S-167919

SUPREME COURT
OF BRITISH COLUMBIA
VANCOUVER REGISTRY

AUG 30 2016

NO
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN

[redacted]

PLAINTIFF

AND

BAYER INC.,
BAYER CORPORATION,
BAYER HEALTHCARE PHARMACEUTICALS, INC.,
BAYER HEALTHCARE, LLC,
JOHNSON & JOHNSON CORPORATION,
JOHNSON & JOHNSON INC.,
JANSSEN INC.,
JANSSEN PHARMACEUTICALS, INC.,
JANSSEN RESEARCH & DEVELOPMENT, LLC ,
MCKESSON CORPORATION and
MCKESSON CANADA CORPORATION

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(s) 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(s),

(a) if you reside anywhere in Canada, within 21 days after the date on which a copy of the filed notice of civil claim was served on you,

(b) if you reside in the United States of America, within 35 days after the date on which a copy of the filed notice of civil claim was served on you,

(c) if you reside elsewhere, within 49 days after the date on which a copy of the filed notice of civil claim was served on you, or

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

CLAIM OF THE PLAINTIFF(S)

Part 1: STATEMENT OF FACTS

A. Introduction

1. This proposed class proceeding involves the prescription drugs, Ciprofloxacin ("Cipro"), Moxifloxacin ("Avelox") and Levofloxacin ("Levaquin"), known as fluoroquinolone antibiotics, (collectively referred to hereinafter as "FLQ", "FLQs" and/or "FLQ drugs"), used to treat certain types of bacterial infections in adults, such as respiratory tract, urinary tract and skin infections.

2. Cipro and Avelox are designed, developed, tested, manufactured, labeled, packaged, marketed, promoted, advertised, distributed, licenced and/or sold by the Defendants,

BAYER INC., BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER HEALTHCARE, LLC, MCKESSON CORPORATION and/or MCKESSON CANADA CORPORATION in North America, including Canada.

3. Levaquin is designed, developed, tested, manufactured, labeled, packaged, marketed, promoted, advertised, distributed, licenced and/or sold by the Defendants, JOHNSON & JOHNSON CORPORATION, JOHNSON & JOHNSON INC., JANSSEN INC., JANSSEN PHARMACEUTICALS, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, MCKESSON CORPORATION and/or MCKESSON CANADA CORPORATION in North America, including Canada.

4. The Plaintiff and the proposed class members allege that Cipro, Avelox and/or Levaquin are defective, dangerous to human health, unfit and/or unsuitable to be marketed and sold to treat infections for which they are not required and lacked proper warnings and directions as to the dangers associated with all of their uses.

B. The Parties

The Representative Plaintiff

5. [redacted]

6. In or about February and August 2014 the Plaintiff was prescribed Avelox for a bacterial respiratory infection and thereafter, suffered certain side effects including, *inter alia*, irreversible peripheral neuropathy (nervous system damage) and aortic dissection (tear or damage to the inner wall of the artery carrying blood out of the heart), requiring open heart surgery.

The Defendants

7. The Defendant, BAYER INC., is a company duly incorporated pursuant to the laws of Canada, registered within British Columbia under number A0088217, and has an attorney,

Michael R. Axford, at 20th Floor, 250 Howe Street, Vancouver, British Columbia, V6C 3R8, Canada.

8. The Defendant, BAYER CORPORATION, is a company duly incorporated pursuant to the laws of the State of Indiana, one of the United States of America, and has a registered agent, Corporation Service Company, at 2595 Interstate Drive, Suite 103, Harrisburg, Pennsylvania, 17110, United States of America.

9. The Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is a company duly incorporated pursuant to the laws of the State of Delaware, one of the United States of America, and has a registered agent, Corporation Service Company, at 2595 Interstate Drive, Suite 103, Harrisburg, Pennsylvania, 17110, United States of America.

10. The Defendant, BAYER HEALTHCARE, LLC, is a company duly incorporated pursuant to the laws of the State of Delaware, one of the United States of America, and has a registered agent, Corporation Service Company, at 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808, United States of America.

11. The Defendant, JOHNSON & JOHNSON CORPORATION, is a company duly incorporated pursuant to the laws of the State of New Jersey, one of the United States of America, and has a registered office at One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933, United States of America.

12. The Defendant, JOHNSON & JOHNSON INC., is a company duly incorporated pursuant to the laws of Canada, registered within British Columbia under number A0097872, and has an attorney, Blakes Vancouver Services Inc., at 595 Burrard Street, Suite 2600, Three Bentall Centre, PO Box 49314, Vancouver, British Columbia, V7X 1L3, Canada.

