# IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Felker v. Teva Branded Pharmaceutical Products R,* 2022 BCSC 1813

Date: 20221017
Docket: S205093
Registry: Vancouver

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

Before: The Honourable Justice Douglas

**Reasons for Judgment on Certification**

In Chambers

| | |
|---|---|
| Counsel for the Plaintiffs: | Sam J. Jaworski<br>Jill McCartney<br>Saro J. Turner |
| Counsel for the Defendant, Janssen, Inc.: | S. Gordon McKee<br>Robin L. Reinertson<br>Karine Russell<br>Andrew Kavanagh |
| Counsel for the Defendant, Teva Branded Pharmaceutical Products R&D, Inc.: | Robert Carson |
| Place and Date of Hearing | Vancouver, B.C.<br>April 25 – 28, 2022 |
| Supplementary Written Submissions of Plaintiffs Received: | May 6, 2022 |
| Supplementary Written Submissions of Janssen Inc. Received: | May 20, 2022 |
| Place and Date of Judgment: | Vancouver, B.C.<br>October 17, 2022 |

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## I. OVERVIEW

[1] This proposed class action relates to the prescription drug, Elmiron, used to treat interstitial cystitis ("IC"), a painful bladder condition.

[2] The proposed representative plaintiffs, Arenlea Felker and Angela Catherine D'Andrea, allege that, when used as intended, Elmiron causes a unique form of pigmentary maculopathy, a disorder of the retina that leads to vision loss. They say this pigmentary maculopathy occurs when Elmiron in the blood stream accumulates in the retinal pigment epithelium (the "RPE"), the outer blood-retinal barrier essential to the structural integrity and health of the retina, thereby causing drug toxicity. They plead that the defendants:

a) Knew or ought to have known of this risk but negligently failed to warn of it on a timely basis;

b) Negligently designed a defective product; and

c) Have been unjustly enriched as a consequence of their actions.

[3] The plaintiffs submit that certification is appropriate because this action relates to the alleged failure of a unique product that has affected many persons in similar ways. They say there is evidence of a common design defect and common failures to warn and that issues related to drug safety can be answered in common for all Canadians who were prescribed Elmiron.

[4] The defendants, Janssen Inc. ("Janssen") and Teva Branded Pharmaceutical Products R&D, Inc. ("Teva"), submit that this certification application ought to be dismissed because:

a) The plaintiffs have failed to recognise the defendants' distinct roles at different times in relation to Elmiron and have not therefore pleaded the material facts required to establish the constituent elements of claims in negligence as against each of them;

b) The proposed class definition is impermissibly broad and bears no rational relationship to the claim or proposed common issues;

c) There is no basis in fact for the proposed common issues; and

d) A class action is not the preferable means of resolving any issue in this case.

[5] In response, the plaintiffs argue that the defendants invite an inappropriate and premature determination of this claim on the merits. They say that the standard of proof on a procedural certification application is low and not one of perfection.

[6] For the reasons that follow, I conclude that the proposed class definition is overly broad and that only one of the plaintiffs' pleaded claims is certifiable: namely, Janssen's allegedly negligent failure to warn of the risk of pigmentary maculopathy associated with Elmiron use after November 2018 and before September 23, 2019.

## II. THE FACTS

### A. Elmiron

[7] Elmiron is the brand name for pentosan polysulfate sodium ("PPS"), a prescription medicine with an approved indication for the treatment of IC, a condition characterized by inflammation and irritation of the bladder wall. PPS is a low molecular weight heparin-like compound. Pharmacologically, it works as an anticoagulant (blood thinner) but its main indication for use is in the treatment of IC. Elmiron has been prescribed in Canada to treat IC since Health Canada approved it in 1993.

[8] Elmiron is the only oral prescription medication in Canada with an approved indication for the treatment of IC. Elmiron has been shown to be efficacious in the treatment of IC but its precise mechanism of action is unknown. Elmiron remains on the market and physicians in Canada continue to prescribe it.

### B. Pigmentary Maculopathy

[9] The plaintiffs rely on the reports of three experts: urologist, Dr. Mary-Ann Lynn Stothers, ophthalmologist, Dr. Kevin Gregory-Evans, and clinical pharmacologist and

epidemiologist, Dr. Mahyar Etminan. The defendants rely on the reports of their own three experts: ophthalmologist, Dr. Carol Schwartz, ophthalmologist and vitreo-retinal specialist, Dr. Jerry Sebag, and ophthalmologist, Dr. Oliver Schein.

[10] Dr. Etminan states as follows in his report dated August 13, 2020:

> The retina is a thin structure that covers the inside of the back of the eye. The retina acts like a camera film as it captures light signals and passes them to the optic nerve which in turn are sent to the brain for processing and creation of visual images. A healthy retina is instrumental in the creation of crisp images. The macula, the centre of the retina, is a delicate structure that is especially responsible for central vision image processing. When the macula is damaged the central vision will be affected. The retinal pigment epithelium (RPE) is the part of the retina that is pigmented and is responsible for its maintenance and nourishment of the retina.

[11] Dr. Etminan references studies from 2018 and 2019 that identify a potential link between Elmiron and pigmentary maculopathy, saying patients in those studies who were diagnosed with a signature form of pigmentary maculopathy secondary to Elmiron presented with at least two hallmark features.

[12] The defendants deny that pigmentary maculopathy is one disease or a unique condition. Rather, they say this term refers instead to a variety of different pathological conditions related to the macula.

[13] Dr. Jerry Sebag describes the structure of the eye in his report. He explains that the retina is a “thin layer of tissue made of nerve cells that lines the inside of the eye, creating an image in electrical signals that are transmitted to the brain where vision is completed”. The macula is found at the centre of the retina (responsible for vision straight ahead) and the RPE is a layer of pigmented cells behind the retina.

[14] Dr. Sebag describes pigmentary maculopathy as follows:

> *‘Pigmentary Maculopathy”* refers to a variety of pathological conditions or diseases of the macula (center of the retina lining the inside of the back of the eye) that feature irregularities in normal levels of pigmentation in the macula. Most commonly, these are age-related macular degeneration, central serous chorioretinopathy, and macular dystrophy. The word “Pigmentary” refers to the amount of brown pigment in the macula, located in cells called “Retinal Pigment Epithelium (RPE)”, a layer of pigmented cells located behind the retina. There can be increased pigmentation, referred to as “hyperpigmentation” or “pigment clumping”, as well as decreased pigmentation, referred to as “hypopigmentation”.

> It is important to appreciate that pigmentary irregularities can occur in the absence of any pathological condition or disease, such as in lightly pigmented people (blonde hair, blue eyes, fair skin tone). Consequently, irregularities in pigment levels of the macula (sometimes called “pigmentary maculopathy”) may or may not have any clinical significance. Indeed, the term “pigmentary maculopathy” has been used in the literature to refer to irregularities of macular pigmentation, but it is important to appreciate that this does not equate with damage to the macula that causes vision loss. In fact, the overwhelming majority of reported cases purported to have pigmentary maculopathy in association with Elmiron therapy do not have vision loss. As noted below, reports of both pigmentary irregularities and vision loss in patients using Elmiron are rare, and may well be due to factors other than Elmiron therapy.

[15] Ophthalmologist, Dr. Schein, describes pigmentary maculopathy in his undated report as follows:

> The term "maculopathy" refers to disorders of the macula, the center of the retina. Maculopathy presents in a myriad of different patterns. The term "pigmentary” refers to a characteristic mottled appearance of the retina based on degeneration of or damage to the retinal pigment epithelium (RPE), one of the layers of the retina. Pigmentary change in the macula may or may not be associated with any loss of vision. There may also be findings of pigment in the macula that do not constitute "pigmentary maculopathy". For example, there may be pigment deposition following trauma or infection. There are many known diseases and conditions that present with pigmentary maculopathy, some with known genetic markers and some with recognized associations with specific drugs.

[16] Ophthalmologist, Dr. Schwartz, states in her report dated September 17, 2021 that pigmentary maculopathy has many possible causes, including age-related macular degeneration, inherited retinal dystrophy, drug toxicity, chronic central serous maculopathy, and trauma. She defines pigmentary maculopathy as follows:

> **What is pigmentary maculopathy?**
>
> 7. Maculopathy is a descriptive term for any disease state that can affect the macula, the central part of the retina. If the eye is analogous to a camera, the retina would be comparable to the film in the camera, the tissue where the image is created. When examined under the microscope, it is composed of 9 distinct cellular layers. One layer is the rods and cones, the receptor cells that sense the incoming light, convert it into an electrical signal and then send it to the brain for interpretation. There is also a pigment layer called the retinal pigment epithelium which is responsible for the nutrition and maintenance of the rods and cones.
>
> 8. The macula is the centre of the retina and is responsible for the highest acuity central vision. There are many different types of maculopathies, ranging from metabolic conditions such as diabetic macular edema to degenerative diseases such as age-related macular degeneration.

> 9. Pigmentary maculopathy is a descriptive term for a group of diseases that causes changes in the pigment layer of the eye (the RPE) in the centre part of the vision (the macula). Akin to how a simple skin rash may have many different causes (such as infectious, inflammatory, environmental irritant), similar-appearing pigment changes in the macula may be due to different disease entities as the eye is only able to respond to insult in a limited number of ways.

### C. The Plaintiffs

[17] Ms. Felker is a 65-year old resident of British Columbia. She has taken Elmiron daily for IC symptoms since 2005 and continues to do so. Ms. Felker deposes that she has experienced progressive symptoms of vision loss in recent years, including blurred central vision, difficulty reading, and poor light to dark adaptation.

[18] Ms. D'Andrea is a 53-year old resident of British Columbia who was added as a plaintiff in this action in January 2022. She was prescribed Elmiron for the treatment of IC in 2004, and took it daily until August 2020. She deposes that she has experienced progressive symptoms of vision loss, including blurred central vision, in recent years. Ms. D'Andrea has been diagnosed with pigmentary irregularities in the macula and Elmiron toxicity.

### D. The Class

[19] The proposed class includes all persons in Canada, excluding Quebec, who were prescribed and ingested Elmiron between December 31, 1993 and the date this action is certified as a class proceeding.

### E. The Defendants

[20] Janssen, formerly known as Janssen-Ortho Inc., is a Canadian pharmaceutical company. It sells and distributes prescription medicines to wholesalers, distributors, and others in Canada; it does not sell directly to consumers. Janssen became the market authorisation holder for Elmiron in 2002. It began selling Elmiron in Canada in 2003 and continues to market and sell this drug in Canada. On the undisputed evidence of Anne Tran, Janssen's Director of Regulatory Affairs, Elmiron was developed by Baker Norton Pharmaceuticals, Inc. ("BNPI").

[21] Teva is a Delaware corporation with its principal place of business in West Chester, Pennsylvania. Based on Affidavit #1 of Brian Shanahan, Teva's Corporate Secretary, Teva has never been responsible for or involved in:

a) Marketing Elmiron in Canada;

b) Maintaining or updating the product monograph for Elmiron in Canada; or

c) Providing notices or warnings in relation to Elmiron in Canada.

[22] Mr. Shanahan deposes further that BNPI was involved in obtaining Health Canada approval for the sale of Elmiron in Canada and, for a period of time in the 1990s, BNPI held the Notice of Compliance ("NOC") issued by Health Canada for Elmiron. On Mr. Shanahan's evidence, Teva is not the same entity as BNPI and Teva was never formerly known as BNPI. BNPI denies it was affiliated with Teva at any time when BNPI held the NOC for Elmiron. Mr. Shanahan deposes as follows:

a) In April 2001, BNPI, a Florida company, was renamed IVAX Laboratories, Inc.;

b) In October 2001, BNPI was renamed IVAX Research, Inc.;

c) In January 2007, IVAX Research, Inc. merged into IVAX Research Holdings, Inc., which changed its name to IVAX Research, Inc.;

d) In January 2007, IVAX Research, Inc. was converted to IVAX Research, LLC;

e) In May 2008, IVAX Research, LLC changed its name to Teva Global Respiratory Research, LLC; and

f) On December 9, 2009, Teva Global Respiratory Research, LLC merged into Teva Women's Health Research, Inc. which changed its name to Teva Branded ("Teva").

[23] Teva submits that since at least January 19, 1998, the NOC for Elmiron has been held by third parties who are not, and never were, affiliated with BNPI or Teva. On the

evidence of Mr. Shanahan, the NOC for Elmiron has been held exclusively since then by the following entities: ALZA Canada, ALZA Corporation, Janssen-Ortho Inc., and Janssen Inc. Mr. Shanahan deposes that, by January 19, 1998, BNPI ceased to be responsible for marketing Elmiron in Canada, maintaining or updating the product monograph for Elmiron in Canada, or monitoring adverse event reports relating to Elmiron. Teva denies that either plaintiff took Elmiron manufactured by BNPI.

### F. The Regulatory Framework

[24] Elmiron is regulated under the *Food and Drugs Act*, R.S.C. 1985, F-27 and may only be sold in Canada with the license and approval of Health Canada. Elmiron received Health Canada approval in 1993 and has been used to treat patients with IC in Canada since then.

[25] Health Canada issues a NOC approving the sale of a drug only if the New Drug Submission complies with the applicable regulations, including the requirements for evidence of safety and effectiveness of the drug for its approved indications, and if the benefits of the drug outweigh the risks: *Food and Drugs Regulations*, C.R.C., c. 870, ss. C.08.002–C.08.004*; Player v. Janssen-Ortho Inc.*, 2014 BCSC 1122 at paras. 83–84 [*Player*]. In Canada, manufacturers of prescription medicines are required to develop and obtain Health Canada approval of a product monograph for each of their approved medicines. Janssen says that the product monograph is regarded as labelling in Canada.

[26] The plaintiffs do not dispute that changes to a product monograph are a normal part of the life-cycle of a medication. A product monograph can be revised by filing a submission for review and approval with Health Canada. Revisions may occur as information becomes available about the potential risks and benefits of a drug.

### G. The Product Monograph for Elmiron

[27] Anne Tran, Associate Director of Regulatory Affairs for Janssen, deposes that the product monograph for Elmiron is accessible to healthcare professionals:

a) On the websites of Health Canada and Janssen;

b) In the Compendium of Pharmaceutical Specialities (the "CPS"), a resource available to all physicians and pharmacists in Canada; and

c) In a leaflet (setting out the consumer information section of the product monograph) attached to each bottle of Elmiron provided to pharmacies and available to patients when they fill their prescriptions.

[28] Janssen denies there was any reported literature describing a possible link between Elmiron and pigmentary maculopathy before November 2018. Janssen says that it submitted a request to Health Canada to revise the Elmiron product monograph after it obtained new information regarding reports of pigmentary maculopathy in long term patient users of Elmiron. In September 2019, Health Canada approved Janssen's proposed changes and the revised product monograph was posted on the Janssen and Health Canada websites. Health Canada's website referenced these revisions and included key information for healthcare professionals about the updated labelling in its Health Product InfoWatch published in October 2019.

[29] The 2019 changes to the Elmiron product monograph approved by Health Canada included reference to reports of pigmentary maculopathy and a warning for consumers to call their doctor if they noticed any vision changes. The following text was added to Part 1 (for healthcare professionals) under the heading "Warnings and Precautions":

> **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 should be considered.

[30] In Part I, under the heading "Post-Market Adverse Drug Reactions", the Elmiron product monograph was further revised to state that "[i]n post-market safety reports, adverse events of dyspnea, pruritus, urticaria and pigmentary maculopathy have been

reported with ELMIRON® use" and "it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure".

[31] Part III of the Elmiron product monograph (the Consumer Information section) was also revised in September 2019 to include reference to vision changes, difficulty reading, and slow adjustment to low or reduced light as potential serious side effects of unknown frequency; consumers were advised to call their doctor if they noticed any vision changes.

[32] In 2020, Janssen submitted another request to Health Canada to revise the Elmiron product monograph; on October 1, 2020, Health Canada approved additional changes. The revised product monograph was posted on the websites of Janssen and Health Canada. Part I of the Elmiron product monograph was further revised to state that Elmiron is contraindicated in patients with a personal history of any macular pathology. The following additional information was included under the ophthalmologic warnings and precautions in Part I of the Elmiron product monograph:

> **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.

[33] Part I of the October 2020 product monograph for Elmiron continued to identify pigmentary maculopathy in the Post-Market Adverse Drug Reactions section, with an additional bolded reference for the reader to review the above-noted warnings and precautions.

[34] The following warning was added to Part III of the Elmiron product monograph (the Consumer Information section):

**Serious Warnings and Precautions**

Do not use ELMIRON® if you have a personal history of eye disease that affects the retina.

Cases of retinal changes (pigmentary maculopathy) have been reported with long-term use of ELMIRON®. This eye disease changes the centre of the retina (called the 'macula'). This may harm your vision and may lead to a permanent decrease or loss of central vision. Tell your doctor and eye doctor right away if you notice any changes in your vision.

While taking ELMIRON®, regular eye exams that include checking your retina are recommended for detection of pigmentary maculopathy. Your doctor will decide when these eye exams are needed, and if the treatment should be continued.

[35] Additional warnings were added to Part III of the Elmiron product monograph:

a) Do not use ELMIRON® if you have a personal history of eye disease that affects the retina (under the heading "When it should not be used");

b) Before you use ELMIRON® talk to your doctor or pharmacist if you have a personal or family history of eye problems and tell your doctor if you notice any changes in your vision (under the heading "Warnings and Precautions"); and

c) Consumers were instructed to talk with their doctor or pharmacist in all cases of 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 centre of their field of vision (in a chart describing serious side effects, how often they happen, and what to do about them).

[36] Janssen denies that statements in the Elmiron product monograph regarding reports of pigmentary maculopathy or retinal changes with long term use of Elmiron are admissions of a cause and effect relationship between Elmiron and pigmentary maculopathy or retinal changes, or that such a relationship is likely. They underscore statements in the product monograph that, because drug reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.

[37] On December 15, 2020, Janssen published a Dear Healthcare Professional Letter (the “DHP Letter”) and posted it on its website. It referenced cases of pigmentary maculopathy or retinal changes that had been reported by long term users of Elmiron. The DHP Letter was approved by Health Canada and posted on its Healthy Canadians recalls and alerts website. Janssen distributed the DHP Letter (by email, fax, or regular mail) to multiple Canadian healthcare professionals including urologists, uro-gynaecologists, ophthalmologists, optometrists, and primary care physicians.

## III. THE CERTIFICATION TEST

### A. Generally

[38] The plaintiffs bear the onus of satisfying the requirements for certification.

[39] The test for certification of a class proceeding is set out in s. 4(1) of the *Class Proceedings Act*, R.S.B.C. 1996, c. 50 [*CPA*]:

> Class certification
>
> **4** (1) Subject to subsections (3) and (4), the court must certify a proceeding as a class proceeding on an application under section 2 or 3 if all of the following requirements are met:
>
> (a) the pleadings disclose a cause of action;

> (b) there is an identifiable class of 2 or more persons;
>
> (c) the claims of the class members raise common issues, whether or not those common issues predominate over issues affecting only individual members;
>
> (d) a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues;
>
> (e) there is a representative plaintiff who
>
> > (i) would fairly and adequately represent the interests of the class,
> >
> > (ii) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and
> >
> > (iii) does not have, on the common issues, an interest that is in conflict with the interests of other class members.

