C A N A D A

(Class Action)
SUPERIOR COURT

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

NO : 500-06- 001179-221

DENISE APPLETON, an individual residing at [redacted]

and

ROY APPLETON, an individual residing at [redacted]

Applicants

v.

PFIZER INC., legal person having its head office at 235, East 42nd Street, New York City, (New York), United States, 10017;

and

PFIZER CANADA ULC, legal person having its head office at 1800-510, West Georgia Street, Vancouver (British Columbia) V6B0M3 and its elected domicile/principal place of business at 17300, Trans-Canada Highway, Kirkland (Québec), H9J 2M5;

and

PF PRISM C.V., limited partnership having its registered seat in Rotterdam, Netherlands, and its head office at Rivium Westlaan 142, Capelle aan den IJssel, 2909LD, Netherlands;

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVES

(Sections 571 *C.C.P.* and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE QUÉBEC SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE APPLICANTS STATE AS FOLLOWS:

I. GENERAL PRESENTATION

A. THE CLASS ACTION

1. The applicants wish to institute a class action on behalf of the natural persons forming part of the class hereinafter described, namely:

> Subgroup 1 :
> Any individual in Canada who has been diagnosed with a major adverse cardiovascular event ("MACE"), which is the composite of total death, myocardial infarction, coronary revascularization, stroke, and hospitalization because of heart failure, and/or a cancer after having used the drugs Xeljanz and/or Xeljanz XR ("tofacitinib");
>
> and
>
> Subgroup 2 :
> Any individual in Canada who suffers or has suffered harm because of the diagnosis of MACE and/or cancer received by a subgroup 1 individual, including his or her spouse, parent, children, and siblings.
>
> OR, AS A SUBSIDIARY :
>
> Subgroup 1 :
> Any individual in Québec who has been diagnosed with a major adverse cardiovascular event ("MACE"), which is the composite of total death, myocardial infarction, coronary revascularization, stroke, and hospitalization because of heart failure, and/or a cancer after having used the drugs Xeljanz and/or Xeljanz XR ("tofacitinib");
>
> and
>
> Subgroup 2 :
> Any individual in Canada who suffers or has suffered harm because of the diagnosis of MACE and/or cancer received by a subgroup 1 individual, including his or her spouse, parent, children, and siblings.

or any other class to be determined by the Court.

2. Xeljanz and Xeljanz XR ("tofacitinib") ("**Xeljanz Products**") are prescription drugs used to treat rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis;

3. Xeljanz Products are designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold by the defendants;

4. This action alleges that the defendants are liable as manufacturers because the safety defect in Xeljanz Products arose from the development, research, testing, manufacturing, licensing, packaging, labeling, notices and warnings, marketing, promotion, distribution, and sale of these products, or from the failure to warn of the increased risks associated with these drugs and how to be protected against them;

5. As a result of the Xeljanz Products safety defect and/or the defendants' acts and omissions, the applicants and class members have suffered and continue to suffer damages for which they are entitled to claim compensation;

B. THE DEFENDANTS

6. Pfizer Inc. is a corporation incorporated pursuant to the laws of Delaware (United States);

7. Pfizer Inc. authors, publishes, and maintains websites as sources of information regarding the safety of Xeljanz Products that are used by consumers worldwide, including in Canada;

8. Pfizer Canada ULC ("**Pfizer Canada**"), is a corporation incorporated pursuant to the laws of British Columbia and has its elected domicile and principal place of business in Kirkland (Québec), the whole as it appears from the *État des renseignements d'une personne morale au registre des entreprises*, produced as **Exhibit P-1**;

9. Pfizer Canada's principal place of business activities is in Kirkland, Québec, which is the location of Pfizer Canada's "Canadian Worldwide Biopharmaceutical Business Head Office" and the company's listed address on all Xeljanz Products' product monographs;

10. Pfizer Canada developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Xeljanz Products in Canada;

11. Pfizer Canada is the sponsor or market authorization holder for Xeljanz Products, meaning that it is the entity authorized by Health Canada to sell Xeljanz Products in Canada;

12. Pfizer Canada is a wholly owned subsidiary of Pfizer Inc.;

13. At times relevant to this action, Pfizer Inc. had responsibility for the operations of Pfizer Canada;

14. PF PRISM C.V. ("**PF PRISM**") is a limited partnership organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, Netherlands;

15. PF PRISM has held the Canadian trademark to "Xeljanz Products" during the times relevant to this action, the whole as it appears from the trademark application, produced as **Exhibit P-2**;