13. The Defendant, JANSSEN INC., is a company duly incorporated pursuant to the laws of Ontario, registered within British Columbia under number A0044416, and has an attorney, Blakes Vancouver Services Inc., at 595 Burrard Street, Three Bentall Centre, Suite 2600, PO Box 49314, Vancouver, British Columbia, V7X 1L3, Canada.

14. The Defendant, JANSSEN PHARMACEUTICALS, INC., is a company duly incorporated pursuant to the laws of the State of Pennsylvania, one of the United States of America, and has a registered agent, CT Corporation System, at Suite 320 - 116 Pine Street, Harrisburg, Pennsylvania, 17101, United States of America.

15. The Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, is a company duly incorporated pursuant to the laws of the State of New Jersey, one of the United States of America, and has a registered agent, CT Corporation System, at Suite 320 - 116 Pine Street, Harrisburg, Pennsylvania, 17101, United States of America.

16. The Defendant, MCKESSON CORPORATION, is a company duly incorporated pursuant to the laws of the State of Delaware, one of the United States of America, and has a registered agent, Corporation Service Company, at 2710 Gateway Oaks Drive, Suite 150N, Sacramento, California, 95833, United States of America.

17. The Defendant, MCKESSON CANADA CORPORATION, is a company duly incorporated pursuant to the laws of Nova Scotia, registered within British Columbia under number A0077176, and has an attorney, Blakes Vancouver Services Inc., at Suite 2600, Three Bentall Centre, P.O. Box 49314, 595 Burrard Street, Vancouver, British Columbia, V7X 1L3, Canada.

18. Bayer AG is a German company, one of the largest pharmaceutical companies in the world, and is the researcher, producer and/or manufacturer of Cipro and Avelox.

19. At all material times to the cause of action herein, the Defendants, BAYER INC., BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC. and/or BAYER HEALTHCARE, LLC, were and are wholly owned North American subsidiaries of Bayer AG.

20. The Defendants, BAYER INC., BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER HEALTHCARE, LLC, are collectively referred to hereinafter as the "Bayer Defendants".

21. At all material times to the cause of action herein, the Bayer Defendants shared the

common purpose of designing, researching, testing, developing, manufacturing, labeling, packaging, marketing, promoting, advertising, licencing, supplying, selling and/or distributing Cipro and/or Avelox in Canada, including the Province of British Columbia, directly or through agents, affiliates or subsidiaries, for profit. The business and interests of each of the Bayer Defendants is interwoven with that of the other and each is the agent of the others.

22. The Defendant, JOHNSON & JOHNSON CORPORATION, is an American medical device, pharmaceutical products and consumer packaged goods manufacturer.

23. At all material times to the cause of action herein, the Defendant, JOHNSON & JOHNSON CORPORATION, and its "Family of Companies", was and is involved in, *inter alia*, the design, research, development, manufacture, sales and/or marketing of pharmaceutical drug products, including Levaquin.

24. At all material times to the cause of action herein, the Defendants, JOHNSON & JOHNSON INC., JANSSEN INC., JANSSEN PHARMACEUTICALS, INC. and JANSSEN RESEARCH & DEVELOPMENT, LLC were and are wholly owned North American subsidiaries of the Defendant, JOHNSON & JOHNSON CORPORATION.

25. The Defendants, JOHNSON & JOHNSON CORPORATION, JOHNSON & JOHNSON INC., JANSSEN INC., JANSSEN PHARMACEUTICALS, INC. and JANSSEN RESEARCH & DEVELOPMENT, LLC are collectively referred to hereinafter as the "Johnson & Johnson Defendants".

26. At all material times to the cause of action herein, the Johnson & Johnson Defendants shared the common purpose of designing, researching, testing, developing, manufacturing, labeling, packaging, marketing, promoting, advertising, licencing, supplying, selling and/or distributing Levaquin in Canada, including the Province of British Columbia, directly or through agents, affiliates or subsidiaries, for profit. The business and interests of each of the Johnson & Johnson Defendants is interwoven with that of the other and each is the agent of the others.

27. At all material times to the cause of action herein, the Defendant, MCKESSON CORPORATION, was and is the largest pharmaceutical distributor in North America, a leading health care information technology company and a provider of decision support software to help physicians determine the best possible clinical diagnosis and treatment plans for patients.

28. At all material times to the cause of action herein, the Defendant, MCKESSON CANADA CORPORATION, was and is a wholly owned subsidiary of the Defendant, MCKESSON CORPORATION, and shared the common purpose of packing, re-packaging and/or distributing Avelox, Cipro and/or Levaquin in Canada, including the Province of British Columbia.

29. The Defendants, MCKESSON CORPORATION and MCKESSON CANADA CORPORATION, are collectively referred to hereinafter as the "McKesson Defendants"

30. At all material times to the cause of action herein, the McKesson Defendants were among the largest distributors of the Bayer Defendants' and Johnson & Johnson Defendants' pharmaceutical drug products, including the FLQs, in North America.