[40] The provisions of s. 4(1) of the *CPA* are mandatory. The court must certify an action as a class proceeding if all the criteria in s. 4(1) are met and there is no other reason to refuse the order: *0790482 B.C. Ltd. v. KBK No. 11 Ventures Ltd.*, 2021 BCSC 1761 at para. 74 [*KBK*]. The plaintiffs must demonstrate "some basis in fact", on admissible evidence, for each of the criteria set out in sections 4(1)(b) to (e): *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at paras. 99–100 [*Pro-Sys*]; *Hollick v. Toronto (City)*, 2001 SCC 68 at paras. 22, 25 [*Hollick*]; *AIC Limited v. Fischer*, 2013 SCC 69 at para. 48 [*Fischer*].

[41] The certification criteria must be construed generously in order to achieve the objectives of class proceedings including access to justice, judicial economy, and behaviour modification: *Sun-Rype Products Ltd. v. Archer Daniels Midland Company*, 2013 SCC 58 at paras. 86, 97 and 109 [*Sun-Rype*]; *Pro-Sys* at para. 137. In order to ensure that the relevant policy goals are realized, courts must be mindful not to impose unduly technical requirements on plaintiffs: *KBK* at para. 77; *Knight v. Imperial Tobacco Canada Limited*, 2006 BCCA 235 at para. 20 [*Knight*]; *Miller v. Merck Frosst Canada Ltd*., 2013 BCSC 544 at paras. 42, 126 [*Miller* BCSC], aff'd 2015 BCCA 353 at para. 53 [*Miller* BCCA].

[42] A judge must not weigh competing evidence on a certification application but must consider the defendants' responding evidence in assessing the certification

criteria: *Marshall v. United Furniture Warehouse Limited Partnership*, 2013 BCSC 2050 at paras. 53-55, aff'd 2015 BCCA 252 [*Marshall*]; *Pro-Sys v. Microsoft Corp*, 2010 BCSC 285 at para. 144, aff'd 2013 SCC 57. Each case must be considered on its own facts, in light of the claims advanced and the evidence adduced: *Pro-Sys* at para. 104; *Ernewein v. General Motors of Canada Ltd.*, 2005 BCCA 540 at para. 33 [*Ernewein*]; *Hollick* at para. 37.

[43] The court has an important gatekeeper role on a certification application: *Krishnan v. Jamieson Laboratories Inc.*, 2021 BCSC 1396 at para. 41 [*Krishnan*]. In *Pro-Sys* at para. 103, the Supreme Court of Canada reaffirmed the importance of certification as a meaningful screening device. While the standard for assessing evidence at certification does not give rise to a determination of the merits, it does not involve such a superficial level of analysis into the sufficiency of the evidence that it would amount to nothing more than symbolic scrutiny: *Pro-Sys* at para. 103.

### B. Do the Pleadings Disclose a Cause of Action?

#### 1. Generally

[44] Section 4(1)(a) of the *CPA* requires the plaintiffs to establish that the pleadings disclose a cause of action on the same "plain and obvious" standard applicable when striking a pleading under R. 9-5(1)(a) of the *Supreme Court Civil Rules* [*SCCR*]: *Pro-Sys* at para. 63; *Hunt v. Carey Canada Inc.,* [1990] 2 S.C.R. 959 at 980, 1990 CanLII 90 [*Hunt*]; *R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42 at paras. 17, 20 [*Imperial Tobacco*]. In other words, a court will only refuse to certify an action on this ground if it is plain and obvious that the plaintiff's claim is bound to fail, assuming the facts alleged in the pleading are true: *Pro-Sys* at para. 63; *Atlantic Lottery Corp. Inc. v. Babstock*, 2020 SCC 19 at para. 19 [*Babstock*]; *Pioneer Corp v. Godfrey*, 2019 SCC 42 at para. 27.

[45] A cause of action is not effectively pleaded and is bound to fail if insufficient material facts are pleaded to support any element of a cause of action: *Sahyoun v. Ho*, 2013 BCSC 1143 at paras. 24–26 [*Sahyoun*]; *Mercantile Office Systems Private Limited v. Worldwide Warranty Life Services Inc.*, 2021 BCCA 362 at paras. 45–48.

Speculation, assumption, and bald conclusory statements do not comprise material facts: *Kindylides v. Does*, 2020 BCCA 330 at paras. 34–35 [*Kindylides*]; *E.B. v. British Columbia (Child, Family and Community Services)*, 2021 BCCA 47 at paras. 46, 65 [*E.B.*].

[46] The claim must be read generously to allow for inadequacies due to drafting frailties and the plaintiff's lack of access to key documents and discovery information; unsettled points of law must be permitted to proceed: *Krishnan* at para. 45. Courts are to consider the claims as they are, or as they may be amended: *Sharp v. Royal Mutual Funds Inc.*, 2020 BCSC 1781 at para. 22 [*Sharp* BCSC], aff'd 2021 BCCA 307 [*Sharp* BCCA].

### 2. Lumping Together of the Defendants

[47] The defendants emphasize their status as separate corporate entities. They say that the plaintiffs have failed to plead the material facts necessary to give rise to the claims advanced against each of them and to give them adequate notice of the claims they must meet: *Kindylides* at para. 34; *Stoneman v. Denman Island Local Trust Committee*, 2010 BCSC 636 at paras. 26–29; *Sahyoun* at paras. 18–19, 36–39, 53–54; *EnerWorks Inc. v. Glenbarra Energy Solutions Inc.*, 2012 ONSC 414 at paras. 36, 42, 61–65 [*EnerWorks*]; *Richardson v. Samsung*, 2018 ONSC 6130 at paras. 29–31. The defendants describe this as a fatal flaw in the plaintiffs' pleading.

[48] Janssen denies it was involved in designing or developing Elmiron, or in obtaining approval for its use in the 1990s. On the affidavit evidence of Ms. Tran, Janssen became the market authorisation holder for Elmiron in Canada in 2002, and began selling Elmiron in Canada in 2003. On the affidavit evidence of Mr. Shanahan, Teva has never been responsible for marketing Elmiron in Canada, maintaining or updating the product monograph for Elmiron in Canada, or otherwise providing notices or warnings in relation to Elmiron in Canada. Mr. Shanahan deposes that, since at least January 19, 1998, the Health Canada-issued NOC has been held by third parties that are not, and never were, affiliated with Teva or BNPI. Teva denies there is any evidence that either representative plaintiff, or any proposed class member, took Elmiron that was

manufactured and sold by BNPI (more than 20 years ago), or that any such person was later diagnosed with pigmentary maculopathy.

[49] The defendants submit that the blanket claims pleaded against them fail to acknowledge or distinguish their different positions in relation to the design, manufacture, marketing, and sale of Elmiron in Canada. They rely on the statements of Justice Voith (then of this Court) in *Canfor Pulp Limited Partnership v. Siemens Building Technologies Ltd.*, 2016 BCSC 2089 at para. 22:

> When several causes of action are being alleged against multiple parties, a statement of claim or third party notice must clearly identify what facts relate to what cause of action and to which party. It is inappropriate to lump defendants together in a pleading and to make blanket allegations against them, unless those defendants were in an identical relationship with the plaintiff. Such pleadings are necessarily imprecise, are overly general, and make it impossible to discern on what basis each of the defendants could be held liable. Such a pleading may be struck for failing to clearly define the issues of fact and law that are to be determined by the court and/or for being vexatious, prejudicial to a fair trial of the proceeding, and an abuse of process. [Citations omitted.]

[50] A defendant owes no duty of care to users in relation to products manufactured and sold by another company absent allegations that the former can control, qualify, or stop the latter's conduct: *Hughes v. Sunbeam Corp. (Canada) Ltd.,* [2000] O.J. No. 4595 (S.C.J.) at para. 59, 2000 CanLII 22685 [*Hughes* ONSC]; on appeal, the Ontario Court of Appeal dismissed the relevant aspects of the appeal, affirming the lower court's reasons on this issue, *Hughes v. Sunbeam Corp. (Canada) Ltd.* (2002), 219 D.L.R. (4th) 467, 2002 CanLII 45051 (Ont. C.A.) at paras. 12–14, 16 [*Hughes* ONCA]; *Goodridge v. Pfizer Canada Inc.,* 2010 ONSC 1095 at para. 100 [*Goodridge*]; *Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681 at para. 54. Teva observes that the plaintiffs do not allege that either it or BNPI could control the conduct of the other entities who sold Elmiron in Canada.

[51] The plaintiffs submit that it can be appropriate to lump defendants together in a pleading, provided the material facts supporting the elements of each cause of action are pleaded and each defendant can understand the case it has to meet. Here, they allege that Teva licensed the right to sell Elmiron in Canada to Janssen on a date

unknown to them. They deny that evidence about how or when this assignment occurred can be considered on a s. 4(1)(a) analysis.

[52] As noted by Justice Horsman (then of this Court) in *MacKinnon v. Pfizer Canada Inc*., 2021 BCSC 1093 at para. 48, rev'd in part 2022 BCCA 151 [*MacKinnon*], *SCCR*, R. 3-1(2) requires a plaintiff to plead a concise statement of the material facts giving rise to a claim. However, a notice of civil claim is to be interpreted generously for the purpose of determining whether a cause of action is disclosed: *Imperial Tobacco* at para. 21. If the plaintiffs' amended notice of civil claim (the "ANOCC") is deficient in the manner the defendants suggest, it would be necessary to consider whether these deficiencies could be cured by way of further amendment: *MacKinnon* at para. 48.

[53] I endorse the views of Horsman J. in *MacKinnon* and find myself in a similar position here. Justice Horsman found that the plaintiffs had pleaded their causes of action in negligence with as much precision as could reasonably be expected at the certification stage, based on the information they then had: *MacKinnon* at para. 49.

[54] In *British Columbia v. Apotex Inc*., 2022 BCSC 1 at para. 79 [*Apotex*], Justice Brundrett cites *Watson v. Bank of America Corporation*, 2014 BCSC 532, var'd 2015 BCCA 362 [*Watson*], a decision of Chief Justice Bauman (as he then was). The comments of Bauman C.J. in *Watson* are instructive:

> [144] In this case, the plaintiff has carefully set out the structure of the credit card industry and the relationships between the various parties are clear. This is not a case where the pleadings merely lump a diverse group of defendants together and claim they conspired to achieve some end state. To the extent there is homogeneity in the pleadings, it is presumably because the defendants are all similar corporate entities that are alleged to have done the same thing: maintained supracompetitive Interchange Fees and the Network Rules. This is not a case like *Research Capital Corp* or *J.G. Young & Son Ltd.* where the defendants included both companies and individuals.

[55] The plaintiffs have not yet had the benefit of full documentary disclosure or examinations for discovery. When the ANOCC was prepared, they did not have the detailed information necessary to distinguish the defendants' roles regarding the manufacture, marketing, and sale of Elmiron. I acknowledge that the defendants filed

responses to the ANOCC in February 2022. However, they did so after the plaintiff, Ms. Felker, filed her notice of application for certification in November 2020. Section 4(1)(a) of the *CPA* precludes me from considering evidence when assessing whether the pleadings disclose a cause of action. It is open to the plaintiffs to amend their pleading to incorporate the factual information the defendants have now provided in their filed affidavits.

[56] I conclude that the plaintiffs' negligence claims are pleaded with sufficient particularity to enable the defendants to understand generally what is being alleged against them. I address the defendants' other criticisms of the ANOCC below when considering the adequacy of the individual pleaded causes of action.

### 3. Negligent Design

[57] The plaintiffs plead that the defendants were negligent in the design of Elmiron. They submit that manufacturers owe a distinct duty of care in designing a product to avoid safety risks and to make the product reasonably safe for its intended purposes: *Cantlie v. Canadian Heating Products Inc.*, 2017 BCSC 286 at para. 189 [*Cantlie*].

[58] The plaintiffs allege that the defendants, individually or jointly, design, develop, manufacture, market, label, and sell PPS under the trade name Elmiron in Canada for the treatment of IC and that they owed the plaintiffs and other class members a duty of care in designing, developing, researching, testing, and monitoring Elmiron. The ANOCC pleads as follows:

> 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.

[59] In a product liability claim, plaintiffs must plead that the defendants owed them a legal duty of care, the product was defective, the defendants were negligent in failing to meet the requisite standard of care, the defect caused the plaintiffs' injuries, and they suffered damage as a result of the defendants' negligence: *Mustapha v. Culligan of Canada Ltd.*, 2008 SCC 27 at para. 3; *James v. Johnson & Johnson Inc.*, 2021 BCSC 488 at para. 94 [*James*].

[60] To plead a reasonable cause of action for negligent design, a plaintiff must identify the design defect that made the product dangerous, or more dangerous to use than it would have been if other safer design choices had been made: *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7950 at paras. 9–12; *Cantlie* at para. 194. The plaintiff must further plead that the defect created a substantial likelihood of harm, and that it was possible to design the product in a safer manner (i.e., that there was a safer alternate product or design): *Player* at paras. 210–211; *James* at para. 77.

[61] The defendants submit that the plaintiffs must plead the material facts necessary to support their claim in negligent design with specificity, including: (1) that an equally efficacious but safer design or formulation of Elmiron was feasible or would have

resulted from additional research, testing, or clinical trials; or (2) that additional research, testing, or clinical trials would have resulted in Elmiron not being marketed: *Williamson v. Johnson & Johnson*, 2020 BCSC 1746 at paras. 150–151 [*Williamson*]; *Martin v. Astrazeneca Pharmaceuticals Plc*, 2012 ONSC 2744 at paras. 135–138 [*Martin*].

[62] The defendants argue that determining whether a manufacturer breached its duty of care in designing a product requires a risk-utility analysis: *Price v. Smith & Wesson Corp.*, 2021 ONSC 1114 at para. 95; *Andersen* at paras. 61–62. They say it is well accepted in Canada that even medication with serious side effects can be marketed provided it has utility for some users and there is an adequate warning of the risks: *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986), 54 O.R. (2d) 92 (C.A.) at 107, 1986 CanLII 114.

[63] In response to the defendants' submissions, but without acknowledging any deficiencies in their pleading as presently drafted, the plaintiffs propose adding the following new paragraph to the ANOCC:

> 73 Had the Defendants properly investigated, studied or researched vision-related adverse reactions to Elmiron during clinical trials or on an ongoing basis after releasing Elmiron into the stream of commerce, then:
>
> a. A safer alternative to Elmiron that does not cause pigmentary maculopathy would have been developed;
>
> b. The Defendants would have included adequate warnings on Elmiron; and/or
>
> c. Elmiron would not have been approved for sale and/or would have been removed from the stream of commerce.

[64] The plaintiffs say the jurisprudence is clear that a court should consider a pleading as it may reasonably be amended, especially when a draft pleading has been provided: *Pantusa v. Parkland Fuel Corporation*, 2022 BCSC 322 at paras. 99–100; and *Kett v. Mitsubishi Materials Corporation*, 2020 BCSC 1879 at para. 82 and 106 [*Kett*], citing *Great Oak v. S & T Accounting*, 2018 ONSC 5934 at para. 12.

[65] The plaintiffs' allegations, as amended, may, or may not, prove accurate at a common issues trial. However, for the purpose of the certification criteria, I must

assume them to be true: *MacKinnon* at para. 51. I am satisfied that, with the addition of proposed para. 73, the plaintiffs have met the low bar required at this stage and adequately pleaded a claim in negligent design.

### 4. Negligent Failure to Warn

[66] The plaintiffs allege that, at all material times, the defendants, individually or jointly, owed them and other class members a duty of care and a duty to warn in marketing, labelling, promoting, and selling Elmiron. They plead particulars of the defendants' alleged negligent failure to warn as follows:

> 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.

[67] Manufacturers owe a specific duty to warn consumers of the dangers inherent in those uses of their products for which they have (or ought to have) knowledge; there will almost always be a heavy onus on manufacturers of medical products to provide clear, complete, and current information concerning the dangers inherent in the ordinary use of their product: *Hollis* at paras. 20, 23, and 29; *James* at para. 101.

[68] The defendants submit that, in pleading a failure to warn, sufficient particulars should be provided regarding: the alleged breach of duty (i.e., what warnings were given, how they were inadequate, and whether they could have been improved at the relevant time), the damages sustained, and how they were caused, in fact and in law, by the defendants' breach: *Cantlie* at para. 203–210, citing *Martin* at paras. 158–159; *James* at paras. 103; *Mustapha* at para. 3.

[69] The defendants say that a manufacturer of a prescription medicine only has a duty to provide warnings to users of its own products: *Hughes* ONSC at paras. 41, 59, aff'd on this point *Hughes* ONCA at paras. 12–14, 16; *Goodridge* at para. 100.

[70] The ANOCC alleges the existence of a duty of care and provides particulars of the defendants' alleged breach of the requisite standard of care. The plaintiffs plead that they have suffered damages as a consequence of the defendants' alleged breach. I make no comment on the merits of the plaintiffs' failure to warn claim as that is not relevant on a certification application: *MacKinnon* at para. 56. I find that the pleadings are adequate to disclose a cause of action in negligence for failure to warn.

### 5. Unjust Enrichment

[71] Finally, the plaintiffs advance a claim in unjust enrichment. They allege that the defendants have been enriched by the amounts paid for Elmiron by the plaintiffs, other class members, and third-party payors, all of whom have suffered a corresponding deprivation. They plead that the defendants' breaches of s. 9(1) of the *Food and Drugs Act*, R.S.C., 1985, c. F-27 and s. 52 of the *Competition Act,* R.S.C. 1985, c. C-34 effectively void any contracts of purchase for Elmiron, thereby negating any juristic reason for the defendants receiving or retaining any benefits from those sales. They seek restitution of those benefits or, alternatively, the remedy of disgorgement. In

advancing an unjust enrichment claim, the plaintiffs rely on the same particulars as those pleaded to support their claim for an alleged negligent failure to warn.

[72] The plaintiffs plead their claim in unjust enrichment in paras. 78–82 of the ANOCC as follows:

> **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.

[73] The defendants describe these allegations as bald assertions that are insufficient to plead a claim in unjust enrichment. They say it is unclear precisely what statutory breaches are alleged, how such actions (if proved) would void contracts of sale for Elmiron, or how consumers who derived benefit from Elmiron have suffered any deprivation. They submit that the plaintiffs are attempting to bootstrap an unjust enrichment claim onto their negligence claim in order to justify an all users class. They deny such a claim is sustainable on the pleadings. In response, the plaintiffs say that the relevant question at this stage is not whether their unjust enrichment claim will succeed, but whether it is doomed to fail, citing *Apotex* at para. 240.

[74] Section 9(1) of the *Food and Drugs Act* provides as follows:

> Deception, etc., regarding drugs

> **9 (1)** No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

[75] Section 52(1) of the *Competition Act* provides as follows:

> False or misleading representations
>
> **52 (1)** No person shall, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever, knowingly or recklessly make a representation to the public that is false or misleading in a material respect.

