Amended further to the Order of the Honourable Madam Justice Douglas dated January 14, 2022

No. S205093
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

Between

ARENLEA FELKER AND ANGELA CATHERINE D'ANDREA

PLAINTIFFS

and

JANSSEN, INC. AND
TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.

DEFENDANTS

Brought under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50

AMENDED NOTICE OF CIVIL CLAIM

(Original Notice of Civil Claim filed on May 15, 2020)

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 PRONOUCED 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 reside anywhere in Canada, within 21 days after the date on which a copy of the filed notice of civil claim was served on you,
(b) if you reside in the United States of America, within 35 days after the date on which a copy of the filed notice of civil claim was served on you,
(c) if you reside elsewhere, within 49 days after the date on which a copy of the filed notice of civil claim was served on you, or
(d) if the time for response to civil claim has been set by order of the court, within that time.

THE PLAINTIFFS' CLAIM

Part 1: STATEMENT OF FACTS

Overview

1. The Defendants design, develop, manufacture, market, label and sell pentosan polysulfate sodium ("**PPS**") in Canada and abroad under the trade name *Elmiron* ("**Elmiron**"). Elmiron is a pharmaceutical drug sold by the Defendants in Canada since 1993 used in the treatment of interstitial cystitis ("**IC**"), a regional pain syndrome affecting the bladder and pelvic area. Exposure to Elmiron causes a permanent vision-threatening eye disease known as pigmentary maculopathy. The Defendants exposed the Plaintiffs and Class Members to retinal toxicity and pigmentary maculopathy by their negligence and failure to warn about the effects of ingesting Elmiron. Through this suit, Canadians who took Elmiron seek to hold the Defendants accountable and recover damages.

The Parties

2. The Plaintiff Felker is a resident of British Columbia. She was prescribed Elmiron by her physician to treat IC in 2005 and has taken it daily since then.

3. The Plaintiff D'Andrea is a resident of British Columbia. She was prescribed Elmiron by her physician to treat IC in 2004 and continued taking it daily until June 2020.

4. The Plaintiffs bring this action on their own behalf and on behalf all persons in Canada who were prescribed and ingested Elmiron between December 31, 1993 and the date this action is certified as a class proceeding (the "**Class**", "**Class Members**" and "**Class Period**").

5. Janssen, Inc., formerly known as Janssen-Ortho Inc. ("**Janssen**") is a corporation incorporated pursuant to the laws of Ontario and registered in British Columbia as an extra-provincial company with an address for service at Suite 2600, Three Bentall Centre, 595 Burrard Street, Vancouver, BC V7X 1L3. Janssen is registered with Health Canada as the sponsor for Elmiron in Canada.

6. Teva Branded Pharmaceutical Products R&D, Inc., formerly known as Ivax Research, Inc., IVAX Research LLC, and Baker Norton Pharmaceuticals, Inc. ("**Teva**") is a corporation incorporated pursuant to the laws of Delaware with an address for service at Suite 104, 3411 Silverside Road, Wilmington, Delaware, 19810 USA. Teva was formerly registered with Health Canada as the sponsor for Elmiron in Canada.

Elmiron

7. Elmiron is the trade name for the prescription pharmaceutical drug PPS. Elmiron is used in the initial and maintenance treatment of IC. Elmiron has a Health Canada Drug Identification Number (DIN) of 02029448. At all material times, Elmiron has been the exclusive brand name by which PPS is sold for human consumption in Canada.

8. Elmiron is administered orally in 100 mg capsules. A typical patient dose pattern for Elmiron is three 100 mg capsules per day. Elmiron takes several months to show efficacy and most individuals taking Elmiron are long-term, chronic users ingesting Elmiron for many years.

Interstitial Cystitis

9. IC is a chronic bladder condition characterized by urinary urgency, nocturia, urinary frequency, and bladder or pelvic pain ranging from mild discomfort to severe pain. IC most often affects women. The exact cause of IC is unknown.

10. Elmiron is one of many available treatments for IC. The Canadian Urological Association ("**CUA**") has established evidence-based guidelines to inform the diagnosis and treatment of IC. Recommended treatment modalities include:

a. conservative therapies such as patient education, dietary modification and bladder training;

b. physical therapies such as acupuncture and trigger point injections;

c. oral medications such as amitriptyline, cimetidine, hydroxyzine, gabapentinoids, quercetin and PPS;

d. intravesical therapies;

e. minimally-invasive surgical procedures; and

f. radical surgical procedures.

The Development, Marketing and Sale of Elmiron by the Defendants

11. PPS is a semisynthetically-produced heparin-like compound first used in the 1950s for its anticoagulant properties in the treatment of varicose veins. The exact mechanism of action of PPS in relieving IC symptoms is unknown. A series of clinical trials in the 1980s found Elmiron to be efficacious in the treatment of IC.

12. Elmiron is a "drug" under the *Food and Drugs Act*, R.S.C. 1985, F-27. It may only be sold in Canada with the license and approval of Health Canada. Teva sponsored the Health Canada application to sell Elmiron in Canada, obtaining approval to market and sell the drug for use in the treatment of IC on December 31, 1993.

