Court File No. VLC-S-S-230605

No._____
Vancouver Registry

In the Supreme Court of British Columbia

Between

LOUISE REES

Plaintiff

and

PFIZER INC., PFIZER CANADA ULC / PFIZER CANADA SRI,
and P.F. PRISM C.V.

Defendants

Brought under the *Class Proceedings Act*, RSBC 1996, c 50

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiff for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim on the plaintiff.

If you intend to make a counterclaim, you or your lawyer must

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUNCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiff,

(a) if you were served with the notice of civil claim anywhere in Canada, within 21 days after that service,

(b) if you were served with the notice of civil claim anywhere in the United States of America, within 35 days after that service,

(c) if you were served with the notice of civil claim anywhere else, within 49 days after that service, or

(d) if the time for response to civil claim has been set by order of the court, within that time.

CLAIM OF THE PLAINTIFF

PART 1: STATEMENT OF FACTS

A. Nature of the Action

1. This is a proposed class proceeding for damages arising from the drug Xeljanz (tofacitinib), prescription medication used to treat rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis. This action arises from 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 Xeljanz Products (as described herein) while they knew, or ought to have known, the drugs were defective and/or there were significant risks that should have been disclosed to the medical community and the public in general.

2. During the relevant times that the Defendants labelled, warned, marketed, distributed, and sold Xeljanz Products, the Defendants failed to warn consumers adequately, or at all, of significant risks of dangerous side effects linked to the use of Xeljanz Products, including serious heart-related problems (such as heart attack and stroke), cancer, blood clots, fractures, and death, as well as an increased risk of several of these side effects in specific populations, including in older patients, in women, in patients who are or were smokers, and in patients with cardiovascular or cancer risk factors. Ultimately, hundreds of patients, including the Plaintiff, have been placed at risk and harmed as a result of the conduct of the Defendants.

3. The Defendants misrepresented that their Xeljanz Products are safe, when in fact these medications cause serious Injuries, Conditions, and Complications (as defined herein). Patients who were prescribed and/or ingested Xeljanz Products were misled as to the drug's safety and efficacy, and as a result have suffered serious Injuries, Conditions, and Complications.

B. The Parties

i. The Plaintiff

4. The Plaintiff, Louise Rees, resides in Victoria, British Columbia and was born in September 1944.

5. In or around September 2019, the Plaintiff was prescribed and began taking Xeljanz to treat her psoriatic arthritis. The Plaintiff continued to be prescribed and ingest Xeljanz until in or around January 2020. During the time of her Xeljanz use, the Plaintiff was 75 years old.

6. Prior to her Xeljanz use, the Plaintiff had a pre-existing heart condition, sinus tachycardia - a type of heartbeat that is characterized by a faster than normal heart rhythm, and issues with unstable angina. The Plaintiff was also a breast cancer survivor, having been diagnosed and having undergone a mastectomy in or around 2009.

7. Subsequent to starting her regular prescriptions for Xeljanz, the Plaintiff experienced concerning signs and symptoms, including multiple angina attacks that have resulted in hospital admissions and have worsened over time.

8. The Plaintiff brings this action on her own behalf and on behalf a class of persons in Canada who are similarly situated, to be further defined on the application for certification (the "Class").

ii. The Defendants

9. The Defendant, Pfizer Inc., is a corporation incorporated pursuant to the laws of Delaware and having a place of business at 235 East 42nd Street, New York City, New York, United States. Pfizer Inc. authors, publishes, and maintains websites as sources of information regarding the safety and efficacy of Xeljanz Products that are used by consumers worldwide, including in Canada. All references in this Notice of Civil Claim to Pfizer Inc. include all of its predecessor corporations.

10. The Defendant, Pfizer Canada ULC / Pfizer Canada SRI ("Pfizer Canada"), is a corporation incorporated pursuant to the laws of British Columbia, with a registered office location in Vancouver, BC. Pfizer Canada designed, developed, tested, researched, manufactured, marketed, supplied, distributed, and/or sold Xeljanz

Products in Canada. 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. 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. All references in this Notice of Civil Claim to Pfizer Canada include all of its predecessor corporations, including, without limitation, Pfizer Canada Inc., and all of their divisions.

