SUPREME COURT
OF BRITISH COLUMBIA
VANCOUVER REGISTRY

OCT 08 2020

ACTION NO. S201005 3
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

GERALD STEWART

PLAINTIFF

AND:

LEO PHARMA INC. AND LEO PHARMA A/S

DEFENDANTS

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

NOTICE OF CIVIL CLAIM

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

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

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

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

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

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

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

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

Time for response to civil claim

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

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

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

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

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

CLAIM OF THE PLAINTIFF

Part 1: STATEMENT OF FACTS

Parties and Overview

1. This action concerns the prescription medication Picato, containing the active pharmaceutical ingredient ingenol mebutate, which is indicated for the treatment of actinic keratosis ("AK"), a skin condition caused by exposure to the sun and UV rays.

2. Picato is a gel for use on the skin (topically) available in 2 strengths, 0.015% and 0.05%.

3. The Plaintiff, Gerald Stewart (the "Plaintiff"), has an address for service of Suite 820 – 980 Howe Street, in the City of Vancouver, in the Province of British Columbia. The Plaintiff had been prescribed and used Picato since May 2019.

4. The Plaintiff brings this action on his own behalf and on behalf of all persons resident in Canada who were prescribed and used Picato, and their beneficiaries pursuant to the *Family Compensation Act*, R.S.B.C. 1996, c. 126 and comparable legislation in the other Provinces and Territories, to be further defined in the Plaintiff's application for class certification.

Defendant Manufacturers

5. The Defendant, Leo Pharma Inc. is an extraprovincial incorporated company with a head office at 44 Chipman Hill, Suite 1000, in the City of St. John, in the Province of New Brunswick and a local registered and records office for service located at Suite 1700 Park Place, 666 Burrard Street, in the City of Vancouver, in the Province of British Columbia.

6. The Defendant, Leo Pharma A/S is a private company in Denmark located at Industriparken 55, DK-2750 Ballerup, Denmark.

7. The Defendants Leo Pharma Inc. and Leo Pharma Inc. Canada are collectively referred to herein as the "Defendants".

8. At all material times, the Defendants manufactured and distributed Picato for sale in Canada.

9. In 2012 the United States' Federal Drug Administration approved ingenol mebutate for use in the United States.

10. In November 2012, Picato received market authorisation in the European Union ("EU"). The potential for Picato to induce skin tumours was considered during Picato's initial marketing authorization in the EU, and the risk of AK progression to squamous cell carcinoma was reflected in Picato's EU risk management plan as an important potential risk.

11. Since 2013, Ingenol mebutate has been marketed in Canada under the Picato brand name. No such information relating to the risk of AK progression to squamous cell carcinoma were made on Picato products marketed and sold in Canada.

12. In 2017, the European product information of Picato was updated to reflect an excess of skin tumours (keratoacanthoma) with the use of ingenol mebutate 0.06% compared to a placebo. No such changes were made on Picato products marketed and sold in Canada.

13. The Canadian product monograph for Picato states, among other things, as follows:

> **INDICATIONS AND CLINICAL USE**
>
> PICATO (ingenol mebutate) is indicated for:
>
> •topical treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (AK) in adults.
>
> **Geriatrics** (≥ 65 years): No overall differences in safety or efficacy were observed between patients aged 65 years and over compared with younger patients (see **ACTION AND CLINICAL PHARMACOLOGY, Special Populations**).
>
> ...
>
> **WARNINGS AND PRECAUTIONS**
>
> **General**
>
> The efficacy of PICATO (ingenol mebutate) in the prevention of squamous cell carcinoma (SCC) associated with actinic keratosis (AK) has not been studied. The rate of SCC reported in the treatment area was comparable in patients treated with PICATO (0.3%) and in vehicle treated patients (0.3%) in the AK clinical studies. SCC in the treatment area was reported in no patients previously treated with PICATO in three prospective, observational long term 1 year follow-up studies.
>
> Clinical data on re-treatment and treatment of more than one area with PICATO is not available (see **DOSAGE AND ADMINISTRATION**, Dosing Considerations).
>
> Clinical data on treatment in immunocompromised patients is not available, but systemic risks are not expected since systemic exposure of ingenol mebutate was not detected following topical treatment with PICATO.

