S 215477

ACTION NO.
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

BETTY JEAN LYTTLE

PLAINTIFF

AND:

TEVA CANADA LIMITED, AURO PHARMA INC., MINT PHARMACEUTICALS INC., PHARMASCIENCE INC., PRO DOC LIMITEE., SANDOZ CANADA INC., SANIS HEALTH INC., SIVEM PHARMACEUTICALS ULC, AND SUN PHARMA CANADA INC.

DEFENDANTS

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

NOTICE OF CIVIL CLAIM

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

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

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

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

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

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

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

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

Time for response to civil claim

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

(a) if you 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 Irbesartan, Losartan and Valsartan medications ("Sartans"), all of which are angiotensin receptor blockers, which are a class of drugs used to treat patients with high blood pressure to help prevent heart attacks and stroke. They are also used in patients with heart failure or those who have had a recent heart attack.

2. The Plaintiff, Betty Jean Lyttle (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 ingested Sivem Losartan 50mg, with DIN 02388804.

3. The Plaintiff brings this action on her own behalf and on behalf of all persons resident in Canada who were prescribed, purchased and/or ingested certain Sartans manufactured and/or packaged by the Defendants that have been recalled due to the presence of an azido impurity above acceptable limits, and their beneficiaries (the "Class Members") pursuant to the *Family Compensation Act,* R.S.B.C. 1996, c. 126, to be further defined in the Plaintiff's application for class certification.

Defendant Manufacturers

4. The Defendant, Teva Canada Limited., has its head office at 30 Novopharm Court, in the City of Toronto, in the Province of Ontario. Its local office is at Suite

1700 - 1055 West Hastings Street, in the City of Vancouver, in the Province of British Columbia.

5. The Defendant, Auro Pharma Inc., is a federal corporation and has its head office at Suite 402 – 3700 Steeles Avenue, in the City of Woodbridge, in the Province of Ontario.

6. The Defendant, Mint Pharmaceuticals Inc., is a business corporation in the Province of Ontario and has a registered office at Unit 1 – 1093 Meyerside Drive, in the City of Mississauga, in the Province of Ontario.

7. The Defendant, Pharmascience Inc., has its head office at 6111, Avenue Royalmount, Bureau 100, in the City of Montreal, in the Province of Quebec.

8. The Defendant, Pro Doc Limitee, is a body corporate with a head office at 2925 Boul Industriel, in the City of Laval, in the Province of Quebec.

9. The Defendant, Sandoz Canada Inc., is an extraprovincial federally incorporated company and has its head office at 110 De Lauzon, in the City of Boucherville, in the Province of Quebec. Its local office is at Suite 400 – 725 Granville Street, in the City of Vancouver, in the Province of British Columbia.

10. The Defendant, Sanis Health Inc., is an extraprovincial federally incorporated company and has its head office at Suite 700 - 22 St. Clair Avenue East, in the City of Toronto, in the Province of Ontario. Its local office is at 3189 Grandview Highway, in the City of Vancouver, in the Province of British Columbia.

11. The Defendant, Sivem Pharmaceuticals ULC, has a registered and records office at Three Bentall Centre, P.O. Box 49314, Suite 2600 – 595 Burrard Street, in the City of Vancouver, in the Province of British Columbia.

12. The Defendant, Sun Pharma Canada Inc., is an extraprovincial company with a head office at 126 East Drive, in the City of Brampton, in the Province of Ontario. Its local address is at Suite 1212 – 1175 Douglas Street, in the City of Victoria, in the Province of British Columbia.

13. At all material times, the above-named defendants (collectively, the "Defendants") manufactured and distributed Sartans for sale in Canada.

14. An azido impurity, (5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole) has been detected in certain Sartans manufactured, distributed and sold by the Defendants at levels higher than recommended under established international guidelines. The azido impurity is considered a mutagen – a chemical substance that can cause a change in the DNA of a cell. These mutations may increase the risk of cancer.

15. A product monograph for Irbesartan tablets manufactured by Sandoz Canada Inc. states, among other things, as follows:

> **What the medicinal ingredient is:**
> Irbesartan
>
> **What the nonmedicinal ingredients are:**
> Cellulose microcrystalline, croscarmellose sodium, hypromellose, lactose monohydrate, hydroxypropylcellulose, magnesium stearate, polyethylene glycol, silica colloidal anhydrous, talc, titanium dioxide.
>
> **Carcinogenicity and Mutagenicity**
> No evidence of carcinogenicity was observed when irbesartan was administered at doses of up to 500/1000 mg/kg/day (males/females, respectively) in rats and 1000 mg/kg/day in mice for 2 years. These doses provided systemic exposures of 3.6-24.9 times (rats) and 3.8-6.2 times (mice) the exposures in humans receiving 300 mg daily.
>
> Irbesartan was not mutagenic in a battery of in vitro tests (Ames microbial test, rat hepatocyte DNA repair test, V79 mammalian cell forward gene mutation assay).