11. Pfizer Canada is a wholly owned subsidiary of Pfizer Inc. At times relevant to this action, Pfizer Inc. had responsibility for the operations of Pfizer Canada.

12. The Defendant, PF PRISM C.V. ("PF Prism"), is a limited partnership (commanditaire vennootschap) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. PF Prism has held the Canadian trademark to "Xeljanz" during the times relevant to this proceeding. All references in this Notice of Civil Claim to PF Prism include all of its predecessor corporations.

13. PF Prism is a wholly owned subsidiary of Pfizer Inc. At times relevant to this action, Pfizer Inc. had responsibility for the operations of PF Prism.

14. Hereinafter, each of the above Defendants shall be collectively referred to as the "Defendants" or "Pfizer".

15. 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, Xeljanz Products in Canada. 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.

16. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Xeljanz Products in Canada. The development of Xeljanz 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 Xeljanz Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in British Columbia and elsewhere.

C. The Defendants' Xeljanz Products

17. "Xeljanz Products" are drug products having the anatomical therapeutic chemical "tofacitinib" (aka "tofacitinib citrate") as their active pharmaceutical ingredient, which were marketed, sold and/or otherwise distributed in Canada by the Defendants under the brand name "Xeljanz", including Xeljanz (5 mg and 10 mg) and Xeljanz XR (11 mg).

18. Xeljanz Products are used to treat certain serious, chronic, and progressive inflammatory conditions. Xeljanz Products are approved to be used to treat rheumatoid arthritis (RA), a condition in which the body attacks its own joints, causing pain, swelling, joint damage, and loss of function. Xeljanz Products are also approved to treat psoriatic arthritis, a condition that causes joint pain and swelling, and ulcerative colitis, which is a chronic, inflammatory disease affecting the colon. Xeljanz Products work by decreasing the activity of the immune system; an overactive immune system contributes to RA, psoriatic arthritis, ulcerative colitis, and polyarticular course juvenile idiopathic arthritis.

19. Xeljanz Products are in the class of medications known as janus kinase (JAK) inhibitors. JAKs are a family of enzymes involved in the initiation of the immune response and are crucial to the development of immune cells. Tofacitinib, the active ingredient of Xeljanz Products, inhibits the activity of JAK enzymes and reduces the inflammatory immune response, thereby reducing signs and symptoms of rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis.

20. Xeljanz (tofacitinib) was developed by Pfizer Inc. and was first approved for use by the FDA in the United States in 2012 to treat rheumatoid arthritis.

21. Pfizer Canada (then known as "Pfizer Canada Inc.") was the original sponsor of the drug in Canada. Pfizer Canada became the market authorization holder (i.e., held the Notice of Compliance for Xeljanz) on April 17, 2014.

22. On June 3, 2014, following Health Canada approval, Pfizer Canada first marketed and sold Xeljanz (5 mg) tablets in Canada.

23. On March 29, 2018, following Health Canada approval, Pfizer Canada first marketed and sold Xeljanz XR (11 mg) extended-release tablets in Canada.

24. On January 30, 2019, Pfizer Canada first marketed and sold Xeljanz (10 mg) tablets in Canada.

25. On February 4, 2019, 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

26. 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

27. There were about 100,000 prescriptions for Xeljanz Products dispensed in Canada from 2014 to 2019. The number of prescriptions filled for Xeljanz Products in Canada has been increasing over time from about 11,000 to 65,000 annually in Canadian retail pharmacies between 2016 and 2020. As the prevalence and incidence of diagnosed rheumatoid arthritis generally increase with age, with the condition most prevalent in older Canadians (over 3% of people aged 70-79 and over 4% of people aged 80 or over), users of Xeljanz Products are statistically much more likely to be older patients.