31. At all material times to the cause of action herein, the McKesson Defendants provided research services to pharmaceutical companies such as the Bayer Defendants and Johnson & Johnson Defendants. The McKesson Defendants offered, *inter alia*, bio-pharmaceutical manufacturing services to accelerate the approval and successful commercialization of speciality pharmaceuticals across the product life cycle. Through their risk evaluation and mitigation strategies, the McKesson Defendants provided pharmaceutical manufacturers, like the Bayer Defendants and Johnson & Johnson Defendants, with a wide range of risk-based services including, *inter alia*, consultation on United States Food and Drug Administration ("FDA") and Health Canada submissions, strategic program designs, data management and assistance with drug launch.

32. The McKesson Defendants distributed the FLQ drugs in Canada, including the Province of British Columbia, which the Plaintiff and the proposed class members ingested resulting in the injuries alleged herein.

C. The Class

33. This action is brought on behalf of members of a class consisting of the Plaintiff and all British Columbia resident persons, including their estates, executors or personal representatives (the "BC Class Members"), who purchased, acquired or used the prescription drugs, Cipro, Avelox and/or Levaquin, fluoroquinolone antibiotics which were designed, tested, developed, manufactured, labeled, packaged, marketed, promoted, advertised, licenced, sold and/or distributed by the Defendants in Canada, including the Province of British Columbia, or such other class definition as the Court may ultimately decide on the motion for certification.

D. Factual Allegations

34. At all material times to the cause of action herein, the Defendants were in the business of, and did design, research, test, develop, manufacture, promote, advertise, market, licence, sell, distribute and/or have acquired and are responsible for related or subsidiary defendants who have designed, researched, tested, developed, manufactured, promoted, advertised, marketed, licenced, sold and/or distributed Cipro, Avelox and/or Levaquin in Canada, including the Province of British Columbia.

35. The Plaintiff and BC Class Members were prescribed and/or otherwise lawfully obtained Cipro, Avelox and/or Levaquin. Thereafter, the Plaintiff and BC Class Members suffered, *inter alia*, irreversible peripheral neuropathy or symptoms of irreversible peripheral neuropathy, and/or a worsening of those symptoms, including pain, burning, tingling, numbness, weakness, alterations of sensation, and/or experienced symptoms of irreversible peripheral neuropathy in addition to injuries to the following body systems: musculoskeletal, neuropsychiatric, sensory, skin and cardiovascular, including aortic dissection.

36. The FLQ drugs are broad-spectrum, synthetic, antibacterial agents marketed and sold in oral tablet, intravenous solution and ophthalmic solution and used to treat lung, sinus, skin and urinary tract infections caused by certain germs called bacteria. They are members of the quinolone class of antibiotics.

37. Quinolones are divided into four generations based on their spectrum of antimicrobial activity. The first generation non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria but resistance developed rapidly.

38. In the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called second generation quinolones included Noroxin (norfloxacin), Cipro, Floxin (ofloxacin) and pefloxacin.

Cipro

39. Cipro was approved by the FDA in 1987 for use in the United States and is the brand name for the antibiotic, ciprofloxacin.

40. Cipro was approved by Health Canada and introduced into the Canadian marketplace in or about 1996 by the Bayer Defendants.

41. Since its introduction to the marketplace Cipro has proven to be a blockbuster drug product for the Bayer Defendants.

42. Fluoroquinolones have long been associated with serious side effects. Many fluoroquinolones have been removed from the marketplace due to unacceptable risks of certain adverse events such as low blood sugar, hyperglycemia, hypoglycemia, kidney failure, anemia and severe liver toxicity.

Avelox

43. Avelox was approved by the FDA in 1999 for use in the United States and is the brand name for the antibiotic, moxifloxacin.

44. Avelox was approved by Health Canada and introduced into the Canadian marketplace in or about 2000 by the Bayer Defendants.

45. With the patent for Cipro set to expire in 2003, the Bayer Defendants set out to develop and effectively market Avelox in order to be more competitive with third and fourth generation fluoroquinolones including Levaquin. Avelox quickly became the Bayer Defendants' heir apparent and successor to Cipro.

46. Similar to Cipro, Avelox has also proven to be a blockbuster drug product for the Bayer Defendants.

47. The Bayer Defendants have claimed that Avelox is safe and effective and has a well-characterized safety profile which has been studied in thousands of patients in clinical trials and post-marketing surveillance studies.

48. However, scientific evidence has established a clear association between Cipro and Avelox and an increased risk of long-term peripheral neuropathy and/or irreversible peripheral neuropathy.

Levaquin

49. Levaquin was approved by the FDA in 1996 for use in the United States and is the brand name for the antibiotic, levofloxacin.