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Carcinogenesis and Mutagenesis

Long-term animal carcinogenicity studies with ingenol mebutate have not been conducted. Ingenol mebutate was not genotoxic or clastogenic in a bacterial mutation (Ames) assay, mouse lymphoma cell assay, or rat *in vivo* micronucleus assay. Ingenol mebutate was positive in the Syrian hamster embryo (SHE) cell transformation test, which detects both genotoxic and epigenetic carcinogens.

Carcinogenic and mutagenic risks to humans receiving treatment with PICATO are considered unlikely since systemic exposure of ingenol mebutate was not detected following topical treatment.

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ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

The mechanism of action of ingenol mebutate in actinic keratosis (AK) is not fully characterized since there is no adequate animal model of AK. *In vivo* and *in vitro* models using tumour cell lines, including squamous cell carcinoma, have shown a dual mechanism of action for the effects of ingenol mebutate: 1) direct cytotoxicity and 2) promoting an inflammatory response characterised by release of inflammatory cytokines and infiltration of immunocompetent cells.

Pharmacodynamics

At a high concentration (100 µg/ml) in vitro and in vivo, studies have shown that ingenol mebutate is cytotoxic.

At lower concentrations (10 to 100 ng/ml), ingenol mebutate activates both novel and classical protein kinase C (PKC) and is associated with immunostimulatory effects. Some classes of PKC activators, such as phorbol esters, are known to be tumour promoters. Ingenol mebutate is structurally related to phorbol esters. The clinical significance of potential proliferative effects via activation of PKC by ingenol mebutate is unknown. However, no evidence of neoplasia was noted in 6 and 9-month dermal repeat dose studies in rats and minipigs (cyclic administration). The risk of tumour induction in humans receiving treatment with PICATO is considered very unlikely due to the short duration of treatment (2-3 days).

...

Carcinogenesis and Mutagenesis

Carcinogenicity studies with ingenol mebutate have not been conducted.

Ingenol mebutate was not mutagenic in an *in vitro* Ames test, mouse lymphoma assay, and *in vivo* rat micronucleus test. An *in vitro* Syrian hamster embryonic (SHE) cell transformation assay was positive. The SHE transformation assay gave a positive result after the 24 h and 7 day exposure periods. There was an increase in toxicity (decrease in relative plating efficiency) and increase in morphologically

transformed colonies (MTC). Toxicity noted at ≥ 0.05 µg/mL at 24 h and after 7 days. A statistical increase in MTC was seen from 0.1 µg/mL at 24 h and 0.025 µg/mL at 7 days.

A 6-month repeat dose IV rat study in 154 rats found that one male and one female dosed twice weekly with 15 µg/kg had a kidney tubular adenoma and tubular hyperplasia of the kidney. A pituitary adenoma was also present in the female with the renal adenoma. At the 1-month recovery kill, one male had a thyroid follicular cell carcinoma. There was no evidence of neoplasia at lower IV doses or in the 6 month dermal rat and 41 week dermal minipig repeat dose studies.

14. On or about January 27, 2020, the UK Medicines and Healthcare products Regulatory Agency announced that the Defendant Leo Pharma A/S was recalling all unexpired Picato stock from pharmacies and wholesalers in the UK as a precautionary measure following the suspension of the marketing authorisation of Picato, while investigations were ongoing relating to the risks associated with the use of Picato and the development of skin cancer.

15. On or about February 11, 2020, the European Commission withdrew the marketing authorisation of Picato at the request of the EU marketing authorisation holder, Leo Laboratories Ltd.

16. On or about July 1, 2020, Health Canada issued a Summary Safety Review, which was triggered by new safety information from international clinical trials that found an increased risk of skin cancer in patients treated with Picato (ingenol mebutate). The review stated as follows:

Potential Safety Issue

Skin cancer

Key Messages

• Picato (ingenol mebutate) is a prescription drug authorized for sale in Canada for use on the skin (topically) in adults to treat actinic keratosis (AK), a condition where thick, hard and scaly patches appear on skin caused by too much exposure to the sun (UV exposure).