13. In February 1994, Teva registered the trademark for "Elmiron" in Canada for "pharmaceutical preparations for use in association with urological, gastrointestinal and/or vascular disorders or medical treatment therefor". Teva continues to assert this trademark in Canada under its former name IVAX Research, LLC.

14. In September 1996, Teva obtained approval from the United States Food and Drug Administration to market and sell Elmiron in the United States.

15. On a date not currently known to the Plaintiff, Teva licensed the right to sell Elmiron in Canada to Janssen.

16. Since December 31, 1993, the Defendants, individually or jointly designed, researched, developed, tested, manufactured, promoted, marketed, monitored, labelled and sold Elmiron as an appropriate treatment for IC in British Columbia and elsewhere in Canada.

17. The Defendants marketed Elmiron as the only orally-administered medication approved to treat symptoms of IC. This is misleading and inaccurate. While Elmiron is the only oral medication approved *specifically* for treatment of IC, it is one of several oral medications recommended for treatment of IC pursuant to the CUA guidelines. As set out above, oral medication is one of six lines of treatment recommended for IC, each of which contains multiple treatment options.

18. Elmiron users typically ingest 300 mg of the drug per day. Only about 6 per cent of the drug is absorbed to the epithelial cells of the bladder. Users must ingest Elmiron for at least 3 to 6 months (often longer) to achieve any benefit. In a March 2012 Citizen's Petition to the FDA, the Defendant Janssen admitted that "the drug has low bioavailability, is poorly absorbed from the gastrointestinal tract, and cannot be assayed by determining serum levels". Given its low efficacy and bioavailability, disclosure of Elmiron's side effects is important so that patients can make an informed decision about whether to start ingesting it at all.

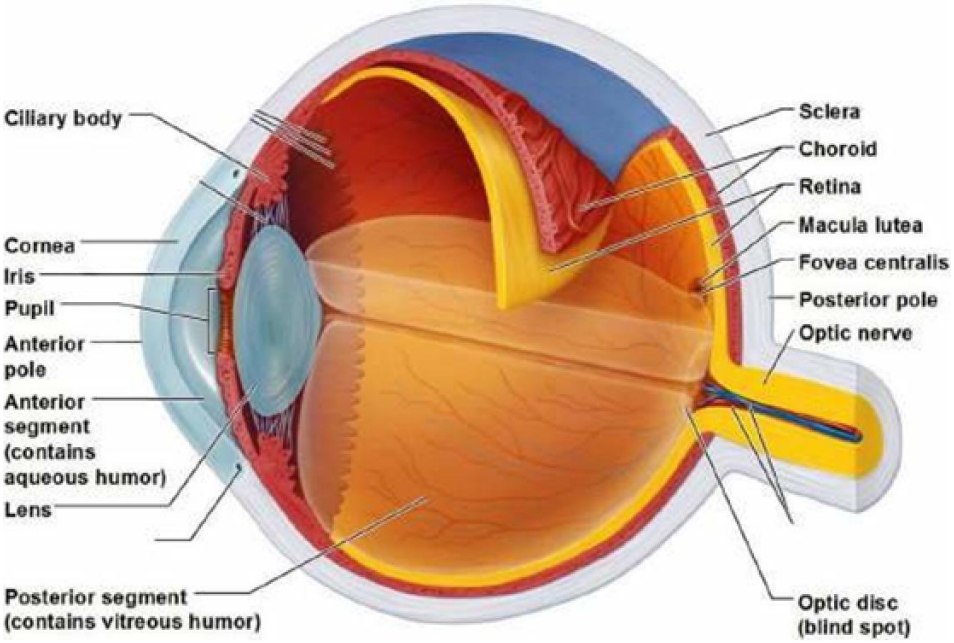
Retinal Toxicity and Pigmentary Maculopathy - Undisclosed Side Effects

19. Ingesting drug compounds that are foreign to the body can lead to drug toxicity. The toxic effects of a drug are dose-dependent and can affect an entire bodily system or a specific organ. Drug toxicity is harmful to human health and manifests as adverse side effects. It is critical that patients and health care professionals be warned of adverse side effects associated with drugs to facilitate an informed treatment decision and to recognize the signs of drug toxicity.