16. PF PRISM C.V. is a wholly owned subsidiary of Pfizer Inc.;

17. At times relevant to this action, Pfizer Inc. had responsibility for the operations of PF PRISM;

18. Hereinafter, each of the above defendants shall be collectively referred to as the "defendants" or "Pfizer";

19. At times relevant to this action, the business of each of the defendants was inextricably interwoven with that of the other and each is the agent of the other for the purposes of developing, researching, testing, manufacturing, licensing, packaging, labelling, marketing, promoting, distributing, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Xeljanz Products in Canada;

20. In view of the close relationship between the defendants and the foregoing, each of the defendants is jointly and severally liable for the acts and omissions of each other and their predecessors;

C. XELJANZ PRODUCTS

21. Xeljanz Products are drugs manufactured by the defendants;

22. Xeljanz Products have "tofacitinib" as their active pharmaceutical ingredient;

23. Tofacitinib is a prescription drug used to treat adults with moderate to severely active rheumatoid arthritis, active psoriatic arthritis, or moderate to severely active ulcerative colitis in people who do not respond well to other medications;

24. It is generally prescribed in combination with other drugs, such as methotrexate, the whole as it appears from a Healthcare Professional Communication, dated December 2, 2019, produced as **Exhibit P-3**;

25. Xeljanz is currently available as 5 mg and 10 mg tablets;

26. Xeljanz XR is currently available as 11 mg extended-release tablets;

27. Xeljanz Products are a Janus Kinase ("**JAK**") inhibitors;

28. JAK is a type of enzyme which helps start the immune response in the body. Xeljanz Products are believed to interfere with the activity of the JAK enzyme to reduce the immune response. This helps reduce signs and symptoms of rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis;

29. Pfizer Canada (then known as "Pfizer Canada Inc.") was the original sponsor of the drug in Canada;

30. Pfizer Canada became the market authorization holder (i.e., held the Notice of Compliance for Xeljanz) on April 17, 2014, the whole as it appears from the product information, produced as **Exhibit P-4**;

31. On June 3, 2014, following Health Canada approval, Pfizer Canada first marketed and sold Xeljanz (5 mg) tablets in Canada, the whole as it appears from the product information, produced as **Exhibit P-5**;

32. On March 29, 2018, following Health Canada approval, Pfizer Canada first marketed and sold Xeljanz XR (11 mg) extended-release tablets in Canada, the whole as it appears from the product information, produced as **Exhibit P-6**;

33. On January 30, 2019, Pfizer Canada first marketed Xeljanz (10 mg) tablets in Canada, the whole as it appears from the product information, produced as **Exhibit P-7**;

34. As it appears from P-7, the name of the market authorization holder for Xeljanz (i.e., holder of the Notice of Compliance for Xeljanz) was updated to "Pfizer Canada ULC" to reflect Pfizer Canada's name change;

35. Xeljanz Products have been approved by Health Canada in 2014 for the treatment of rheumatoid arthritis and in 2018 for the treatment of adult patients with moderately to severely active ulcerative colitis and the treatment of adult patients with active psoriatic arthritis, the whole as it appears from the defendants press released dated September 10th, 2018, produced as **Exhibit P-8**;

36. Six product monographs dated respectively December 11, 2017, September 11, 2018, February 4, 2019. July 2, 2019, October 24, 2019, and December 9, 2021, have been prepared by the defendants for Xeljanz Products, the whole as it appears from these product monographs, produced *en liasse* as **Exhibit P-9**;

37. The number of prescriptions filled for Xeljanz Products in Canada has been increasing from about 11,000 to 65,000 in Canadian retail pharmacies between 2016 and 2020, the whole as it appears from Health Canada' summary safety review, produced as **Exhibit P-10**;

II. MANUFACTURERS LIABILITY (sections 1468, 1469 and 1473 *C.C.Q.*)

A. BREACH OF THE DUTY OF SAFETY

38. The defendants have breached their duty of safety with respect to Xeljanz Products;

39. A link between the use of Xeljanz Products and increased risks of heart related problems and cancer has been found;

40. On February 25, 2019, the U.S. Food and Drug Administration ("**FDA**") issued a safety announcement alerting the public that recent analysis of an ongoing clinical trial by Pfizer found an increased risk of blood clots in the lungs and deaths in certain rheumatoid arthritis patients prescribed higher doses of Xeljanz. The alert stated that, when FDA first approved tofacitinib in 2012, the FDA required a clinical trial among patients with rheumatoid arthritis to evaluate the risk of heart-related events, cancer, and opportunistic infections, that patients in the trial were required to be at least 50 years old and have at least one cardiovascular risk factor, and that the trial would continue and was expected

to be completed by the end of 2019, the whole as it appears from this safety announcement, produced as **Exhibit P-11**;