Irbesartan was negative in several tests for induction of chromosomal aberrations (in vitro – human lymphocyte assay; in vivo – mouse micronucleus study).

16. A product monograph for Losartan tablets manufactured by Sandoz Canada Inc. states, among other things, as follows:

What the medicinal ingredients are:

Losartan potassium and hydrochlorothiazide

What the important nonmedicinal ingredients are:

Sandoz Losartan HCT and Sandoz Losartan HCT DS contain the following non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropylcellulose, hypromellose, magnesium stearate, silicified microcrystalline cellulose, silicon dioxide, talc and titanium dioxide. Sandoz Losartan HCT 50 mg/12.5 mg and Sandoz Losartan HCT DS 100 mg/25 mg also contain lake quinoline yellow and polyethylene glycol. Sandoz Losartan HCT 50 mg/12.5 mg contains 4.24 mg (<1 mmol) of potassium and, Sandoz Losartan HCT 100 mg/12.5 mg and Sandoz Losartan HCT DS 100 mg/25 mg contain 8.48 mg (<1 mmol) of potassium, as losartan potassium.

Carcinogenesis

Losartan: Losartan potassium was not carcinogenic when administered at maximum tolerated dosage levels to rats and mice for 105 weeks (maximum dose of 270 mg/kg/day) and 92 weeks (maximum dose of 200 mg/kg/day), respectively.

Mutagenesis

Losartan: Losartan potassium was negative in the microbial mutagenesis and V-79 mammalian cell mutagenesis assays. In addition, there was no

evidence of direct genotoxicity in the in vitro alkaline elution and in vitro chromosomal aberration assays. Similarly, there was no induction of chromosomal aberrations in bone marrow cells of male or female mice after the administration of toxic oral doses of up to 1500 mg/kg (4500 mg/m2). In addition, the active metabolite E-3174 showed no evidence of genotoxicity in the microbial mutagenesis, in vitro alkaline elution, and in vitro chromosomal aberration assays.

Losartan – Hydrochlorothiazide: Losartan potassium–hydrochlorothiazide was negative in the Ames microbial mutagenesis assay and the V-79 Chinese hamster lung cell mutagenesis assay. In addition, there was no evidence of direct genotoxicity in the in vitro alkaline elution assay in rat hepatocytes and in vitro chromosomal aberration assay in Chinese hamster ovary cells at noncytotoxic concentrations.

17. A product monograph for Valsartan tablets manufactured by Sandoz Canada Inc. states, among other things, as follows:

What the medicinal ingredient is:
Valsartan and hydrochlorothiazide.

What the non-medicinal ingredients are:
Sandoz Valsartan HCT tablets: Colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, and titanium dioxide.

18. The product monographs for Sartans manufactured by the other Defendants are similar or identical to the above monographs. None of the Defendants' product monographs list azido impurities as a component of the Sartans nor do they list cancer or mutagenicity as a risk to consumers using Sartans.

19. On or about May 30, 2021, Health Canada issued a recall (the "Recall") advising that "Health Canada is informing Canadians that several companies are recalling

multiple lots of irbesartan, losartan and valsartan drug products after tests found an azido impurity above the acceptable limit..."

> Irbesartan, losartan and valsartan are all prescription angiotensin receptor blocker (ARB) drugs, which are also known as "sartans." Sartans are a class of drugs used to treat patients with high blood pressure to help prevent heart attacks and stroke. They are also used in patients with heart failure or those who have had a recent heart attack.
>
> The azido impurity, (5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole, is considered a mutagen. A mutagen is a chemical substance that can cause a change in the DNA of a cell. These mutations may increase the risk of cancer but the specific risk for this azido impurity to cause cancer in humans is unknown.
>
> There are established international guidelines that recommend that mutagenic impurities be kept at or below a specific level because exposure to a mutagen over the long term at a level above what is considered to be safe, has the potential to increase the risk of cancer. A person taking a drug daily for 70 years that contains this azido impurity at or below the acceptable level is not expected to have an increased risk of cancer

20. The affected products were identified as follows by Health Canada (the "Affected Drugs"):

Product	**Company**	**DIN**	**Lot**	**Expiry**
Irbesartan				
IRBESARTAN 150 mg TABLETS	Pro Doc Ltd.	02365200	617491	July 2021
IRBESARTAN 150 mg TABLETS	Pro Doc Ltd.	02365200	618112	March 2022
IRBESARTAN 150 mg TABLETS	Pro Doc Ltd.	02365200	624632	January 2023
IRBESARTAN 150 mg TABLETS	Pro Doc Ltd.	02365200	624633	January 2023
IRBESARTAN 150 mg TABLETS	Pro Doc Ltd.	02365200	630546	May 2023
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	615929	June 2021
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	617091	June 2021
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	617264	June 2021

IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	620694	March 2022
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	624189	May 2022
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	624190	May 2022
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	624191	January 2023
IRBESARTAN 300 mg TABLETS	Pro Doc Ltd.	02365219	624192	January 2023
IRBESARTAN 75 mg TABLETS	Pro Doc Ltd.	02365197	616518	June 2021
IRBESARTAN 75 mg TABLETS	Pro Doc Ltd.	02365197	619960	November 2021
IRBESARTAN 75 mg TABLETS	Pro Doc Ltd.	02365197	622192	May 2022
IRBESARTAN 75 mg TABLETS	Pro Doc Ltd.	02365197	622193	December 2022
IRBESARTAN HCT/TABLET/150/12.5 mg	Sivem Pharmaceuticals ULC	02385317	JN5054	January 2022
IRBESARTAN HCT/TABLET/150/12.5 mg	Sivem Pharmaceuticals ULC	02385317	JV2163	April 2022
IRBESARTAN HCT/TABLET/150/12.5 mg	Sivem Pharmaceuticals ULC	02385317	JY7867	June 2022
IRBESARTAN HCT/TABLET/150/12.5 mg	Sivem Pharmaceuticals ULC	02385317	KT2519	May 2023
IRBESARTAN HCT/TABLET/150/12.5 mg	Sivem Pharmaceuticals ULC	02385317	KT2520	May 2023
IRBESARTAN HCT/TABLET/300/12.5 mg	Sivem Pharmaceuticals ULC	02385325	JP2979	January 2022
IRBESARTAN HCT/TABLET/300/12.5 mg	Sivem Pharmaceuticals ULC	02385325	JP2980	January 2022
IRBESARTAN HCT/TABLET/300/12.	Sivem Pharmaceuticals	02385325	JU8206	April 2022

5 mg	ULC			
IRBESARTAN HCT/TABLET/300/12.5 mg	Sivem Pharmaceuticals ULC	02385325	JU8207	April 2022
IRBESARTAN HCT/TABLET/300/25 mg	Sivem Pharmaceuticals ULC	02385333	JX8881	June 2022
IRBESARTAN HCT/TABLET/300/25 mg	Sivem Pharmaceuticals ULC	02385333	JX8882	June 2022
IRBESARTAN HCT/TABLET/300/25 mg	Sivem Pharmaceuticals ULC	02385333	JB0216	May 2021
IRBESARTAN/TABLET/150 mg	Sivem Pharmaceuticals ULC	02385295	KC7215	July 2021
IRBESARTAN/TABLET/300 mg	Sivem Pharmaceuticals ULC	02385309	KF8325	July 2021
IRBESARTAN-HCTZ 150/12.5 mg TABLETS	Pro Doc Ltd.	02365162	JN4976	January 2022
IRBESARTAN-HCTZ 150/12.5 mg TABLETS	Pro Doc Ltd.	02365162	JU3231	January 2022
IRBESARTAN-HCTZ 150/12.5 mg TABLETS	Pro Doc Ltd.	02365162	JY1913	June 2022
IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pro Doc Ltd.	02365170	HW0586	February 2021
IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pro Doc Ltd.	02365170	HW0587	February 2021
IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pro Doc Ltd.	02365170	JR7823	February 2022
IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pro Doc Ltd.	02365170	JR7824	February 2022
IRBESARTAN-HCTZ 300/12.5 mg	Pro Doc Ltd.	02365170	JU7506	April 2022