28. During the period of time that the Defendants' Xeljanz Products have been approved for use in Canada, there have existed safer and economically feasible alternative treatment options in Canada for rheumatoid arthritis, psoriatic arthritis,

and ulcerative colitis, which can be used in lieu of Xeljanz Products, including, but not limited to, other pharmaceutical options, such as disease-modifying anti-rheumatic drugs, steroid pills, corticosteroid injections, non-steroidal anti-inflammatory drugs, and analgesics, as well as non-pharmaceutical options, such as heat and cold therapy, physiotherapy, occupational therapy, exercise, and diet.

D. Risks of Serious Injuries, Conditions, and Complications

29. The ingestion of Xeljanz Products, drugs which disrupt the human body's natural cell growth and immune response, can lead to serious adverse side effects with significant consequences, such as the development of malignant tissues (i.e., cancers), myocardial infarctions (i.e., heart attacks), thrombosis (i.e., blood clots), fractures (i.e., broken bones), and death, including especially in certain special populations.

30. At all material times, the Defendants knew or ought to have known that Xeljanz Products could cause major adverse cardiovascular events (MACE), including myocardial infarction (heart attack) and stroke, cancers, including lymphomas, lung cancer, breast cancer, colorectal cancer, gastric cancer, melanoma, non melanoma skin cancer, prostate cancer, pancreatic cancer and renal cell carcinoma, Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis, fractures, including osteoporotic fractures, and death (i.e. all-cause mortality), as well as associated injuries, conditions, complications, and symptoms, including, but not limited to, for myocardial infarction: pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin,

sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat; for lung cancer: worsening cough, shortness of breath, chest pain, loss of appetite, coughing up blood, fatigue, unexplained weight loss; for lymphomas: painless swelling of lymph node, swollen tonsils, fever, chills, night sweats, feeling tired, itching, unexplained weight loss, lesions, loss of appetite, persistent coughing, difficulty breathing or not being able to breathe, headache; for skin cancer: lesions during or after therapy or if existing lesions change appearance; for deep vein thrombosis: swelling, pain or tenderness in the leg; for pulmonary embolism: sharp chest pain, coughing up blood, sudden shortness of breath; and for fractures: broken bones (collectively "Injuries, Conditions, and Complications").

31. At all material times, the Defendants knew or ought to have known that specific special populations who were users of Xeljanz Products, including, in particular, older patients (aged 65 years and older), current or past smokers, patients with cardiovascular or cancer risk factors, and female patients, were at an increased or specific risk of Injuries, Conditions, and Complications, including, but not limited to, the risk of serious infections, all-cause mortality, cardiovascular events, malignancies, non-melanoma skin cancer, gastrointestinal perforations, interstitial lung disease, venous thromboembolism, and arterial thromboembolis, being higher for older patients, the risk of major adverse cardiovascular events being higher for current or past smokers, the risk of thrombosis, malignancies, and major adverse cardiovascular events being higher for patients with cardiovascular risk factors, the risk of malignancies being higher for patients with cancer risk factors, and the risk of broken bones being higher for women.

E. Adverse Event Reports and Regulatory Action

32. The increased risk of Injuries, Conditions, and Complications which have been linked with use of Xeljanz Products, including the elevated risks in certain cohorts of patients, have been the subject of thousands of adverse events reports filed to, multiple safety reviews undertaken by, and warning communications issued from Health Canada and the U.S. Food and Drug Administration ("FDA").

33. Health Canada's Canada Vigilance Adverse Reaction Online Database contains adverse reaction reports about suspected adverse reactions to health products, which are submitted by consumers and health professionals, as well as manufacturers and distributors (aka market authorization holders). The Canada Vigilance Adverse Reaction Online Database contains over 16,000 adverse reaction reports involving "Xeljanz" as a suspected product, filed to Health Canada through to the end of August 2021. Of these reports, over 8,000 were filed prior to February 25, 2019, before any regulatory announcements concerning Xeljanz Products had been issued by either Health Canada or the FDA.

