



Court File No. **VLC-S-S-205093**

No.  
Vancouver Registry

**IN THE SUPREME COURT OF BRITISH COLUMBIA**

Between

ARENLEA FELKER

PLAINTIFF

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

**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 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 PLAINTIFF'S 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 Plaintiff 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 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 brings this action on her 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**”).

4. 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.

5. 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***

6. 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.

7. 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***

8. 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.

9. Elmiron is one of many available treatments for IC. The Canadian Urological Association 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***

10. 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.

11. 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.

12. 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.

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

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

15. 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.

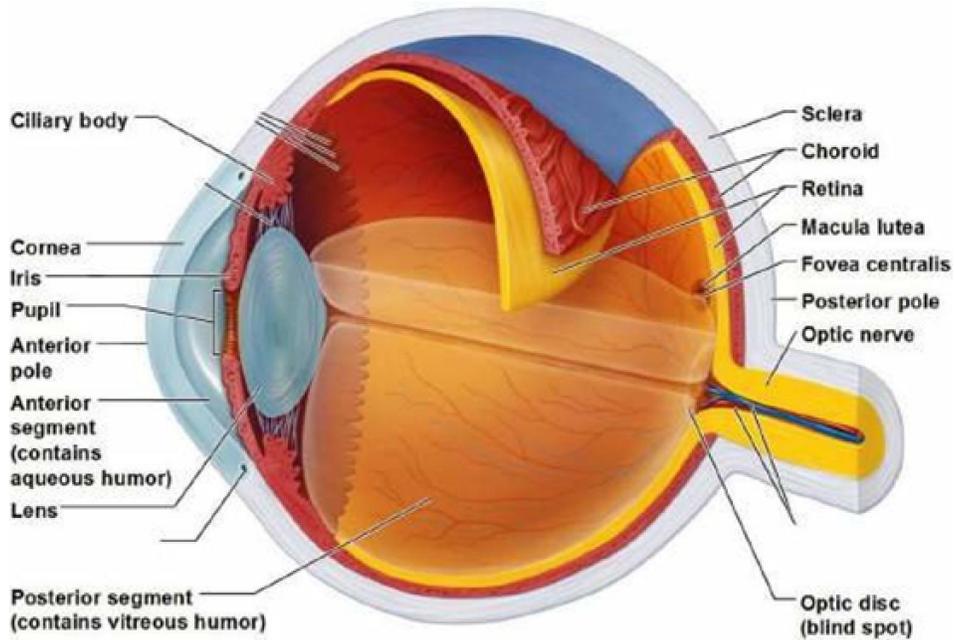
### ***Retinal Toxicity and Pigmentary Maculopathy - Undisclosed Side Effects***

16. 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.

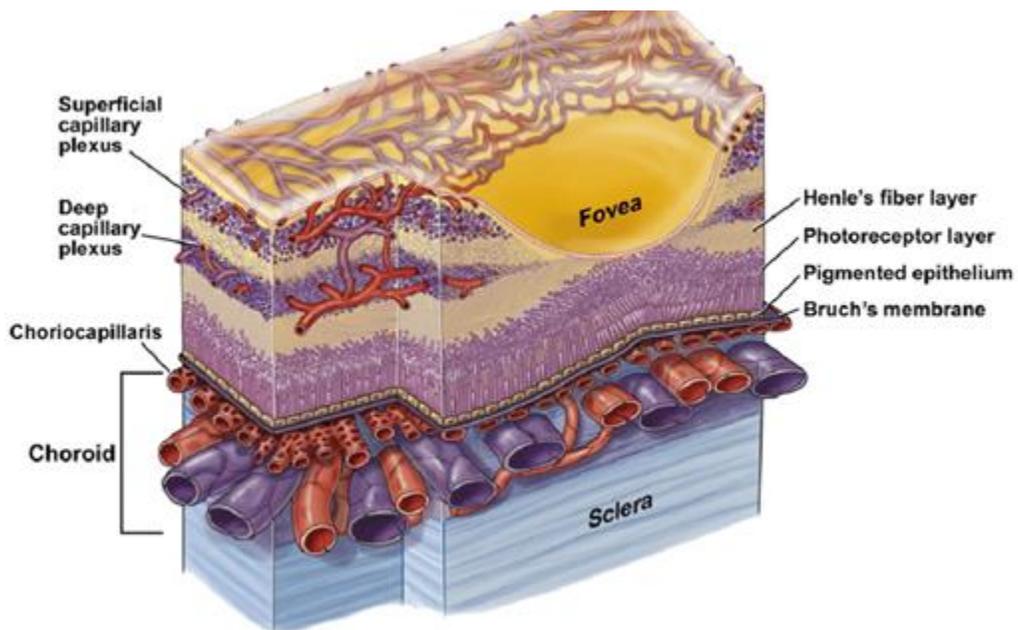
17. With its highly-concentrated network of blood vessels and minimal ability to regenerate, the retina is particularly vulnerable to drug toxicity. The retina is a thin membrane of nerve cells lining the inner surface of the back of the eye. It senses light and sends signals to the brain to enable vision.