[76] In *Palmer v. Teva Canada Ltd.*, 2022 ONSC 4690 [*Palmer*], the plaintiffs alleged a breach of s. 52(1) of the *Competition Act*. Justice Perell found that this claim had not been adequately pleaded:

> [252] In the immediate case, it is plain and obvious that a claim for breach of s. 52(1) of the *Competition Act* in support of the statutory cause of action under s. 36(1) will fail for two reasons.
>
> [253] First, the claim fails because the *Competition Act* does not impose a general duty of disclosure, and the failure of the Defendants to warn that valsartan was shoddy product but not an imminently dangerously defective drug is not a misrepresentation for the purposes of s. 52 of the *Competition Act*. A failure to disclose a non-dangerous defect in a product is not a representation for the purposes of s. 52 of the *Competition Act*.
>
> [254] Second, the claim fails because to establish a breach of section 2(1) and to obtain damages under section 36(1), a plaintiff must prove actual loss or damage caused by a materially false or misleading representation. […]

[77] It is unclear from the ANOCC precisely how the defendants allegedly breached the statutes referenced. The plaintiffs do not plead the material facts necessary to support these allegations. Bare allegations and conclusory legal statements based on assumption or speculation are not material facts: they are incapable of proof and are not therefore assumed to be true for the purposes of a motion to determine whether a legally viable cause of action has been pleaded: *Palmer* at para. 146. In my view, asserting statutory breaches without pleading the underlying material facts necessary to support them is insufficient to meet the requirements of s. 4(1)(a) of the *CPA*.

[78] The three requisite elements of a claim in unjust enrichment are well-established in Canadian law: *Pro-Sys* at para. 85; *Garland v. Consumers' Gas Co.*, 2004 SCC 25 at para. 30 [*Garland*]; *Bhangu v. Honda Canada Inc.*, 2021 BCSC 794 at para. 70 [*Bhangu*]. A claimant has a cause of action in unjust enrichment where there has been: (1) an enrichment of the defendant; (2) a corresponding deprivation of the plaintiff; and (3) no juristic reason for the enrichment: *Garland* at para. 30. Justice Brown, speaking for the majority, explained the two-stage analytical approach to determining whether there is a juristic reason for the enrichment in *Babstock* at para. 70:

> The juristic reason element of the unjust enrichment analysis proceeds in two stages. First, the plaintiff must demonstrate that the defendant's enrichment cannot be justified by any of the established categories of juristic reason. If none of the established categories of juristic reason are present, the plaintiff has a *prima facie* case for unjust enrichment. At the second stage, the defendant can rebut the plaintiff's *prima facie* case by showing that there is a residual reason to deny recovery (*Moore*, at paras. 57 – 58).

[79] In *Babstock* at para. 71*,* Brown J. found that the plaintiff's unjust enrichment claim was destined to fail on the pleadings alone:

> Here, I do not have to go beyond the first stage of the analysis. The plaintiffs' own pleadings allege that there was a contract between ALC and the plaintiffs under which the plaintiffs paid to play VLTs. A defendant that acquires a benefit pursuant to a valid contract is justified in retaining that benefit (*Moore*, at para. 57). Nothing in the pleadings, apart from perhaps the allegations of criminal conduct that I have determined are bound to fail, could serve to vitiate the alleged contract between the plaintiffs and ALC. It follows that I agree with the appellants that the plaintiffs' unjust enrichment claim has no reasonable chance of success.

[80] The defendants deny that the risk of an adverse reaction or injury, such as the alleged risk of pigmentary maculopathy due to Elmiron use, is a legally recognized detriment for the purposes of unjust enrichment, citing *Spring v. Goodyear Canada Inc.*, 2021 ABCA 182 at paras. 49, 52 [*Spring*]. In *Spring*, the plaintiff pleaded that Goodyear had been unjustly enriched by profits earned from the sale of tires it knew were defective, dangerous, and unfit for use, and that there was no juristic reason for Goodyear's enrichment. While *Spring* did not involve a prescription medication, I accept that those allegations are analogous here.

[81] The Court of Appeal recently considered an unjust enrichment claim in the context of a certification application in *Sharp* BCCA at paras. 82–93. The defendants

describe the plaintiffs' deficient pleading in *Sharp* BCCA as comparable to the bald assertions in the ANOCC. In *Sharp* BCCA, the plaintiffs advanced claims allegedly arising from negligent advice provided to them by an investment advisor; the plaintiffs paid investors' fees into a fund and not to the investment advisor directly. By analogy, Elmiron is not sold directly to patients but rather through pharmacies by prescription only. The defendants liken the facts in *Sharp* BCCA to the presence of third-party intermediaries in the case before me.

[82] The plaintiffs allege that the defendants' statutory breaches void contracts for the sale of Elmiron, and that there is therefore no juristic reason for the defendants' enrichment. However, they do not plead the material facts necessary to particularize those alleged breaches with any specificity: *Kerr v. Baranow*, 2011 SCC 10 at para. 40. The plaintiffs in *Sharp* BCCA sought a return of the fees paid to the defendant for the sale of RBC funds, while retaining their investments in those funds and any profits from them. The defendants submit that, by analogy, the plaintiffs here seek the return of amounts paid to third party intermediaries for Elmiron, a drug which they received and ingested. While the plaintiffs in *Sharp* BCCA attempted to correct this deficiency in their pleading, the chambers judge found that it could not be remedied as there was clearly a juristic reason for the defendants' enrichment: *Sharp* BCCA at paras. 91–92. The Court in *Sharp* BCCA held that the appellants offered no principled justification for the result they sought, apart from the respondent's wrongdoing, which it explained "falls within the normative basis for a disgorgement remedy rather than a claim in unjust enrichment": *Sharp* BCCA at para. 92.

[83] The ANOCC does not address the chain of contract issue arising from the sale of Elmiron through third party pharmacy intermediaries. The plaintiffs do not allege that they received no therapeutic benefit from taking Elmiron to treat their IC. In fact, they acknowledge in para. 11 of the ANOCC that Elmiron is efficacious for this purpose. They plead in para. 2 that Ms. Felker has taken it daily since 2002 to treat her IC.

[84] In *Palmer,* Perell J. was asked to consider the adequacy of an unjust enrichment claim on a certification application in a proposed class action involving a prescription

drug. After reviewing the required constituent elements of a claim in unjust enrichment, Perell J. found that it was plain and obvious the plaintiff's claim was doomed to fail for three reasons. His comments are instructive:

> [267] First, there has been no transfer of money, goods, or valuable services from the Class Members to the Defendants. The Class Members dealt directly with the pharmacies or hospital dispensaries that dispensed valsartan, which is a prescription drug. Thus, an unjust enrichment claim does not sound at all for this type of product liability case.
>
> [268] I appreciate that in *Pro-Sys Consultants Ltd. v. Microsoft Corporation* [2013 SCC 57], the Supreme Court of Canada did not close the door on a transfer of wealth that was indirect between the plaintiff and the defendant as providing the basis for an unjust enrichment claim. There, however, is no direct or indirect transfer of wealth in the immediate case because up until the recall, the Class Members received value in exchange for what they paid or what was paid for them for the drugs, which no one suggests did not serve their indicated purpose of treating hypertension.
>
> [269] Second, the unjust enrichment claim is bound to fail because the deprivation that the Class Members suffered in the immediate case was non-monetary; it was a deprivation in the quality of valsartan that had been purchased. The valsartan was not as safe as it should have been. Courts in recent decisions in proposed products liability class actions, which I would adopt, such as *Kane v. FCA US LLC* [2022 SKQB 69] and *Spring v. Goodyear Canada* Inc., [2021 ABCA 18, rev'g 2020 ABQB 252], have recognised that the loss from a shoddy good is not the type of deprivation or transfer of wealth that is amenable to an unjust enrichment claim.
>
> [270] In *Kane v. FA US LLC*, Justice Elson stated at paragraph 143:
>
> > [T]he plaintiff's pleaded allegations do not disclose the required elements of an unjust enrichment claim. Following the analysis articulated in *Spring*, the proposed class members could not be said to have sustained a deprivation when they purchased a class vehicle. Instead of the tires acquired in *Spring*, the class members received vehicles. The fact that one or more of the vehicles may have had safety defects, for which another remedy may be available, does not create the kind of deprivation contemplated in a claim for unjust enrichment. Moreover, any enrichment FCA may have contractually received from the sale of a class vehicle, whether defective or not, cannot be said to have occurred in the absence of a juristic reason.
>
> [271] Third, as mentioned in *Kane v. FCA US LLC*, even if the deprivation in the immediate case was a type of deprivation for unjust enrichment and even if there has been a transfer of wealth to the Defendants, then the contract of sale between the Defendants and the retailer of the pharmaceuticals is a juristic reason for the transfer of wealth.

[85] I appreciate that *Palmer* involved an alleged manufacturing defect that resulted in contamination of the drug, Valsartan. There is no comparable allegation in the case before me. However, in my view, the above-noted principles are germane here.

[86] I find that the plaintiffs have not pleaded the material facts necessary to establish the constituent elements of a viable claim in unjust enrichment. As in *Sharp* BCCA and *Palmer*, they do not explain why the amounts they paid for the product (in this case, Elmiron) ought to be returned, despite the fact that they received and ingested this drug. I also find that the unjust enrichment pleading adds nothing to the plaintiffs' claim generally as they have an adequate remedy in negligence: *Spring* at para. 48.

### 6. Restitution and Disgorgement

[87] The plaintiffs seek restitution based on unjust enrichment or, alternatively, the disgorgement of profits wrongfully earned or retained by the defendants from the sale of Elmiron (instead of defective tires, as in *Spring*). In *Babcock* at para. 23, the Supreme Court of Canada reviewed the difference between the remedies of restitution and disgorgement: restitution restores the benefit moved from the plaintiff to the defendant, while disgorgement is measured only by the defendant's wrongful gain, and no corresponding damage to the plaintiff must be proven.

[88] Given my finding that the plaintiffs have not pleaded a viable cause of action in unjust enrichment, I conclude that I need not address the corresponding pleaded remedies of restitution and disgorgement. By extension, they also fail.

### 7. Conclusion on the Pleaded Causes of Action

[89] I grant the plaintiffs leave to amend the ANOCC to add proposed para. 73 (as set out above) pursuant to the *CPA*, s. 5(6). With this addition, I conclude that their pleading in negligence is adequate for the purpose of meeting the certification criteria in s. 4(1)(a) of the *CPA*. In my view, the plaintiffs have not pleaded a viable unjust enrichment claim.

### C. Evidentiary Issues

[90] Determining whether there are at least two members of an appropriately defined class requires me to consider the defendants' objections to documents the plaintiffs have filed on this certification application.

#### 1. Statements on Information and Belief

[91] In his Affidavit #1, sworn January 28, 2022, Michael Luna, law clerk with the Ontario law firm of Siskinds LLP, deposes that Ms. D'Andrea advises him, and he believes, that had she known there was a risk of vision loss linked to the ingestion of Elmiron at the time of her initial prescription in 2004, or learned of this after she began using Elmiron, she would have pursued other treatment options for her IC instead of Elmiron. The defendants say this is inadmissible hearsay that purports to describe Ms. D'Andrea's state of mind and the decisions she may, or may not, have made if the Elmiron label had been different when she was prescribed and ingested this drug.

[92] In response, the plaintiffs submit that this evidence is admissible pursuant to *SCCR*, R. 22-2(13). They note that Ms. D'Andrea is identified as the source of Mr. Luna's information and belief. Because a certification hearing does not seek a final order, they say that the requirements of *SCCR*, R. 22-2(13) have been met, citing *Albert v. Politano*, 2013 BCCA 194 at para. 22 and *Sharp* BCSC at para. 29.

[93] Ideally, this information would have been set out in Ms. D'Andrea's own sworn affidavit. However, in my view, the plaintiffs' failure to do so is not fatal to admission of the impugned paragraphs in Mr. Luna's affidavit into evidence: *Bhangu* at para. 18; *Jiang v. Piccolo*, 2020 BCSC 1584 at paras. 43–45. Affidavit evidence based on information and belief is admissible on an interlocutory application. I conclude that the requirements of *SCCR*, R. 22-2(13) have been met. Accordingly, I find that the statements in paras. 15–16 of Mr. Luna's Affidavit #1 regarding Ms. D'Andrea are admissible on this application.

### 2. Evidence of Class Size

[94] Paralegal, Adrian Harte, in para. 21 of her Affidavit #2 sworn August 19, 2020, deposes that Slater Vechio LLP has been contacted by "several individuals" in BC and across Canada who claim to have experienced vision loss after having been prescribed Elmiron. Mr. Luna, in para. 12 of his Affidavit #1 sworn January 28, 2022, deposes that, as of January 27, 2022, Siskinds LLP had been contacted by approximately 147 people across Canada who claim to have experienced vision loss after ingesting Elmiron. He deposes further that, of those 147 people, nine have confirmed diagnoses of pigmentary maculopathy/pentosan maculopathy and six others have confirmed diagnoses for macular degeneration. In para. 13 of his Affidavit #1, Mr. Luna deposes that he is advised by Mr. Jaworski, BC class counsel, that, as of January 27, 2022, Slater Vecchio LLP had been contacted by 77 people across Canada who claim to have suffered injuries as a result of ingesting Elmiron, 14 of whom have confirmed maculopathy issues.

[95] The defendants object to this evidence on the basis it is inadmissible hearsay. They submit that, apart from the cause of action requirement in s. 4(1)(a) of the *CPA*, it is well-established that the normal rules of evidence apply on a certification application: *Ernewein* at para. 31; *Martin* at paras. 25 and 39–40; *Huebner v. PR Seniors Housing Management Ltd., D.B.A. Retirement Concepts*, 2021 BCSC 837 at para. 14 [*Huebner*]. They say that the plaintiffs must discharge their evidentiary burden on admissible evidence.

[96] The plaintiffs deny this evidence is being tendered for the truth of its contents. Accordingly, they deny it is hearsay. Rather, they submit that it is being tendered to show that numerous people have contacted plaintiffs' counsel and claimed vision loss after ingesting Elmiron. They argue this evidence is admissible as some basis in fact that two or more people are interested in the adjudication of the proposed common issues. They regard the fact that Mr. Luna took no steps to confirm the diagnoses of these individuals as inconsequential since the merits of individual claims are irrelevant on this application, citing *Pro-Sys* at para. 99.

[97] Ms. Harte is a paralegal with the Vancouver firm of Slater Vechio LLP. In para. 1 of her Affidavit #2, she states that she has direct knowledge of the matters to which she deposes in her affidavit, except where stated to be on information and belief, in which case she believes the person on whose information she relies. There is no indication in para. 21 of Ms. Harte's Affidavit #2 that she relies on information and belief for those statements. Accordingly, on its face, it appears that she has personal information of the matters stated in para. 21 of her Affidavit #2.

[98] Mr. Luna deposes that, as a law clerk with Siskinds LLP, he has direct knowledge of the matters set out in his affidavit, except where stated to be on information and belief, in which case he believes them to be true. He specifies in his Affidavit #1 when he deposes based on information and belief; there is no indication that the statements in para. 12 of his Affidavit #1 are based on information and belief. Accordingly, on its face, it appears that Mr. Luna has direct knowledge of those matters.

[99] In para. 13 of his Affidavit #1, based on information from Mr. Jaworski, Mr. Luna makes statements about the number of individuals who have contacted Slater Vechio LLP from across Canada claiming to have suffered injuries as a result of ingesting Elmiron, and the nature of those alleged injuries. Mr. Jaworski is identified by name and Mr. Luna deposes that he believes the information Mr. Jaworski provided. I therefore conclude that the statements in para. 13 of Mr. Luna's Affidavit #1 comply with *SCCR*, R. 22-2(13) and are admissible as some basis in fact regarding the number of individuals who have contacted plaintiffs' counsel to express an interest in this proceeding: *Albert v. Politano*, 2013 BCCA 194 at paras. 19–22; *Sharp v. Royal Mutual Funds Inc*., 2019 BCSC 2357 at paras. 29, 31–32; *Huebner* at para. 25.

[100] I accept that it would have been impractical for plaintiffs' counsel to obtain 224 separate affidavits from the individuals who contacted their firms about this action. It is unclear what is meant by "several individuals" in para. 21 of Ms. Harte's Affidavit #2. Ultimately, I conclude that these statements, and those referenced in para. 12 of Mr. Luna's Affidavit #1, are admissible, not for their truth, but as some "basis in fact" for assessing the potential class size: *John Doe v. R.*, 2015 FC 236 at para. 11. However, it

is unclear from the affidavits of Ms. Harte and Mr. Luna when these individuals started taking Elmiron, how long they did so, and if, or when, they discontinued Elmiron.

### 3. FDA NDA Documents

[101] Galena Evans is a paralegal with Slater Vechio LLP. Attached to her Affidavit #1 sworn February 18, 2021, is a document entitled “Appendix D - Safety Reports Filed with the FDA” dated June 1995. Ms. Evans describes it as comprising part of the FDA New Drug Application (“NDA”) file NDA20193 in relation to Elmiron; attached to Mr. Luna’s Affidavit #1 are 620 pages of documents described as the FDA NDA for Elmiron (collectively, the “FDA Documents”).

[102] The plaintiffs submit that the FDA Documents describe a wide range of adverse events related to Elmiron that were reported in the late 1980s and early 1990s. They allege that the defendants either were, or ought to have been, aware of them. Notably, none of these reported adverse events is described as pigmentary maculopathy. Four (out of 36) reference visual complaints, the particulars of which are set out below.

| **Dosage** | **Duration** | **Reported Adverse Event** | **Relationship to Elmiron by Assigned Investigator** |
|---|---|---|---|
| 100 mg TID | 2/92 to 11/92 | Optic Neuritis | Remote |
| 100 mg TID | 9/91 to 2/10/93 | Bilateral Retinopathy | Unrelated |
| 100 mg TID | 11/92 to 3/10/93 | Blurred Vision, Left Central Optic Vein Occlusion | Possible |
| 100 mg TID | 3/10/93 to 6/6/93 | Filmy Sensation Over Left Eye; Possible Left Optic Neuritis | Unrelated |

[103] The FDA Documents include screenshots from the FDA's adverse events reporting system public dashboard for vision-related adverse outcomes for Elmiron. They reference the information set out below.

| Year | Adverse Events | Year | Adverse Events | Year | Adverse Events |
|---|---|---|---|---|---|
| 1997 | 9 | 1998 | 18 | 1999 | 3 |
| 2000 | 5 | 2001 | 3 | 2003 | 1 |
| 2004 | 2 | 2005 | 1 | 2006 | 2 |
| 2009 | 3 | 2010 | 3 | 2011 | 5 |
| 2012 | 3 | 2013 | 1 | 2014 | 3 |
| 2015 | 8 | 2016 | 5 | 2017 | 4 |
| 2018 | 7 | 2019 | 46 | 2020 | 274 |
| 2021 | 1 | | | | |

[104] The defendants object to the admissibility of the FDA Documents. They say that, in order for them to be admissible for the truth of any statements contained therein, a deponent must assert that they were informed as to the authenticity and veracity of their contents by the author or someone with personal knowledge of the document, and that the deponent believes the facts contained in the document are true: *L.M.U. v. R.L.U.*, 2004 BCSC 95 at paras. 31–37 [*L.M.U.*]. They submit that the extent to which documents are admissible as proof of the truth of their contents depends on the nature of the statements: *L.M.U.* at paras. 26, 28, 32, 36.