50. Levaquin was approved by Health Canada and introduced into the Canadian marketplace in or about 1997 by the Johnson & Johnson Defendants.

51. In 2003, after generic versions of Cipro went on the market, one of the Johnson & Johnson Defendants' key strategies was to displace Cipro as the leading fluoroquinolone on the market. Subsequently, Levaquin became the number one prescribed fluoroquinolone in the world.

52. The Johnson & Johnson Defendants have claimed that in a large number of clinical trials Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections.

53. However, the scientific evidence has established a clear association between Levaquin and an increased risk of long-term peripheral neuropathy and irreversible peripheral neuropathy, irregardless of whether the patient stopped using the FLQs once symptoms developed.

54. Prior to applying to the FDA and Health Canada for approval of their FLQs, the Defendants knew, or ought to have known, that use of FLQs were associated with and/or would cause chronic and/or permanent peripheral neuropathy and/or other serious bodily injuries including, *inter alia*, aortic dissection.

55. By 1988, the Defendants possessed scientific evidence which they knew, or ought to have known, constituted a "safety signal" that the use of FLQs was associated with peripheral paraesthesia, a form of peripheral nerve damage, which required further investigation and study.

56. The Defendants failed to adequately inform and warn the Plaintiff, BC Class Members, and/or prescribing physicians of the serious and dangerous risks associated with the use of FLQs concerning irreversible peripheral neuropathy as well as other serious bodily injuries, including, *inter alia*, aortic dissection, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, physical impairment, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

57. The warning label, product monograph and/or prescribing information for Avelox from 2003 to February 2007 failed to advise patients and their prescribing physicians that FLQ use could result in irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia,* aortic dissection.

58. In or February 2007 the warning label, product monograph and/or prescribing information for Avelox was revised which misled and deceived patients and their prescribing physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare". The Avelox warning label, product monograph and/or prescribing information also omitted any mention of the possibility that FLQ use could result in irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia,* aortic dissection.

59. On or about January 20, 2012 the warning label, product monograph and/or prescribing information for Avelox was again revised but which continued to mislead and deceive patients and their prescribing physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare". Nor did the further revision mention of the possibility that FLQ use could result in irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia,* aortic dissection.

60. The warning label, product monograph and/or prescribing information for Cipro from 2004 to August 2013 also misled and deceived patients and their prescribing physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare". The Cipro warning label, product monograph and/or prescribing information during this time period also omitted any mention of the possibility that FLQ use could result in irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia*, aortic dissection.

61. In August 2013, after mounting evidence of the relationship between fluroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the Defendants' existing warnings regarding peripheral neuropathy were inadequate.

62. In or about August 2013, the warning label, product monograph and/or prescribing information for Cipro was revised whereby the statement that peripheral neuropathy occurred in only "rare" cases was removed. Further, the warning stated that Cipro should be discontinued if the patient experienced symptoms of neuropathy in order to prevent the development of an irreversible condition. This statement incorrectly implies to patients and physicians that, if the patient stops using the drugs immediately after symptoms occur, the symptoms are reversible. Nor does the warning disclose the serious, progressive and disabling nature of FLQ induced irreversible neuropathy.

63. The warning label, product monograph and/or prescribing information for Levaquin from 2003 to 2007 failed to advise patients and their prescribing physicians that FLQ use could result in irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia,* aortic dissection.

64. In or about July 2007, the warning label, product monograph and/or prescribing information for Levaquin was revised but which misled and deceived patients and their prescribing physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare" and that discontinuation of the drug would prevent the development of an irreversible condition. Nor did the revision disclose the serious, progressive and disabling nature of FLQ induced irreversible neuropathy.

65. As of 2014 the product monograph for Avelox stated the following:

"Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones including AVELOX.

Patients under treatment with AVELOX should be advised to inform their doctor prior to continuing treatment if symptoms of neuropathy such as pain, burning, tingling, numbness, or weakness develop (see Averse Reactions, Post-Market Adverse Drug Reactions)"

The product monograph for Cipro stated the following as of 2014:

"*Peripheral Neuropathy: Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including CIPRO and CIPRO Oral Suspension."*

Ciprofloxacin should be discontinued if the patient experience symptoms of neuropathy including pain, burning, tingling, numbness and/or weakness, or is found to have deficits in light touch, pain, temperature, position sense, vibratory sensation, and/or motor strength in order to prevent the development of a irreversible condition (see Adverse Reactions)"

The product monograph for Levaquin stated the following as of 2014:

> *"Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense and vibratory sensation in order to prevent the development of an irreversible condition."*

66. The warning labels, product monographs and/or prescribing information for Avelox, Cipro and/or Levaquin remain inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy following their use.