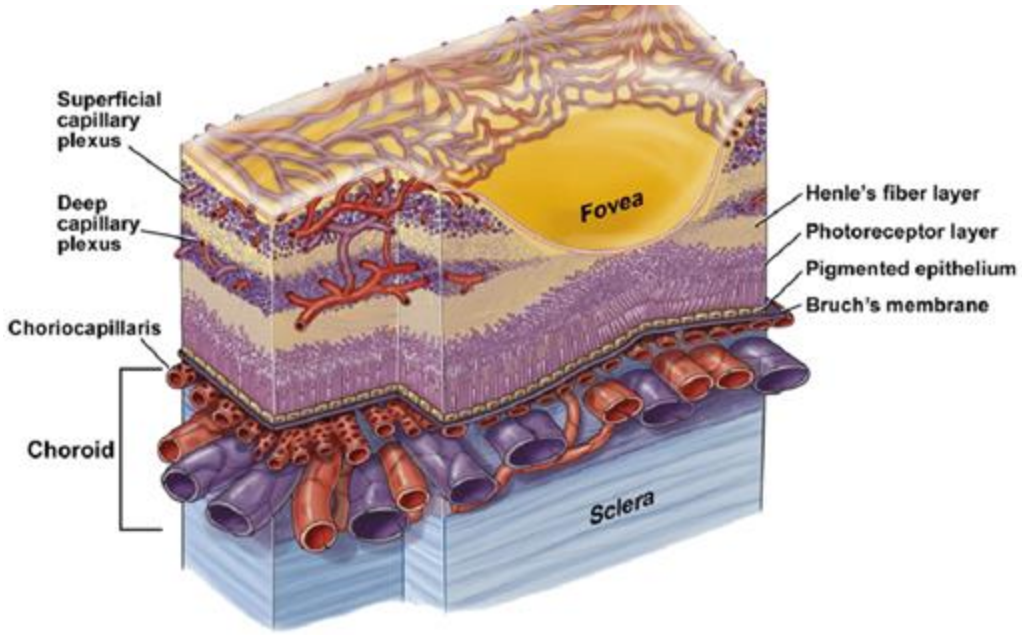
20. With its highly-concentrated network of blood vessels and minimal ability to regenerate, the retina is particularly vulnerable to drug toxicity. The retina is a thin membrane of nerve cells lining the inner surface of the back of the eye. It senses light and sends signals to the brain to enable vision.

21. When used as intended, Elmiron causes pigmentary maculopathy, a unique form of retinal disease leading to significant vision loss. Pigmentary maculopathy occurs when Elmiron circulating through the blood stream accumulates in the retinal pigment epithelium ("**RPE**"), causing drug toxicity. RPE is a specialized layer of the retina forming the outer blood-retinal barrier. Among its many functions, it transports nutrients, absorbs light and protects against photooxidation. RPE is essential to the structural integrity and health of the retina.

22. Elmiron accumulates in RPE particularly in the area of the *macula lutea*. The *macula lutea* is the small pigmented area of the retina near the optic disc that provides central vision. Near the center of the *macula lutea* is the *fovea centralis*, the part of the retina responsible for the eye's sharpest, most acute vision.



Anatomy of the eye



Cross-section detail – layers of the retina

23. The signature RPE changes of pigmentary maculopathy are only visible with Colour Fundus ("CF"), Fundus Autoflorescence ("FAF") and Optical Coherence Tomography ("OCT") imaging. Patients with pigmentary maculopathy often have focal nodules and hyperpigmented spots visible on CF, FAF and OCT on RPE surrounding the f*ovea centralis.*

24. Symptoms of Elmiron-toxicity induced pigmentary maculopathy include *inter alia*:

a. poor light to dark adaptation;

b. blurred vision;

c. difficulty reading;

d. change in eye colour;

e. dark spots in vision;

f. warped and distorted presentation of lines; and

g. muted, less vivid colors.

The Defendants' Failure to Test and Monitor Elmiron

25. At all material times, the Defendants knew or ought to have known that ingesting Elmiron causes retinal toxicity and pigmentary maculopathy.

26. During the new drug application process for Elmiron in the United States, the FDA noted that "Elmiron works by binding to exposed epithelium," which may explain its apparent effect on the urinary bladder epithelium.

27. The Defendants knew or ought to have known of the potential for Elmiron to bind to other epithelial cells such as RPE. The Defendants failed to adequately test for these adverse effects during the drug approval phase, or to conduct ongoing monitoring for such adverse events after Elmiron was approved.

28. In an unmasked clinical trial of 2,499 patients conducted in the late 1980s and early 1990s before Health Canada approved Elmiron, patients receiving Elmiron experienced vision-related adverse side effects, including optic neuritis, amblyopia and retinal hemorrhage. The Defendants did not investigate these side effects through further research or study, adequately or at all, even though the Defendants relied upon this very clinical trial when seeking approval of Elmiron for sale in Canada.

29. As early as 1991, a study published in *Investigative Ophthalmology & Visual Science* (*Leschey, et al.*)[1] identified that PPS inhibits the growth and proliferation of RPE cells, thereby impairing an important physiological pathway for retinal health.

30. Almost immediately after Elmiron was approved for sale in the United States, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron. Between 1997 and 2021, over 400 cases of vision-related adverse reactions were reported to the FDA, including 27 within the first two years that of FDA approval.

31. The Defendants have failed to warn patients, their health care professionals and Health Canada of the risk of retinal toxicity and pigmentary maculopathy associated with ingesting

[1] Leschey, et al. Inhibition of Growth Factor Effects in Retinal Pigment Epithelial Cells. Investigative Ophthalmology & Visual Science. May 1991; 32 (6): 1770-1778.

Elmiron. Because of this, health care professionals may not know to look for the indicia of pigmentary maculopathy on FAF and OCT imaging. A health care professional managing a patient's IC will not know to look out for vision changes in a patient. As a result, pigmentary maculopathy can be mistaken for other well-known macular disorders such as pattern dystrophy and age-related macular degeneration, or can go undiagnosed and untreated entirely.

