, troubles and inconveniences and for loss of income, the whole with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Quebec*, reckoned from the date of service of the present motion;

CONDEMN Respondents jointly and severally to pay each Group Member punitive damages in the amount determined by the court, the whole with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Quebec*, reckoned from the date of service of the present motion;

ORDER the collective recovery of the damage claims;

CONDEMN Respondents jointly and severally to pay such other amounts and grant Group Members such further relief as this Honourable Court may determine as being just and proper;

ORDER the Respondents to implement a medical monitoring regime, which will be more fully described and established during the hearing on the merit of the case;

THE WHOLE with cost, including the costs of all exhibits, experts, expertises and publication notices.

THAT it be declared that any Group Member who has not requested exclusion from the Group be bound by any judgement to be rendered on the class action in accordance with the *Code of Civil Procedure*;

THAT the delay for exclusion be fixed at sixty (60) days from notice to Group Members and that at the expiry of such delay, any Group Member who has not requested exclusion be bound by any such judgment;

THAT it be ordered that a notice to the Members be published in the Journal de Montréal and in The Gazette;

THAT Respondents be ordered to assume the publication costs of the Notice to Members;

THAT the record be referred to the Chief Justice so that he may fix the district wherein the class action is to be brought and the judge before whom it will be heard;

THAT the clerk of this Court be ordered, upon receiving the decision of the Chief Justice, in the event that the class action brought I another district, to transmit the present record to the clerk of the designated district;

The whole with cost to follow the suit.

Montreal, August 23rd, 2010

SYLVESTRE, FAFARD, PAINCHAUD
Attorneys for Petitioner