[105] The plaintiffs seek to rely on the FDA Documents as evidence of the defendants' understanding of Elmiron's mechanism of action and their knowledge of reported adverse events at material times, regardless of the truth of the specific reports. They say this is a non-hearsay purpose, requiring only that they authenticate the documents. Additionally, they submit that the clinical data in Appendices C and D of the FDA

Documents is admissible as a business records exception to the hearsay rule pursuant to the *Evidence Act*, R.S.B.C. 1996, c. 124, s. 42, citing *Cambie Surgeries Corporation v. British Columbia (Attorney General),* 2018 BCSC 859 at para. 16.

[106] The plaintiffs say it is clear on the face of the adverse event reports in the FDA Documents that they were prepared contemporaneously with receipt of information by persons whose job it was to record it as part of the FDA NDA process for Elmiron. They note that, while the defendants are themselves capable of confirming the authenticity of these documents, the plaintiffs have nonetheless tendered affidavit evidence to demonstrate how the FDA NDA file can be obtained through official online databases. They submit that the defendants are attempting to leverage the informational imbalance that exists in class actions before they have had the benefit of a fulsome discovery.

[107] It is not apparent on the face of the FDA Documents who prepared them or when, how the recorded information is to be interpreted, or what, if any, steps the defendants ought to have taken in response to it. The plaintiffs have retained qualified experts who could have been asked to comment on those matters.

[108] I accept that the FDA Documents relate to the FDA NDA process for Elmiron and reference reports of vision-related adverse events. However, without expert assistance, I am unable to conclude that any of those adverse events relates to Elmiron-induced pigmentary maculopathy, or that this information ought to have prompted the defendants to take certain steps. On the uncontroverted evidence of defence ophthalmologist, Dr. Schwartz, none of the ocular events referenced in the safety reports in the FDA Documents relates to pigmentary maculopathy; she says they describe disorders involving different parts of the eye and not the macula. There is no dispute that the FDA approved Elmiron in 1996.

[109] I conclude that the FDA Documents are not admissible for their truth. I accept them as some basis in fact that there were vision-related adverse event reports to the FDA before the FDA approved Elmiron. However, without expert assistance, I am unable to reach any conclusions about what, if anything, the FDA Documents ought to have prompted the defendants to do in response to the information contained in them.

### 4. Scientific Literature

[110] The plaintiffs also rely on scientific literature referenced in the FDA Documents. The defendants object to them doing so and deny that merely attaching articles to an affidavit makes them admissible.

[111] One of the articles appended to Ms. Harte's Affidavit #2 is entitled "Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium [PPS]" authored by Pearce et al in November 2018 (*Ophthalmology 2018; 125: 1793 – 1802 © 2018 by the American Academy of Opthalmology*) (the "Pearce Article"). The Pearce Article references a three-month placebo-controlled study of 258 patients (before FDA approval of Elmiron in 1996) that had no vision-related safety signals. It also discusses an unmasked clinical trial in 2012 of 2,499 patients receiving PPS for up to four years with reports of optic neuritis, amblyopia, and retinal hemorrhage. Pearce et al stated that it was unclear if these cases were attributed to the drug itself, noting that the longest trial to their knowledge evaluated PPS for a mean duration of 90 months.

[112] In his Affidavit #2, Mr. Luna describes how he obtained the FDA Documents from the publicly-accessible US FDA website. Included in the FDA Documents is a review of a study, apparently conducted in 1991, entitled PPS "Review of a New Molecular Entity", authored by Baker et al and reviewed by M. Daniel Gordin, Ph.D. Under the heading "Background and Synopsis" the following statements appear:

> Pentosan Polysulfate (PPS) is indicated for the treatment of interstitial cystitis and works by adhering to the exposed mucosal layer of the bladder epithelium thereby decreasing the diffusion of urine components through the bladder wall.

[113] Another review of PPS by M. Daniel Gordin, Ph.D. from July 1993, contained in the FDA Documents appended to Mr. Luna's affidavits, states that "Elmiron works by binding to exposed epithelium".

[114] Plaintiffs' counsel submit that the defendants knew, or ought to have known, about this information. They rely on it as some basis in fact that Elmiron might affect exposed epithelium inside and outside the bladder the same way, including the RPE. They allege in para. 27 of the ANOCC that the defendants "knew or ought to have

known of the potential for Elmiron to bind to other epithelial cells such as the RPE". There are other statements in the FDA Documents that suggest the effectiveness of orally administered Elmiron (or PPS) for IC is dependant on sufficient amounts of unchanged PPS being absorbed from the GI tract, and its subsequent excretion as unchanged PPS into the bladder, where it then binds to the exposed mucosal epithelium. Plaintiffs' counsel say that these statements can be linked to another article entitled the "*Inhibition of Growth Factor Effects in Retinal Pigment Epithelial Cells*", authored by Leschey et al in 1991 (the "Leschey Article").

[115] Plaintiffs' counsel also point to the statements of Dr. Etminan in his August 13, 2020 report (at page 10) that retinopathy secondary to Elmiron seems to primarily affect the RPE and that, although an exact mechanism of maculopathy secondary to Elmiron is not known, there is ample scientific evidence by which one could infer a postulated mechanism for this effect. Dr. Etminan says it is possible that the glycosaminoglycan structures of Elmiron and the RPE can interact leading to deposition and accumulation of Elmiron molecules within the RPE structure.

[116] The admissibility of scientific articles on certification applications was considered in *Schwoob v. Bayer Inc.*, 2013 ONSC 2207 [*Schwoob*]. As here, affidavit evidence was filed appending published journal articles regarding issues relevant to the action. Justice Crane admitted the articles, but only for a limited purpose, namely to demonstrate that knowledge of combination oral contraceptives (including those distributed by the defendant) is not a closed subject, that research is ongoing, and that information and understanding regarding their health effects is diverse and continuing: *Schwoob* at paras. 38–39.

[117] In *Johnson v. Ontario*, 2016 ONSC 5314 [*Johnson*], sworn affidavits were filed attaching inquest material, newspaper articles, and an Ombudsman report. Justice Grace held that this evidence was not admissible for the truth of its contents but agreed this did not mean it was wholly inadmissible on a certification motion, finding that it could be considered, along with any inherent frailties, to determine whether the moving party had met the onus of establishing some basis in fact for the certification

requirements: *Johnson* at para. 67 citing *Ewert v. Canada (Attorney General)*, 2016 BCSC 962 at paras. 39–40, rev'd in part 2019 BCCA 187.

[118] In *Vester v. Boston Scientific Ltd.*, 2017 ONSC 1095 [*Vester*], the defendant challenged the admissibility of documentary evidence filed by someone who did not have personal knowledge of the documents, beyond stating that she accessed and printed them from public websites and retrieved others from a court reporter. No witness authenticated the documents or gave any evidence to support the truth or reliability of their contents. Justice Perell held that some of the documents were admissible, not for the truth of their contents, but for the fact that they were written or published documents and that some might fall within the categorical or principled exceptions to the rule against hearsay. The documents were not considered for the purpose of determining the merits of either the plaintiffs' claim or the defence to it: *Vester* at paras. 31–33.

[119] The defendants submit that plaintiffs' counsel effectively assumes the role of an expert witness by purporting to interpret the technical scientific articles appended to the various affidavits in evidence as some basis in fact that the defendants knew or ought to have known that Elmiron can inhibit the growth of the RPE cells. I agree. It was open to the plaintiffs to have one of their experts interpret these articles and to draw a link between reference in them to the effect of Elmiron on exposed epithelium in the bladder and its effect on the RPE, and to opine about what, if any, steps this information ought to have prompted the defendants to take. I decline to make inferences about these matters without expert assistance.

[120] I do not rely on the scientific articles appended to the affidavits of Ms. Harte and Mr. Luna for their truth, except to the extent they have been interpreted by appropriately qualified experts. I accept that they provide some basis in fact for concluding that there has been ongoing research into the effect of Elmiron on the RPE.

### D. Is there a Proper Class?

[121] The parties disagree about whether or not there is evidence of two or more members of an appropriately defined class. The proposed class includes:

> All persons in Canada, excluding Quebec, who were prescribed and ingested Elmiron between December 31, 1993 and the date this action is certified as a class proceeding.

[122] The plaintiffs submit that this definition is clear, does not reference the merits, includes objectively identifiable class members and the relevant class period, and cannot be narrowed without excluding members who may have a valid claim: *Sun-Rype* at paras. 58, 84. They say there is a rational relationship between the proposed class (all of whose members have been prescribed and ingested Elmiron) and the common issues, noting that proposed class members' claims need not be identical at the certification stage and that not every class member must have a provable claim. They say the evidentiary record establishes that members of the proposed class potentially number in the tens of thousands.

[123] The defendants deny the proposed class definition meets the requirements of s. 4(1)(b) of the *CPA* on the grounds:

a) It is overly broad and includes persons with no plausible or triable claim that is rationally connected to the proposed common causation issues;

b) It is overly broad with respect to timing given the absence of any basis in fact for the asserted common issues in negligence; and

c) There is no evidence of a class of two or more persons who have a triable claim and who are members of an appropriately narrow class.

[124] The defendants highlight the fact that the authorized class in the Québec Elmiron class action is confined to individuals who have been diagnosed with pigmentary maculopathy, up to the date the Elmiron product monograph was revised on September 23, 2019 (to reference reports of pigmentary maculopathy). On that basis alone, they say it is patently obvious that the proposed all-users class could be narrowed.

[125] Teva denies there is evidence that any plaintiff or putative class member took Elmiron that was manufactured and sold by BNPI or Teva, let alone one who later developed pigmentary maculopathy. It submits that a class should not be certified

against a defendant if there is no evidence of class members with claims against that party, citing *Williamson* at paras. 227–232; *Marshall* para. 139; *Magill v. Expedia Inc.,* 2013 ONSC 683 at paras. 73–76.

[126] Section 4(1)(b) of the *CPA* requires that there be an identifiable class of two or more persons. The class definition is intended to: (i) identify those persons who have a potential claim for relief against the defendants; (ii) define the parameters of the lawsuit so as to identify those persons who are bound by its result; and (iii) describe who is entitled to notice of the action. Achieving these purposes generally requires objective criteria that does not turn on the merits of the claim: *Sun-Rype* at paras. 57–58.

[127] Evidence that there is a class of two or more persons who satisfy s. 4(1)(b) of the *CPA* is necessary to justify engaging the class action process which, given its scale and complexity, ought not to be invoked at the behest and for the benefit of a single complainant: *Martin* at paras. 203–204, citing *Bellaire v. Independent Order of Foresters* (2004), 5 C.P.C. (6th) 68 at para. 33, [2004] O.J. No. 2242 (S.C.J.). The class must identify members by objective criteria that are rationally connected to the pleaded claims and the common issues: *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 38 [*Dutton*]; *Jiang v. Peoples Trust Company*, 2017 BCCA 119 at para. 73; *Chartrand* at para. 46. Chief Justice McLachlin explained this requirement in *Hollick* at para. 19:

> […] The difficult question, however, is whether each of the putative class members does indeed have a claim – or at least what might be termed a "colourable claim" – against the respondent. To put it another way, the issue is whether there is a rational connection between the class as defined and the asserted common issues. […]

[128] The plaintiffs bear the onus of demonstrating that the class could not be defined more narrowly, without excluding those with a valid claim: *Hollick* at para. 21. A class definition will not be overly broad even if it includes some class members who may ultimately be unsuccessful in establishing a claim: *Sun-Rype* at para. 114; *MacKinnon* at para. 82.

[129] In *Williamson,* the plaintiff alleged that perineal use of talc-based baby powder could cause ovarian cancer and ovarian cysts. The proposed class definition included

all purchasers and users of the baby powder in Canada, including men, purchasers who did not use the products, women who did not use the products perineally, and women who had not been diagnosed with any type of ovarian cancer or ovarian cyst. The action was not certified. Justice Armstrong found the proposed class to be overbroad because it included individuals with no plausible or triable claim: *Williamson* at paras. 188–235.

[130] In *Benning v. Volkswagen Canada Inc.*, 2006 BCSC 1292 [*Benning*], the plaintiff alleged that defective locks rendered the defendant's vehicles more susceptible to break-ins. The proposed class definition included claims by class members who had experienced no vehicle break-ins. The proposed class was found to be overly broad: *Benning* at paras. 80–89.

[131] In *Jones v. Zimmer GMBH*, 2011 BCSC 1198 at paras. 41–42, aff'd 2013 BCCA 21 [*Jones*], a class action involving allegations of personal injury from a prosthetic hip implant, Justice Bowden held that the fact the class definition may include persons who did not suffer any injury is an expected outcome of a class definition. In *Tiboni v. Merck Frosst Canada Ltd.* (2008), 295 D.L.R. (4th) 32 at para. 78, 2008 CanLII 37911 (Ont. S.C.J.) [*Tiboni*], Justice Cullity found this to be "virtually ordained by the authorities that preclude merits-based definitions". In *Tiboni*, the rate of problems among the defined class was apparently only .57%: *Jones* at para. 42.

[132] Janssen denies it is the role of the courts on certification motions to take on the responsibility of class counsel and to fashion a proper class definition, particularly in the absence of an evidentiary basis for doing so, citing *Caputo v. Imperial Tobacco Ltd.* (2004), 236 D.L.R. (4th) 348 at para. 41, 2004 CanLII 24753 (Ont. S.C.J.) [*Caputo*]. However, Justice Winkler in *Caputo* also noted in the same paragraph that it may be appropriate for the court to amend a class definition:

> 41 The plaintiffs prevail upon me to amend the class definition to redefine the class in any way necessary to render this action certifiable. In my view, this approach is not what McLachlin C.J. was advocating in *Hollick*. As I read her reasons, the court may either reject certification where the class is not properly defined or otherwise grant a conditional certification on the basis that the plaintiffs will have to provide an acceptable definition to the court. <u>In some circumstances, it may be appropriate for the court to alter or amend a class definition to be consistent with other findings made on a certification motion.</u> That is not the case here. What the plaintiffs suggest is akin to having the court

> perform the role of class counsel by making wholesale changes to arrive at a definition that the court itself would accept. That goes beyond a simple exercise of discretion and verges into the prohibited territory of descending "into the arena" with the parties to the motion. (Emphasis added.)

[133] The defendants submit that, when many of the members of the proposed class do not share in the causes of action and common issues asserted, the requirement of an identifiable class is not satisfied: *Wuttunee v. Merck Frosst Canada Ltd.*, 2009 SKCA 43 at paras. 128–129; *Williamson* at paras. 188–201.

[134] Based on Affidavit #1 of Ms. Tran, Janssen's records indicate that there have been over 553,300 prescriptions for Elmiron filled in Canada from 2015 to July 2021. She deposes that this number will be higher than the number of persons who have used Elmiron as most persons who have taken this drug have had multiple prescriptions over an extended period of time.

[135] The defendants rely on Dr. Sebag's opinion that, even if there is a specific presentation of pigmentary maculopathy connected to long-term Elmiron use, it would be rare. Ms. Tran deposes as follows:

a) As of the end of August 2021, Janssen had received reports of vision-related adverse events in 18 individuals in Canada who were reported to have been prescribed and used Elmiron;

b) Five reports were received by Janssen in 2005, 2006, 2007, 2008, and 2016 respectively, none of which reported macular degeneration, pigmentary maculopathy or retinal changes; and

c) Thirteen reports were received by Janssen in 2020 and 2021, six of which included reports of macular degeneration, pigmentary maculopathy, or retinal changes.

[136] Janssen emphasizes that, of the six reports it received in 2020 and 2021:

(a) One is a legal claim regarding Ms. Felker (whose records show she does not have pigmentary maculopathy or objective evidence of vision loss);

(b) One is a legal claim by Ms. D'Andrea (whom they say has no objective evidence of vision loss and whose pigmentary irregularities they attribute to probable age-related macular degeneration or central serous chorioretinopathy);

(c) Another report is a legal claim regarding the plaintiff in a similar proposed class action in Ontario;

(d) One was initiated by a published case report of a Québec resident; and

(e) The other two reports contain little information and do not include any medical evidence or medical reports to permit any assessment.

[137] While the plaintiffs assert that they are aware of higher numbers of individuals who claim to have been adversely affected by Elmiron, the defendants describe the evidence on which the plaintiffs rely as vague, ambiguous, and inadmissible.

[138] I conclude that the proposed class definition is overly broad. The class must be rationally connected to the common issues: *Hollick* at paras. 19–20; *Chartrand* at para. 46; *Jiang* at para. 73. The plaintiffs' proposed amended common issues are confined to individuals who ingested Elmiron and developed pigmentary maculopathy. On the evidence before me, reports of pigmentary maculopathy in Elmiron users are rare. The "signature" form of Elmiron-induced pigmentary maculopathy discussed in the studies referenced by Dr. Etminan in his August 2020 report would be a subset of this group. In this context, I do not agree that an all users class is appropriate. On the evidence before me, it would include a large number of individuals with no viable claim and would bear no rational connection to the ANOCC, the plaintiff's certification application, or the amended common issues, all of which reference pigmentary maculopathy in relation to Elmiron use. In my view, the class definition is appropriately confined to individuals with pigmentary maculopathy. The changes Janssen made to the Elmiron product monograph in 2019 and 2020 reference pigmentary maculopathy. Accordingly, I conclude that this condition is sufficiently identifiable to form the basis for a class definition.

[139] In my view, the proposed time frame is also overly broad. I conclude that there is no basis in fact for it to extend before November 2018 (when the Pearce Article was published) or after September 23, 2019 (when the Elmiron product monograph was substantially amended to include reference to pigmentary maculopathy).

[140] I accept that Ms. D'Andrea qualifies as a member of an appropriately defined class. On the uncontroverted expert evidence, Ms. Felker does not have pigmentary maculopathy; Dr. Sebag opines about other possible causes for her reports of impaired vision based on his review of her medical records. I am not persuaded that Ms. Felker qualifies as a member of an appropriately defined class. Based on Janssen's evidence, and Mr. Luna's affidavit evidence about the individuals who have contacted plaintiffs' counsel to date, I find there is some basis in fact to conclude that there may be at least one other such member. However, the evidence does not permit me to determine when any of these individuals began taking Elmiron or how long they continued doing so.

[141] In my view, there is no basis in fact to conclude that there is at least one member of an appropriately defined class who developed pigmentary maculopathy after ingesting Elmiron sold by BNPI or Teva between 1993 (when Elmiron was approved by Health Canada) and 1998 (when BNPI last sold Elmiron in Canada). Ms. D'Andrea started taking Elmiron in 2004; Ms. Felker began doing so in 2005. There is no evidence on this application of at least one person who took Elmiron between 1993 and 1998 and developed pigmentary maculopathy.