34. On February 25, 2019, the FDA issued a public Drug Safety Communication and a press release from the director of the FDA's Center for Drug Evaluation and Research, altering patients and healthcare professionals 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. Although Pfizer's post-market clinical trial of Xeljanz Products had been ongoing since 2012, no warnings were made by the Defendants to the public or to health professionals about any findings concerning any possible risks of with the use of Xeljanz Products prior to the FDA's February 2019 announcement.

35. On March 15, 2019, Health Canada issued an information update that it would be conducting a safety review after the ongoing clinical trial run by the Defendants, which was 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.

36. On July 26, 2019, the FDA issued a public Drug Safety Communication and a Medical Product Safety Information bulletin, altering patients and healthcare professionals, alerting the public and the medical community 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.

37. 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.

38. On June 18, 2020, Health Canada issued a summary safety review decision regarding Xeljanz and Xeljanz XR (tofacitinib), assessing the potential risk of blood clots in the deep veins (venous thromboembolic events), which stated that Health Canada had concluded that there is a link between the risk of potentially life-threatening blood clots in the veins, known as venous thromboembolic events (VTE), and the use of Xeljanz (tofacitinib) and that Xeljanz/Xeljanz XR should be avoided in patients at increased risk of thrombosis, should be discontinued in patients with signs of thrombosis, and should be used at the lowest dose that works well and for the shortest duration in patients with ulcerative colitis.

39. On February 4, 2021, the FDA issued a public Drug Safety Communication and a Medical Product Safety Information bulletin, altering patients and healthcare professionals 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. 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.

40. On April 6, 2021, Health Canada informed the public 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.

41. On September 1, 2021, issued a public Drug Safety Communication and a Medical Product Safety Information bulletin, altering patients and healthcare professionals that the FDA 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 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.

42. On January 12, 2022, Health Canada issued a summary safety review decision regarding Xeljanz and Xeljanz XR (tofacitinib), assessing the potential risk of serious heart-related problems and cancer, which stated that Health Canada had found a link between the use of Xeljanz/Xeljanz XR and the risks of serious heart-related problems and cancer and these risks were increased especially in older patients, in patients who are current or past smokers, and in patients with cardiovascular or cancer risk factors.

43. On January 12, 2022, Health Canada also issued a public 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. 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.

44. On January 12, 2022, Health Canada also issued a letter to Healthcare Professionals to notify them of the findings of the summary safety review concerning Xeljanz use and increased risks of serious heart-related problems and cancer and to advise healthcare professionals to avoid Xeljanz in patients who may be at increased risk of thrombosis, use avoid Xeljanz with caution in older patients, especially geriatric patients (above 65 years of age), patients who are current or past smokers, and patients with other CV or malignancy risk factors, use avoid Xeljanz at the lowest effective dose and for the shortest duration needed to achieve/maintain therapeutic response in patients with ulcerative colitis (UC), and to closely monitor patients for signs and symptoms of infection during and after treatment with avoid Xeljanz.

45. The January 2022 Health Canada advisories were prompted by the results of the post-authorization study conducted by the Defendants, named *Cardiovascular and Cancer Risk with Tofacitinib in Rheumatoid Arthritis*. 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). 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.

46. On September 16, 2022, Health Canada issued a summary safety review decision regarding Xeljanz/Xeljanz XR (tofacitinib) and other JAK inhibitors, assessing the potential risks of serious heart-related problems, blood clots, cancer and death, which stated that Health Canada had reviewed the final findings of the post-authorization study, *Cardiovascular and Cancer Risk with Tofacitinib in Rheumatoid Arthritis*, and that the final findings linked Xeljanz/Xeljanz XR to higher risks of serious heart-related problems, cancer and death, and confirmed the initial findings of an increased risk of blood clots from 2019.

47. On October 31, 2022, Health Canada issued a public information update to notify consumers of the recent summary safety review decision, which advised that Health Canada had assessed and confirmed the risks of serious heart-related problems, fatal blood clots, and cancer with Xeljanz/Xeljanz XR and that the Canadian labelling for all JAK inhibitors was being updated to include the risks of serious heart-related problems, fatal blood clots and cancer.