32. In *Lyons et al*,[2] published in *Obstetrics and Gynecology* in 2020, the authors made the following screening and follow-up recommendations:

a. Providers discuss the risks associated with pentosane polysulfate with their patients and prescribe the lowest necessary dose and duration of pentosane polysulfate for patients who require long-term treatment. Providers may discuss alternative treatments for interstitial cystitis at their discretion.

b. A baseline examination with fundus photography, optical coherence tomography, and fundus autofluorescence imaging.

c. Testing is repeated within 5 years after pentosane polysulfate initiation and annually thereafter. Some patients may be at higher risk for developing penstosan polysulfate maculopathy and may benefit from either more frequent screening examinations or drug avoidance.

d. It is recommended that patients diagnosed with pentosane polysulfate maculopathy stop taking the drug and discuss alternative interstitial cystitis management options with their treating physician.

Academic Studies

33. Retinal toxicity and pigmentary maculopathy associated with Elmiron has been widely reported in the ophthalmological community since 2018 or earlier. The Defendants were aware of this research and these findings.

[2] Lyons, et al. Pentosan Polysulfate-Associated Macular Disease in Patients with Interstitial Cystitis. Obstetrics & Gynecology. May 2020; 135(5): 1091-1094.

34. In November 2018, a research team at Emory Eye Center in Atlanta, GA (*Pearce et al.*)[3] published a retrospective case series evaluating six patients at a single clinical center who had taken Elmiron at 200mg to 400mg daily doses for a median of 15.5 years. The authors described a novel disease referred to as pigmentary maculopathy associated with chronic exposure to PPS. They suggested that retinal cells may be accumulating PPS or a toxic metabolite over time. This report contained the first public mention of the pre-Health Canada approval clinical trial referred to above.

35. In a letter to the editor of the journal *Urology*,[4] IC experts Robert Moldwin and Curtis Nickel responded to the Emory findings with concern, noting "it is quite unlikely that urologists treating patients with [IC] ever would have made this association."

36. In May 2019, researchers at the Emory Eye Center (*Foote et al.*)[5] submitted a new study of ten IC patients who had taken Elmiron and experienced macular disease. The study reported that retinal imaging with FAF and OCT imaging demonstrated abnormalities primarily in the RPE.

37. In October 2019, researchers at Harvard Medical School (*Huckfeldt et al*)[6] published a case study of a 62-year-old female patient who had used 200 mg of Elmiron daily for 18 years. The patient presented with blurred vision, impaired night vision and pigmentary changes in the retina while taking Elmiron. The authors describe progressive pigmentary maculopathy in the absence of any genetic or other cause for up to six years after the patient had stopped taking Elmiron, suggesting that progressive maculopathy continues for years after cessation of Elmiron.

[3] Pearce, et al. Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium. Ophthalmology. 2018 Nov; 125(11): 1793-1802.
[4] Nickel, J.C. and Moldwin, R. Re: FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials: Future Direction for Research. J Urol 2018 200(5): 1122.
[5] Foote, et al. Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary Changes and Vision Loss. AUA 2019 Abstract MP47-03.
[6] Heckfeldt, et al. Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium. Ophthalmic Surg Lasers Imaging Retina. 2019; 50: 656-659.

38. In November 2019, researchers at the Emory Eye Center (*Jain et al.*)[7] published the results of a medical cohort study using data from a large U.S. medical claims database from 2002 to 2016. The study found a significant association between PPS exposure and macular disease.

39. In 2019, researchers at Kaiser Permanente undertook a clinical population-based study of Elmiron users focusing on pigmentary maculopathy. Of 91 patients who had taken an average of 5,000 pills over a 15-year period, 22 patients showed clear signs of pigmentary maculopathy, with eye damage having increased with the quantity of Elmiron taken.

40. Studies on mice have also confirmed retinal function loss resulting from systemic PPS administration.[8]

Changes to Product Monograph

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

42. 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 Janssen's Canadian website.

43. Between December 31, 1993 and September 23, 2019, the Defendants did not warn Class Members, including the Plaintiff, or their health care professionals, or notify Health Canada, of the risk of retinal toxicity, pigmentary maculopathy or any other vision-related adverse side

[7] Jain, et al. Association of Macular Disease with Long-Term Use of Pentosan Polysulfate Sodium: Findings from a US Cohort. Br. J. Ophthalmol. Epub ahead of print [30 Jan 2020]. Doi: 10.1136/bjophthalmol-2019-314765.
[8] Girardot, et al. Systemic Pentosan Polysulfate Administration Causes Retinal Function Loss in the C57BI/6J Mouse. Investigative Ophthalmology & Visual Science. 2019; 60: 2352.

effects associated with Elmiron ingestion, notwithstanding that the Defendants knew or ought to have known of such risks.

44. On September 23, 2019, Janssen revised the Product Monograph.

45. "Part I" of the Product Monograph now states *inter alia*:

> Ophthalmologic
>
> Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosan polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptation. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with long-term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

46. "Part III" of the Product Monograph now states under the heading "WARNINGS AND PRECAUTIONS", the sentence "Call your doctor if you notice any changes in your vision." This sentence is not bolded, underlined or otherwise highlighted.