41. On March 15, 2019, Health Canada issued an information update that it would be conducting a safety review after an ongoing clinical trial run by the defendants, designed specifically to assess the risk of cardiovascular events, cancer and opportunistic infections in rheumatoid arthritis, found an increased risk of blood clots in the lungs and of death when Xeljanz is taken at a high dose of 10 mg, twice per day, the whole as it appears from this information update, produced as **Exhibit P-12**;

42. On July 26, 2019, the FDA issued a safety announcement alerting the public to new warnings for Xeljanz about an increased risk of blood clots and of death with a 10 mg twice daily dose. The alert stated that the changes to the warnings were approved by the FDA after reviewing interim data from the safety clinical trial of tofacitinib in patients with rheumatoid arthritis to evaluate the risk of heart-related events, cancer, and infections, and that the trial was ongoing, the whole as it appears from this safety announcement, produced as **Exhibit P-13**;

43. On December 2, 2019, Health Canada issued a letter to Healthcare Professionals to advise of an increased incidence of thrombosis in patients treated with Xeljanz observed in the large, ongoing post-marketing study and of an update to the Canadian product monograph for Xeljanz regarding the risk of thrombosis, the whole as it appears from this letter, produced as **Exhibit P-14**;

44. Following the safety concerns of thrombosis, the defendants updated the Xeljanz Products Monographs;

45. The increased risk of thrombosis has been included in the Serious Warnings and Precautions Box of the product monographs, the whole as it appears from P-9 (product monographs dated October 24, 2019);

46. Although Pfizer's post-market clinical trial of Xeljanz Products' users had been ongoing since 2012 and had been designed specifically to evaluated risks of heart-related events and cancer, and although results from the trial were reported to the public as early as February 2019, prior to February 2021, no government-issued warnings were made to the public or to health professionals about any findings from the trial concerning possible risks of serious heart-related problems, such as heart attacks and strokes, or cancers associated with the use of Xeljanz Products;

47. On February 4, 2021, the FDA issued a drug safety communication to alert the public that preliminary results from the safety clinical trial conducted by Pfizer, to evaluate the risk of serious heart-related events, cancer, and infections, showed an increased risk of serious heart-related problems and cancer with Xeljanz Products;

48. The alert stated that the clinical trial was now complete and initial results show a higher occurrence of serious heart-related events and cancer in rheumatoid arthritis patients treated with tofacitinib compared to patients treated with a tumor necrosis factor (TNF) inhibitor, and the FDA was awaiting additional results from the trial, the whole as it appears from this letter, produced as **Exhibit P-15**;

49. On April 6, 2021, Health Canada informed that it was conducting another safety review of Xeljanz Products after the post-authorization clinical trial conducted by Pfizer identified an increased risk of serious heart-related issues and cancer in trial participants, the whole as it appears from an information update, produced as **Exhibit P-16**;

50. On September 1, 2021, the FDA issued a drug safety communication to announce that it would be requiring changes to the Boxed Warning on Xeljanz Products and other JAK inhibitors to include the risk of serious heart-related events, cancer, blood clots, and death, following review of a clinical trial of Xeljanz Products, the whole as it appears from the drug safety communication, produced as **Exhibit P-17**;

51. The alert stated that the FDA's review of the final trial results of Pfizer safety clinical trial of patients with rheumatoid arthritis showed a higher rate of serious heart-related events such as heart attack and stroke, cancer, blood clots, and death in patients treated with high or low doses of Xeljanz compared to those treated with TNF blockers;

52. On January 12, 2022, Health Canada issued an information update to advise that it had completed a safety review of Xeljanz and that the review confirmed a link between the use of Xeljanz Products and the increased risks of serious heart-related problems and cancer, especially in older patients, patients who are current or past smokers, and patients with cardiovascular or cancer risk factors, the whole as it appears from P-16;

53. Health Canada's review also found that all patients treated with Xeljanz 10 mg twice daily had a higher risk of death, blood clots and serious infections, compared to patients treated with Xeljanz 5 mg twice daily or tumour necrosis factor inhibitors;