TABLETS				
IRBESARTAN-HCTZ 300/25 mg TABLETS	Pro Doc Ltd.	02365170	JS0731	February 2022
MINT- IRBESARTAN /HCTZ 150/12.5 mg TABLETS	Mint Pharmaceuticals Inc.	02392992	180501 1398	August 2021
MINT- IRBESARTAN /HCTZ 300/12.5 mg TABLETS	Mint Pharmaceuticals Inc.	02393018	180501 1402	August 2021
MINT- IRBESARTAN /HCTZ 300/25.0 mg TABLETS	Mint Pharmaceuticals Inc.	02393026	180501 1576	August 2021
pms-IRBESARTAN 150 mg TABLETS	Pharmascience Inc.	02317079	617492	July 2021
pms-IRBESARTAN 150 mg TABLETS	Pharmascience Inc.	02317079	624634	January 2023
pms-IRBESARTAN 150 mg TABLETS	Pharmascience Inc.	02317079	630661	May 2023
pms-IRBESARTAN 75 mg TABLETS	Pharmascience Inc.	02317060	617466	November 2021
pms-IRBESARTAN 75 mg TABLETS	Pharmascience Inc.	02317060	617467	November 2021
pms-IRBESARTAN 75 mg TABLETS	Pharmascience Inc.	02317060	617468	November 2021
pms-IRBESARTAN 75 mg TABLETS	Pharmascience Inc.	02317060	620272	November 2021
pms-IRBESARTAN 75 mg TABLETS	Pharmascience Inc.	02317060	622195	December 2022
pms-IRBESARTAN 75 mg TABLETS	Pharmascience Inc.	02317060	624738	December 2022
pms-IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pharmascience Inc.	02328526	621822	July 2021
pms-IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pharmascience Inc.	02328526	621823	November 2021
pms-IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pharmascience Inc.	02328526	625318	February 2022
pms-IRBESARTAN-	Pharmascience	02328526	625902	January

HCTZ 300/12.5 mg TABLETS	Inc.			2022
pms-IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pharmascience Inc.	02328526	629920	July 2022
pms-IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pharmascience Inc.	02328526	631052	October 2022
pms-IRBESARTAN-HCTZ 300/12.5 mg TABLETS	Pharmascience Inc.	02328526	632583	November 2022
pms-IRBESARTAN-HCTZ 300/25 mg TABLETS	Pharmascience Inc.	02328534	624235	June 2021
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB4714 6	April 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB4714 7	April 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB4714 8	April 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB5769 1	May 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB5768 8	May 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB5768 9	May 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	AB5882 7	May 2023
RAN-IRBESARTAN Tablets 150 mg	Sun Pharma Canada Inc.	02406829	399065 5	November 2021
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB4714 4	April 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB4714 5	April 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB5830 5	May 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB5830 4	May 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB5831 2	May 2023

RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB5831 4	May 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB5882 8	May 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB5769 6	May 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB7049 6	June 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB7049 8	June 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	AB7049 9	June 2023
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	399135 8	November 2021
RAN-IRBESARTAN Tablets 300 mg	Sun Pharma Canada Inc.	02406837	399136 0	November 2021
RAN-IRBESARTAN Tablets 75 mg	Sun Pharma Canada Inc.	02406810	AB4714 3	April 2023
RAN-IRBESARTAN Tablets 75 mg	Sun Pharma Canada Inc.	02406810	AB5847 3	May 2023
RAN-IRBESARTAN Tablets 75 mg	Sun Pharma Canada Inc.	02406810	AB5882 9	May 2023
RAN-IRBESARTAN Tablets 75 mg	Sun Pharma Canada Inc.	02406810	399410 1	November 2021
Sandoz IRBESARTAN 150 mg TABLETS	Sandoz Canada Inc.	02328488	KC721 6	July 2021
Sandoz IRBESARTAN 300 mg TABLETS	Sandoz Canada Inc.	02328496	KF8326	July 2021
Sandoz IRBESARTAN HCT 150/12.5 mg TABLETS	Sandoz Canada Inc.	02337428	JF5840	August 2021
Sandoz IRBESARTAN HCT 150/12.5 mg TABLETS	Sandoz Canada Inc.	02337428	JN4197	January 2022
Sandoz IRBESARTAN HCT 150/12.5 mg	Sandoz Canada Inc.	02337428	JN4971	January 2022

TABLETS				
Sandoz IRBESARTAN HCT 150/12.5 mg TABLETS	Sandoz Canada Inc.	02337428	JU3217	January 2022
Sandoz IRBESARTAN HCT 150/12.5 mg TABLETS	Sandoz Canada Inc.	02337428	JV2167	April 2022
Sandoz IRBESARTAN HCT 150/12.5 mg TABLETS	Sandoz Canada Inc.	02337428	JF8892	August 2021
Sandoz IRBESARTAN HCT 150/12.5 mg TABLETS	Sandoz Canada Inc.	02337428	JN4191	January 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JA4033	February 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	HY738 3	May 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JA4034	May 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JE2529	July 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JK7459	October 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JK7460	October 2021
Sandoz IRBESARTAN HCT	Sandoz Canada Inc.	02337436	JM3516	October 2021

300/12.5 mg TABLETS				
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JM3517	November 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JR7821	February 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JU7500	April 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JU7501	April 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JU7502	April 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JU7503	April 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JY0147	April 2022
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JE2529	July 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JM4631	November 2021
Sandoz IRBESARTAN HCT 300/12.5 mg TABLETS	Sandoz Canada Inc.	02337436	JZ2686	April 2022
Sandoz	Sandoz Canada	02337444	JB0221	May 2021