47. "Part III" of the Product Monograph now includes the following chart:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Headache	✓		
	Abdominal pain	✓		
	Diarrhea	✓		
	Rash		✓	
	Abnormal liver function test		✓	
	Blood in stool		✓	
	Nose bleed		✓	
	Gum bleeding		✓	
Uncommon	Dizziness	✓		
	Bruising		✓	
	Allergic reactions			✓
Unknown	Vision changes: difficulty reading; slow adjustment to low or reduced light		✓	

48. The September 23, 2019 changes to the Product Monograph are not adequate warnings because they minimize and understate the nature and severity of the risk of vision-related adverse side effects relative to the gravity of the potential harm.

49. On October 1, 2020, the Janssen further revised the Product Monograph. The October 1, 2020 changes gave increased prominence to the serious ophthalmologic side effects of Elmiron:

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ELMIRON® is contraindicated in patients with a personal history of any macular pathology. Cases of pigmentary maculopathy have been reported with long-term use of ELMIRON®. Baseline and regular retinal examinations are recommended for early detection of pigmentary maculopathy. The benefits and risks of treatment with ELMIRON® should be assessed periodically for each patient (see **CONTRAINDICATIONS** and **WARNINGS AND PRECAUTIONS, Ophthalmologic**).

50. The substance of the warning in Part I of the Product Monograph was further revised in the October 1, 2020 changes:

> **Ophthalmologic**
> Cases of pigmentary maculopathy have been reported with long-term use of ELMIRON® (see **ADVERSE REACTIONS, Post-Market Adverse Drug Reactions**). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor. Visual symptoms in these cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The benefits and risks of treatment with ELMIRON® should be considered for all patients, may change over time, and should be assessed periodically for each patient. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary macular pathology, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal exam (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. For patients continuing with ELMIRON® therapy, it is recommended to perform baseline and periodic comprehensive retinal examinations (see above) and detailed ophthalmologic histories for early detection of pigmentary maculopathy. Patients should be informed that changes in vision should be reported and evaluated. If pigmentary maculopathy or other retinal changes are confirmed, risks and benefits of continuing treatment should be discussed including discontinuation of treatment, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.
>
> The benefit-risk profile of continued treatment with ELMIRON® in patients whose pain has not improved by 6 months is not known.

51. Part III of the October 1, 2020 changes to the Product Monograph includes the following update regarding the serious side effect of pigmentary maculopathy:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown	Pigmentary Maculopathy (Eye disease that affects the retina): difficulty reading; slow adjustment to low or reduced light, blurry vision, blurry or wavy vision near or in the center of your field of vision		✓	

52. On December 15, 2020 Janssen issued a letter to Canadian healthcare professionals warning of the risk of pigmentary maculopathy associated with Elmiron use (the "**Dear Healthcare Professional Letter**"), which includes *inter alia* the following text:

Important Safety Information on ELMIRON (pentosan polysulfate sodium) and the Risk of Pigmentary Maculopathy

janssen
PHARMACEUTICAL COMPANIES of Johnson & Johnson

2020/12/15

Audience
Healthcare professionals including urologists, urogynecologists, ophthalmologists, optometrists, family physicians, and pharmacists.

Key messages

- **Cases of pigmentary maculopathy have been reported with long-term use of ELMIRON.**
- **ELMIRON is now contraindicated in patients with a personal history of any macular pathology.**
- **Healthcare professionals are advised to:**
  - **assess the benefits and risks with their patients before initiating treatment with ELMIRON and periodically thereafter.**
  - **obtain detailed ophthalmologic history in all patients before starting treatment with ELMIRON.**
  - **perform baseline and regular retinal examinations for early detection of macular pathology.**
  - **counsel patients to report changes in vision such as difficulty reading, slow adjustment to low or reduced light, blurred vision including blurry or wavy vision near or in the centre of the field of vision.**
- **The Canadian Product Monograph for ELMIRON has been updated to include the new contraindication and further strengthen the information about the risk of pigmentary maculopathy.**

53. The Defendants have not issued any purported warnings or recalls with respect to Elmiron other than the aforementioned changes to the Product Monograph and the Dear Healthcare Professional Letter.

54. The Defendants have not warned health care professionals, Health Canada or individual users of the risk of progressive degenerative vision changes continuing after cessation of Elmiron ingestion.

Harm to Plaintiffs and Class Members

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

56. Subsequent to ingesting Elmiron, the Plaintiff Felker has suffered and continues to suffer physical and mental injury, loss and damage. In particular, the Plaintiff Felker has suffered symptoms of vision loss characteristic of pigmentary maculopathy, including:

e. blurred vision;

f. difficulty reading;

g. poor light to dark adaptation;

h. muted, less vivid colours; and

i. other injuries that may develop or become known in the future.

57. Subsequent to ingesting Elmiron, the Plaintiff D'Andrea has suffered and continues to suffer physical and mental injury, loss and damage. In particular, the Plaintiff D'Andrea has suffered symptoms of vision loss characteristic of pigmentary maculopathy, including blurred and distorted vision.

58. Had the Plaintiffs been aware of the nature and severity of the risk of retinal toxicity, pigmentary maculopathy and vision-related adverse side effects associated with ingesting Elmiron, they would not have agreed to take Elmiron. They would have explored one or more of the many other viable treatment options for IC.