[142] The plaintiffs could not have predicted that I would reject their proposed all users class or that I would find Ms. Felker is not a member of an appropriately defined class. Accordingly, I grant plaintiffs' counsel leave pursuant to s. 5(6) of the *CPA* to file an additional affidavit, identifying at least one other proposed class member who meets the narrowed class definition, as set out herein, within three months following release of these reasons. As noted by Branch J. in *Krishnan v. Jamieson Laboratories Inc.*, 2021 BCSC 2127 at para. 9, the court has some responsibility to ensure that absent proposed class members are treated fairly.

[143] In *Jiang v. Peoples Trust Company*, 2018 BCSC 299, aff'd 2019 BCCA 149 [*Jiang*], the chambers judge allowed the plaintiffs to file further evidence in order to establish that the plaintiff was a resident of British Columbia; there is no indication in the decision that a separate hearing occurred: *Jiang* at para. 40.

[144] If the plaintiffs fail to file an additional affidavit within this time frame, this action will not be certified since, absent this evidence, there is no basis in fact for finding that there are at least two members of an identifiable class, as required by s. 4(1)(b) of the *CPA*. If the plaintiffs file such an affidavit, Janssen is directed to confirm, within 14 days, whether it accepts that certification should issue against it, consistent with the balance of these reasons: *Krishnan* at para. 134. Failing agreement, the parties may set a further one-hour hearing to address any residual argument on this issue: *Krishnan* at para. 134.

[145] The class definition can always be amended pursuant to s. 5(6) of the *CPA* if new evidence should arise.

## E. Are there Common Issues?

### 1. Generally

[146] Section 4(1)(c) of the *CPA* requires that the claims of the class members raise common issues, whether or not they predominate over issues affecting only individual members. In order to establish commonality, evidence that the acts alleged actually occurred is not required; rather, the factual evidence required at the certification stage is relevant to establishing whether these questions are common to all the class members: *Pro-Sys* at para. 110.

[147] The key elements of a common issue are summarized in *Pro-Sys* at para. 108:

a) An issue will be common only when its resolution is necessary to the resolution of each class member's claim;

b) It is not essential that the class members be identically situated vis-à-vis the opposing party;

c) It is not necessary that common issues predominate over non-common issues but class members' claims must share a substantial common ingredient to justify a class action; and

d) Success for one class member must mean success for all (i.e., all members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent).

[148] Commonality should be approached purposively: the question is whether class proceedings will avoid duplication of fact-finding or legal analysis: *Stanway v. Wyeth Canada Inc.*, 2012 BCCA 260 at para. 9 [*Stanway* BCCA]; *Vivendi Canada Inc. v. Dell'Aniello,* 2014 SCC 1 at para. 44 [*Vivendi*]. This requirement must not be applied inflexibly; a common question can exist even if the answer might vary from one member of the class to another: *Vivendi* at para. 44. For a question to be common, success for one member of the class does not necessarily have to lead to success for all the members to the same extent, but success for one member must not result in failure for another: *Vivendi* at para. 45. It need only advance the claim of each class member to a sufficient extent that it warrants answering on a collective, as opposed to individual, basis.

[149] If an issue is one that the court at trial could decide only by reference to the facts relating to the claim of each class member, it lacks commonality: *Ernewein* at para. 32; *Brown v. Canadian Imperial Bank of Commerce,* 2012 ONSC 2377 at paras. 116, 118, aff'd 2013 ONSC 1284 (Div. Ct.), aff'd 2014 ONCA 677. In *Rumley v. British Columbia*, 2011 SCC 69 at para. 29, McLachlin C.J.C. confirmed that an issue would not satisfy the common issues test if it was framed in overly broad terms:

> […] It would not serve the ends of either fairness or efficiency to certify an action on the basis of issues that are common only when stated in the most general terms. Inevitably such an action would ultimately break down into individual proceedings. That the suit had initially been certified as a class action could only make the proceeding less fair and less efficient.

[150] There must be evidence to establish some basis in fact for each of the proposed common issues that the plaintiffs seek to have certified (i.e., evidence and some basis

in reality to show that an issue exists and that a judge would be able to assess it in common): *Williams* at paras. 257–258. Each of the proposed issues must be considered separately: *Sandhu v. HSBC Finance Mortgages Inc.*, 2016 BCCA 301 at para. 122; *Marshall* at para. 143; *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42 at para. 140(c).

[151] The focus at certification is not on how many individual issues there might be but whether there are any issues which necessarily resolve each class member's claim or a substantial ingredient of each member's claim: *Stanway v. Wyeth Canada Inc.*, 2011 BCSC 1057 at para. 41, aff'd *Stanway* BCCA [*Stanway* BCSC].

[152] As noted by the Court of Appeal in *Trotman v. WestJet Airlines Ltd.*, 2022 BCCA 22 at para. 57 [*Trotman*], the commonality inquiry is not a test of the merits:

> The certification judge is not to conduct an adjudication on the merits. There need only be some basis in fact for the proposition that the issue can be determined on a classwide basis: see *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 99 [*Pro-Sys*], citing *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 25. The evidence at this stage "goes only to establishing whether these questions are common to all the class members": *Pro-Sys* at para. 110. Said another way: "is there some evidence of class-wide commonality, that is some evidence that the proposed common issue can be answered on a class-wide basis": *Grossman v. Nissan Canada*, 2019 ONSC 6180.

[153] The plaintiffs submit that the common issues relating to Elmiron are a necessary first step in resolving the proposed class members' claims and that certification is therefore appropriate: *Stanway* BCCA at para. 13, citing *Harrington v. Dow Corning Corp*., 2000 BCCA 605 at para. 63.

[154] The defendants deny that the plaintiffs have provided any basis in fact to support the existence, and therefore certification, of the proposed common issues. They submit that the uncontradicted evidence of their experts demonstrates there is no commonality in the overly broad issues framed by the plaintiffs and that the proposed common issues will not significantly advance individual claims. They say there is a two-step approach in certification actions that requires the plaintiffs to adduce some evidence to support: (1) the existence of the proposed common issue; and (2) the commonality of each proposed common issue: *Krishnan* at para. 115; *Bhangu* at paras. 97–99; *Jensen v. Samsung Electronics Co. Ltd.*, 2021 FC 1185 at paras. 193–217 [*Jensen*]; *Kuiper* at

para. 29; *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 6098 (Div. Ct.) at paras. 14–15 [*Batten*]; *Simpson v. Facebook, Inc.*, 2022 ONSC 1284 (Div. Ct.) at paras. 25–29. In their submission, this approach serves the purpose of the certification test, namely to filter out manifestly unfounded and frivolous claims and to require more than symbolic scrutiny: *Jensen* at para. 213, citing *Pro-Sys* at para. 103.

[155] Justice Skolrood highlights the uncertainty in the law on this point in *Chow v. Facebook, Inc.*, 2022 BCSC 1237 at paras. 80–82:

> [80] The Supreme Court of Canada also held in *Pro-Sys* at para. 110 that "[i]n order to establish commonality, evidence that the acts alleged actually occurred is not required. Rather, the factual evidence required at this stage goes only to establishing whether these questions are common to all the class members."
>
> [81] This statement has resulted in some uncertainty in lower courts about whether the “some basis in fact” test applies to both the existence of the common issues and whether the issues can be answered across the class (the two-step approach) or only to the latter question (the one-step approach). See for example: *Kaplan v. Casino Rama Services Inc.*, 2019 ONSC 2025 at paras. paras. 50–54 (noting disagreement amongst lower courts including the Ontario Court of Appeal, expressing preference for a one-step approach but opting for a two-step one out of an abundance of caution), cited and followed by *Simpson* on this point at para. 43; *Bhangu v. Honda Canada Inc.*, 2021 BCSC 794 at paras. 97–99 (two-step approach); *Krishnan v. Jamieson Laboratories Inc.*, 2021 BCSC 1396 at para. 127 (two-step approach), citing to *Bhangu*; *Gomel v. Live Nation Entertainment, Inc.*, 2021 BCSC 699 at para. 133 (one-step approach); *Pearce v. 4 Pillars Consulting Group Inc.*, 2019 BCSC 1851 at para. 206 (one-step approach), aff'd but not on this point 2021 BCCA 198.
>
> [82] It is unnecessary for me to resolve the issue on this certification application as, in my view, the plaintiffs’ application fails on the ground that there is no basis in fact to conclude that the proposed common issues can be decided on a class wide basis.

[156] I have adopted a two-step approach in assessing the proposed common issues.

### 2. The Proposed Common Issues

**Can ingesting Elmiron cause pigmentary maculopathy, including pigmentary maculopathy that continues after ceasing Elmiron use? (Common Issues 1 and 2)**

[157] The plaintiffs’ first two proposed common issues address general causation questions and are stated as follows:

1 Can ingesting Elmiron cause pigmentary maculopathy?

2 Can ingesting Elmiron cause symptoms of pigmentary maculopathy that continue after ceasing to take Elmiron?

[158] The plaintiffs say these issues are factual, focused exclusively on Elmiron, and that determination in favour of the class will significantly advance all class members' claims. Alternatively, they argue that, even if it is determined that Elmiron use cannot cause pigmentary maculopathy, this common answer will dispose of all class members' claims. Either way, they submit that certification is justified. It is their position that, as in *Miller* BCCA, they have presented incontrovertible evidence of a defendant altering its behaviour to warn users of the health risks at issue, namely Janssen's revision of the product monograph for Elmiron: *Miller* BCCA at para. 60.

[159] A plaintiff seeking to certify a common issue involving general causation must show that a methodology, capable of proving and measuring harm on a class-wide basis, exists; a plaintiff is not required to show proof of harm: *Kirk v. Executive Flight Centre Fuel Services Ltd.*, 2019 BCCA 111 at para. 103 [*Kirk*]. In other words, the plaintiff is required to demonstrate "that there is a realistic way to test the common issue at trial": *Kirk* at para. 105. The plaintiffs describe the evidentiary threshold as low and not onerous at this early stage: *Kirk* at para. 105; *Miller* BCCA at para. 53.

[160] Proposed methodologies are not to be held to a robust or rigorous standard at the certification stage; the court is not to assess competing expert evidence: *Pro-Sys* at paras. 117–119; *Stanway* BCSC at para. 47; *Stanway* BCCA at paras. 47–49. Methodology in this context is not to be confused with a prescribed scientific methodology but refers instead to whether there is any plausible way in which the plaintiff can legally establish the causation issue: *Miller* BCCA at para. 53. The existence of a "gold standard" randomized, double blind, clinical trial is not necessary in pharmaceutical cases: *Miller* BCCA at para. 49.

[161] The methodology must offer a realistic prospect of establishing loss on a class-wide basis: *Pro-Sys* at para. 118. The methodology cannot be purely theoretical or hypothetical; it must be grounded in the facts of the particular case and there must be

some evidence of the availability of the data to which the methodology is to be applied: *Pro-Sys* at para. 118; *Kirk* at para.107.

[162] The defendants describe the general causation issues framed by the plaintiffs as too general and nebulous to constitute common issues within the meaning of section 4(1)(c) of the *CPA*. They note that pigmentary maculopathy is not a single condition. Notably, Janssen's 2019 and 2020 revisions to the Elmiron product monograph consistently reference pigmentary maculopathy. At best, the defendants say there is some evidence of reports of pigmentary maculopathy, or a specific presentation of the same, in patients who used Elmiron. They submit that this evidence, which the plaintiffs' own experts acknowledge requires further research, does not rise to the "some basis in fact" level required to support the proposed common issue that Elmiron causes pigmentary maculopathy in all or any of its presentations.

[163] The defendants rely on *Martin* where Horkins J. refused to certify a proposed general causation common issue and held as follows at para. 227:

> A certification judge cannot perform the task of assessing a common issue if it is unclear what it means. Some evidence from a medical expert explaining the phrase "metabolic disturbance as well as secondary issues flowing therefrom" is required so the court can perform its task under s. 5. The plaintiffs have simply borrowed the words from *Heward* and assumed that the court will certify them in this case. That is not good enough. There must be some evidence to explain the meaning of the words together with some evidence that Seroquel can cause "related metabolic disturbances as well as secondary injuries flowing therefrom" and that this can be assessed in common.

### a) Scientific Literature

[164] The defendants submit that pigmentary maculopathy in a small number of patients with a long-term history of Elmiron use was first reported in the Pearce Article. The authors concluded that additional investigation was warranted. The abstract to the Pearce Article summarizes the authors' conclusions as follows:

> We describe a novel and possibly avoidable maculopathy associated with chronic exposure to PPS. Patients reported symptoms of difficulty reading and prolonged dark adaptation despite generally intact visual acuity and subtle fundoscopic findings. Multimodal imaging and functional studies are suggestive of a primary RPE injury. Additional investigation is warranted to explore causality further.

[165] The Pearce Article is the earliest reported article referenced by Dr. Gregory-Evans, the plaintiffs' ophthalmologist expert, in his discussion of general causation in his August 13, 2020 report. The defendants deny the Pearce Article demonstrates any association or causal connection between pigmentary maculopathy and Elmiron, or that a causal link has yet been established.

[166] The plaintiffs also rely on the Leschey Article appended to Ms. Evans' Affidavit #1, citing it as some basis in fact for the proposition that Elmiron inhibits the growth and proliferation of RPE cells, thereby impairing an important physiological pathway for retinal health. The abstract to the Leschey Article notes that several agents (including PPS) were examined for their effect on growth factor-stimulated processes in RPE cells. It states as follows:

> Several agents were examined for their effect on growth factor-stimulated processes in retinal pigment epithelial (RPE) cells. DNA synthesis was assessed by 3H-thymidine incorporation in density-arrested cells using previously determined maximally effective concentrations of various growth factors with and without test substances. Cell migration was assessed in Boyden chamber assays. For each test substance, trypan blue exclusion was used to determine noncytotoxic concentrations, and the effect of several concentrations were assessed on selected growth factors. The most effective, nontoxic concentration was then used for comparisons. Two cationic proteins, protamine and histone type II B, caused inhibition of RPE chemotaxis and 3H-thymidine incorporation induced by several growth factors, but a cationic polypeptide, polylysine, did not. Protamine and histone, were particularly effective inhibitors of acidic and basic fibroblast growth factors (FGF) but not if they were exposed to cells and then removed before growth factor addition. They had no effect on serum-stimulated chemotaxis or 3H-thymidine incorporation even when used in the presence of serum. Three anionic substances, heparin, pentosan polysulfate, and suramin, also inhibited RPE chemotaxis and 3H-thymidine incorporation induced by several different growth factors. They were less effective inhibitors of the FGFs than protamine and histone but were better inhibitors of serum-induced effects. Also unlike protamine and histone, the anionic substances maintained their inhibitory effect even when removed before growth factor addition. Since migration and proliferation of RPE cells are important processes in the pathogenesis of proliferative vitreoretinopathy, these agents and their mechanism of action deserve further study for potential therapeutic applications. Invest Ophthamol Vis Sci 32:1770-1778, 1991

[167] Leschey et al concluded as follows:

> This study has important implications with respect to PVR [Pathogenesis of Proliferative Vitreoretinopathy]. We identified several agents that modulate RPE migration and

> proliferation, two processes that have been implicated in its pathogenesis. Further work is needed to determine if these agents have similar effects in animal models of PVR. In addition, our results suggest the presence of at least two ways in which the stimulatory effect of growth factors can be modulated in RPE. Elucidation of the mechanism of these modulating effects may suggest a novel approach for treatment and prophylaxis of PVR.

[168] I interpret this paragraph to mean that the results of this study were preliminary and that more work needed to be done before they could be considered determinative. The defendants emphasize that the Leschey Article has not been interpreted by any expert who provided evidence on this application; they deny it is readily accessible to a lay reader. I agree. I conclude that, except to the extent the various scientific articles referenced by the plaintiffs are interpreted by an appropriately qualified expert, they are of limited assistance in establishing some basis in fact for the proposed common issues.

### b) Plaintiffs' Expert Evidence re: General Causation

#### i. Dr. Mahyar Etminan, Pharmacologist/Epidemiologist

[169] Dr. Mahyar Etminan is a clinical pharmacologist, epidemiologist, and Associate Professor of Ophthalmology and Visual Sciences at the University of British Columbia. He completed a Doctor of Pharmacy degree from Idaho State University in 2001 and a Master's degree in Clinical Epidemiology from the University of Toronto in 2003.

[170] At the request of plaintiffs' counsel, Dr. Etminan authored a report dated August 13, 2020, opining on a methodology by which to determine whether or not there is a causal link between Elmiron use and pigmentary maculopathy. He discusses the three main types of study designs (in order from weakest to strongest) that allow scientists to answer clinical questions, including adverse drug reactions. They include: (1) case reports and case series; (2) observational studies; and (3) randomized clinical trials.

[171] While Dr. Etminan concedes that case reports and case series alone cannot demonstrate cause and effect, he says they play a critical role in generating hypotheses for clinical research questions. In observational studies, investigators examine a hypothesized link between a drug and a specific outcome in a large population. While randomized controlled clinical trials are considered the strongest form of study design,

Dr. Etminan notes that they are not well-suited to an examination of rare drug safety questions due to small sample size, short follow-up periods, and ethical limitations.

[172] According to Dr. Etminan, several studies have identified a potential link between Elmiron and pigmentary maculopathy. He states that patients in studies diagnosed with pigmentary maculopathy secondary to Elmiron present with at least two hallmarks: 1) vitelliform (orange-yellowish) deposits; and 2) atrophy of the RPE. Dr. Etminan confirms that Pearce et al were the first to publicly report cases of maculopathy in six patients taking Elmiron in 2018.

[173] Dr. Etminan states that retinopathy secondary to Elmiron seems to affect primarily the RPE; he opines that, while an exact mechanism for maculopathy secondary to Elmiron is unknown, there is ample scientific evidence by which to infer a postulated mechanism for this effect. He says multiple studies have shown that it takes years of exposure to Elmiron for maculopathy to occur; in his view, this means that the delayed harmful effect of Elmiron probably continues after it is discontinued.

[174] According to Dr. Etminan, it is virtually impossible to demonstrate with 100% certainty that a drug causes a particular condition. However, he states that it is possible to infer a causal relationship from the best available scientific evidence. He identifies the Bradford Hill criteria, noting they are often applied to establish causation in science. He cites five of these criteria in his report, saying it is not always necessary for all of them to be present in order to establish causation. They include:

a) The presence of a temporal relationship;

b) The presence of a dose response relationship;

c) Biologic plausibility;

d) Specificity; and

e) Consistency.

[175] Although not part of the Bradford Hill criteria, Dr. Etminan would also analyze the totality of the scientific evidence to determine whether there is a causal link between Elmiron and maculopathy. He concedes that maculopathy secondary to Elmiron is rare. He notes (in reference to the specificity criterion) that the type of maculopathy described by Elmiron is unique to this drug, and that all other drugs used to treat IC are chemically distinct from Elmiron and have not been shown to cause maculopathy. He therefore concludes that this phenomenon may be specific to Elmiron.

[176] Ultimately, Dr. Etminan opines that there is a robust, workable methodology by which to assess the likelihood that Elmiron can cause maculopathy. Defence counsel underscore that, on Dr. Etminan's own evidence, this work has yet to be done.

