

**SUPREME COURT
OF BRITISH COLUMBIA
VANCOUVER REGISTRY**

JUL 23 2018



S-188114
ACTION NO.
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN

MAY MAZARELLA VENTURA

PLAINTIFF

AND:

**TEVA CANADA LIMITED, SANDOZ CANADA INC., PRO DOC LIMITEE,
SANIS HEALTH INC., SIVEM PHARMACEUTICALS ULC AND**

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.

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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 drug, Valsartan, which is prescribed for the treatment of mild to moderate essential hypertension.
2. The Plaintiff, May Mazarella Ventura, has an address for service at 820 – 980 Howe Street, in the City of Vancouver, in the Province of British Columbia. The Plaintiff had been prescribed Valsartan to control hypertension. She brings this action on her own behalf and on behalf of a proposed class of similarly situated persons who were prescribed Valsartan in Canada (or alternatively, British Columbia), to be further defined in the Plaintiff's application for class certification.
3. The Defendant, Teva Canada Limited (hereinafter "Teva") is a body corporate, duly registered under the *Business Corporations Act*, SBC 2002, c. 57 and amendments thereto as an extraprovincial federally incorporated company and has an office within the Province of British Columbia at Suite 2200, 1055 West Hastings Street, in the City of Vancouver, in the Province of British Columbia.
4. The Defendant, Sandoz Canada Inc. (hereinafter "Sandoz") is a body corporate, duly registered under the *Business Corporations Act*, SBC 2002, c. 57 and amendments thereto as an extraprovincial federally incorporated company and has an office within the Province of British Columbia at 800 – 885 West Georgia Street, in the City of Vancouver, in the Province of British Columbia.
5. The Defendant, Sanis Health Inc. (hereinafter "Sanis") is a body corporate, duly registered under the *Business Corporations Act*, SBC 2002, c. 57 and amendments thereto as an extraprovincial federally incorporated company and

has an office within the Province of British Columbia at 3189 Grandview Highway, in the City of Vancouver, in the Province of British Columbia.

6. The Defendant, Sivem Pharmaceuticals ULC (hereinafter "Sivem") is a body corporate, duly registered under the *Business Corporations Act*, SBC 2002, c. 57 and amendments thereto and incorporated pursuant to the laws of the Province of British Columbia and has a registered and records office at Suite 2600, Three Bentall Centre, P.O. Box 49314, 595 Burrard Street, in the City of Vancouver, in the Province of British Columbia.
7. The Defendant, Pro Doc Limitee (hereinafter "Pro Doc") is a body corporate, further particulars of which will be provided when they are known to the Plaintiff.
8. The Defendant, Zhejiang Huahai Pharmaceuticals (hereinafter "Zhejiang") is a body corporate, headquartered at Xunqiao, Linhai, Zhejiang, China, further particulars of which will be provided when they are known to the Plaintiff.
9. An impurity, N-nitrosodimethylamine (NDMA), was present in the Valsartan. The chemical was reportedly supplied by Zhejiang Huahai Pharmaceuticals. NDMA is a potential human carcinogen, which means that it could cause cancer with long-term exposure.
10. On a product monograph for Valsartan, Sandoz Canada Inc. states, among other things, as follows:

What the medication is used for:

- Treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate.

[...]

Valsartan and hydrochlorothiazide has been evaluated for safety in more than 7616 patients treated for essential hypertension.

[...]

In controlled clinical trials, discontinuation due to Adverse Experience (AEs) occurred in 2.3% and 3.1% of patients treated with valsartan and hydrochlorothiazide and placebo, respectively. The more common EAs resulting in discontinuation of therapy with valsartan and hydrochlorothiazide were dizziness and headaches.

11. The product monograph for Valsartan issued by Sandoz Canada Inc. does not list cancer as a risk to consumers of the product.
12. On July 9, 2018, Health Canada issued a safety alert (the "Recall") advising that several drugs containing the ingredient valsartan were being recalled by the manufacturers.
13. The information on the Health Canada website regarding the Recall included advice as to the following:
 - (a) Keep taking your medicine if it contains valsartan, unless you have been told to stop by your doctor or pharmacist;
 - (b) If you are taking any medication containing valsartan, speak to your pharmacist who can tell you if your medicine is being recalled;
 - (c) If you have been taking an affected product, contact your health care practitioner as soon as possible to discuss your treatment options.

The Plaintiff Ventura

14. The Plaintiff Ventura was taking Valsartan as prescribed at all material times.
15. As a result of defective nature of the Valsartan that she received, the Plaintiff Ventura has incurred damages including:
 - (a) general damages for personal injury including development of breast cancer requiring surgery;
 - (b) income loss and loss of income earning capacity;

- (c) special damages; and
- (d) such further and other damages as shall be proven at trial.

16. The Plaintiff would not have used Valsartan had she been provided accurate information and/or warnings.

Part 2: RELIEF SOUGHT

17. The Plaintiff claims, on her 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 Plaintiffs as the representative Plaintiffs 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;
- (f) 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;
- (g) costs;
- (h) interest pursuant to the *Court Order Interest Act*, R.S.B.C. 1996, c. 79; and
- (i) such further and other relief this Honourable Court may deem just.

Part 3: LEGAL BASIS

Negligence and Failure to Warn

18. As the manufacturers, marketers, developers, distributors, labelers and/or importers of Valsartan, and/or its components, 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.

19. The Defendants owed a duty to the Plaintiff and class members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, and selling Valsartan.

20. The Defendants owed a duty of care to the Plaintiff and class members to ensure that Valsartan was safe and effective for its intended use. Particulars of the Defendants' negligence include:
 - (a) failing to ensure that Valsartan and/or its components were manufactured to product standards;
 - (b) supplying contaminated Valsartan to consumers;
 - (c) failing to implement appropriate quality control testing when they received raw materials from their supplier in China, being Zhejiang Huahai Pharmaceuticals;
 - (d) employing inadequately trained personnel in the design and/or manufacturing of Valsartan;
 - (e) placing Valsartan on the market when they knew or ought to have known that the drugs had potential risks that outweighed their 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 Valsartan once the risks were known to them;
 - (h) manufacturing and/or marketing a product that was not fit for the purpose for which it was intended;
 - (i) failing to manufacture and/or market a product in a good and workmanlike manner and in accordance with generally accepted standards; and
 - (j) such further and other particulars of negligence as will be alleged at trial.

Business Practices and Consumer Protection Act

21. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of Valsartan 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 ingested Valsartan are "consumers" and the Defendants were "suppliers" within the meaning of the BPCPA.
22. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Valsartan had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of Valsartan. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Valsartan 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 Valsartan.
23. 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 her own behalf and on behalf of class members who purchased Valsartan in Canada. Such relief includes the disgorgement of the profits or revenues received by the Defendants from the sale of Valsartan in Canada.
24. 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 Valsartan which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

Causation and Damages

25. As a result of the Defendants' negligence and the Defendants' breach of the BPCPA, 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.

26. 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.

27. 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

28. 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.

Jurisdiction

29. 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 Valsartan 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 has 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.

Plaintiff's 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: 23/July/2018


 Signature of Michael Elliott
 plaintiff lawyer for plaintiff