59. The Plaintiffs' 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.

60. The Plaintiffs will be more susceptible to future degenerative changes to her vision as a result of taking Elmiron. The Plaintiffs' retinal toxicity and vision loss will continue after Elmiron cessation.

61. The Plaintiffs have 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. The Plaintiffs continues to undergo medical care and treatment and continues to sustain damages. Class Members in other provinces or territories have sustained similar damages.

62. As a result of her injuries, the Plaintiffs have received and in the future will continue to receive care and services from family members.

63. The Plaintiffs paid for Elmiron out of their own pocket. Third Party payors have also indemnified a portion of the cost of the Plaintiff's Elmiron from time to time.

64. At all material times, the Plaintiffs and Class Members were in a relationship of proximity with the Defendants.

Part 2: RELIEF SOUGHT

65. The Plaintiffs claims, on their own behalf and on behalf of the Class Members:

j. an order certifying this action as a class proceeding under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50 (the "***Class Proceedings Act***");

k. general damages;

l. an accounting and restitution or, alternatively, disgorgement, of the cost of Elmiron for purchases in Canada;

m. punitive damages;

n. special damages;

o. past and future damages "in trust" for services provided by family members;

p. Recovery of health care costs pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27 and similar legislation in other provinces;

q. pre-judgment and post-judgment interest under the *Court Order Interest Act*, RSBC 1996, c 79; and

r. Such further and other relief as this Honourable Court may deem just.

Part 3: LEGAL BASIS

66. The Plaintiffs and Class Members plead and rely on the *Class Proceedings Act*, the *Limitation Act*, SBC 2012, c 13, the *Court Order Interest Act*, RSBC 1996, c 79, the *Negligence Act*, RSBC 1996, c 318, the *Food and Drugs Act*, RSC 1985, c F-27, the *Emergency Program Act*, Ministerial Order No. M098, *Family Compensation Act*, RSBC 1996, c 126, the *Supreme Court Civil Rules*, and related enactments.

Negligent Design

67. At all material times the Defendants, individually or jointly, owed the Plaintiffs and other Class Members a duty of care in designing, developing, researching, testing and monitoring Elmiron.

68. Each of the Defendants breached its duty of care to the Plaintiffs and other Class Members, particulars of which include, *inter alia:*

a. failing to conduct adequate tests and clinical trials prior to releasing Elmiron into the stream of commerce to determine the nature and degree of risks associated with ingesting Elmiron;

b. after Elmiron was released into the stream of commerce, failing to conduct ongoing tests and clinical trials with long-term follow-up to determine the nature and severity of side effects from drug toxicity associated with ingestion of Elmiron, adequately or at all;

c. failing to investigate, study or research vision-related adverse reactions reported during clinical trials of Elmiron when they knew or ought to have known of such adverse reactions, adequately or at all;

d. after Elmiron was released into the stream of commerce, failing to investigate, study or research vision-related adverse reactions of Elmiron when they knew or ought to have known of such adverse reactions, adequately or at all;

e. failing to ensure that Elmiron was fit for its intended purpose, both before releasing it into the stream of commerce and on an ongoing basis thereafter;

f. failing to monitor the post-market effects of Elmiron, including, but not limited to, in accordance with s C.02.023 of the *Food and Drug Regulation*, CRC c 870;

g. failing to investigate, research, study and consider the effects of long-term chronic use characteristic of the majority of Elmiron patient use patterns, adequately or at all; and

h. failing to provide Health Canada with complete and accurate clinical and nonclinical data throughout the approval process for Elmiron and on an ongoing basis subsequent to its approval.

Failure to Warn

69. At all material times the Defendants, individually or jointly, owed the Plaintiffs and other Class Members a duty of care and a duty to warn in marketing, labelling, promoting and selling Elmiron.

70. Each of the Defendants breached its duty of care to the Plaintiffs and other Class Members, particulars of which include, *inter alia:*

a. failing to warn Class Members, their health care professionals and/or Health Canada of the nature and severity of any foreseeable risk of retinal toxicity, pigmentary maculopathy and vision-related adverse side effects associated with ingesting Elmiron, adequately or at all;

b. failing to provide any, or adequate, updated and current information to Class Members, their health care professionals and/or Health Canada respecting the risks associated with Elmiron ingestion in a timely manner as such information became available from time to time;

c. failing to provide any, or adequate, warning in the Product Monograph for Elmiron of the nature and severity of any foreseeable risk of retinal toxicity, pigmentary maculopathy and vision-related adverse side effects associated with ingesting Elmiron, in a timely manner or at all;

d. failing to warn Class Members, their health care professionals and/or Health Canada that vision-related adverse side effects including pigmentary maculopathy can continue to progress even after cessation of Elmiron use, adequately or at all;

e. failing to conform with applicable labelling, disclosure and reporting requirements pursuant to the *Food and Drugs Act* s-ss 9(1), 21.71, and s-ss C.01.003, C.01.017, C.01.018, C.02.023 of the *Food and Drug Regulations*;

f. failing to promptly report to Health Canada all adverse events that came to the attention of the Defendants subsequent to Elmiron's approval for sale in Canada;

g. failing to provide complete and accurate information in the Product Monographs for Elmiron, in a timely manner or at all;

h. after learning of the risk of retinal toxicity and pigmentary maculopathy associated with Elmiron ingestion, failing to issue adequate warnings, publicize the problem, recall Elmiron and otherwise act properly and in a timely manner to alert Class Members, their health care professionals and/or Health Canada to such risks.