IRBESARTAN HCT 300/25 mg TABLETS	Inc.			
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JB0222	May 2021
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JC4402	June 2021
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JC4404	June 2021
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JH2487	June 2021
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JR7112	January 2022
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JR7833	January 2022
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JU3181	February 2022
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JW951 2	May 2022
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JW951 3	May 2022
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	KC175 0	August 2022
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JE1833	June 2021
Sandoz IRBESARTAN HCT 300/25 mg TABLETS	Sandoz Canada Inc.	02337444	JR8726	January 2022
Losartan				
AURO-LOSARTAN 100 mg TABLETS	Auro Pharma Inc.	02403358	WB101 9001-A	14 August 2022

AURO-LOSARTAN 100 mg TABLETS	Auro Pharma Inc.	02403358	WB101 9001-B	14 August 2022
AURO-LOSARTAN 25 mg TABLETS	Auro Pharma Inc.	02403323	WB251 9001-A	14 August 2022
AURO-LOSARTAN 50 mg TABLETS	Auro Pharma Inc.	02403331	WB501 9001-A	14 August 2022
AURO-LOSARTAN 50 mg TABLETS	Auro Pharma Inc.	02403331	WB501 9001-B	14 August 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	215111 9	November 2023
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	008062 0	June 2023
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	009062 0	June 2023
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	210101 8	October 2021
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	202021 9	February 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	203021 9	February 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	204021 9	February 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	209061 9	June 2022
LOSARTAN/TABLET/ 100 mg	Sivem Pharmaceuticals ULC	02388812	210091 9	September 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	211091 9	September 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	212091 9	September 2022

LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	2130919	September 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	2050420	April 2023
LOSARTAN/TABLET/ 100 mg	Sivem Pharmaceuticals ULC	02388812	2060420	April 2023
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	2070817	August 2021
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	2040218	February 2022
LOSARTAN /TABLET/100 mg	Sivem Pharmaceuticals ULC	02388812	2140919	September 2023
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	0050919	September 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	0060919	September 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	0070919	September 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	0080919	September 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	00809 19A	September 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	0101019	October 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	010101 9A	October 2022
LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	0030120	January 2023

LOSARTAN /TABLET/25 mg	Sivem Pharmaceuticals ULC	02388790	004012 0	January 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	112101 8	October 2021
LOSARTAN/TABLET/ 50 mg	Sivem Pharmaceuticals ULC	02388804	113101 8	October 2021
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	113081 9	August 2022
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	114081 9	August 2022
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	115081 9	August 2022
LOSARTAN/TABLET/ 50 mg	Sivem Pharmaceuticals ULC	02388804	116081 9	August 2022
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	118091 9	September 2022
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	107022 0	February 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	108022 0	February 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	109022 0	February 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	110022 0	February 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	111022 0	February 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	106022 0	February 2023

LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	1170919	September 2023
LOSARTAN /TABLET/50 mg	Sivem Pharmaceuticals ULC	02388804	1120620	June 2024
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2010219	February 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2010420	April 2023
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2020219	February 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2020420	April 2023
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2030420	April 2023
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2040219	February 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2060419	April 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2080619	June 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2080918	September 2021
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2091018	October 2021
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2101018	October 2021
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2161119	November 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2171119	November 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2030218	February 2022
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2070419	April 2023
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2181119	November 2023
TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2191119	November 2023

TEVA-LOSARTAN 100 mg TABLETS	Teva Canada Ltd.	02357976	2140919	September 2023
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0010219	February 2022
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0020419	April 2022
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0030419	April 2022
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0031018	October 2021
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0040120	January 2023
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0040919	September 2022
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0050620	June 2023
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0050919	September 2022
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0060620	June 2023
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0070620	June 2023
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0010120	January 2024
TEVA-LOSARTAN 25 mg TABLETS	Teva Canada Ltd.	02380838	0020120	January 2024
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	1040120	January 2023
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	1030120	January 2023
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	1040419	April 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	1050419	April 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	1060419	April 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	1070419	April 2022
TEVA-LOSARTAN 50	Teva Canada	02357968	108091	September

mg TABLETS	Ltd.		8	2021
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	109081 9	August 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	109091 8	September 2021
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	110081 9	August 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	110101 8	October 2021
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	111081 9	August 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	111101 8	October 2021
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	112101 8	October 2021
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	113081 9	August 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	118091 9	September 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	101012 0	January 2024
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	103021 8	February 2022
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	108041 9	April 2023
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	112081 9	August 2023
TEVA-LOSARTAN 50 mg TABLETS	Teva Canada Ltd.	02357968	114101 8	October 2022
Valsartan				
Sandoz Valsartan 160 mg TABLETS	Sandoz Canada Inc.	02356767	KT9598	March 2023
Sandoz Valsartan 320 mg TABLETS	Sandoz Canada Inc.	02356775	KT8923	April 2023
Sandoz Valsartan 320 mg TABLETS	Sandoz Canada Inc.	02356775	KV6185	March 2023
Sandoz Valsartan 80 mg TABLETS	Sandoz Canada Inc.	02356759	KT7180	March 2023