• Health Canada reviewed the risk of skin cancer with Picato based on new safety information from international clinical trials that found an increased risk of skin cancer in patients treated with this drug.

• Health Canada's review concluded that there may be a link between Picato and the risk of skin cancer.

• Health Canada will ask for additional information from the manufacturer to determine whether Picato continues to be an effective and safe treatment option for actinic keratosis (AK).

Overview

Health Canada reviewed the potential risk of skin cancer with the use of Picato. The review was triggered by new safety information from international clinical trials that found an increased risk of skin cancer in patients treated with Picato.

Use in Canada

• Picato (ingenol mebutate) is a prescription drug authorized for sale in Canada for topical use in adults to treat actinic keratosis (AK), a condition where thick, hard, and scaly patches appear on skin that has been damaged by too much sun (UV) exposure.

• Ingenol mebutate has been marketed in Canada since 2013 under the brand name Picato. Picato is a gel for use on the skin (topically) available in 2 strengths, 0.015% and 0.05%.

• There were about 5,000 prescriptions filled for Picato in Canada in 2019.

Safety Review Findings

• Health Canada reviewed the available information from searches of the Canada Vigilance database, evidence given by the manufacturer, and studies published in scientific and medical literature.

• Health Canada's review focused on 43 international clinical trials and found that there was enough evidence to link the use of Picato with skin cancer.

• Health Canada reviewed 29 case reports (including one Canadian case) of skin cancer in patients treated with Picato. Of the 29 cases, 26 cases were found to be possibly linked. In the other 3 cases (including the Canadian case), a link was found to be unlikely because of the presence of the skin cancer inside and outside of the area treated with the drug. Assessing whether the skin cancer was related to the use of Picato was challenging in all 29 cases due to several factors including a medical history of skin cancer or use of other medications known to increase the risk of skin cancer.

• Health Canada assessed 12 studies published in scientific and medical literature in order to determine the link between the use of Picato and skin cancer. Health Canada's review found that 6 of the 12 studies had evidence of skin cancer with the use of Picato.

• The European Medicines Agency (EMA) has also reviewed this safety issue. In April 2020, it concluded that Picato may increase the risk of skin cancer and that its risks outweigh its benefits. On February 11, 2020, the manufacturer voluntarily withdrew the product from the European market.

• Picato is currently authorized for sale in other countries including the United States of America, Australia, and New Zealand.

Conclusions and actions

• Health Canada's review found that there may be a link between Picato and the risk of skin cancer.

• Health Canada will ask for additional information from the manufacturer to determine whether the benefits of the use of Picato continue to outweigh its risks as a treatment option for AK.

• Health Canada will continue to monitor safety information involving Picato to identify and assess potential risks, as it does for all health products on the Canadian market. Health Canada will take appropriate and timely action if and when new health risks are identified.

17. On or about July 2, 2020, the European Medicines Agency issued the following statement regarding the risks associated with the use of Picato:

Risks of Picato for actinic keratosis outweigh benefits

On 30 April 2020, EMA completed its review of Picato (ingenol mebutate), a gel for treating the skin condition actinic keratosis, and concluded that the medicine may increase the risk of skin cancer and that its risks outweigh its benefits.

The review looked at results of a study comparing Picato with imiquimod (another medicine for actinic keratosis). After 3 years, 6.3% of patients treated with Picato (15 out of 240 patients) developed skin cancer, particularly squamous cell carcinoma, in the treated skin area compared with 2% of patients treated with imiquimod (5 out of 244 patients).

Data from other studies with ingenol mebutate or a similar medicine ingenol disoxate, laboratory studies and reports received since the medicine has been on the market were also assessed in the review.

It was noted that recent data from a study on the effectiveness of actinic keratosis treatments supported the previous observation, detailed in the medicine's product information, that Picato's effectiveness decreases over time.

Picato is no longer authorised in the EU as the marketing authorisation was withdrawn on 11 February 2020 at the request of LEO Laboratories Ltd, the company that marketed the medicine.