Causation and Damages

71. As a result of the Defendants' negligence in the design, development, research, testing, monitoring, marketing, labelling, promotion and sale of Elmiron, the Plaintiffs and other Class Members have suffered and continue to suffer losses and damages, including:

a. personal injury;

b. loss of income earning capacity, past and future;

c. loss of housekeeping capacity, past and future;

d. cost of future care;

e. out of pocket expenses; and

f. damages "in trust" for service provided by family members, past and future.

72. At all material times the Defendants were in a close and proximate relationship to the Plaintiffs and other Class Members. The damages and losses suffered by the Plaintiffs and other Class Members are the reasonably foreseeable consequences of the Defendants' aforementioned negligence and failure to warn.

73. Additionally, the Plaintiffs plead the following, as amended, on behalf of the Class Members:

a. *Survival of Actions Act*, RSA 2000, c S-27;

b. *The Survival of Actions Act*, SS 1990, c S-66.1;

c. *Survival of Actions Act*, RSNS 1989, c 453;

d. *Survival of Actions Act*, RSNB 2011, c 227;

e. *Survival of Actions Act*, RSPEI 1988, c S-11;

f. *Survival of Actions Act*, RSNL 1990, c S-32;

g. *Family Compensation Act*, RSBC 1996, c 126;

h. *Fatal Accidents Act*, RSY 2002, c 86;

i. *Fatal Accidents Act*, RSA 2000, c F-8;

j. *The Fatal Accidents Act*, RSS 1978, c F-11;

k. *Fatal Accidents Act*, SNu 2010, c 14;

l. *The Fatal Accidents Act*, CCSM c F50;

m. *Family Law Act*, RSO 1990, c F 3;

n. *Fatal Accidents Act*, RSNL 1990, c F-6;

o. *Fatal Accidents Act*, RSNB 2012, c 104;

p. *Fatal Injuries Act*, RSNS 1989, c 163; and

q. *Fatal Accidents Act*, RSPEI 1988, c F-5.

Health Care Costs

74. The Province of British Columbia provides coverage for health care services to British Columbia residents through the Medical Services Plan and Health Insurance BC.

75. The Plaintiffs are each a "beneficiary" within the meaning of the *Medicare Protection Act*, R.S.B.C. 1996, c. 286 and any amendments.

76. The Plaintiffs and Class Members have a claim for the recovery of health care costs, past and future, incurred on their behalf by the British Columbia Ministry of Health and by other provincial and territorial governments. The Plaintiffs plead the following provincial and territorial statutes, as amended, in support of a claim for recovery of health care costs incurred by provincial and territorial governments:

a. *Health Care Cost Recovery Act*, SBC 2008, c 27;

b. *Medicare Protection Act*, RSBC 1996, c 286;

c. *Pharmaceutical Services Act*, SBC 2012, c 22;

d. *Hospital Act*, RSA 2000, c H-12;

e. *Crown's Right of Recovery Act*, SA 2009, c C-35;

f. *The Health Administration Act*, RSS 1978, c H-0.0001 (formerly known as the *Department of Health Act*);

g. *Health Services Insurance Act*, CSSM s H35;

h. *Health Insurance Act*, RSO 1990, c H.6;

i. *Home Care and Community Services Act*, 1994, SO 1994, c26;

j. *Health Services Act*, RSNB 1973, c H-3;

k. *Medical Services Payment Act*, RSNB 1973, c M-7;

l. *Hospital Services Act*, RSNB 1973, c H-9;

m. *Family Services Act*, SNB 1980, c F-2.2;

n. *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8;

o. *Health Services Payment Act*, RSPEI 1988, c H-2;

p. *Health Services and Insurance Act*, RSNS 1989, c 197;

q. *Hospital Insurance Agreement Act*, RSN 1990, c H-7;

r. *Medical Care and Hospital Insurance Act*, SNL 2016, c M-5.01;

s. *Hospital Insurance and Health and Social Services Administration Act*, RSNWT 1988, c T-3;

t. *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-3;

u. *Medical Care Act*, RSNWT (Nu) 1988, c M-8;

v. *Health Insurance Act*, CQLR c A-29; and

w. *Hospital Insurance Act*, RSQ c A-28.

77. But for the Defendants' aforementioned negligence and failure to warn, the Plaintiffs and other Class Members would not have incurred the expense of purchasing Elmiron. The Plaintiffs and other Class Members claim as special damages their out-of-pocket expenses incurred in purchasing Elmiron. Third party payors have a subrogated interest in repayment of the cost of Elmiron incurred on behalf of the Plaintiffs and other Class Members.

Unjust Enrichment

78. As set out above, the Defendants have been enriched by the amounts paid by the Plaintiffs and Class Members, and third party payors on their behalf, for Elmiron.