48. On November 1, 2022, Health Canada also issued a letter to Healthcare Professionals to notify them of the recent summary safety review decision, which advised that the final results of a clinical trial conducted with Xeljanz showed higher risks of MACE, thrombosis, malignancy, serious infections and fatal events,

compared to TNFi, a group of medicines that suppress the body's natural response to tumor necrosis factor (TNF), in RA patients.

F. Changes to Product Warnings

49. As the sponsors of Xeljanz in Canada, the Defendants have at all material times been responsible for ensuring that health care professionals and consumers are fully and adequately warned of any foreseeable health risks and adverse side effects associated with Xeljanz ingestion. One means by which the Defendants must communicate such risks is through the product monograph for Xeljanz in Canada (the "Product Monograph"). The Product Monograph is a document containing information on the uses, dosages and risks associated with Xeljanz. "Part I" of the Product Monograph is directed at health care professionals in Canada. "Part III" of the Product Monograph is directed at consumers in Canada.

50. The Product Monograph is distributed by the Defendants directly and indirectly to health care professionals and individual patients in Canada. The Product Monograph is made available on Pfizer's Canadian website.

51. Despite all the available information regarding the Injuries, Conditions, and Complications linked to Xeljanz use, the Defendants were negligent and failed to adequately or appropriately change the label or product monograph in a timely manner or take adequate or appropriate steps to warn the medical community and users of the drug regarding these effects on vision for patients taking Xeljanz.

52. At times relevant to this action, the product monograph, as well as the label and prescribing information that accompanied Xeljanz when prescribed to patients, has

contained insufficient warnings related to risks of the Injuries, Conditions, and Complications, including malignancies (i.e. cancers), myocardial infarctions (i.e. heart attacks), thrombosis (i.e. blood clots), fractures (i.e. broken bones), and death, including especially in certain special populations.

53. Before October 2019, the Defendants did not provide any warning whatsoever in the Xeljanz product monograph of any risk of thrombosis (blood clots) associated with Xeljanz use or of any specific or increased risks of Injuries, Conditions, and Complications to patients with cardiovascular risk factors.

54. On or about October 24, 2019, the product monograph was revised significantly to add warnings about the risk of thrombosis, which were aimed at both health care professional and consumers, including, but not limited to:

(a) Warnings for thrombosis were added to the monograph for the first time, which specifically warned of deep vein thrombosis, arterial thrombosis and pulmonary embolism;

(b) Patients were advised to "Stop taking the drug and get immediate medical help" if they experience any of several symptoms related to each of a blood clot in the leg or blood clot in the lung; and

(c) the "Serious Warnings and Precautions" sections in the product monograph directed at healthcare professionals and patients (aka the "Black Box Warnings" – the most stringent warnings for drugs and medical devices) were revised to add a specific subsection on Thrombosis, with the section

directed at healthcare professionals including specific language about an increased risk for patients with cardiovascular risk factors.

55. Before December 2021, the Defendants did not provide any warning whatsoever in the Xeljanz product monograph of any risk of myocardial infarction (i.e. heart attack) associated with Xeljanz use or of any specific or increased risks of Injuries, Conditions, and Complications to older patients or current or past smokers.

56. On or about December 9, 2021, the product monograph was revised significantly to add warnings about the risk of serious heart-related problems and cancer, which were aimed at both health care professional and consumers, including, but not limited to:

(a) A warning for major adverse cardiovascular events was added to the monograph for the first time, which specifically warned of heart attacks,

(b) New warnings concerning cancers were added, included specific detailed warnings addressing increased observations of lung cancers and lymphomas,

(c) The population-specific warning section for geriatric patients was amended to warn of increased risks of all-cause mortality, cardiovascular events, malignancies, and thromboembolism, and other additional warnings;

(d) Increased mortality was added to the clinical trial adverse drug reactions,

(e) Lung cancer and lymphoma (cancer of the lymphatic system) were added as "Uncommon" serious side effects in the Patient Medication Information,

(f) Myocardial infarction (heart attack) was added as a "Common" serious side effect in the Patient Medication Information;

(g) Patients were advised to "Stop taking the drug and get immediate medical help" if they experience any of several symptoms related to each of lung cancer, lymphoma, and heart attack; and

(h) The "Serious Warnings and Precautions" sections were revised to add a specific subsection on Major Adverse Cardiovascular Events, as well as specific language about increases of cancer (including lung cancer) and heart attacks identified in certain patients 50 years or older. Additional cautions were also to the added for older patients, current or past smokers, or patients with cardiovascular risk factors (including unstable angina) and cancer risk factors (including a history of malignancy).