Information for patients

• Picato, a gel used on the skin to treat actinic keratosis, may increase the risk of skin cancer.

• A study showed that patients treated with Picato had a higher number of cases of skin cancer in the area of skin where the medicine was applied than patients using another treatment, imiquimod.

...

The Plaintiff

18. The Plaintiff used Picato. He was prescribed and started taking it in May 2019.

19. As a result of the defective nature of the Picato that he received, the Plaintiff has incurred damages including:

    (a) General damages for the tort of battery;

(b) Personal injury including prolonged and serious mental distress;

(c) The increased material risk of developing skin cancer;

(d) Special damages for the cost of medical monitoring and medical tests incurred to the date of trial and future care costs for ongoing medical monitoring and medical tests;

(e) The cost of purchasing Picato that was unfit for the purpose intended;

(f) Damages in accordance with s. 36 of the *Competition Act*, RSC 1985, c. C-34 for a breach of s. 52; and

(g) Such further and other damages as shall be proven at trial.

20. The Plaintiff would not have used Picato had he been informed its use posed an increased risk of developing skin cancer and had he been provided accurate information and/or warnings.

Part 2: RELIEF SOUGHT

21. The Plaintiff claims, on his own behalf, and on behalf of a class of similarly situated persons resident in Canada, as follows:

(a) An order certifying this action as a class proceeding and appointing the Plaintiff as the representative Plaintiff under the *Class Proceeding Act*;

(b) General damages;

(c) Special damages;

(d) Punitive damages;

(e) Relief pursuant to the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2, and comparable legislation in the other provinces and territories;

(f) Relief pursuant to the *Competition Act*, RSC c. C-34;

(g) Recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c.27, and comparable legislation in the other provinces and territories;

(h) Costs;

(i) Interest pursuant to the *Court Order Interest Act*, R.S.B.C. 1996, c. 79; and

(j) Such further and other relief this Honourable Court may deem just.

Part 3: LEGAL BASIS

Negligence and Failure to Warn

22. As the manufacturers, marketers, developers, distributors, labelers and/or importers of Picato, the Defendants were in such a close and proximate relationship to the Plaintiff, and other Class Members, as to owe them a duty of care. They caused the drug to be introduced into the stream of commerce in Canada, and they knew that any dangers or adverse effects related to the drug would cause foreseeable injury to the Plaintiff and Class Members.

23. The Defendants owed a duty to the Plaintiff and Class Members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, and selling Picato.

24. The Defendants owed a duty of care to the Plaintiff and Class Members to ensure that Picato was safe and effective for its intended use. Particulars of the Defendants' negligence include:

(a) Failing to ensure that Picato was manufactured to product standards;

(b) Supplying an unsafe product to consumers;

(c) Failing to implement appropriate quality control testing for the raw materials they manufactured, or in the alternative when they received raw materials from their supplier;

(d) Employing inadequately trained personnel in the design, manufacturing, and/or quality control of Picato;

(e) Placing Picato on the market when they knew or ought to have known that Picato had potential risks that outweighed its potential benefits;

(f) Manufacturing and/or marketing a product that they know, or ought to have known, had an unreasonably high risk of causing illness and/or harm to consumers;

(g) Failing to implement a timely recall of Picato once the risks were known to them;

(h) Failing to update Picato's product information or monographs with the risks associated with the use of Picato and the development of skin tumours (keratoacanthoma) once those risks were known to them;

(i) Manufacturing and/or marketing a product that was not fit for the purpose for which it was intended;

(j) Failing to manufacture and/or market a product in a good and workmanlike manner and in accordance with generally accepted standards; and

(k) Such further and other particulars of negligence as will be alleged at trial.

Battery

25. By applying Picato onto their skin, Class Members were exposed to toxic carcinogens, constituting a harmful and offensive contact to the person.

26. Despite the fact that the Plaintiff and Class Members willingly applied Picato, they were unaware that Picato contained carcinogens. The Plaintiff and Class Members would not have applied Picato if they knew they were also applying carcinogens, and as such, did not consent.