67. The onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible. Although this injury can be severe and debilitating, the language regarding the "rare" risk of peripheral neuropathy was among a long list of adverse reactions that were included on the warning labels, product monographs and/or prescribing information of the Defendants FLQ drugs. The warning language was in no way highlighted for the benefit of prescribing physicians and patients.

68. The Defendants failed to issue any "Dear Doctor", "Dear Healthcare Professional", "Health Professional Communications" and/or "Public Communications" that were specific to Cipro, Avelox and/or Levaquin as to the risk of developing irreversible peripheral neuropathy and/or aortic dissection. Further, the Defendants failed to disclose the serious and dangerous side effect of irreversible peripheral neuropathy when promoting Cipro, Avelox and/or Levaquin to physicians.

69. Despite their knowledge that their FLQ drugs were associated with an elevated risk of prolonged and/or irreversible peripheral neuropathy, the Defendants' promotional campaign was focused on the purported safety profile of their FLQs.

70. FDA and Health Canada regulations require that drug manufacturers monitor and report adverse events associated with their marketed drug products. The drug manufacturers are required to review all adverse experience information pertaining to their drug products obtained from any source, foreign or domestic, including from commercial marketing experience, post-marketing clinical investigations, post-marketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers. Drug manufacturers review this information for "safety signals" regarding their products.

71. The FDA and Health Canada have recognized that case reports and case series can play important roles in serving as safety signals. In fact, a single, well-documented case report can be viewed as a safety signal, particularly if the case report describes a positive rechallenge. A single case report may be sufficient to establish a causal relationship between the use of a drug product and an adverse event.

72. In the pharmaceutical industry, including within Defendants' companies, safety signals generally indicate the need for further investigation and study.

73. After a safety signal is identified, the Bayer Defendants and Johnson & Johnson Defendants are obligated to further assess the safety signal to determine whether it represents a potential safety risk that should be included in drug product labeling, product monograph and/or prescribing information.

74. The Johnson & Johnson Defendants claim to continually collect and monitor information on the safety and effectiveness of their drug products and in cooperation with the FDA, Health Canada, and/or other health authorities, incorporate the new data into their drug product labels, product monographs and/or prescribing information so physicians and patients can make informed decisions as to their use.

75. The Bayer Defendants likewise claim that they maintain accurate drug product labels, product monographs and/or prescribing information that share information about the benefits and risks associated with fluoroquinolone use and report all adverse events to the FDA, Health Canada and/or other health authorities.

76. Despite these representations, as early as 1988 there was evidence in the medical literature of peripheral nerve damage associated with FLQ therapy relating to ciprofloxacin representing a safety signal that the Bayer Defendants and Johnson & Johnson Defendants ignored in contravention of governmental regulations.

77. Beyond the numerous safety signals generated by internal post-marketing review and the medical literature, the Defendants were also put on notice of an association between fluoroquinolone use and peripheral neuropathy by the FDA Office of Drug Safety in 2001 and 2003. As a result of its review, the FDA Office of Drug Safety recommended that "peripheral neuropathy" be added to the labeling for Cipro and Levaquin as it had been for Floxin.

78. The Defendants failed to provide adequate information to the medical community about the frequency with which adverse events indicative of peripheral neuropathy were being reported. Prior to the August 2013 label, product monograph and/or prescribing information change for Cipro, the Defendants knew, or should have known, that FLQ associated neuropathies could be rapid, permanent and disabling, and that such injuries were not, as they had been stating, "rare".

79. The pre-2013 FLQ warning labels, product monographs and/or prescribing information further represented that "the most common adverse drug reactions were nausea, headache, diarrhea, insomnia, constipation, and dizziness".

80. Although the Johnson & Johnson Defendants represented, through their labeling, product monographs and/or prescribing information, to patients and the medical community that central nervous system ("CNS") adverse events such as paresthesias were "rare" and were not a common adverse drug reaction, the Johnson & Johnson Defendants knew as early as the mid-1990s the opposite to be true from their own post-marketing experience that the "most frequently reported" CNS adverse events, both in and outside the United States, were dizziness, paraesthesia and headache. Despite this, the Johnson & Johnson Defendants deliberately avoided listing "paraesthesia" in their marketing statements, product labels, monographs and/or prescribing information as one of the most common adverse drug

reactions. The trend of symptoms indicative of peripheral neuropathy including, *inter alia*, pain, burning, tingling, numbness, weakness, and/or alterations of sensation, continued to be one of the most frequently reported CNS adverse events for all Defendants up to the labeling, product monograph and/or prescribing information change in August 2013.

81. The Defendants failure to adequately warn physicians resulted in:

(a) patients receiving FLQs instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which patients presented to the physician; and

(b) physicians failing to warn and instruct patients or consumers about the risk of long-term peripheral nervous system injuries associated with the FLQs.