57. Before May 2022, the Defendants did not provide any warning whatsoever in the Xeljanz product monograph of any risk of fractures (broken bones) associated with Xeljanz use or of any specific or increased risks of Injuries, Conditions, and Complications to female patients (aside from those related to pregnancy and breast-feeding).

58. On or about May 9, 2022, the product monograph was revised significantly to add warnings about the risk of fractures, which were aimed at both health care professional and consumers, including, but not limited to:

(a) A warning section on fractures, directed at health care professionals, was added to the monograph for the first time, which specifically warned of

osteoporotic fractures, and urged doctors that caution should be applied when using Xeljanz in patients with known risk factors for fractures such as geriatric patients, female patients, and patients using corticosteroids;

(b) A warning was added that a dosage of Xeljanz 10 mg BID is not recommended for rheumatoid arthritis or psoriatic arthritis;

(c) Broken bones was added as a "Common" serious side effect in the Patient Medication Information; and

(d) Patients were advised to talk to a healthcare professional before taking Xeljanz if they have risk factors for broken bones, such as if they are older than 65 years of age, are a woman, or take corticosteroids.

G. The Defendants Failed to Warn of the Risks Linked to Xeljanz Use

59. At all material times, the Defendants knew or should have known that the risks of using their Xeljanz Products including severe Injuries, Conditions, and Complications.

60. 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 Xeljanz Products.

61. At all material times, the Defendants did not provide adequate safety data to Health Canada with respect to their Xeljanz Products.

62. At all material times, the Defendants, through its servants and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold their Xeljanz

Products without adequate warnings of the products' serious side effects and unreasonably dangerous risks.

H. The Plaintiff and Class Have Suffered Harm from Xeljanz Use

63. Class Members, including the Plaintiff, suffered harms and losses as a result of the Defendants' negligence and failure to warn.

64. Subsequent to ingesting Xeljanz, the Plaintiff and Class Members have suffered and continue to suffer physical and mental injury, loss and damage. In particular, the Plaintiff has suffered serious heart-related issues, including angina attacks, and experienced symptoms of heart racing, clamminess, chest pain, and pain radiating up the jaw.

65. Had the Plaintiff and Class Members been aware of the nature and severity of the risk of Injuries, Conditions, and Complications associated with ingesting Xeljanz, they would not have agreed to take Xeljanz and would have explored one or more of the many other viable treatment options available to them. In particular, had the Plaintiff been aware of the nature and severity of the risk of Injuries, Conditions, and Complications associated with ingesting Xeljanz, including the increased risks that were present for her as an older patient, a woman, and a person with cardiovascular and cancer risk factors, she would not have agreed to take Xeljanz and would have explored one or more of the many other viable treatment options for her arthritis.

66. The Plaintiff's injuries have and will continue to cause her suffering, loss of enjoyment of life, permanent physical disability, loss of earning capacity, past and

future, and loss of housekeeping capacity, past and future. Other Class Members have suffered similar injuries.

67. The Plaintiff has suffered injury to her cardiovascular health and will be more susceptible to future degenerative changes to her cardiovascular health as a result of taking Xeljanz. The Plaintiff's angina attacks have increased in severity and frequency after Xeljanz cessation.

68. The Plaintiff has sustained damages for the cost of medical treatment, including past and future cost of health care services provided by the government of British Columbia. Other Class Members have suffered similar injuries, as have the governments of other provinces and territories in Canada. In particular, as a result of her serious heart-related issues, the Plaintiff has undergone multiple admissions to hospitals emergency rooms, cardiology examinations, and a variety of specialized tests, including ECGs, x-rays, blood tests, and the wearing of a Holter monitor. The Plaintiff continues to undergo medical care and treatment and continues to sustain damages. Class Members in other provinces or territories have sustained similar damages.