54. The recent Health Canada advisory was prompted by the results of the post-authorization study conducted by the Defendants, the whole as it appears from a study named *Cardiovascular and Cancer Risk with Tofacitinib in Rheumatoid Arthritis*, produced as **Exhibit P-18**;

55. This study is discussed briefly in the most recent product monograph, dated December 9, 2021 (P-9);

56. The study reveals incidence rates and hazard ratios for various adverse effects, between participants taking Xeljanz 5 mg BID, Xeljanz 10 mg BID (reduced to 5 mg BID partway through study), and those taking TNF inhibitors (TNFi);

57. According to the researchers, incidences of major adverse cardiovascular events and cancer were higher among the combined tofacitinib dose groups — at 3.4% and 4.2%, respectively — compared with the TNF inhibitor arm — 2.5% and 2.9%, respectively. Hazard ratios were 1.33 (95% CI, 0.91-1.94) for major adverse cardiovascular events and 1.48 (95% CI, 1.04-2.09) for cancers, meaning tofacitinib failed to show noninferiority with TNF inhibitors, the whole as it appears from an article published on January 26, 2022 entitled *Tofacitinib linked to higher cardiovascular, cancer risks than TNF inhibitors in RA*, produced as **Exhibit P-19**;

58. Prior to December 2021, the product monograph, as well as the label and prescribing information that accompanied Xeljanz Products when prescribed to patients, did not provide sufficient warnings for patients and healthcare professionals related to increased risks of serious heart-related problems and cancer;

59. Changes to the relevant sections of the product monograph were minimal between those dated December 11, 2017, through July 2, 2019, the whole as it appears from P-9;

60. The current monograph, dated December 9, 2021 (P-9), changed significantly from the previous ones:

- A warning for major adverse cardiovascular events was added;
- The sections on malignancy were greatly expanded;
- The population-specific warning section for geriatric patients was amended to warn of increased risks of all-cause mortality, cardiovascular events, malignancies, and thromboembolism, among other additional warnings;

61. Also, the defendants' *Patient Medication Information* has been updated to add the following warnings:

- Lymphoma, lung cancer, and other cancers have been reported in patients treated with Xeljanz Products;
- Blood clots in the veins (deep vein thrombosis, DVT), arteries (arterial thrombosis) or lungs (pulmonary embolism, PE) can happen in some people taking Xeljanz Products;
- Major heart problems have been reported in Rheumatoid Arthritis patients treated with Xeljanz Products;

the whole as it appears from **Exhibit P-20**;

62. To illustrate the changes between the product monographs, a comparison document has been prepared and is produced as **Exhibit P-21**;

B. CAUSAL LINK

63. There is a presumption of liability of the defendants as manufacturers, since prior to December 9, 2021, no sufficient indication was provided as to the increased risks of serious heart-related issues and cancer associated with the use of Xeljanz Products or as to the means of preventing these increased risks;

64. Considering the above, there is a causal link because the harm suffered by the applicant Denise and class members constitutes the concrete materialization of the danger;

III. CIVIL LIABILITY (section 1457 *C.C.Q.*)

A. DEFENDANTS' FAULT

65. In any event, and without limiting the foregoing, the defendants' conduct constitutes a fault engaging their civil liability under section 1457 *C.C.Q.*;

66. Ultimately, hundreds of patients, including the applicant Denise, have been placed at risk and harmed because of the conduct of the defendants, as well as their families;

67. The defendants did not undertake sufficient studies and testing to determine whether Xeljanz Products were safe for those who used it;

68. The defendants developed, manufactured, licensed, packaged, labelled, marketed, promoted, distributed, and sold the Xeljanz Products without thorough and adequate pre- and post-market research and testing;

69. The defendants have not adequately tested Xeljanz Products in a manner that fully reveals the magnitude of the increased risks associated with their use;

B. CAUSAL LINK

70. The damages suffered by the applicants and class members, that they continue to suffer, are a direct and immediate consequence of the above;

71. The extent of the increased risks involved was not known and could not have been known by the applicants and class members;

72. The damages suffered by the applicants and class members, that they continue to suffer, would not have occurred but for the defendants' misconduct;

IV. DAMAGES

i) *Damages of the applicant Denise and members of subgroup 1*

73. The damages suffered by the applicant Denise and the members of subgroup 1, that they continue to suffer, constitute the concrete materialization of the danger related to Xeljanz Products;