Sandoz Valsartan 80 mg TABLETS	Sandoz Canada Inc.	02356759	KT9515	April 2023
VALSARTAN 160 mg TABLETS	Sanis Health Inc.	02366967	KT9597	March 2023

The Plaintiff

21. The Plaintiff was taking Sivem Losartan. Her prescription was for 50mg with Drug Identification Number (DIN) of 02388804 which is included on the list of Affected Drugs.

22. Numerous lots of Sivem Losartan are on the Health Canada recall list and were recalled as of May 30, 2021.

23. As a result of the defective nature of the medication that she ingested, the Plaintiff has incurred damages including:

    (a) General damages for the tort of battery;

    (b) Personal injury including mental distress;

    (c) The increased material risk of developing cancer and organ damage/failure;

    (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 a drug 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.

24. The Plaintiff would not have purchased and/or used the Affected Drugs had she been informed they contained an azido impurity above the acceptable limit and if she had been provided accurate information and/or warnings, particularly since there are alternative drugs available on the Canadian market that do not contain azido impurities above the acceptable limit.

Part 2: RELIEF SOUGHT

25. The Plaintiff claims, on her own behalf, and on behalf of the Class Members, 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,* R.S.C. 1985, c. C-34;

(g) Relief pursuant to s. 219 of the Quebec *Consumer Protection Act,* C.Q.L.R. c. P-40.1;

(h) 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;

(i) Costs;

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

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

Part 3: LEGAL BASIS

Negligence and Failure to Warn

26. As the manufacturers, marketers, developers, distributors, labelers and/or importers of the Affected Drugs, and/or their 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 Affected Drugs to be introduced into the stream of commerce in Canada, and they knew that any dangers or adverse effects related to the Affected Drugs would cause foreseeable injury to the Plaintiff and Class Members.

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

28. The Defendants owed a duty of care to the Plaintiff and Class Members to ensure that the Affected Drugs were safe and effective for their intended use. Particulars of the Defendants' breaches of its duty of care include:

    (a) Failing to ensure that the Affected Drugs and/or their components were manufactured to product standards;

    (b) Supplying contaminated drugs 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 the Affected Drugs;

    (e) Placing the Affected Drugs 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 the Affected Drugs once the risks were known to them;

(h) Manufacturing and/or marketing a product that was not fit for the purposes for which they were intended;

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

(j) Such further and other particulars as will be alleged at trial.

Unjust Enrichment

29. Further, and in the alternative, the Plaintiff pleads that she and the Class Members are entitled to claim and recover based on equitable and restitutionary principles.

30. As an expected and intended result of the unlawful conduct, the Defendants have profited and benefited from purchases of the Affected Drugs which would not have been made but for the unlawful conduct.

31. By illegally and deceptively promoting the Affected Drugs, directly, through their control of third parties, and by acting in concert with third parties, the Defendants have been unjustly enriched by the receipt of the revenue from the sale of the Affected Drugs:

(a) Revenue was acquired in a manner in which the Defendants cannot in good conscience retain;

(b) The integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;

(c) Absent the Defendants' tortious conduct, the Affected Drugs could not have been marketed nor would the Defendants have received any revenue from their sale in Canada; and

(d) The Defendants engaged in wrongful conduct by putting into the marketplace pharmaceutical products which cause or have the potential to cause serious risk of injury.

32. The Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to the Plaintiff and the Class Members.

Battery

33. By ingesting the Affected Drugs, the Plaintiff and the Class Members were exposed to toxic carcinogens, constituting a harmful and offensive contact to the person.

34. Despite the fact that the Plaintiff and the Class Members willingly ingested the Affected Drugs, they were unaware that the Affected Drugs contained carcinogens. The Plaintiff and the Class Members would not have ingested the Affected Drugs if they knew they were also ingesting carcinogens, and as such, did not consent.

35. By distributing the Affected Drugs, the Defendants intended the drugs to be ingested and thereby exposed the Class Members to the toxic carcinogens.

36. Since a time that is presently not known to the Plaintiff, the Defendants knew that the Affected Drugs contained the contaminants and therefore intended Class Members be exposed to the carcinogens.