82. The failure of the Defendants to include appropriate warnings in their drug product labels, product monographs and/or prescribing information as published to the medical community also resulted in an absence of adequate warnings in patient medical information presented directly to consumers, either as part of sample packages or as part of the prescription they received from retail pharmacies.

83. Despite the Defendants' knowledge and failure to adequately warn patients and their physicians of the above, the Defendants continued to market their FLQs as a first-line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics were and are available.

84. In or about November 2015 before an FDA advisory committee, the Johnson & Johnson Defendants and Bayer Defendants publicly acknowledged that their FLQs can cause neuropathy. Further, the FDA advisory committee found that the benefits and risks for systematic fluoroquinolone drugs did not support the current labeled indications for the treatment of bacterial sinusitis, bronchitis and uncomplicated urinary tract infections.

85. The Bayer Defendants' and the Johnson & Johnson Defendants' duty of care in disseminating drug product information extends to those patients, such as the Plaintiff and

BC Class Members, who have been injured by either brand-name or generic ingestion of the FLQs, and/or as a result of prescriptions written in reliance on the Defendants' drug product information. The Defendants knew, or ought to have known, that prescribing physicians would rely upon the warnings, product labeling, product monographs and/or prescribing information disseminated by the Defendants for Cipro, Avelox and/or Levaquin in prescribing brand-name or generic FLQs for patients such as the Plaintiff and BC Class Members.

E. *Limitation Act* - Discoverability

86. The Plaintiff and BC Class Members incorporate by reference all prior paragraphs of this Notice of Civil Claim as if fully set forth herein.

87. The running of the *Limitation Act*, R.S.B.C., 1996 c. 266 has been tolled by reason of the Defendants' fraudulent concealment. The Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiff, BC Class Members and their prescribing physicians the true risks associated with the Defendants' FLQ drugs including the actual incidence of fluoroquinolone induced peripheral neuropathy, the serious, progressive and disabling nature of fluoroquinolone induced peripheral neuropathy, the rapid onset of fluoroquinolone induced peripheral neuropathy and the irreversibility of fluoroquinolone induced peripheral neuropathy.

88. The time, place and substance of the Defendants' alleged fraud is set forth as follows.

89. Between 1995 and 2002, fluoroquinolone became the most commonly prescribed class of antibiotics to adults in North America. The explosive increase in fluoroquinolone prescriptions was a direct result of the Defendants' deliberate decision to reframe their FLQs from a "big gun" antibiotic that should be reserved for serious infections to a "first choice" antibacterial that was appropriate for a wide range of mild infections.

90. As such, the Defendants marketed their FLQs for routine infections despite knowing that their FLQs should be reserved for more serious conditions.

91. A key obstacle to the Defendants re-branding scheme was their awareness of the nature and extent of peripheral neuropathy that could result from taking the FLQs. The Defendants knew from their post-marketing experience that the most frequently reported adverse events concerned CNS symptoms related to dizziness, paraesthesia and headache. Paraesthesia is a medical term that refers to a burning or prickling sensation that is usually felt in the hands, arms, legs or feet and is considered a hallmark of peripheral neuropathy.

92. At all material times to the cause of action herein, the Defendants were aware that reports of neuropathy associated symptoms exceeded the number of reports of headaches and insomnia and were comparable to the frequency of dizziness and nausea.

93. The Bayer Defendants were also well aware that the frequency of peripheral neuropathy symptoms was at least on par with incidence of more minor side effects. For the majority of time that Avelox was sold and marketed by the Bayer Defendants, neuropathy and symptoms indicative of neuropathy remained among the frequently reported adverse events among Avelox users.

94. Given their close association with peripheral neuropathy, the frequent occurrence of paraesthesia and other neuropathy symptoms among fluoroquinolone users posed a significant hurdle to the Defendants' objective of expanding the use of their FLQs for mild infections. The Plaintiff and BC Class Members say that if physicians were adequately warned about the risk of serious peripheral neuropathy, they would have been much more hesitant to prescribe the FLQs for the type of routine infections that the Defendants were targeting through their marketing strategies. As such, the Defendants elected to conceal the true nature of the risk.

95. In order to continue to trumpet the allegedly "excellent" safety profile of their FLQs, the Defendants omitted any discussion of the significant risk of paraesthesia, hypoesthesia, dysesthesia and weakness and instead focused on what would be perceived as more mild and acceptable benign side effects such as headaches, nausea or dizziness, while concealing the equally common but far more serious symptoms of peripheral neuropathy through misrepresentations or omissions.

96. Through their marketing materials and campaigns the Defendants promoted and emphasized the safety profile of their FLQs by disclosing the occurrence of only mild symptoms while concealing the presence of more serious and more frequent symptoms of peripheral neuropathy. In doing so, the Defendants misled prescribing physicians regarding the true risks and side effects associated with their FLQs.