### ii. Dr. Gregory-Evans, Ophthalmologist

[177] Dr. Kevin Gregory-Evans is an ophthalmologist in active clinical practice and a tenured professor in Ophthalmology at the University of British Columbia. He authored a report dated August 13, 2020 at the request of plaintiffs' counsel.

[178] Dr. Gregory-Evans was asked to comment on a methodology by which to assess a causal link between Elmiron ingestion and retinal toxicity, pigmentary maculopathy, and vision loss. He references the 2018 retrospective study discussed in the Pearce Article, reporting macular pigmentary changes in the RPE associated with vitelliform-like deposits in six people exposed to Elmiron. He says it has been proposed that Elmiron inhibits FGF (Fibroblast Growth Factor) pathways which leads to RPE toxicity, citing Greenlee T. et al., 2019. He confirms that this hypothesis awaits prospective experimental evidence and that alternative causal links are also possible.

[179] In Dr. Gregory-Evans' opinion, it is biologically plausible that, when used as intended, Elmiron has the propensity to cause retinal toxicity leading to pigmentary maculopathy and vision loss. He says multiple retrospective studies have shown an association between pigmentary maculopathy and chronic Elmiron use in IC patients.

[180] Dr. Gregory-Evans agrees that prospective human studies would provide stronger evidence than retrospective clinical data analysis and that the strongest

evidence would be based on prospective double-blind studies involving a large number of human subjects divided into two groups (one exposed to a placebo and the other to Elmiron). He confirms that while such a study would take many years to complete, non-human studies could explore possible causative associations between Elmiron and maculopathy.

[181] In addition to the study of cells from model systems, Dr. Gregory-Evans says it is possible to study the effects of drugs directly on living human or animal cells through primary tissue culture (i.e., from donor RPE cells and those grown *in vitro*) and from commercially available cell lines and retinal cells manufactured from stem cell technology. While the evidence from tissue culture studies is considered weaker than that from human or model system studies, he notes that these studies could be completed much more quickly (often in weeks) than those involving animal model systems (months to years) or prospective human studies (years to decades).

[182] Dr. Gregory-Evans was also asked if a methodology exists to assess whether pigmentary maculopathy and symptoms of vision loss can progress after Elmiron use is discontinued. He referenced a report of one such case (Huckfeldt RM et al, 2019), noting that retrospective studies in large numbers of people who have discontinued long-term Elmiron use should be undertaken to verify this finding. He opines that this should be feasible through urology patient databases and drug usage databases. In his view, if significant numbers of such human cases are discovered, animal model system and cell culture experiments could be done. He concludes by stating that the results of these human, animal model, and tissue culture experiments would be sufficient to extrapolate reliable conclusions of causative toxicity to the general population.

[183] In Dr. Gregory-Evans' opinion, these methodologies could be used to build on existing work to determine whether a causal link between Elmiron ingestion and retinal toxicity, pigmentary maculopathy, and vision loss could be established. Defence counsel submit that Dr. Gregory-Evans' report clearly demonstrates that substantial work remains to be done before this causal link can be established.

#### iii. Dr. Mary-Ann Lynn Stothers, Urologist

[184] Dr. Stothers is a urologist and professor in the Department of Urologic Sciences at the University of British Columbia. She has sub-speciality training in neuro-urology, urodynamics, reconstructive urology, and female urology. At the request of plaintiffs' counsel, she authored a report dated August 19, 2020, commenting on the definition, natural history, diagnosis, underlying proposed causes, and treatment of IC.

[185] Dr. Stothers confirms that IC symptoms can be disabling, particularly if experienced chronically, and that IC negatively impacts the quality of patients' lives by affecting sleep, mental health, and social functioning. She states that there is no single approach to the treatment of IC, treatment must be individualized, and care can be required for years or even decades.

[186] Dr. Stothers describes Elmiron as the most-studied oral medication in use for IC. She cites nine scientific publications obtained from an Ovid/Medline search of pigmentary maculopathy and referenced in the peer-reviewed medical literature discussing PPS and maculopathy. The earliest one she identifies is the Pearce Article published in November 2018. Since 2019, it has been Dr. Stothers' practice to inform her patients about the possible vision-related side effects of PPS and to ask them about symptoms of vision loss or reduced vision.

### c) Defendants' Expert Evidence re: General Causation

#### i. Dr. Jerry Sebag, Opthalmologist

[187] Dr. Jerry Sebag is an ophthalmologist and vitreo-retinal specialist, a Senior Research Scientist, and a professor of Clinical Ophthalmology at the University of California. He authored a report at Janssen's request.

[188] Dr. Sebag describes the postulate that Elmiron therapy causes pigmentary changes in the macula as theoretical, noting there is no evidence from any research or clinical study that proves causation; rather, there are only suggestions of possible associations. He states that all existing data shows that, if a PPS maculopathy exists, such a condition would be rare and present in only a small number of patients. He says

that, even if reliable future studies were to demonstrate causation with statistical significance, the clinical significance would likely be minimal, since in most purported cases to date, claims of vision loss have been primarily based on subjective patient symptoms and not clinical evaluations detecting objective vision loss. In his view, the macular changes reported in the literature do not represent a unique condition related to purported toxicity and there are several plausible alternative explanations for patient complaints of vision loss and macular irregularities that are unrelated to Elmiron use.

[189] According to Dr. Sebag, it would be necessary to demonstrate the absence of confounding effects from IC itself before the existence of a pigmentary maculopathy resulting from Elmiron therapy could be established. On his evidence, this had not yet been done when he wrote his (undated) report.

[190] Dr. Sebag explains that pigmentary irregularities and foci of macular atrophy are detectable by physical examination and with fundus photography. He notes that patients with some or all of these findings following Elmiron therapy are very few in number. He references an analysis conducted in 2020 of 27,693 medical claims in the US between 2002 and 2016 published in the British Journal of Ophthalmology by Jain N. et al in 2020. Those authors found that, after five years of Elmiron therapy, only 9 of 3,012 (0.3%) patients had macular irregularities. After 7 years, there were only 10 such patients out of 1,604 (0.6%). Based on this and other information, he concludes that the calculated incidence of macular irregularities (not necessarily disease or maculopathy) was determined to fall in the “very rare” frequency category. He also notes that pigmentary irregularities of the macula have been found in IC patients who have never had Elmiron therapy.

[191] Based on his review of Ms. D’Andrea’s medical records, Dr. Sebag opines that she has pigmentary irregularities which could be related to age-related macular degeneration, central serous chorioretinopathy, or macular dystrophy. Based on his review of Ms. Felker’s records, he concludes that she has normal vision and no evidence of pigmentary maculopathy.

### ii. Dr. Oliver Schein, Ophthalmologist

[192] Dr. Oliver Schein is an ophthalmologist and a professor in the Departments of Ophthalmology and Epidemiology at John Hopkins University School of Medicine. He completed residencies in internal medicine and ophthalmology, a Masters in Public Health, and fellowships in Preventive Ophthalmology and Corneal Disease. He was retained by Janssen to author a report in this case.

[193] Dr. Schein states that, since 2018, there have been reports of a specific type of pigmentary maculopathy among a small number of patients with a history of exposure to Elmiron. He explains the hierarchy that applies when assessing clinical research: at the bottom are case series which (apart from exceptionally rare circumstances not applicable here) do not inform strength of association or causation, in the middle are observational or retrospective studies, and at the top are randomized clinical trials (described by him as an impractical study design for rare events that may occur several years after exposure).

[194] Dr. Schein reviews the principal retrospective studies regarding Elmiron maculopathy, stating that none, either individually or in concert, demonstrate a causal relationship between Elmiron and pigmentary maculopathy. While he acknowledges the existence of case reports, he says that, in the absence of reliable evidence of causation, it is not possible to conclude that the drug effect progresses after cessation. He states that many patients with prior Elmiron exposure are likely to develop a variety of maculopathies in the decades following cessation of the drug, and that most likely have nothing to do with prior Elmiron exposure. In his view, the concept of causation is fraught with limitations from an epidemiological perspective.

[195] In Dr. Schein’s opinion, there is insufficient evidence to establish that Elmiron causes the specific presentation of pigmentary maculopathy that has been described in the literature. He describes the available epidemiological studies as weak; in his view, few of the Bradford Hill criteria (even acknowledging their limitations) are met. He denies this weak evidence provides a methodology by which to establish causation.

### iii. Dr. Carol Schwartz, Ophthalmologist

[196] Dr. Carol Schwartz is an ophthalmologist at Sunnybrook Health Sciences Centre in Toronto, Ontario and an assistant professor of Ophthalmology at the University of Toronto. She has sub-speciality fellowship training in the diagnosis and treatment of medical diseases of the retina and choroid. She was retained by Teva and prepared a report dated September 17, 2021.

[197] Dr. Schwartz discusses the various causes of pigmentary maculopathy and the multiple factors to consider in attempting to determine the most likely underlying cause of this condition in particular patients. She reviewed the adverse events described in the FDA Documents. She states that four of these events relate to ocular problems and that, of those four, none relates to pigmentary maculopathy but instead describe disorders involving a different part of the eye and not the macula.

## d) Reply by Plaintiffs' Experts

[198] Dr. Etminan prepared a reply report dated October 22, 2021. In summary, he states that a number of case series and epidemiologic studies have demonstrated an increase in the risk of maculopathy with Elmiron and while (like all epidemiologic studies) they have limitations, the totality of this evidence strongly suggests an increase in the risk of maculopathy among users of Elmiron.

[199] Dr. Gregory-Evans responds to Dr. Schein's report in his reply report dated October 28, 2021. He concedes that the concept of a hierarchy of value for evidence is sound and that determining the causal relationship between Elmiron use and pigmentary maculopathy would benefit from laboratory-based work and clinical studies. He acknowledges (as reported by others including Pearce et al, 2018 and Hanif et al, 2019) that, while more work needs to be done, this does not mean that the results of reported case series can be ignored. In his view, the existing body of data can be used to assist in assessing the cause and effect relationship between Elmiron use and pigmentary maculopathy.

### e) Methodology to Prove General Causation

[200] To certify a common issue regarding general causation (i.e., whether Elmiron can cause a particular side effect or adverse event), the plaintiffs must show some basis in fact that the issue can be determined on a class-wide basis at a common issues trial. The defendants submit that the plaintiffs have overstated the scientific evidence filed in support of this certification application. They deny it establishes an association between long term Elmiron use and pigmentary maculopathy, noting that the mere reporting of such events in patients who use Elmiron is not evidence of causation. They argue that the existing data is insufficient to establish whether Elmiron can cause pigmentary maculopathy, describing the plaintiffs' suggestion that Elmiron can cause a unique "signature" form of this disease as only hypothetical.

[201] In *Pro-Sys* at para. 118, the Supreme Court of Canada held that where expert evidence is required to establish the commonality of a proposed common loss or causation issue, the issue should not be certified unless there is evidence demonstrating a plausible and credible methodology capable of providing an answer to the question on a common basis:

> […] [T]he expert methodology must be sufficiently credible or plausible to establish some basis in fact for the commonality requirement. This means that the methodology must offer a realistic prospect of establishing loss on a class wide basis […]. The methodology cannot be purely theoretical or hypothetical, but must be grounded in the facts of the particular case in question. There must be some evidence of the availability of the data to which the methodology is to be applied.

[202] In *Charlton v. Abbott Laboratories Ltd.*, 2015 BCCA 26, the BC Court of Appeal confirmed that plaintiffs bear the burden of showing some evidence of a plausible and workable methodology for resolving the causation common issue on a class wide basis, stating as follows at para. 84:

> Where the applicants seek to address questions of causation on a class-wide basis and where causation is said to give rise to the commonality of interests, there must be some evidence of a methodology that will enable them to prove causation on a class-wide basis. While that rule is most clearly evident in cases brought by indirect purchasers, such as the claims considered in the 2013 Supreme Court trilogy, there is in my view no basis in principle to distinguish such claims insofar as this requirement is concerned. The evidence at the certification hearing must support the conclusion that certification of the common

> issue will advance the claim as pleaded. Where the proposed common issue is causation, there must be some evidence that issue may be resolved on a class-wide basis. Seeking evidence of a methodology of addressing causation for the class serves the objective of class proceedings and the *Ac*t must be applied with a purposive approach.

See also paras. 89–92; *Williamson* at para. 272; *Andriuk v. Merrill Lynch Canada Inc.,* 2014 ABCA 177 at paras. 10–11, 14.

[203] The defendants submit that even if the proposed common issues were restricted to pigmentary maculopathy and no longer reference "symptoms of vision loss" (as plaintiffs' counsel now propose in the amended common issues), the plaintiffs have failed to provide an evidentiary basis for a methodology that could establish general causation at a common issues trial. They say the current scientific literature discusses a potential link or association between a particular presentation of pigmentary maculopathy and Elmiron use, and that an association is not the same as causation: *Wise v. Abbott Laboratories, Ltd.*, 2016 ONSC 7275 at paras. 10–17 [*Abbott*]. Notably, Perell J. confirms in *Abbott* that "an association between a danger and a product may give rise to a duty to warn even if the association cannot be characterized as a causal connection".

[204] The defendants deny that an updated product monograph referring to reports of pigmentary maculopathy in patients using Elmiron is either evidence or an admission of causation. As noted in the product monograph for Elmiron, because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or to establish a causal relationship to drug exposure. I conclude that Janssen's substantive changes to the Elmiron product monograph in 2019 and 2020 constitute some basis in fact to support a possible link between Elmiron use and pigmentary maculopathy.

[205] The defendants note that *Stanway*, a decision on which the plaintiffs rely, was expressly considered and distinguished in *Charlton* where the Court of Appeal drew an important distinction between cases where: (a) there is evidence by which causation may be proven, but the experts disagree on the interpretation of it and the extent of the

increased risk; and (b) those where the experts are uncertain whether there is a risk to the class as a whole and cannot describe a methodology for addressing this question: *Charlton* at para. 113. The defendants say that the former is capable of being certified and the latter is not. In *Stanway*, a large, randomized controlled study established a connection between estrogen-progestin therapy and the risk of breast cancer; the parties' experts disagreed about the degree of the increased risk. By contrast, the defendants submit that *Charlton* and this case both fall on the opposite end of the spectrum. They say that, as in *Charlton*, the plaintiffs' experts are uncertain whether there is a risk that Elmiron causes pigmentary maculopathy and acknowledge that more research and data is needed.

[206] The Court of Appeal considered the methodology requirement to certify a common issue regarding general causation in *Kirk*. After reviewing *Pro-Sys*, *Charlton*, and other authorities, Justice Garson held that a proposed methodology will not satisfy the certification requirements if it shows only how a loss can be measured, rather than how such a loss can be established on a class-wide basis: *Kirk* at para. 106. Justice Garson decided that Mr. Kirk had to provide (among other things) some evidence of the availability of the data to which the methodology was to be applied: *Kirk* at para. 107. The plaintiff in *Kirk* failed to meet this requirement.

[207] In *Williamson*, the plaintiff's expert opined that further research was necessary to address the issue of causation: *Williamson* at para. 272. Justice Armstrong found that while there was no obligation at the certification stage for the plaintiff to prove causation, some facts or data are necessary to implement the plaintiff's proposed methodology: *Williamson* at para. 272. Ultimately, Armstrong J. found that the plaintiff's reliance on possible future developments was insufficient to meet the requirement of a credible methodology or mechanism to establish general causation:

> [273] Having analyzed the evidence, I find that plaintiff's reliance on future events concerning the possibility of a Health Canada decision is not sufficient to meet the requirement that a credible methodology or mechanism establish the general causation question or capable of proving that talc may be the cause of ovarian cancer. It also does not address the question of the relationship between talc use and non-epithelial ovarian cancer or ovarian cysts.

[208] The defendants acknowledge that the plaintiffs and their experts are not required to prove the existence of all facts or data that would be needed to implement the proposed methodology at the certification stage. However, they submit that the low threshold regarding methodology does not eliminate the requirement for evidence of the existence of data to which the methodology can be applied, citing *Ewert v. Nippon Yusen Kabushiki Kaisha*, 2019 BCCA 187 at para. 104 [*Ewert*]. They submit that the plaintiffs have offered no evidence to establish that there is a plausible or credible methodology based on existing data and evidence that has a realistic prospect of establishing a causal link between Elmiron use and pigmentary maculopathy for the class as a whole.

[209] In *Ewert*, after citing *Fischer*, where Justice Cromwell clarified the "some basis in fact" standard on certification, Justice Hunter held as follows at para. 104:

> I take from this that some basis in fact is to be contrasted with no basis in fact (as in *Chadha*). It is required that a plaintiff lead some evidence that there is a plausible and realistic methodology to establish loss on a class-wide basis, but where the methodology consists of an economic model, it is not necessary to build the model or identify with precision what information will be used to populate the model, as long as there is some evidence that information will be available to do so. [Emphasis in original.]

[210] Notably, Hunter J.A. refers to evidence that will be available (presumably, at the common issues trial); he does not state that such evidence must be available at the certification stage.

[211] During the certification hearing, plaintiffs' counsel advised that they had learned of the existence of a retrospective observational cohort study currently being conducted by Janssen Research & Development LLC entitled "Post-authorization Safety Study and Real-world Evaluation of the Use of Pentosan Polysulfate Sodium and the Development of Pigmentary Maculopathy and Pigmentary Retinopathy" (the "Study"). By consent, pursuant to s. 5(6) of the *CPA*, they tendered an additional affidavit, appending a summary document describing the Study. This document was extracted from the website ClinicalTrials.gov, an online database of clinical studies provided by the US National Library of Medicine, part of the US government National Institute of Health.

Plaintiffs' counsel advised that this is currently the only publicly available document describing the Study.

[212] Plaintiffs' counsel submit that the purpose of the Study is to evaluate the incidence and prevalence rates of pigmentary maculopathy among three groups: (1) a "clean cohort" of participants who had their first documented exposure to Elmiron on or after May 22, 2018; (2) an "overall cohort" of participants who had their first documented exposure to Elmiron any time beginning January 1, 2015 and who are assumed to have relatively longer exposure than other cohorts; and (3) an "Interstitial Cystitis (IC) Cohort" of participants who had at least one diagnosis of IC beginning January 1, 2015 and no documented Elmiron exposure.

[213] Plaintiffs' counsel say the Study is admissible evidence that a Janssen entity is conducting a retrospective cohort study on the terms described in a document, taken from the website of a U.S. government agency, and authenticated by the affiant's description of how and when he accessed it. While they remain of the view that the proposed common issues are certifiable without consideration of the Study, they submit that its existence adds to the "totality of evidence" referenced by Dr. Etminan and strengthens the case for certification. They say it further undermines the defendants' argument that there is insufficient evidence of "some basis in fact" that the general causation question can be determined at a common issues trial based on the methodologies the plaintiffs' experts have proposed.

[214] As an observational retrospective study, the Study falls in the middle of the hierarchy of scientific evidence described by the experts. Plaintiffs' counsel submit that it satisfies the criteria of observational or retrospective studies discussed by Dr. Schein because it evaluates two groups with varying exposure to Elmiron and one control group with no exposure to Elmiron. He notes that the Study considers a variety of characteristics including age, sex, race, ethnicity, and comorbidities, described by Dr. Schein in his report as potential "confounders".