37. Alternatively, the tort of battery is made out because the Defendants were willfully blind or recklessly indifferent to whether the Affected Drugs contained heightened levels of the azido impurities. The Defendants took no steps to investigate and address the lack of quality controls at their manufacturing facilities and the impact of changes to the manufacturing process when they

knew there was a risk or likelihood that the Affected Drugs would or could be contaminated - either as a result of the lack of quality controls or because the changes in the manufacturing process would or could result in an increase in the level of azido impurities. In this context of knowing of the risk, the Defendant took no steps or insufficient steps to determine whether the carcinogens were in the drugs, therefore amounting to reckless indifference.

Breach of GMP Regulations

38. As pleaded, the Defendants were required to demonstrate that as generic drug manufacturers, the drugs they were offering were the same as the brand name, in that the active ingredients and the therapeutic effect were the same. Implicit in this is that they were obligated to ensure that the drugs they were offering did not contain any other ingredients that would alter the efficacy of the drug. The contaminants in the Affected Drugs changed the quality, safety and effectiveness of the Affected Drugs and the Defendants were required to inform users and Health Canada.

39. Similarly, 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 high levels of azido impurities likely would have been discovered.

40. As set out in the GMP Regulations, the Defendants had obligations to ensure that the drugs manufactured at their facilities or suppliers met all required specifications. The Defendants also had direct, or alternatively, constructive, knowledge that the manufacturing facilities had several deviations that were not compliant with the GMP Regulations and that changes in manufacturing practices introduced the contaminants to the Affected Drugs.

41. 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 impurities and contaminants in the Affected Drugs at an earlier point, when the contaminants were likely first introduced into the Affected Drugs.

42. The Defendants knew, or should have known on the basis of their own monitoring of their manufacturing facilities, that the Affected Drugs did, or could contain serious contaminants which could (and did) cause harm and yet did not recall the Affected Drugs until May 30, 2021, after regulators including Health Canada published concerns with the Affected Drugs.

43. Further, the harm to the Plaintiff and 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 GMP Regulations. The Defendants introduced the risk of wrongs by manufacturing the Affected Drugs, particularly when they were aware of their shortcomings and thus should have managed and minimized the risk, especially when the Plaintiff and the Class Members had no control over the ingestion of contaminants and carcinogens.

44. The Defendants acted with reckless indifference to the consequences of failing to implement appropriate quality control processes, in the face of their duty to do so, and knew that they were consequently placing the Plaintiff and the Class Members at significant risk.

45. The Defendants were aware of the risk that certain consequences could result from contaminants in the Affected Drugs but were indifferent to the risk. The Defendants continuously failed to establish, maintain and enforce appropriate quality control processes, despite the well-known risks associated with the manufacturing process of the Affected Drugs. The Defendants' failure to

implement appropriate quality control processes was an unreasonable risk to take and constituted reckless indifference.

46. The Defendants' failure to implement appropriate quality control 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.

47. By failing to implement adequate quality control measures, the Defendants knew their practices were not in conformity with their obligations under GMP 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.

48. As a direct result of the Defendants' wrongful acts as pleaded herein, the Plaintiff and the Class Members ingested contaminated drugs manufactured by the Defendants, which intentionally caused harmful or offensive contact with the Plaintiff to which the Plaintiff and the 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

49. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the Affected Drugs for personal use by the Plaintiff and by the 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 the Class Members who ingested Affected Drugs are "consumers" and the Defendants were "suppliers" within the meaning of the BPCPA.

50. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Affected Drugs had the capability, tendency or effect of

deceiving or misleading consumers regarding the safety and efficacy of the Affected Drugs. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of Affected Drugs 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 the Affected Drugs.

51. 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 their own behalf and on behalf of Class Members who purchased Affected Drugs in Canada. Such relief includes the disgorgement of the profits or revenues received by the Defendants from the sale of Affected Drugs in Canada.

52. By placing their trademark on the medication thereby identifying the Defendants as the manufacturer and/or distributor of Affected Drugs, the Defendants intended to convey to consumers that the drugs were of high quality and were manufactured by a reputable pharmaceutical company.

53. 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 the Affected Drugs which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

Competition Act

54. As a result of its representations and omissions about the Affected Drugs, the Defendants breached s. 52 of the *Competition Act*, R.S.C. c. C-34 (the "*Competition Act*") and committed an unlawful act because their representations and omissions:

    (a) Were made for the purpose of promoting, directly or indirectly, the use of their drug;

(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.

55. The Plaintiff and the Class Members suffered damages as a result of the Defendants' unlawful breach of s. 52 of the *Competition Act*. Those damages include the cost of purchasing the drug.

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

Causation and Damages

57. As a result of the Defendants' negligence and the Defendant's breach of the BPCPA and/or the *Competition Act* and/or other similar legislation in the other provinces and territories, the Plaintiff and the 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 the 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.