27. By distributing the Picato, the Defendants intended the drugs to be applied and thereby exposed the Class Members to the toxic carcinogens.

28. Since a time that is presently not known to the Plaintiff, each Defendant knew that the drugs contained the contaminants and therefore intended Class Members be exposed to the carcinogens.

29. Alternatively, the tort of battery is made out because the Defendants were willfully blind or recklessly indifferent to whether Picato contained carcinogens. The Defendants took no steps (or alternatively, insufficient steps) to investigate and address the carcinogenicity of their product when they knew there was a risk or likelihood that Picato would or could be harmful. In this context of knowing of the risk, the Defendants took no steps or insufficient steps to determine the carcinogenicity of Picato, therefore amounting to reckless indifference.

30. The Defendants had obligations under the *Food and Drug Regulations* (C.R.C., c. 870), Part C, Division 2 – Good Manufacturing Practices (the "GMP regulations"). No distributor or importer can sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with the requirements set out in the GMP regulations. These regulations require an importer to test all lots or batches of a drug before they are sold in Canada. Had the Defendants done so, the carcinogenic ingredients in Picato likely would have been discovered.

31. If the Defendants had complied with the GMP regulations that required them to ensure that all drugs that were imported were fabricated, packaged/labelled, tested and stored in accordance with the requirements set out in the GMP regulations in order to ensure quality, safety and effectiveness, they likely would have discovered the carcinogens in Picato at an earlier point.

32. The Defendants knew, or should have known on the basis of their own monitoring of their manufacturing facilities, that the Picato did, or could contain carcinogens which could (and did) cause harm and yet the Defendants did not recall Picato prior to any of the health authority warnings.

33. Further, the harm to the Class Members fell within the ambit of risk that the Defendants' enterprise created or exacerbated through failing to implement appropriate quality control processes, as required by the *Food and Drug Regulations*. The Defendants introduced the risk of wrongs by manufacturing Picato, particularly when they were aware of its shortcomings and thus should have managed and minimized the risk, especially when Class Members had no control over the application of carcinogens.

34. The Defendants acted with reckless indifference to the consequences of failing to implement appropriate quality control and/or pre-market and post-market investigation processes, in the face of their duty to do so, and knew that they were consequently placing the Class Members at significant risk.

35. The Defendants were aware of the risk that certain consequences could result from carcinogens in the Picato but were indifferent to the risk. The Defendants continuously failed to establish, maintain and enforce appropriate quality control processes and/or pre-market and post-market investigation, in order to mitigate and/or investigate risks associated with use of Picato. The Defendants' failure to implement appropriate safetyprocesses was an unreasonable risk to take and constituted reckless indifference.

36. The Defendants' failure to implement appropriate safety processes constituted either conscious wrongdoing or a marked departure from the standards by which responsible and competent pharmaceutical manufacturers govern themselves when manufacturing pharmaceutical products in Canada.

37. By failing to implement adequate quality control measures, the Defendants knew their practices were not in conformity with their obligations under the *Food and Drug Regulations* or industry standards, and knew it was wrong to have done nothing or to decide not to do anything with reckless indifference to the consequences.

38. As a direct result of the Defendants' wrongful acts as pleaded herein, the Plaintiff applied a topical carcinogen manufactured by the Defendants, which intentionally caused harmful or offensive contact with the Plaintiff to which the Plaintiff and Class Members did not consent. As a result, the Defendants committed the tort of battery. The Plaintiff suffered damages as a result of the battery, including enhanced risk of cancer, physical bodily injury comprised of changes at a cellular or molecular level, emotional upset, prolonged mental distress, anxiety and will require therapy and extensive medical monitoring.

Business Practices and Consumer Protection Act

39. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of Picato for personal use by the Plaintiff and by Class Members were "consumer transactions" within the meaning of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 ("*BPCPA*"). With respect to those transactions, the Plaintiff and Class Members who purchased and applied Picato are "consumers" and the Defendants were "suppliers" within the meaning of the *BPCPA*.

40. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Picato had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of Picato. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Picato, including as described above in paragraph 11, were deceptive acts and practices contrary to s. 4 of the *BPCPA*. The Defendants' deceptive acts and practices included the failure to properly disclose all material facts regarding the risks of using Picato.

41. As a result of the Defendants' deceptive acts and practices, the Plaintiff and Class Members have suffered loss and damages. The Plaintiff seeks injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss. 171 and 172

of the *BPCPA* on his own behalf and on behalf of Class Members who purchased Picato in Canada. Such relief includes the disgorgement of the profits or revenues received by the Defendants from the sale of Picato in Canada.

42. By placing their trademark on the medication thereby identifying the Defendants as the manufacturers and/or distributors of Picato, the Defendants intended to convey to consumers that Picato was of high quality and was manufactured by a reputable pharmaceutical company.

43. The declaratory and injunctive relief sought by the Plaintiff in this case includes an order under s. 172 of the *BPCPA* that the Defendants advertise any judgment against them and that they properly inform consumers and their physicians of the risks of Picato which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

Breaches of the Competition Act

44. As a result of their representations about Picato, the Defendants breached section 52 of the *Competition Act*, RSC c C-34 (the "*Competition Act*") and committed an unlawful act because their representations:

    (a) were made for the purpose of promoting, directly or indirectly, the use of Picato;

    (b) were made for the purpose of promoting indirect or directly, any business interests of the Defendants;

    (c) were made to the public;

    (d) were made knowingly and recklessly; and

    (e) were false and misleading in a material respect.

45. The Plaintiff and the Class Members suffered damages as a result of the Defendants' unlawful breach of section 52 of the *Competition Act*. Those damages include

    (i) purchasing and using Picato when they would not have otherwise done so;

    (ii) the cost of purchasing Picato; and

    (iv) other losses incidental to their harms caused by their use of Picato.

46. The Plaintiff and Class Members also seek their costs of investigation, pursuant to section 36 of the *Competition Act*.

Unjust Enrichment

47. As a result of the Defendants' solicitations, offers, advertisements, promotions, sales and supply of Picato to the Plaintiff and class members, the Defendants were unjustly enriched and benefited therefrom. The material facts are pleaded in paragraphs 39 through 43.

48. As a result of the Defendants' sale and supply of Picato, the Plaintiff and class members suffered a corresponding deprivation.

49. There is no juristic reason why the Defendants' enrichment should be permitted, including at equity, under contract or pursuant to any statutory obligations.

50. The Defendants have accordingly been unjustly enriched to the extent of those amounts paid by the Plaintiff and class members.

Causation and Damages

51. As a result of the Defendants' negligence and the Defendants' breach of the *BPCPA*, and/or other similar legislation in the other provinces and territories, the Plaintiff and Class Members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage suffered by the Plaintiff and Class Members which were caused or materially contributed to by the aforementioned acts of the Defendants include:
    (a) Personal injury;
    (b) Special damages for medical expenses and out of pocket expenses;
    (c) Loss of both past and prospective income; and
    (d) Cost of future care.

52. The Plaintiff and Class Members have suffered injuries which are permanent and lasting in nature, including diminished enjoyment of life, as well as the need for lifelong medical monitoring and/or treatment.

53. The conduct of the Defendants warrants a claim for punitive damages. They have conducted themselves in a high-handed, wanton and reckless manner, and without regard to public safety.

54. This case raises issues of general deterrence. A punitive damage award in this case is necessary to express society's condemnation of conduct such as the Defendants', to advance public safety and to achieve the goal of both specific and general deterrence.