69. As a result of her injuries, the Plaintiff has received, and in the future will continue to receive, care and services from family members. Other Class Members will require similar care.

70. The Plaintiff and Class Members paid some or all of the costs for Xeljanz out of their own pocket. Third Party payors have also indemnified some or all of the costs for Xeljanz used by the Plaintiff and Class Members.

71. At all material times, the Plaintiffs and Class Members were in a relationship of proximity with the Defendants. But for the Defendants' wrongful conduct, the Plaintiff would not have incurred damages.

PART 2: RELIEF SOUGHT

72. The Plaintiff claims, on her own behalf and on behalf of all members of the proposed class, as follows:

(a) an order certifying this action as a class proceeding and appointing her as representative Plaintiff for the Class, to be further defined on the application 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 Xeljanz Products;

(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 who underwent a medical procedure where the Defendants' Xeljanz Products were used or as aggregated following a trial on the common issues;

(e) non-pecuniary damages in an amount to be assessed for each person who underwent a medical procedure where the Defendants' Xeljanz Products were used;

(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 sale of their Xeljanz Products;

(g) damages for family members, pursuant to provincial legislation and common law in each province, where applicable, including the *Family Compensation Act,* R.S.B.C. 1996, c. 126

(h) punitive, aggravated, and exemplary damages in an amount to be determined at trial;

(i) costs for the administration of any court award or judgment obtained in this action;

(j) recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Costs Recovery Act*, SBC, 2008, c 27 and similar legislation in other provinces, where applicable;

(k) interest pursuant to the *Court Order Interest Act*, RSBC 1996 c 79; and

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

PART 3: LEGAL BASIS

73. In bringing this action on behalf of a class which includes residents of Canada who used Xeljanz Products at any time on or before the date of the certification order, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings Act*, the *Food and Drugs Act*, RSC, 1985, c F-27 and regulations thereunder, the *Negligence Act*, RSBC 196 c 333, as amended and regulations thereunder, and the *Court Jurisdiction and Proceedings Transfer Act*, RSBC 2003, c 28. The

Plaintiff also brings this action on behalf of a class which includes 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 pleads and relies upon the applicable provincial legislation and common law, including the British Columbia *Family Compensation Act,* R.S.B.C. 1996, c. 126 and regulations thereunder.

A. Causes of Action

i. Negligence

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

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

(b) design their Xeljanz Products so as to avoid safety risks and to make them reasonably safe for their intended purposes;

(c) see that there were no defects in manufacture of their Xeljanz Products that were likely to give rise to injury in the ordinary course of use;

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

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

(f) warn consumers of dangers inherent in the use of their Xeljanz Products of which they knew or ought to have known;

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

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

75. The Defendants negligently breached their duty of care.

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

(a) failure to ensure that their Xeljanz 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) failure to ensure that their Xeljanz Products were free of any manufacturing defects that would expose recipients to Injuries, Conditions, and Complications;

(c) failure to adequately test their Xeljanz 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;

(d) adopting unreasonable and/or careless and/or defective product design resulting in Injuries, Conditions, and Complications;

(e) designing their Xeljanz Products in a way which created a substantial likelihood of harm when there existed safer alternative designs and/or products which were economically feasible to manufacture;

(f) failure to provide Health Canada complete and accurate information with respect to their Xeljanz Products as it became available;

(g) failure to conduct any or adequate follow-up studies on the efficacy and safety of their Xeljanz Products;

(h) failure to conduct any or adequate long-term studies of the risks of their Xeljanz Products;

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

(j) failure to adequately monitor, evaluate and act upon reports of adverse reactions to their Xeljanz Products in Canada and elsewhere;

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

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

(m) failure, after noticing problems with their Xeljanz Products, to issue adequate warnings, timely recall their Xeljanz Products, publicize the problems and otherwise act properly and in a timely manner to alert the

public, including adequately warning the Plaintiff and her physician of their Xeljanz Products' inherent dangers, including but not limited to the danger of Injuries, Conditions, and Complications;

(n) failure to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Xeljanz Products;

(o) representation that their Xeljanz 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;

(p) misrepresentation of the state of research pertaining to the purported benefits of their Xeljanz Products and their associated risks, including the risk of Injuries, Conditions, and Complications;

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

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

(s) failure to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, RSC 1985, c F 27 and its associated regulations;

(t) failure to properly supervise their employees, subsidiaries and affiliated corporations;

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

(v) 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.