58. The Plaintiff and the 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.

59. 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.

60. 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

61. The Plaintiff and the 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 relies upon health and hospital insurance legislation in British Columbia and similar legislation elsewhere and claims health care costs incurred by herself and Class Members and paid by provincial and territorial governments:

(a) On behalf of Her Majesty the Queen in right of the Province of New Brunswick, the Plaintiff claims on her behalf and on behalf of all the Class Members, the cost of "entitled services" under *Health Services Act*, S.N.B. 2014, c. 112, ss. 1 and 3 and General Regulation, NB Reg 84-115, s. 2 and Schedule II;

(b) On behalf of the government of British Columbia, the Plaintiff claims on her behalf and on behalf of all the Class Members, the past and future cost of providing "health care services" under *Health Care Costs Recovery Act*, S.B.C. 2008, c. 27, ss. 1-3 and 7 and *Health Care Costs Recovery Regulation*, BC Reg 397/2008, s. 3;

(c) On behalf of Her Majesty in right of Alberta and the Minister of Health of Saskatchewan, the Plaintiff claims on her behalf and on behalf of all the Class Members, the direct and indirect costs of past and future "health services" under *Crown's Right of Recovery Act*, SA 2009, c. C-

35, ss. 1 and 38 and *Crown's Right of Recovery Regulation*, Alta Reg 87/2012, s. 3; and The *Health Administration Act*, RSS 1978, c H-0.0001, s. 19;

(d) On behalf of the Minister of Health of Manitoba, the Plaintiff claims on her behalf and on behalf of all the Class Members, the past and future cost of "insured hospital, medical, and other services under *The Health Services Insurance Act*, RSM 1987, c. H35, ss. 2, 97 and *The Medical Services Insurance Regulation*, Man Reg 49/93, s. 1;

(e) On behalf of Her Majesty in right of the Province of Nova Scotia, the Plaintiff claims on her behalf and on behalf of all the Class Members, the past and future cost of "insured hospital services", and other care, services, and benefits under *Health Services and Insurance Act*, RSNS 1989, c. 197, ss. 2 and 18;

(f) On behalf of the Government of Yukon, and the Ministers of Health of the Northwest Territories and Nunavut, the Plaintiff claims on her behalf and on behalf of all the Class Members, the cost of providing "insured services", including in-patient and out-patient services under *Hospital Insurance Services Act*, RSY 2002, c. 112, ss. 1 and 10-11 and *Yukon Hospital Insurance Services Regulations*, YCO 1960/35, s. 2; *Hospital Insurance and Health and Social Services Administration Act*, RSNWT 1988, c. T-3, ss. 1 and 19-20 and *Hospital Insurance Regulations*, RRNWT 1990, c. T-12, s. 1; *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-3, ss. 1 and 19-20 and *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c. T-3, s. 1;

(g) On behalf of the Ontario Health Insurance Plan, the province of Quebec, the Minister of Health and Wellness of Prince Edward Island, and the Crown in right of Newfoundland and Labrador, the Plaintiff claims on her behalf and on behalf of all the Class Members, the cost of "insured services" under *Health Insurance Act*, RSO 1990, c. H.6,

ss. 1, 11.2, and 30-31 and General, RRO 1990, Reg 552; *Hospital Insurance Act*, CQLR c. A-28, ss. 1 and 1 O and Regulation respecting the application of the *Hospital Insurance Act*, CQLR c A-28, r. 1, s. 3 and *Health Insurance Act*, CQLR A-29, ss. 1, 3, and 18; *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8, ss. 1 and 14 and General Regulations, PEI Reg EC539/63, s. 1; and *Hospital Insurance Agreement Act*, RSNL 1990, c. H-7, s. 5 and *Hospital Insurance Regulations*, CNLR 742/96, s. 2 and Schedule.

Jurisdiction

62. 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 the Affected Drugs in British Columbia;

    (b) The Plaintiff resides in British Columbia; and

    (c) The Plaintiff's damages were sustained in British Columbia.

Plaintiffs' address for service:	**RICE HARBUT ELLIOTT LLP** Barristers and Solicitors 820 - 980 Howe Street Vancouver, BC V6Z 0C8 **CHARNEY LAWYERS PC** 151 Bloor Street W., Suite 602 Toronto, ON M5S 1S4
Fax number address for service (if any):	Nil
E-mail address for service (if any):	service@rhelaw.com
Place of trial:	Vancouver
The address of the registry is:	800 Smithe Street, Vancouver

Date: 7/JUN/2021

Counsel for the Plaintiff,
Anthony Leoni
Theodore P. Charney

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 generic prescription medications contaminated with a probable mutagen, 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