74. As previously mentioned, a link between use of Xeljanz Products and increased risks of heart related problems and cancer has been found;

75. Considering that, the applicant Denise, and the members of subgroup 1 are therefore repeatedly harmed, which harm will have an impact for the rest of their lives;

76. As a result of the foregoing, the applicant Denise, and the members of subgroup 1 have suffered and continue to suffer serious bodily, moral, and material damages for which they are entitled to be compensated, given their diagnosis and all that this implies, such as suffering, pain, inconvenience, stress, anguish, loss of enjoyment of life, loss of self-esteem, but also for loss of income, expenses, and loss of time, etc.;

ii) *Damages of the applicant Roy and members of subgroup 2*

77. Applicant Roy and the members of subgroup 2 have been harmed by having a family member or a loved one with a diagnosis of heart-disease or cancer;

78. Applicant Roy and the members of subgroup 2 have suffered and continue to suffer serious moral and material damages for which they are entitled to be compensated, as inconvenience, stress, anguish, loss of enjoyment of life and loss of consortium, but also for loss of income, expenses, and loss of time, etc.;

V. FACTS GIVING RISE TO THE APPLICANTS CLAIMS

i) *Applicant Denise*

79. The applicant Denise is an individual residing [redacted];

80. In or around November 2020, the applicant Denise was prescribed and began taking Xeljanz XR to treat her rheumatoid arthritis, as it appears from her medical and pharmaceutical records, produced as **Exhibit P-22 (under sealed)**;

81. She continued to be prescribed and ingested Xeljanz XR until in or around May 2021. During the time of her Xeljanz XR use, she turned 60 years old;

82. After starting her regular prescriptions for Xeljanz XR, she began to experience concerning signs and symptoms;

83. In or around April 2021, she underwent a biopsy of sample cells and/or tissue and was diagnosed with a form of carcinoma (i.e., cancer), the whole as it appears from P-22 (under sealed);

84. In or around May 2021, her rheumatologist advised her to stop taking Xeljanz XR while undergoing cancer treatments;

85. In or around July 2021, she underwent surgery to remove cancerous tissue, which required her to make an overnight, out-of-town stay, and which resulted in permanent scarring, the whole as it appears from P-22;

86. In or around September 2021, she made three trips to hospitals, including one out-of-town, to address healing complications that had arisen from the surgery;

87. In or around October 2021, the applicant Denise began a five-week program of radiation treatments, totaling 25 sessions, and subsequent to the treatments she was prescribed a hormone drug that she will be required to take on an ongoing basis for the next 10 years, the whole as it appears from P-22;

88. As a result of her use of the defendants' Xeljanz Products and their acts and omissions, Denise has suffered from severe bodily injuries, including cancer, and emotional damages;

89. She has been advised that she will require ongoing care and treatment. She continues to experience ongoing issues and impairments related to her cancer that impact her activities of daily living, including severe, ongoing pain; insomnia; difficulties tending to her personal care and hygiene; mobility issues; recurrent severe fear and anxiety; and

diminished abilities to care for her adult daughter who has Williams Syndrome, a developmental disorder that causes her mental delays, physical limitations, and serious medical issues concerning her cardiovascular health, and for whom she is the primary caregiver;

90. Prior to the use of Xeljanz Products, she received no warnings about the increased risks associated with their use;

91. She did not know the nature and extent of the harms that could result from the anticipated and reasonably foreseeable use of Xeljanz Products. Otherwise, she would not have started using it;

92. As a result of the foregoing, she is entitled to compensation for the bodily, moral, and material damages suffered and which she continues to suffer to this day;

ii) *Applicant Roy*

93. Applicant Roy [redacted] of the applicant Denise. Denise and Roy have [redacted]

94. Because of [redacted] cancer, he has suffered harms such as stress, fear of losing [redacted] and he worries about [redacted] short- and long-term health;

95. Since the diagnosis, he continues to experience anxiety about the evolution of [redacted] condition;

96. In addition, [redacted] illness greatly affects his way of life and his projects;

97. In fact, he must assume many more household tasks because of the condition of [redacted] as well as handle more personal support tasks for [redacted] with Williams Syndrome;

98. Also, he must now ask for help from certain members of her family to carry out tasks related to the maintenance of [redacted]r home or to care for [redacted] daughter;

99. As a result of the foregoing, he is entitled to claim compensation for the moral and material damages suffered and which he continues to suffer to this day;