Health Care Cost Recovery

55. The Plaintiff and Class Members have a claim for the recovery of health care costs incurred on their behalf by the British Columbia Ministry of Health Services and by other provincial and territorial governments. The Plaintiff pleads the *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27 and the comparable legislation from the other provinces and territories:

    (a) The Minister of Health of Alberta, for the cost of health services received by Class Members pursuant to Part 5, Division 1, of the *Hospital Act*, R.S.A. 2000, c. H-12, as amended, including in-patient and out-patient services, transportation services, public health services, mental health services and drug services;

    (b) The Minister of Health of Saskatchewan, for the cost of health services received by Class Members pursuant to s. 19(5) of *The Department of Health Act*, S.S. 1978, c. D-17, as amended;

    (c) Health Insurance BC for the cost of insured services received by Class Members pursuant to the *Medicare Protection Act*, R.S.B.C. 1996, c. 286, as amended, including prescribed services of hospitals and health facilities, prescribed medically necessary services rendered by physicians and prescribed health care services rendered by prescribed practitioners;

    (d) The Minister of Health and Social Services of Quebec, for the cost of all insured services furnished or to be furnished pursuant to s. 10 of the *Hospital Insurance Act*, R.S.Q. c. A-28;

    (e) Her Majesty the Queen in Right of the Province of New Brunswick, for the cost of entitled services received by Class Members pursuant to s. 5 of the *Health Services Act*, R.S.N.B. 1973, c. H-3, as amended, including accommodation and meals, necessary nursing services, laboratory, radiological and other diagnostic procedures, drugs, use of operating rooms, case rooms and anesthetic facilities, and routine surgical supplies;

    (f) Her Majesty the Queen in Right of the Province of Nova Scotia, for the cost of insured hospital services received by Class Members pursuant to s. 18 of the

Health Services and Insurance Act, R.S.N.S. 1989, c. 197, as amended, including benefits under the Insured Prescription Drug Plan, ambulance services to which the Province has made payment and insured professional services;

(g) The Minister of Health of Newfoundland and Labrador, for the cost of insured services received by Class Members pursuant to s. 5 of the *Hospital Insurance Agreement Act*, R.S.N. 1990, c. H-7, s. 5, as amended.

Jurisdiction

56. The Plaintiff relies on ss. 13, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c. 28 and pleads that there is a real and substantial connection between the subject matter of this action and the Province of British Columbia for the following reasons:
    (a) The Defendants marketed and sold Picato in British Columbia;
    (b) The Plaintiff resides in British Columbia; and
    (c) The Plaintiff's damages were sustained in British Columbia.

Form 11 (Rule 4-5 (2))

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff claims the right to serve this pleading/petition on the Defendants outside British Columbia on the ground that:

The Plaintiff has at all material times have been a resident of British Columbia and has suffered loss in British Columbia. The Supreme Court of British Columbia has jurisdiction with respect to this matter and the Plaintiff pleads the *Court Jurisdiction and Proceedings Transfer Act*, 2003, SBC Chapter 28 and amendments thereto.

Plaintiffs' address for service:	**RICE HARBUT ELLIOTT LLP** Barristers and Solicitors 820 - 980 Howe Street Vancouver, BC V6Z 0C8
Fax number address for service (if any):	(604) 682-0587
E-mail address for service (if any):	Nil
Place of trial:	Vancouver
The address of the registry is:	800 Smithe Street, Vancouver

Date: 7/OCT/2020

Counsel for the Plaintiff,
Jesse R. Kendall

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

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

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

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

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

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

Appendix

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

A claim for negligence, failure to warn and, *inter alia*, breach of consumer protection legislation relating to undisclosed cancer risks associated with the use of Picato (ingenol mebutate), with injury, loss and damages to the Plaintiff and a class of similarly situated persons resident in Canada.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

a motor vehicle accident

medical malpractice

X another cause

A dispute concerning:

☐ contaminated sites

☐ construction defects

☐ real property (real estate)

☐ personal property

☐ the provision of goods or services or other general commercial matters

☐ investment losses

☐ the lending of money

☐ an employment relationship

☐ a will or other issues concerning the probate of an estate

X a matter not listed here

Part 3: THIS CLAIM INVOLVES:
[*Check all boxes below that apply to this case*]

X a class action

☐ maritime law

☐ aboriginal law

☐ constitutional law

☐ conflict of laws

☐ none of the above

☐ do not know

Part 4:
[*If an enactment is being relied on, specify. Do not list more than 3 enactments.*]

1. *Class Proceedings Act*, R.S.B.C. 1996, c. 50
2. *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27
3. *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2