18. 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.

19. 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**

20. The signature RPE changes of pigmentary maculopathy are only visible with Colour Fundus (“CF”), Fundus Autofluorescence (“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 *fovea centralis*.

21. 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.

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

23. In an unmasked clinical trial of 2,499 patients conducted 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.

24. 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 Elmiron. Because of this, eye health care professionals may not know to look for the indicia of pigmentary maculopathy on CF, 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.

## *Academic Studies*

25. 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.

26. In November 2018, a research team at Emory Eye Center in Atlanta, GA (*Pearce et al.*)<sup>1</sup> 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.

27. In May 2019, researchers at the Emory Eye Center (*Foote et al.*)<sup>2</sup> 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.

28. In October 2019, researchers at Harvard Medical School (*Huckfeldt et al.*)<sup>3</sup> 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.

---

<sup>1</sup> Pearce, et al. Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium. *Ophthalmology*. 2018 Nov; 125(11): 1793-1802.

<sup>2</sup> Foote, et al. Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary Changes and Vision Loss. AUA 2019 Abstract MP47-03.

<sup>3</sup> Heckfeldt, et al. Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium. *Ophthalmic Surg Lasers Imaging Retina*. 2019; 50: 656-659.

29. In November 2019, researchers at the Emory Eye Center (*Jain et al.*)<sup>4</sup> 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.

30. 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.

31. Studies on mice have also confirmed retinal function loss resulting from systemic PPS administration.<sup>5</sup>

### ***Changes to Product Monograph***

32. 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.

33. 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.

34. 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

---

<sup>4</sup>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.

<sup>5</sup> Girardot, et al. Systemic Pentosan Polysulfate Administration Causes Retinal Function Loss in the C57Bl/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.

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

36. “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.

37. “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.

38. “Part III” of the Product Monograph now includes the following chart:

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
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	✓		
	Diarhea	✓		
	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		✓	

39. 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.

40. The Defendants have not issued any purported warnings or recalls with respect to Elmiron other than the aforementioned changes to the Product Monograph.

41. 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 Plaintiff and Class Members***

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

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

- a. blurred vision;
- b. difficulty reading;
- c. poor light to dark adaptation;
- d. muted, less vivid colours; and
- e. other injuries that may develop or become known in the future.

44. Had the Plaintiff 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, she would not have agreed to take Elmiron. She would have explored one or more of the many other viable treatment options for IC.

45. 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.

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

47. 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. 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.

48. As a result of her injuries, the Plaintiff has received and in the future will continue to receive care and services from family members.

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

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

## **Part 2: RELIEF SOUGHT**

51. The Plaintiff claims, on her own behalf and on behalf of the Class Members:

- a. 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*");
- b. general damages;

- c. an accounting and restitution or, alternatively, disgorgement, of the cost of Elmiron for purchases in Canada;
- d. punitive damages;
- e. special damages;
- f. past and future damages “in trust” for services provided by family members;
- g. 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;
- h. pre-judgment and post-judgment interest under the *Court Order Interest Act*, RSBC 1996, c 79; and
- i. Such further and other relief as this Honourable Court may deem just.

### **Part 3: LEGAL BASIS**

52. The Plaintiff 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***

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

54. Each of the Defendants breached its duty of care to the Plaintiff 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***

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

56. Each of the Defendants breached its duty of care to the Plaintiff 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***

57. As a result of the Defendants' negligence in the design, development, research, testing, monitoring, marketing, labelling, promotion and sale of Elmiron, the Plaintiff 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.

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

59. Additionally, the Plaintiff pleads 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***

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

61. The Plaintiff is a “beneficiary” within the meaning of the *Medicare Protection Act*, R.S.B.C. 1996, c. 286 and any amendments.

62. The Plaintiff 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 Plaintiff pleads 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.

63. But for the Defendants' aforementioned negligence and failure to warn, the Plaintiff and other Class Members would not have incurred the expense of purchasing Elmiron. The Plaintiff 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 Plaintiff and other Class Members.

### ***Unjust Enrichment***

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

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

66. 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 Plaintiff or Class Members paid for Elmiron.

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

68. In the alternative, justice and good conscience require that the Defendants disgorge to the Plaintiff 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***

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

### ***Punitive Damages***

70. 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 Plaintiff 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***

71. The Plaintiff 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.

72. The Plaintiff 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.

73. The Plaintiff 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 Plaintiff 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 Plaintiff 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*

74. The Plaintiff 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.

75. The Plaintiff 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 plaintiff

Anthony A Vecchio QC

James A Richards

Saro J Turner

Nicole M Kelly

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 plaintiff claims 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 Plaintiff 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

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]*

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,