[215] Finally, plaintiffs' counsel submit that the Study responds to defence counsel's criticism of Dr. Gregory-Evans' proposed methodologies as implausible on the basis the

proposed studies have not yet been undertaken and the data is presently unavailable. The plaintiffs reject this submission which they say calls for proof of the ultimate issue on the merits. They say the Study demonstrates that research regarding the association between Elmiron use and pigmentary maculopathy is ongoing.

[216] The results of the Study are unknown. It apparently commenced on or about November 30, 2021, after the defendants had filed their responses to the plaintiffs' certification application. While its estimated completion date was June 2022, it is unclear whether or not the Study concluded by then.

[217] Defence counsel's response to the Study is two-fold: firstly, the court must be satisfied (among other things) that there is sufficient information available at the certification stage to establish a viable, plausible way to prove general causation at trial; secondly, it is premature to make any assumptions about what, if anything, the Study will demonstrate. Janssen does not dispute that the Study is currently being conducted (by a different corporate entity than Janssen), or the authenticity of the document in evidence summarising it. However, they caution against reaching any conclusions about whether or not the Study will address their experts' criticisms of some of the existing retrospective studies regarding Elmiron use and pigmentary maculopathy. They endorse the comments of Lax J. in *Andersen* at para. 46, citing Posner J., that the court is not the place for scientific guesswork, even of the inspired sort, and that the law lags science and does not lead it.

[218] There is a debate among the experts in this case about whether or not there currently exists a plausible methodology, based on available scientific data, by which to establish a causal link between Elmiron use and pigmentary maculopathy. I am not required to weigh expert evidence on a certification application. I need not assess whether the plaintiffs' claims will ultimately succeed on the merits.

[219] In my view, the plaintiffs' expert evidence, taken as a whole, is sufficient to provide some basis in fact for concluding that there is a plausible methodology by which the plaintiffs can establish general causation, including causation regarding the effects of Elmiron after it is discontinued, at a common issues trial. The evidence does not

permit me to conclude that the plaintiffs are currently able to prove a causal link between Elmiron use and pigmentary maculopathy. However, in my view, requiring them to do so at this stage would be an impermissible intrusion into the merits. I conclude that the general causation issues are both common to the class and can be answered across the class.

**Did the defendants owe a duty of care to the class? (Common Issues 3 and 5)**

[220] Plaintiffs' proposed common issues 3 and 5 are stated as follows:

> 3 Did Teva Branded Pharmaceutical Products R&D, Inc. owe a duty of care to the class members regarding Elmiron?
>
> 5 Did Janssen, Inc. owe a duty of care to the class members regarding Elmiron?

[221] The plaintiffs argue that whether a drug manufacturer owes a duty of care to the consumers of its products is a common legal question that forms a significant part of any product liability claim in negligence. They say there is some basis in fact that each defendant, as a one-time registered sponsor of Elmiron with Health Canada, owes a duty of care to the class members who were the target consumers of this drug in Canada.

[222] The standard of care in products liability cases is described as "the duty to take reasonable care in the circumstances": *Williamson* at para. 99. This duty applies to the design of the product, and the requirement to warn users of the danger and risk in the nature of a product: *Williamson* at para. 101. The plaintiffs' stated common issue references only a general duty of care.

[223] The defendants acknowledge that each of them owed certain duties of care to users of their own products (but not to users of the other's product). Janssen admits that it owed a duty to warn users (or their physicians) of risks inherent in the use of its products of which it knew or ought to have known. However, it denies there is any basis in fact to certify a duty of care common issue related to the design or testing of Elmiron relating to its own conduct because the uncontradicted evidence establishes that Janssen did not design or seek the initial regulatory approval for the sale of Elmiron.

[224] Teva submits that there is no evidence whatsoever that any plaintiff or putative class member took Elmiron that it manufactured or sold. Accordingly, it says there is no basis in fact for certifying a common issue related to the duty of care of BNPI or Teva for products that the plaintiffs used which were manufactured and sold by others. Teva denies that it was in any relationship with the users of Elmiron marketed by other entities, let alone a proximate one, citing *Imperial Tobacco* at para. 41.

[225] On the evidence before me, BNPI, a predecessor to Teva, had some ongoing involvement in the sale of Elmiron after Health Canada approved it in 1993 until 1998. I conclude that proposed common issue 3 is not certifiable. Determination of this issue is not common to an appropriately defined class.

[226] I find that proposed common issue 5 is certifiable. Determination of this issue is common to the class as a whole and can be answered across the class. While Janssen acknowledges owing some duty to the end users of its own products, it has made no formal admission that it owed a duty of care to the plaintiffs.

**If the defendants owed a duty of care to the class, was it breached?**

[227] The plaintiffs' proposed common issues 4 and 6 are stated as follows:

> 4 If the answer to Question 1 or 2, and 3, is "yes", did Teva Branded Pharmaceutical Products R&D, Inc. breach this duty of care and if so when?
>
> 6 If the answer to Question 1 or 2, and 5, is "yes", did Janssen, Inc. breach this duty of care and if so, when?

[228] The plaintiffs advance two claims in negligence: negligent design and a negligent failure to warn. Proposed common issues 7 and 8 specifically relate to breach of a duty to warn. I therefore interpret proposed common issues 4 and 6 as relating to breach of a duty of care in connection with the plaintiffs' negligent design claim. In my view, this is the only possible interpretation that avoids overlapping common issues.

[229] The plaintiffs submit that whether any defendant breached a duty of care to the class members is a common question as it focuses exclusively on the defendants'

conduct. In negligent design claims, a court can analyse whether a defendant exercised reasonable care by looking at a manufacturer's conduct and balancing the inherent risk of the product as designed, and considering its utility and cost as compared to a safer alternate product or design: *Player* at para. 210.

[230] The defendants deny there is any basis in fact for the existence of a common issue regarding breach of a duty of care in the design and testing of Elmiron. They say the plaintiffs bear the onus of adducing some evidence that Elmiron, as designed, was unsafe, based on an appropriate risk/benefit analysis at the relevant time. They quote Lord Simonds in The Wagon Mound case, cited in *Double Bar L Ranching Ltd. v. Bavvet Corp.*, [1996] 10 W.W.R. 673 at para. 38, 1996 CanLII 5057 (Sask. C.A.) [*Double Bar L Ranching*] as follows:

> […] "After the event even a fool is wise". But is it not the hindsight of a fool; it is the foresight of the reasonable man which alone can determine responsibility.

[231] Teva relies on *Goodridge*, a case where the plaintiffs pleaded negligent design; the Ontario Superior Court found that the alleged harm (i.e., that the drug was associated with a propensity for suicidal behaviour) was not the result of any design choice. Teva describes the real issue there as the adequacy of the warning. It adopts the statement of Perell J. at para. 98 in *Goodridge* that it would "not be fair or just to make the innovator liable for failing to do something that should and can only be done by others". BNPI has not sold Elmiron in Canada since 1998. Further, Teva has never been involved in the marketing, labelling, or promoting of Elmiron in Canada.

[232] The plaintiffs allege negligence in the design of Elmiron. The plaintiffs' experts do not address this issue. I accept that I must not assess or weigh evidence at this stage, except for the purpose of determining whether the certification criteria have been met. However, there must be some basis in fact, in addition to pleaded allegations, to support a common issue related to negligent design. It is notably absent here. While I accept, as stated by Dr. Stothers, that Elmiron is not the only way to treat IC, no expert opines that another, equally efficacious, treatment option exists or would exist if different tests had been conducted or different design decisions made in the manufacture of Elmiron. In the absence of such evidence, I am not persuaded that there is any basis in

fact to support certifying proposed common issues related to a breach of duty regarding negligent design. I therefore decline to certify common issues 4 and 6.

**Did the defendants breach a duty to warn the class of the risks associated with ingesting Elmiron? (Common Issues 7 and 8)**

[233] Proposed common issues 7 and 8 are stated as follows:

> 7 Did Teva Branded Pharmaceutical Products R&D, Inc. breach a duty to warn class members of risks of associated with ingesting Elmiron, and if so when?
>
> 8 Did Janssen, Inc. breach a duty to warn class members of the risks associated with ingesting Elmiron, and if so when?

[234] The defendants submit that, in order to certify a common issue related to breach of a duty to warn, there must be some evidence of the existence of the issue, namely some evidence that the existing warnings were inadequate at some point and that the defendant(s) knew or ought to have known this at the relevant time, citing *Martin* at para. 159. However, this paragraph relates to the sufficiency of pleadings and not the certification of common issues.

[235] Janssen denies there is any basis in fact for the existence of an issue regarding breach of a duty to warn. It highlights the absence of any evidence or expert opinion about the sufficiency of the warnings in the Elmiron product monograph, either before or after the warning of pigmentary maculopathy was added in September 2019. They submit that updating a product monograph alone is not evidence of a breach of duty.

[236] None of the plaintiffs' experts offer opinions about the adequacy of the Elmiron warnings at any time. The adequacy of a warning must be assessed in light of the state of knowledge at the relevant time, without the benefit of hindsight: *Double Bar L Ranching*; *Lapointe v. Hôpital Le Gardeur*, [1992] 1 S.C.R. 351 at 362–363, 1992 CanLII 119; *Andersen* at paras. 57, 214.

[237] In *Martin,* Horkins J. of the Ontario Superior Court found there was no evidence to support an issue regarding breach of the duty to warn and no evidence that the

warnings or labelling for Seroquel were inadequate. The plaintiffs failed to adduce any expert evidence to support this common issue; their expert offered no opinion about the adequacy of the warnings for the alleged health conditions: *Martin* at para. 295.

[238] On the uncontroverted evidence before me, neither Teva, nor its predecessor BNPI, has been involved in the sale of Elmiron in Canada since 1998. Given my finding that there is no basis in fact to support common issues regarding a failure to warn before November 2018, I conclude that proposed common issue 7 (which relates exclusively to Teva) is, by extension, not certifiable.

[239] In my view, there is some basis in fact to support the proposed common issue related to Janssen's alleged breach of a duty to warn. On the evidence before me, the Pearce Article was the first reference in the publicly reported literature to a possible association between Elmiron and pigmentary maculopathy. In my view, there is no basis in fact to support certifying a common issue related to a failure to warn of pigmentary maculopathy associated with Elmiron use before November 2018. For the reasons already stated, I conclude that the FDA Documents and the scientific articles appended to the affidavits of Ms. Harte and Mr. Luna are alone insufficient for this purpose, except to the extent they have been interpreted by appropriately qualified experts. None of the plaintiffs' experts opines that the information in any of these documents ought to have prompted the defendants to take steps to warn Elmiron users of the possible risk of contracting pigmentary maculopathy as a result of taking this drug before 2018.

[240] I also find that there is no basis in fact to support a common issue related to a failure to warn after September 23, 2019 (when Janssen substantially amended the product monograph for Elmiron to add warnings related to pigmentary maculopathy). The plaintiffs' experts do not comment on the adequacy of the 2019 and 2020 changes to the Elmiron product monograph. I conclude that there is no basis in fact to support a finding that these warnings were deficient.

[241] In this context, I conclude that proposed common issue 8 is certifiable. For additional clarity, I find that there is some basis in fact to support a common issue regarding a failure to warn between November 2018 and September 23, 2019.

**Are the defendants jointly and severally liable for damages caused by a breach of duty? (Common Issue 9)**

[242] The plaintiffs' proposed common issue 9 is stated as follows:

> 9 If both of the defendants breached a duty of care owed to class members, are the Defendants jointly and severally liable for damages caused by such a breach?

[243] The plaintiffs describe the issue of the defendants' joint and several liability in this negligence claim as a pure question of law that is suitable for determination as a common issue, citing *Matthews v. La Capitale Civil Service Mutual*, 2020 BCSC 787 at paras. 136–138 and the *Negligence Act*, R.S.B.C. 1996, c. 333, s. 4.

[244] It is the defendants' position that this proposed common issue does not meaningfully advance the action and is not properly certifiable. They say the plaintiffs have failed to plead joint and several liability properly and that there is no factual foundation to support any joint and several liability common issue.

[245] Given my finding that there is no basis in fact to support certifying any common issue against Teva (apart from those regarding general causation), it follows that there is no basis in fact for certifying common issue 9 regarding joint and several liability.

**Have the defendants been unjustly enriched by their conduct? (Common Issue 10 and 11)**

[246] The plaintiffs' proposed common issues 10 and 11 are stated as follows:

> 10 Was the defendant, Teva Branded Pharmaceutical Products R&D, Inc., unjustly enriched by its conduct and, if so, should the court order restitution or disgorgement, and in what amount?
>
> 11 Was the defendant, Janssen, Inc. enriched by its conduct and, if so, should the court order restitution or disgorgement, and in what amount?

[247] Given my finding that the plaintiffs have failed to plead a viable claim in unjust enrichment, I decline to certify proposed common issues 10 and 11.

**What is the appropriate distribution of restitution or disgorgement to the class and should the defendants pay the costs of distribution? (Common Issue 12)**

[248] The plaintiffs' proposed common issue 12 is stated as follows:

> 12 If the answer to either or both of question 10 or 11 is "yes", what is the appropriate distribution of restitution or disgorgement to the class, and should any or all of the Defendants pay the costs of distribution?

[249] Given my finding that the plaintiffs have pleaded no viable unjust enrichment claim, common issues related to the remedies of restitution or disgorgement are, by extension, not certifiable. I therefore decline to certify common issue 12.

**Does the defendants' conduct justify punitive damages and, if so, in what amount? (Common Issues 13 and 14)**

[250] Proposed common issues 13 and 14 are stated as follows:

> 13 If the Defendants, or any of them, breached a duty of care owed to class members, were the Defendants, or any of them, guilty of conduct that justifies punishment?
>
> 14 If the answer to the preceding question is "yes" and if the aggregate of compensatory damages awarded to class members does not achieve the objectives of retribution, deterrence, and denunciation in respect of such conduct, what amount of punitive damages is awarded against the Defendants, or any of them?

[251] The plaintiffs propose a bifurcated approach to punitive damages: namely, splitting the question of whether the defendants' conduct warrants punishment from issues about whether punitive damages ought to be awarded and, if so, in what amount, citing *Chalmers v. AMO Canada Company*, 2010 BCCA 560 at para. 31; *Sherry v. CIBC Mortgage Inc.*, 2015 BCSC 490 at para. 21, rev'd in part but not on this issue at 2016 BCCA 240; *Gomel v. Live Nation Entertainment, Inc.*, 2021 BCSC 699 at paras. 165–167; *MacKinnon* at paras. 144–150; *Williamson* at paras. 295–299; *Miller* BCSC at paras. 188–193.

[252] The defendants submit that a punitive damages question provides no basis for certifying a class action or that a common issue about punitive damages is certifiable in

the absence of other certifiable common issues: *Batten* at para. 27. They submit that there must be an evidentiary basis for a punitive damages common issue: *Kirk* at paras. 138–142. They deny one exists here.

[253] The Court of Appeal addressed punitive damages as a common issue in *Kirk*, confirming that this may be properly certified as a common issue in appropriate cases: *Kirk* at para. 138, citing *Rumley* at para. 34. In *Kirk*, the Court found that the plaintiff had failed to put forward some basis in fact to support this common issue. Specifically, the facts pleaded did not allege, and the evidence referred to did not describe, any conduct which could be characterized as a marked departure from the ordinary standards of decent behaviour or as high-handed, oppressive, or malicious: *Kirk* at para. 140. Justice Garson, speaking for the Court, noted that dissatisfaction does not give rise to an award for punitive damages and that, while the certification process is "decidedly not meant to be a test of the merits of the action", the standard for assessing evidence at certification does not involve such a superficial level of analysis into the sufficiency of the evidence that it would amount to nothing more than symbolic scrutiny: *Kirk* at para. 141, citing *Hollick* at para. 16 and *Pro-Sys* at para. 103.

[254] In *MacKinnon v. Pfizer Canada Inc.*, 2022 BCCA 151, Justice Harris, speaking for the Court, allowed an appeal, in part, from the decision of the certification judge to certify punitive damages, in the absence of any basis in fact to support this issue:

> [7] As I read the judgment, the judge proceeded to certify the punitive damages issue solely on the basis of the allegations contained in the pleadings. The respondents have not pointed to material beyond the pleadings that establish a basis in fact for the certification of this common issue. This is, I think, an error in principle. It is inconsistent with the reasoning and result in *Sharp*. Accordingly, I would allow the appeal in respect of this issue, and set aside that part of the order certifying punitive damages as a common issue.

[255] I decline to certify common issues 13 and 14 for the same reason. There is no material beyond the ANOCC to establish some basis in fact for the certification of this issue: *Palmer* at para. 302.

**What is the appropriate distribution of damages to the class and are the defendants liable to pay interest on any award? (Common Issues 15 and 16)**

[256] Finally, the plaintiffs' proposed common issues 15 and 16 are stated as follows:

> 15 If the answer to the preceding question is "yes", what is the appropriate distribution of damages to the class, and should any or all of the Defendants pay the costs of distribution?
>
> 16 Are any or all Defendants liable to pay interest on an award?

[257] The plaintiffs say that common issues focused on the appropriate distribution of a punitive damages award, costs owed by the defendants in regard to such a distribution, and interest on any award, are pure questions of law relating exclusively to the defendants' conduct and therefore suitable for determination as common issues, citing *676083 B.C. Ltd. v. Revolution Resource Recovery Inc.*, 2019 BCSC 2007 at para. 150, rev'd in part 2021 BCCA 85 [*Revolution Resource*].

[258] The wording of common issue 15 is contingent on an affirmative answer to common issue 14 (which relates exclusively to punitive damages). I therefore interpret common issue 15 as relating exclusively to punitive (and not general) damages. I have declined to certify punitive damages as a common issue. Accordingly, no purpose would be served in certifying a common issue related to the distribution of such an award. I decline to certify common issues related to costs or interests as stated in common issues 15 and 16. In my view, those matters are best addressed following determination of any individual issues.

### f) Conclusion on Common Issues

[259] In summary, I find that there is some basis in fact to certify proposed common issues 1 and 2 (regarding general causation), and common issues 5 and 8 (regarding Janssen's duty of care and breach of a duty to warn). For the above-noted reasons, I conclude that the other proposed common issues are not certifiable.

## F. Is a Class Proceeding the Preferable Procedure?

### 1. Generally

[260] Section 4(1)(d) of the *CPA* requires that a class proceeding be the preferable procedure for the fair and efficient resolution of the common issues; the plaintiffs bear the onus of proof on this issue: *Kett* at para. 170, citing *Fischer* at para. 48. Section 4(2) of the *CPA* outlines the non-exhaustive factors a court must consider when assessing preferability. They are not conditions precedent that the plaintiff must prove will be fully achieved in a class action; no one factor predominates over the others: *Bodnar v. Community Savings Credit Union*, 2015 BCCA 504 at para. 51; *Lockyer-Kash v. Workers' Compensation Board of British Columbia*, 2015 BCCA 70 at para. 54.