VI. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH CLASS MEMBER

100. Each class member used Xeljanz Products and has afterwards been diagnosed with MACE and/or a cancer or is a close relative of such a class member;

101. None of the class members were adequately, sufficiently, and timely advised that the use of Xeljanz Products carried serious and irreversible increased risks of developing MACE and/or a cancer, as described above;

102. Each class member is entitled to make a claim for the bodily, moral and/or material damages suffered and that they continue to suffer;

VII. COMPOSITION OF THE CLASS

103. The composition of the class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings, with respect to section 575 (3) *C.C.P.*, for the following reasons:

(a) Applicants do not know the precise number of people who have used and/or use Xeljanz Products, which are spread across the country and/or province, and the number of their family members affected;

(b) Applicants do not and cannot know the identity of individuals who have used and/or use Xeljanz Products and has been diagnosed with a MACE and/or cancer since medical and pharmaceutical records are confidential, nor the identity of their affected family members;

(c) According to the Canada Vigilance Adverse Reaction Online Database, 160 cases of cancer and 850 case of cardiac disorders have been reported, the whole as it appears from the extracts of the Database, produced *en liasse* as **Exhibit P-23**;

(d) The names and addresses of persons who may be members of the class are unknown to the applicants;

(e) The facts alleged in the foregoing paragraphs make it difficult, if not impossible, to contact each class member to obtain a mandate or to proceed by way of joinder;

VIII. COMMON ISSUES

104. The identical, similar, or related questions of law or fact between each class member and the defendants and which the applicants seek to have decided by the class action are:

(a) Does the use of Xeljanz Products cause a danger, namely an increased risks of major adverse cardiovascular events (MACE) and cancer for people who have used it and/or use it?

(b) If the answer to this question is yes, did the defendants fail to adequately, sufficiently, and timely inform class members of this danger?

(c) Can class members rely on the presumption of product liability to establish the causal link?

(d) Did the defendants know, or should they have known that there were increased risks of MACE and cancer associated with Xeljanz Products?

(e) Did the defendants otherwise commit any wrongful doing that gives rise to civil liability including:

- By failing to conduct adequate testing and studies both before and after the introduction of Xeljanz Products to the Canadian market?
- By failing to test adequately Xeljanz Products in a manner that fully reveals the magnitude of the risks of MACE and cancer associated with their use?

(f) Are class members entitled to claim damages for bodily, moral, and material damages?

IX. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

105. The remedy that the applicants seek to pursue for the benefit of the class members is a class action in damages, based on product liability;

106. The conclusions sought by the applicants against the defendants are as follows:

GRANT the action;

CONDEMN the defendants jointly and severally to pay to class members an amount to be determined in compensation for the bodily, moral and/or material damages suffered and which they will continue to suffer;

ORDER the processing of individual claims by class members pursuant to sections 599 to 601 *C.C.P.* unless evidence on the merits makes it possible to order collective recovery;

CONDEMN the defendants to pay the costs incurred for any investigation necessary to establish its liability in this case, including the extrajudicial fees of the lawyers and out-of-court disbursements;

CONDEMN the defendants to pay to class members the costs of distributing the funds to class members;

THE WHOLE with legal costs and additional indemnity pursuant to section 1619 *C.C.Q.*, including all costs for expert fees and publication of notices to class members;

107. The applicants suggest that this class action take place before the Superior Court of Justice in the district of Montréal:

(a) The defendant Pfizer Canada has its principal place of business in Kirkland, Québec, in the judicial district of Montréal;

(b) Many class members reside, more generally, in the Montréal division;

108. The applicants, who seek to obtain the status of representative, can adequately represent the class members, for the following reasons:

(a) The applicant Denise used Xeljanz Products;

(b) The applicant Denise received a cancer diagnosis and her and her husband suffer the consequences;

(c) The applicant Denise has contacted the undersigned counsel and has offered to act as a representative in this class action to assist people similarly situated to herself and applicant Roy has subsequently agreed to act as a representative of the members of subgroup 2; and

(d) They understand the nature of the action;

(e) They are available to dedicate the necessary time for the action and to collaborate with class members;

(f) They do not have any conflict of interests with the other class members on the common issues;

109. The present application is well-founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present *Application for authorization to Institute a class action and to obtain the status of representatives*;

AUTHORIZE the institution of a class action as an originating application in damages;

GRANT the applicants' representative status for persons in the following class:

Subgroup 1 :
Any individual in Canada who has been diagnosed with a major adverse cardiovascular event ("MACE"), which is the composite of total death, myocardial infarction, coronary revascularization, stroke, and hospitalization because of heart failure, and/or a cancer after having used the drugs Xeljanz and/or Xeljanz XR ("tofacitinib");

and

Subgroup 2:
Any individual in Canada who suffers or has suffered harm because of the diagnosis of MACE and/or cancer received by a subgroup 1 individual, including his or her spouse, parent, children, and siblings.