97. The treating physicians for the Plaintiff and BC Class Members would have received some form of these marketing materials and with them, the repeated misrepresentations and concealment regarding the FLQs' safety profile, the risk of irreversible peripheral neuropathy and associated symptoms.

98. Despite the claims in their marketing materials, the Defendants were aware that paraesthesia and other symptoms indicative of peripheral neuropathy had occurred frequently in FLQ patients. The Defendants' marketing materials deliberately omitted any reference of neuropathy type symptoms in their long list of side effects even though the neuropathy type symptoms occurred with similar, if not greater, frequency than the headaches, constipation, nausea, diarrhea, insomnia and dizziness they repeatedly referred to.

99. Failing to disclose the high incidence of neuropathy and neuropathy associated symptoms was not the only way in which the Defendants concealed the true risk of FLQ induced peripheral neuropathy. The Defendants also misrepresented the extent of the injury. The Defendants did this in at least three ways:

(a) they concealed the true risk of irreversible peripheral neuropathy;

(b) they concealed the fact that the irreversible peripheral neuropathy caused by their FLQs is often the result of a rapid onset of symptoms or, in other words, a patient could suffer permanent nerve injuries after taking as few as one or two FLQ pills; and

(c) the Defendants misrepresented the severity of the injury and failed to disclose that it can be serious and disabling.

100. The Defendants knew at least by the mid-1990s that their FLQs were capable of inducing prolonged and irreversible peripheral neuropathy. This knowledge came from the numerous adverse event reports the Defendants received and which were concealed from the medical community.

101. The Defendants were also aware of and concealed the fact that, while many patients experience a rapid onset of symptoms, other patients suffered injuries after a delay in onset even though patients only took the FLQs for a week or two.

102. The Defendants also concealed the severity of the permanent peripheral neuropathy caused by their FLQs. In numerous adverse event reports, the Defendants learned of the serious and disabling nature of the irreversible peripheral neuropathy that can result from use of the FLQs.

103. The Defendants fraudulently concealed from physicians, patients, and the medical community that the development of peripheral neuropathy could be permanent.

104. It was not until about 2004 that the Defendants provided any kind of warning to patients and/or their prescribing physicians in Canada regarding the risk of peripheral neuropathy. It was at this point in time that the Defendants warned that paresthesia (peripheral paralgesia) had been reported "rarely". The warning failed to disclose the true risk of irreversible peripheral neuropathy, the possibility of rapid onset, or the serious and disabling nature of the injury.

105. By underscoring the "rare" incidence of neuropathy among FLQ users, the Defendants reinforced the misleading statements in their marketing materials that the most frequent symptoms were minor reactions such as headaches, nausea, dizziness and diarrhea.

106. The Defendants through their product labeling, monographs and/or prescribing information mislead physicians, patients and the medical community by representing that patients experiencing symptoms of peripheral neuropathy should discontinue treatment "in order to prevent the development of an irreversible condition." By including this language, Defendants led patients and their physicians to believe that permanent peripheral

neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. This was false. The Defendants knew that cases of peripheral neuropathy associated with fluoroquinolone use could be permanent, irregardless of when the patient stopped taking the drug.

107. At all material times to the cause of action herein, the Defendants had a duty to disclose all facts about the risks associated with use of their FLQs. However, Defendants failed to disclose in their FLQ drug labels that the onset of peripheral neuropathy is often rapid, discontinuation of the drug will not ensure that the peripheral neuropathy is reversible, or that neuropathy symptoms were among the most common side effects and were not rare.

108. Further, the Defendants intentionally misrepresented the number of reported cases of peripheral neuropathies by improperly excluding certain forms of peripheral neuropathy from the total number of cases counted towards the condition. As such, the Defendants concealed the true risk profile of their drug product. This allowed the Defendants to falsely represent to the medical community and patients in their labeling that reported cases of peripheral neuropathy were "rare," thereby vastly minimizing the risk.

109. The Defendants also adopted procedures to conceal the incidence of peripheral neuropathy and the nature and extent of the risk of irreversible neuropathy by manipulating adverse event reporting requirements.

110. The Defendants have publicly recognized that their FLQs should not be used as a first-line treatment for minor sinusitis, bronchitis and urinary tract infections. Contrary to this representation, the Defendants marketed and promoted their FLQs for more than a decade to physicians, hospitals, and the medical community as a first-line treatment for uncomplicated sinusitis, bronchitis and urinary tract infections. All the while, the Defendants concealed from the medical community that key opinion leaders, including its own personnel, acknowledged that the drug product was inappropriate for such use.