[261] S. 4(2) of the *CPA* provides as follows:

> (2) In determining whether a class proceeding would be the preferable procedure for the fair and efficient resolution of the common issues, the court must consider all relevant matters including the following:
>
> (a) whether questions of fact or law common to the members of the class predominate over any questions affecting only individual members;
>
> (b) whether a significant number of the members of the class have a valid interest in individually controlling the prosecution of separate actions;
>
> (c) whether the class proceeding would involve claims that are or have been the subject of any other proceedings;
>
> (d) whether other means of resolving the claims are less practical or less efficient;
>
> (e) whether the administration of the class proceeding would create greater difficulties than those likely to be experienced if relief were sought by other means.

[262] A preferability analysis is conducted through the lens of the three principal purposes of class proceedings: judicial economy, access to justice, and behaviour modification: *Pro-Sys* at para. 137; *Fischer* at paras. 22, 48. It requires consideration of two core concepts: (1) whether or not the class proceeding would be a fair, efficient, and manageable method of advancing the claim; and (2) whether a class proceeding would be preferable to other reasonably available means of resolving the claims of class members (such as joinder, test cases, or consolidation): *Hollick* at para. 28; *Knight* at

para. 24, citing *Cloud v. Canada (Attorney General)* (2004), 247 D.L.R. (4th) 667, 2004 CanLII 45444 (Ont. C.A.).

[263] The test for determining preferability involves a comparative exercise that considers the extent to which the proposed class action might achieve the goals of the *CPA*; the ultimate question is whether other available means of resolving the claim are preferable, not if a class action would fully achieve those goals: *Fischer* at para. 23.

[264] Chief Justice McLachlin elaborated as follows in *Hollick*:

> [29] […] As one commentator writes:
>
> > […] In the abstract, common issues are always best resolved in a common proceeding. However, it is important to adopt a practical cost-benefit approach to this procedural issue, and to consider the impact of a class proceeding on class members, the defendants, and the court.
>
> See Branch, *supra*, at para. 4.690. I would endorse that approach.
>
> [30] […] I cannot conclude, however, that the drafters intended the preferability analysis to take place in a vacuum. There must be a consideration of the common issues in context. As the Chair of the Attorney General's Advisory Committee put it, the preferability requirement asks that the class representative "demonstrate that, <u>given all of the circumstances of the particular claim</u>, [a class action] would be preferable to other methods of resolving these claims and, in particular, that it would be preferable to the use of individual proceedings": [citation omitted]. [Emphasis in original]

[265] The most common access to justice barrier is an economic one, which arises when an individual cannot bring a claim because of the high cost of litigation relative to the modest value of the claim: *Fischer* at para. 27. The plaintiffs say those comments are applicable here. They highlight s. 7(a) of the *CPA* which provides that a court must not refuse to certify a proceeding as a class proceeding merely because the relief sought includes a claim for damages that would require individual assessment after determination of the common issues. They note that this action involves a national class (excluding Québec), whose claims are not the subject of any other actively litigated proceedings in Canada. They submit that if the class action does not proceed, the objectives of deterrence and behaviour modification will not be addressed: *Pro-Sys* at para. 141. They say that, on this issue, a class action is not only the preferable procedure but the only one available to serve these objectives.

### 2. Do questions of fact or law common to the members of the class predominate over any questions affecting only individual members?

[266] The plaintiffs submit that the common issues in this case predominate over any individual issues which may remain after resolution of the common issues, and that resolution of the common issues need not determine liability. They argue that the proposed common issues address the predominant liability issue in each class member's claim against the defendants, citing *Service v. University of Victoria*, 2019 BCCA 474 at para. 59. In *Sharp* BCCA, the Court observed as follows:

> [187] This Court has noted that "[w]hile the predominance of individual issues over common issues is not determinative of the requirement for a substantial common ingredient in the factual or legal issues among the proposed class members, it is a significant consideration in the preferable procedure analysis: *Thorburn v. British Columbia (Public Safety and Solicitor General)*, 2013 BCCA 480 at para. 48. See also *Baker v. Rendle*, 2017 BCCA 72 at para. 50.

[267] Section 7(a) of the *CPA* provides that "[t]he court must not refuse to certify a proceeding as a class proceeding merely because […] the relief claimed includes a claim for damages that would require individual assessment after determination of the common issues". Where there are more fundamental individual issues that precede any assessment of damages, such as specific causation (both in terms of warnings and damages), section 7(a) of the *CPA* may not apply: *Sharp* BCCA at para. 192.

[268] The defendants say that potential class members would face largely the same costs to litigate their claims at the individual issues stage as if they were bringing individual actions, citing *Williams v. Mutual Life Assurance Co. of Canada* (2003), 226 D.L.R. (4th) 112 at para. 54, 2003 CanLII 48334 (Ont. C.A.).

[269] The common issues related to general causation and the alleged breach of a duty to warn are essential to a determination of all class members' claims. Resolving all these issues in one proceeding would avoid a multiplicity of proceedings on the same issues with potentially inconsistent findings. I accept that individual causation issues and the assessment of damages would remain after a common issues trial.

[270] General causation is a central focus of the parties' expert reports. Substantial time was devoted to this complex issue at the certification hearing. In my view, it would likely present an economic bar to class members attempting to litigate individual claims. I adopt the comments of Horsman J. in *MacKinnon*; in my view they are equally applicable here:

> [160] While there are individual issues that will have to be determined in order for any class member to succeed in their claims, those issues do not predominate. A common issue trial will resolve a fundamental controversy between the parties, which is the question of general causation. The complexity of that issue is apparent from the material filed on this certification application, and that complexity would act as a barrier to any class member attempting to individually litigate their claims. If general causation is established on a common issues trial, this would advance the claims of all class members. If it is not established, all class members would benefit by the result, which is to the defendants' advantage.

[271] I appreciate that the signature form of pigmentary maculopathy thought to be associated with Elmiron use is a rare condition and that the class may be small. However, I conclude that even a relatively small class would benefit from the advantages afforded by a class proceeding.

[272] As in *MacKinnon*, the advantage of a class proceeding from the plaintiffs' perspective is that it would not place the burden of marshalling the resources necessary to prosecute this claim on individual plaintiffs. The advantage to the defendants is the prospect that, if the plaintiffs' case on causation is found to be lacking in merit, the claims of all class members will be disposed of in a single proceeding: *MacKinnon* at para. 162. In the circumstances, I conclude that the general causation issues predominate in this case and that a class action would promote judicial economy and access to justice.

### 3. Do a significant number of the class members have a valid interest in individually controlling the prosecution of separate claims?

[273] It is common ground that no putative class member wishes to pursue their claims on an individual basis. This factor favours certification.

### 4. Would the class proceeding involve claims that are or have been the subject of any other proceeding?

[274] This is the proposed national class action for alleged pigmentary maculopathy due to Elmiron use. There are two other class proceedings involving overlapping subject matter. Both were filed by class counsel for the plaintiffs in this action or by an affiliated law firm. One was filed in the Ontario Superior Court of Justice on June 19, 2020; that action is currently in the process of being stayed pending a decision on this application seeking certification on behalf of a national class. The second parallel class action is limited to Québec residents. It was filed in the Superior Court of Québec on July 8, 2020, and certified as a class action on November 16, 2021; that decision is subject to a pending application for leave to appeal.

[275] The defendants submit that the plaintiffs' emphasis on the authorization of an Elmiron class action in Québec is misplaced since the standard for authorization of a class action in Québec is materially different and less stringent than its counterpart in common law provinces: *L'Oratoire Saint-Joseph du Mont-Royal v. J.J.*, 2019 SCC 35 at paras. 57–59; *Vivendi* at para. 53; *Code of Civil Procedure*, C.Q.L.R., c. C-25.01, art. 575; *D'Amico c. Procureure générale du Québec*, 2019 QCCA 1922 at para. 43. They note that the class certified in Québec was limited to persons in Québec diagnosed with pigmentary maculopathy following their use of Elmiron (i.e., not all Elmiron users, as proposed here). The only conclusion I am able to reach from the parallel Québec certification decision is that the judge who heard this application was ultimately satisfied that certification in Québec was justified based on the evidentiary record before him.

### 5. Are other means of resolving the claims less practical or efficient?

[276] The plaintiffs say that, if the defendants assert that a class proceeding is not the preferable procedure, they must provide a realistic alternative proposal, supported with an evidentiary foundation: *Jer v. Samji*, 2013 BCSC 1671 at para. 208, rev'd in part but not on this issue, 2014 BCCA 116. They submit that it would be antithetical to permit the defendants to defeat certification by reliance on bald assertions that consolidation, test cases, joinder, or individual actions are preferable to a class proceeding as a mere

assertion that these procedures exist does not mean they are to be preferred: *Kwicksutaineuk/Ah-Kwa-Mish First Nation v. British Columbia (Agriculture and Lands)*, 2010 BCSC 1699 at para. 214, rev'd on other grounds 2012 BCCA 193.

[277] According to the defendants, the claims of any individuals who have been diagnosed with pigmentary maculopathy after using Elmiron would be better addressed with individual claims, perhaps with coordinated discovery. They say that the *SCCR* offer flexibility and procedures which would avoid unnecessary duplication of costs and effort, without the need for the more complex and expansive procedures of a class action.

[278] For the above-noted reasons, including, in particular, the complexity of the general causation issues, I am not satisfied that there are any preferable alternatives to a class action, even if the class is relatively small.

### 6. Would administration of the class proceeding create greater difficulties than those likely to be experienced if relief were sought by other means?

[279] The plaintiffs submit that individual litigation is the only real alternative the defendants could offer to a class proceeding in this case. However, they suggest that this approach is an illusory alternative for most class members given its cost relative to the comparatively low value of some class members' claims. Given the complex general causation issues and the associated cost of litigating them, I agree.

### 7. The Purpose of Class Proceedings

[280] The plaintiffs submit that, as in *Pro-Sys*, if the class action does not proceed, the objectives of deterrence and behaviour modification will not be addressed. They say this class action is not only the preferable procedure in this case, but the only one available to serve these objectives, citing *Pro-Sys* at para. 141. The defendants characterize the plaintiffs' submissions regarding access to justice and behaviour modification as hypothetical, speculative, and unsupported by the evidence.

[281] I have found that the negligent failure to warn claim is certifiable. By extension, there will be an issue in this case about whether or not Janssen took reasonable steps on a timely basis to warn Elmiron users of the risk of pigmentary maculopathy. A class action could therefore advance the goals of deterrence and behaviour modification.

#### 8. Conclusion on Preferability

[282] Ultimately, for the above-noted reasons including, in particular, the complexity of the general causation issues, I conclude that the plaintiffs have met their burden of establishing that a class proceeding is the preferable procedure for the fair and efficient resolution of the common issues in this case: *MacKinnon* at para. 163.

### G. Is there an Adequate Representative Plaintiff with a Proper Litigation Plan?

[283] I next consider whether there is an adequate representative plaintiff with a proper litigation plan.

#### 1. Adequacy of the Plaintiffs

[284] To satisfy s. 4(1)(e) of the *CPA*, a proposed representative plaintiff must: (1) fairly and adequately represent the interests of the class; (2) have produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding; and (3) have no interest that conflicts with those of other class members on the common issues. A proposed representative plaintiff must also be a member of the defined class.

[285] A proposed representative plaintiff need not have a claim that is typical of the class, nor be the best possible representative; the test for determining the adequacy of a proposed representative plaintiff is whether they have a common interest with other class members and will vigorously prosecute the action: *Kirk* at para. 154; *Miller* BCCA at para. 75; *Campbell v. Flexwatt Corp.* (1997), 44 B.C.L.R. (3d) 343 at paras. 75–76, 1997 CanLII 4111 (C.A.).

[286] The parties disagree about whether Ms. Felker is an appropriate representative plaintiff. The defendants deny she has a tenable claim on the evidence or qualifies as a

class member on any reasonable class definition that is rationally connected to the claims as pleaded and the proposed common issues. They say she must have an interest in common with the class members and will vigorously and capably prosecute the interests of the class: *Dutton* at para. 41; *Cantlie* at para. 358. Dr. Sebag concludes that Ms. Felker has no abnormal findings on physical examination and diagnostic testing and no evidence of pigmentary maculopathy. He opines that her vision is normal.

[287] The defendants deny that a representative plaintiff is merely a litigation vehicle for others. They submit that Ms. Felker must have a cause of action against at least one of the defendants; they say that certification of a class action may be denied where the proposed representative plaintiff has no valid cause of action: *Birrell v. Providence Health Care Society*, 2007 BCSC 668 at paras. 66, 70–71 var'd 2009 BCCA 109; *Koo and Gingras v. Canadian Airlines International Ltd.*, 2000 BCSC 281 at paras. 80–81.

[288] In *Martin,* Horkins J. found there was a lack of evidence to show that the representative plaintiffs' claims were anchored in the class action based on the medical records produced. Justice Horkins ultimately concluded that the proposed representative plaintiffs were not suitable representative plaintiffs and that this criterion was therefore not satisfied: *Martin* at paras. 365–368. The defendants deny this case is one of those rare exceptions where permitting an individual with no claim to represent a class is justified, as permitted by s. 2(4) of the *CPA*, noting that the plaintiffs adduced no evidence on this issue: *Revolution Resource* at para. 177.

[289] Ms. D'Andrea's medical records are appended to Mr. Luna's Affidavit #2. They include records from Dr. Steve Levasseur of Retina Surgical Associates Inc. dated February 3, 2021, indicating the presence of RPE changes in the macula and a recorded impression of Elmiron retinal toxicity and binocular diplopia of undiagnosed etiology. Repeat fundus autofluorescence, electroretinogram, and strabismus evaluation were recommended.

[290] Dr. Sebag opines that Ms. D'Andrea has pigmentary irregularities in the macula which could be due to age-related macular degeneration (for which she has a positive family history, several important risk factors, and a prior diagnosis), central serous

chorioretinopathy, or macular dystrophy. The defendants note that Ms. D'Andrea has not had the kind of diagnostic tests suggested by the relevant literature as important if Elmiron use is a suspected cause of her maculopathy. They submit that there are many possible alternative causes for her pigmentary irregularities.

[291] The plaintiffs respond by saying that the defendants are attempting to engage in an impermissible battle of the experts in an effort to defeat this class proceeding at the certification stage.

[292] Ms. Felker and Ms. D'Andrea have both sworn affidavits deposing that they consent to being representative plaintiffs in this action, are aware of the corresponding obligations, and agree to assume them. I am satisfied on the evidence that Ms. D'Andrea is an appropriate representative plaintiff. Given the common issues that I have found to be certifiable, I conclude that Ms. Felker is not an appropriate representative plaintiff.

### 2. Litigation Plan

[293] Section 4(1)(e)(ii) of the *CPA* mandates that the representative plaintiff(s) have a suitable plan for advancing the proceeding on behalf of the class.

[294] The purpose of the litigation plan at the certification stage is to assist the court by providing a framework within which the case may proceed and to demonstrate that the representative plaintiff and class counsel have a clear grasp of the complexities apparent in the case at the time of certification and a plan to address them: *Koubi v. Mazda Canada Inc.*, 2010 BCSC 650 at para. 195, rev'd on other grounds 2012 BCCA 310; *Singer* at para. 223. The court need not scrutinize the plan at the certification hearing; it is expected that plans will require amendments as the case proceeds: *Fakhri et al. v. Alfalfa's Canada Inc. cba Capers*, 2003 BCSC 1717 at para. 77, aff'd 2004 BCCA 549.

[295] The defendants describe the plaintiffs' litigation plan as inadequate, saying it is comprised almost entirely of boilerplate terms which fail to address the individual issues that would inevitably remain (even if all the proposed common issues were certified)

and the inherent complexities of this proposed class action: *Revolution Resource* at para. 181. They rely on the statements of Horkins J. in *Martin*:

> [370] […] a plan that simply sets out the usual steps that occur in any litigation is not acceptable: see *Bellaire*, at para. 52.
>
> [371] The plan must provide sufficient detail that corresponds to the complexity of the litigation. The litigation plan will not be workable if it fails to address how the individual issues that remain after the determination of the common issues are to be addressed. [citation omitted.]

[296] The defendants say that the plaintiffs' proposed litigation plan purports to incorporate various discovery orders that depart from the *SCCR* and would significantly prejudice the defendants regarding the timing of document production, the types of documents to be produced, and examinations of individuals to be undertaken. In their view, these matters are properly the subject of case management, if the case is certified, and not incorporation in the certification order. The plaintiffs no longer seek to incorporate their proposed litigation plan into the certification order. The parties agree that approval of the form and manner of providing notice will be determined by further order of this Court.

[297] In my view, the litigation plan is adequate at this stage: *Krishnan* at para. 238.

## IV. DISPOSITION

[298] This certification application is adjourned for three months to permit the plaintiffs an opportunity to file additional affidavit evidence identifying at least one other class member who meets the narrowed class definition, as set out in these reasons. If they fail to do so within this time frame, this action will not be certified.

[299] If there are any issues arising from these reasons, counsel are at liberty to apply to speak to them.

"Douglas J."

## SCHEDULE A – AMENDED PROPOSED COMMON ISSUES

### Negligence and Failure to Warn

**1-** Can ingesting Elmiron cause pigmentary maculopathy?

**2-** Can ingesting Elmiron cause symptoms of pigmentary maculopathy that continue after ceasing to take Elmiron?

**3-** Did Teva Branded Pharmaceutical Products R&D, Inc. owe a duty of care to the class members regarding Elmiron?

**4-** If the answer to Question 1 or 2, and 3, is “yes”, did Teva Branded Pharmaceutical Products R&D, Inc. breach this duty of care and if so when?

**5-** Did Janssen, Inc. owe a duty of care to the class members regarding Elmiron?

**6-** If the answer to Question 1 or 2, and 5, is “yes”, did Janssen, Inc. breach this duty of care and if so, when?

**7-** Did Teva Branded Pharmaceutical Products R&D, Inc. breach a duty to warn class members of risks of associated with ingesting Elmiron, and if so when?

**8-** Did Janssen, Inc. breach a duty to warn class members of the risks associated with ingesting Elmiron, and if so when?

**9-** If both of the defendants breached a duty of care owed to class members, are the Defendants jointly and severally liable for damages caused by such a breach?

### Unjust Enrichment

**10-** Was the defendant, Teva Branded Pharmaceutical Products R&D, Inc., unjustly enriched by its conduct and, if so, should the court order restitution or disgorgement, and in what amount?

**11-** Was the defendant, Janssen, Inc. enriched by its conduct and, if so, should the court order restitution or disgorgement, and in what amount?

**12-** If the answer to either or both of questions 10 or 11 is “yes”, what is the appropriate distribution of restitution or disgorgement to the class, and should any or all of the Defendants pay the costs of distribution?

**Punitive Damages**

**13-** If the Defendants, or any of them, breached a duty of care owed to class members, were the Defendants, or any of them, guilty of conduct that justifies punishment?

**14-** If the answer to the preceding question is “yes” and if the aggregate of compensatory damages awarded to class members does not achieve the objectives of retribution, deterrence, and denunciation in respect of such conduct, what amount of punitive damages is awarded against the Defendants, or any of them?

**15-** If the answer to the preceding question is “yes”, what is the appropriate distribution of damages to the class, and should any or all of the Defendants pay the costs of distribution?

**16-** Are any or all Defendants liable to pay interest on an award?