OR, AS A SUBSIDIARY:

Subgroup 1:
Any individual in Québec who has been diagnosed with a major adverse cardiovascular event ("MACE"), which is the composite of total death, myocardial infarction, coronary revascularization, stroke, and hospitalization because of heart failure, and/or a cancer after having used the drugs Xeljanz and/or Xeljanz XR ("tofacitinib");

and

Subgroup 2:
Any individual in Canada who suffers or has suffered harm because of the diagnosis of MACE and/or cancer received by a subgroup 1 individual, including his or her spouse, parent, children, and siblings.

or any other class to be determined by the Court.

IDENTIFY the identical, similar, or related questions of law to be treated collectively in the class action to be instituted as follows:

(a) Does the use of Xeljanz Products cause a danger, namely an increased risks of major adverse cardiovascular events (MACE) and cancer for people who have used it and/or use it?

(b) If the answer to this question is yes, did the defendants fail to adequately, sufficiently, and timely inform class members of this danger?

(c) Can class members rely on the presumption of product liability to establish the causal link?

(d) Did the defendants know, or should they have known that there were increased risks of MACE and cancer associated with Xeljanz Products?

(e) Did the defendants otherwise commit any wrongful doing that give rise to civil liability including:

- By failing to conduct adequate testing and studies both before and after the introduction of Xeljanz Products to the Canadian market?
- By failing to test adequately Xeljanz Products in a manner that fully reveals the magnitude of the risks of MACE and cancer associated with their use?

(f) Are class members entitled to claim damages for bodily, moral, and material damages?

IDENTIFY the conclusions sought from the class action to be instituted as follows:

GRANT the action;

CONDEMN the defendants jointly and severally to pay to class members an amount to be determined in compensation for the bodily, moral and/or material damages suffered and which they will continue to suffer;

ORDER the processing of individual claims by class members pursuant to sections 599 to 601 *C.C.P.* unless evidence on the merits makes it possible to order collective recovery;

CONDEMN the defendants to pay the costs incurred for any investigation necessary to establish its liability in this case, including the extrajudicial fees of the lawyers and out-of-court disbursements;

CONDEMN the defendants to pay to class members the costs of distributing the funds to class members;

THE WHOLE with legal costs and additional indemnity pursuant to section 1619 *C.C.Q.*, including all costs for expert fees and publication of notices to class members;

DECLARE that all class members that have not requested their exclusion from the class in the prescribed delay will be bound by any judgement to be rendered on the class action to be instituted;

FIX the delay of exclusion at 60 days from the date of the publication of the notice to class members;

ORDER the publication of a notice to class members pursuant to section 591 *C.C.P.* in a manner to be determined;

THE WHOLE with costs.

Québec, March 9, 2022

Siskinds Desmeules

SISKINDS DESMEULES AVOCATS
Me Caroline Perrault and Me Erika Provencher
caroline.perrault@siskinds.com
erika.provencher@siskinds.com
Lawyers of the applicants

43, rue de Buade, bureau 320
Québec (Québec) G1R 4A2
Téléphone : 418-694-2009
Télécopieur : 418-694-0281
Notification : notification@siskinds.com

SUMMONS
(articles 145 and following
C.C.P.)

Filing of a judicial application

Take notice that the applicants have filed this *Application for authorization to institute a class action and to obtain the status of representatives* in the office of the Superior Court of Québec in the judicial district of Montréal.