77. The risks associated with use of the Defendants' Xeljanz Products, including Injuries, Conditions, and Complications in all persons receiving their Xeljanz Products, were in the exclusive knowledge and control of the Defendants. The extent of the risks was 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 Xeljanz Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Xeljanz Products to the Plaintiff and putative class members, and to their physicians.

B. Damages

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

79. 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.

80. 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' Xeljanz Products.

81. 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.

82. 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.

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

C. Jurisdiction

84. There is a real and substantial connection between British Columbia and the facts alleged in this proceeding. The Plaintiff and Class Members plead and rely upon the *Court Jurisdiction and Proceeding Transfer Act*, SBC 2003, c 28 in respect of the Defendants. Without limiting the foregoing, a real and substantial connection exists between British Columbia and the facts alleged in this proceeding pursuant to sections 10(f) to 10(h) of the *CJPTA* because this proceeding:

(a) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia;

(b) concerns a tort committed in British Columbia; and

(c) concerns a business carried on in British Columbia.

Plaintiff's address for service:	**Siskinds LLP** **Barristers & Solicitors** 275 Dundas Street, Unit 1 London, ON N6B 3L1
Fax number address for service (if any):	1.519.660.7859
E-mail address for service (if any):	jill.mccartney@siskinds.com
Place of trial:	Vancouver, British Columbia
The address of the registry is:	800 Smithe Street, Vancouver, BC, V6Z 2E1

Date: 25 Jan 2023

Signature of lawyer for Plaintiff
James E. Boyd
Jill S. McCartney
Charles M. Wright

Rule 7-1 (1) of the Supreme Court Civil Rules states:

(1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,

(a) prepare a list of documents in Form 22 that lists

(i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and

(ii) all other documents to which the party intends to refer at trial, and

(b) serve the list on all parties of record.

Appendix

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This is a claim for injuries, loss and damages suffered as a result of the Defendants' negligence in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Xeljanz Products.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

[ ] a motor vehicle accident
[ ] medical malpractice
[x] another cause

A dispute concerning:

[ ] contaminated sites
[ ] construction defects
[ ] real property (real estate)
[ ] personal property
[x] the provision of goods or services or other general commercial matters
[ ] investment losses
[ ] the lending of money
[ ] an employment relationship
[ ] a will or other issues concerning the probate of an estate
[ ] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[x] a class action
[ ] maritime law
[ ] aboriginal law
[ ] constitutional law
[ ] conflict of laws
[ ] none of the above
[ ] do not know

Part 4:

Class Proceedings Act, RSBC 1996, c 50
Food and Drugs Act, RSC, 1985, c F-27
Negligence Act, RSBC 196 c 333
Family Compensation Act, RSBC 1996, c 126
Health Care Costs Recovery Act, SBC, 2008, c 27
Court Jurisdiction and Proceedings Transfer Act, SBC 2003, c 28

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff, Louise Rees, claims the right to serve this pleading on the Defendants outside British Columbia on the ground that there is a real and substantial connection between British Columbia and the facts alleged in this proceeding and the Plaintiff and other Class Members plead and rely upon the *CJPTA* in respect of these Defendants. Without limiting the foregoing, a real and substantial connection between British Columbia and the facts alleged in this proceeding exists pursuant to section 10(f) to 10(h) of the *CJPTA* because this proceeding:

(f) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia;

(g) concerns a tort committed in British Columbia; and

(h) concerns a business carried on in British Columbia.