79. The Plaintiffs and Class Members, and third party payors on their behalf, have been deprived by the payment of those amounts for Elmiron.

80. There is no juristic reason why the Defendants should have received or retain this benefit. In particular, the breaches of the *Food and Drugs Act*, s 9(1) and associated regulations, and the *Competition Act*, RSC 1985, c C-34, s 52, negate any juristic reason by which the Defendants should have received or should retain this benefit and voids any contract under which the Plaintiffs or Class Members paid for Elmiron.

81. As a result of their actions, the Defendants have been unjustly enriched. The Plaintiffs and Class Members are entitled to restitution of the benefits received by the Defendants on account of the sale of Elmiron in Canada.

82. In the alternative, justice and good conscience require that the Defendants disgorge to the Plaintiffs and Class Members an amount attributable to the benefits received by them on account of the sale of Elmiron in Canada.

Joint and Several Liability

83. The Defendants are jointly and severally liable for the actions and damages allocable to any of them.

Punitive Damages

84. The Defendants' actions described herein were high-handed, oppressive, and reprehensible conduct that departs to a marked degree from the ordinary standards expected of designers, developers, testers, researchers, marketers, labelers and sellers of pharmaceuticals for human consumption, thereby unnecessarily endangering the health of the Plaintiffs and other Class Members. In particular, the Defendants' failures to investigate the pre-approval vision-related adverse reactions before 1993, the Defendants' delay in updating the Product Monograph following the release of the Emory study in 2018, and the Defendants' failures to recall Elmiron in Canada, demand an award of punitive damages.

Limitation Periods

85. The Plaintiffs or Class Members could not reasonably have known that loss or damage had occurred, that it was caused or contributed to by acts of the Defendants, or that a court proceeding would be an appropriate means to seek to remedy the injury until September 23, 2019. The harm is ongoing.

86. The Plaintiffs and Class Members rely on the doctrines of postponement, discoverability, and fraudulent concealment per *Pioneer Corp v Godfrey* to postpone the running of the limitation period until September 23, 2019.

87. The Plaintiffs and Class Members plead and rely on and the *Limitation Act*, SBC 2012, c 13, and in particular ss 8 and 21(3). In the alternative, or in addition, the Plaintiffs and Class Members rely on the *Limitation Act*, SBC 2012, c 13, s 30 and the *Limitation Act*, RSBC 1996, c 266. In addition, the Plaintiffs and Class Members in British Columbia plead and rely on the *Emergency Program Act*, Ministerial Order No. M098 to suspend the running of the limitation period from March 26, 2020.

Service

88. The Plaintiffs and Class Members have the right to serve this Notice of Civil Claim on the Defendant Teva Branded Pharmaceutical Products R&D, Inc. pursuant to the *Court Jurisdiction and Proceedings Transfer Act*, SBC 2003, c 28, s 10 (*CJPTA*), because there is a

real and substantial connection between British Columbia and the facts on which this proceeding is based.

89. The Plaintiffs and Class Members rely on the following grounds, in that this action concerns:

a. a tort committed in British Columbia (*CJPTA*, s 10(g));
b. restitutionary obligations that, to a substantial extent, arose in British Columbia (*CJPTA*, s 10(f)); and
c. a business carried on in British Columbia (*CJPTA*, s 10(h)).

Plaintiff's address for service:

Slater Vecchio LLP
1800 - 777 Dunsmuir Street
Vancouver, BC V7Y 1K4

Fax number for service: 604.682.5197

Email address for service: service@slatervecchio.com

Place of trial: Vancouver, BC

The address of the registry is:

800 Smithe Street
Vancouver, BC
V6Z 2E1

Date: May 15, 2020

Signature of lawyer for plaintiffs

Anthony A Vecchio QC

Charles Wright

James A Richards

Saro J Turner

Sam J Jaworski

Mathew P Good

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.

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The plaintiffs claim the right to serve this pleading on the defendant Teva Branded Pharmaceutical Products R&D, Inc. outside British Columbia on the ground that the *Court Jurisdiction and Proceedings Transfer Act*, SBC 2003, c 28, s 10 (*CJPTA*) applies because there is a real and substantial connection between British Columbia and the facts on which this proceeding is based. The Plaintiffs and Class Members rely on the following grounds, in that this action concerns:

- a tort committed in British Columbia (*CJPTA*, s 10(g));
- restitutionary obligations that, to a substantial extent, arose in British Columbia (*CJPTA*, s 10(f)); and
- business carried on in British Columbia (*CJPTA*, s 10(h)).

Appendix

[*The following information is provided for data collection purposes only and is of no legal effect.*]

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This is a proposed class proceeding regarding undisclosed side effects of the Elmiron drug.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

[*Check one box below for the case type that best describes this case.*]

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

[ ] 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:

[*Check all boxes below that apply to this case*]

[x] a class action

[ ] maritime law

[ ] aboriginal law

[ ] constitutional law

[ ] conflict of laws

[ ] none of the above

[ ] do not know

Part 4:

Limitation Act, SBC 2012, c 13, Court Order Interest Act, RSBC 1996, c 79, Negligence Act, RSBC 1996, c 318,