Exhibits supporting the application

In support of the *Application for authorization to institute a class action and to obtain the status of representatives*, the applicants intend to use the following exhibits :

EXHIBIT P-1: *État des renseignements d'une personne morale au registre des entreprises* (Pfizer Canada ULC);

EXHIBIT P-2: Canadian trademark for Xeljanz;

EXHIBIT P-3: Healthcare Professional Communication dated December 2nd, 2019;

EXHIBIT P-4: Xeljanz Product information, dated April 17, 2014;

EXHIBIT P-5: Xeljanz Product information (5 mg);

EXHIBIT P-6: Xeljanz Product information (11 mg);

EXHIBIT P-7: Xeljanz Product information (10 mg);

EXHIBIT P-8: Defendants press release dated September 10th, 2018;

EXHIBIT P-9: Product monographs for Xeljanz *(en liasse)*;

EXHIBIT P-10: Health Canada' Summary Safety Review;

EXHIBIT P-11: FDA' Safety Announcement dated February 25, 2019;

EXHIBIT P-12: Health Canada's Information Update dated March 15th, 2019;

EXHIBIT P-13: FDA's Safety Announcement dated July 26th, 2019;

EXHIBIT P-14: Health Canada's letter to Healthcare Professionnals dated December 2nd, 2019;

EXHIBIT P-15: FDA's Drug Safety Communication dated February 4, 2021;

EXHIBIT P-16: Health Canada's Information Update dated April 6th, 2021 and January 12th, 2022;

EXHIBIT P-17: FDA's Drug Safety Communication dated September 1st, 2021;

EXHIBIT P-18: Steven R. Ytterberg, M.D. and als. : *Cardiovascular and Cancer Risk with Tofacitinib in Rheumatoid Arthritis* dated January 27, 2022;

EXHIBIT P-19: Jason Laday : *Tofacitinib linked to higher cardiovascular, cancer risks than TNF inhibitors in RA* dated January 26, 2022;

EXHIBIT P-20: Defendants' Patient Medication Information;

EXHIBIT P-21: Comparison document to illustrate the changes between Xeljanz product monographs;

EXHIBIT P-22: Applicants' medical and pharmaceutical records (under sealed);

EXHIBIT P-23: Extracts of the Canada Vigilance Adverse Reaction Online Database *(en liasse)*.

Defendants' answers

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montréal, situated at 1, Notre Dame E, Montréal, QC, H2Y 1B6, within 15 days of service of this application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the applicants' lawyers or, if the applicants are not represented, to the applicants.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgementmay be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the cases required by the Code, cooperate with the applicants in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of this summons. However, in family matters or if you have no domicile, residence or establishment in Québec, it must be filed within 3 months after service; or

- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Where to file the judicial application

Unless otherwise provided, the judicial application is heard in the judicial district where your domicile is located, or failing that, where your residence or the domicile you elected or agreed to with plaintiff is located. If it was not filed in the district where it can be heard and you want it to be transferred there, you may file an application to that effect with the court.

However, if the application pertains to an employment, consumer or insurance contract or to the exercise of a hypothecary right on the immovable serving as your main residence, it is heard in the district where the employee's, consumer's or insured's domicile or residence is located, whether that person is the plaintiff or the defendant, in the district where the immovable is located or, in the case of property insurance, in the district wherethe loss occurred. If it was not filed in the district where it can be heard and you want it to be transferred there, you may file an application to that effect with the special clerk of thatdistrict and no contrary agreement may be urged against you.

Transfer of application to the Small Claims Division

If you qualify to act as an applicant under the rules governing the recovery of small claims, you may contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Convening a case management conference

Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing that, the protocol is presumed to be accepted.

Notice of presentation of an application

Applications filed in the course of a proceeding and applications under Book III or V of the Code—but excluding applications pertaining to family matters under article 409 and applications pertaining to securities under article 480—as well as certain applications under Book VI of the Code, including applications for judicial review, must be accompanied by a notice of presentation, not by a summons. In such circumstances, the establishment of a case protocol is not required.

Québec, March 9, 2022

SiskInds Desmeules

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caroline.perrault@siskinds.com
erika.provencher@siskinds.com
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C A N A D A
PROVINCE DE QUÉBEC
DISTRICT DE MONTRÉAL

COUR SUPÉRIEURE
(Chambre des actions collectives)

NO : 500-06-001179-221

DENISE APPLETON

and

ROY APPLETON

Applicants

v.

PFIZER CANADA ULC/PFIZER CANADA SRI

et als.

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVES (Sections 571 *C.C.P.* and following)

BB-6852 **Casier 15**
Me Caroline Perrault **N/D : 67-262**

SISKINDS DESMEULES | Avocats s.e.n.c.r.l.
43, rue de Buade, bureau 320, Québec (Québec) G1R 4A2
TÉLÉPHONE 418-694-2009 (Sans frais 1-877-735-3842)
TÉLÉCOPIEUR 418-694-0281
NOTIFICATION notification@siskinds.com
SISKINDS.com/qc