111. The Defendants were required under governmental regulations to revise their product labeling, monographs and/or prescribing information as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not

have been proved. Despite the information known to the Defendants as averred to herein, the Defendants deliberately failed to update their FLQ drug labels, product monographs and/or prescribing information to reflect the rapid onset of symptoms, the risk of developing permanent peripheral neuropathy, the severity of nerve damage or the higher incidence of neuropathy symptoms. The Defendants knew, prior to Plaintiff' and BC Class Members use of the FLQ drugs, that CNS related effects were one of the most common adverse effects of quinolones and the onset of events like peripheral neuropathy could be rapid and irreversible. Despite this information, the Defendants deliberately failed to update their FLQ drug labels, marketing materials, educational and promotional documents and statements to reflect this important safety information or to modify their marketing materials.

112. In failing to update their FLQ drug labels, product monographs, prescribing information and/or marketing materials, the Defendants intended that the misinformation contained in the drug label, product monograph, prescribing information and/or marketing material would be relied upon by Plaintiff, BC Class Members and their prescribing physicians. As a direct result of the Plaintiff's, BC Class Members' and their prescribing physicians' reliance on the false information contained within the FLQ drug labels, the Plaintiff and BC Class Members were prescribed and took the Defendants' FLQs and developed permanent peripheral neuropathy and other serious bodily injuries including, *inter alia*, aortic dissection.

113. The nature of Plaintiff's and BC Class Members' injuries and the relationship of such injuries to the FLQs was inherently undiscoverable prior to the full dissemination of the disclosure of risk information that began in or about August 2013.

114. As such, the discovery rule should be applied to toll the running of the *Limitation Act* until the Plaintiff and BC Class Members knew, or through reasonable care and diligence ought to have known, of their claims against the Defendants.

115. The Plaintiff and BC Class Members did not discover and through the exercise of reasonable care and due diligence could not have discovered, their illnesses and injuries or their relationship to the FLQs until after full dissemination of the disclosure of risk information by the Defendants.

116. In the alternative, the facts of Plaintiff's and BC Class Members' claims made it impossible for them to discover the true nature of their injuries and/or causes of action within the applicable limitation periods. In particular, the Defendants' misrepresentations and omissions that constituted active concealment regarding the true nature of the risks associated with their FLQ drugs prevented the Plaintiff and BC Class Members from discovering the wrongful acts on which their causes of action are based. The Plaintiff and BC Class Members were advised that their injuries were due to some other potential cause(s) or that the cause of their injuries was not knowable or idiopathic.

117. Unlike ordinary consumers of prescription drug products, drug manufacturers are held to the standard of experts on their products. Further, unlike ordinary consumers, drug manufacturers are obligated to keep abreast of scientific knowledge, discoveries, advances and research in the field related to their products and are presumed to know what is imparted thereby. Conversely, ordinary consumers such as the Plaintiff and BC Class Members, are not presumed, as are drug manufacturers, to have superior or continuing knowledge of medical and scientific evidence concerning the drugs they take, particularly with respect to drugs they have previously ingested.

118. The Plaintiff and BC Class Members, as ordinary consumers, had no reason to suspect that their use of the Defendants' FLQs might have caused or contributed to their development of permanent peripheral neuropathy until after August 2013 at the earliest because of the Defendants' fraudulent concealment of the risk as averred to herein. Further, physical symptoms alone, without knowing or being able to discern the cause, are insufficient to start the running of the *Limitation Act*. This is certainly true for those class members whose symptoms did not begin to develop until weeks or months after their last use of the FLQ drugs. It also applies to those class members who suffered symptoms for months or years after being prescribed the FLQs but who were misdiagnosed and only later came to be correctly diagnosed with permanent peripheral neuropathy, or who were told by their treating physician that their peripheral neuropathy could not be related to their usage of the FLQ drugs, or who, after consulting their physicians, were not told that usage of the FLQ drugs was not the cause of their injuries.

119. The lack of awareness concerning the causal relationship between the FLQs and

irreversible peripheral neuropathy was not the result of silence or passive concealment. The Defendants, through their marketing statements and labeling, made affirmative representations and engaged in deliberate omissions to the medical community and patients, both of which suggested, expressly and impliedly, that symptoms of neuropathy were reversible, thereby excluding suspicion of any drug induced relationship or cause and preventing subsequent discovery.

120. As a result of Defendants' actions, the Plaintiff, BC Class Members and/or their prescribing physicians were unaware and could not reasonably know or have learned through reasonable diligence, that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

121. As such, the Defendants are estopped from relying on the *Limitation Act* because of their fraudulent concealment of the true character, quality and nature of their FLQs. The Defendants were under a duty to disclose the true character, quality and nature of their FLQs as this was non-public information over which the Defendants had, and continue to have, exclusive control and because the Defendants knew that this information was not available to the Plaintiff, BC Class Members and/or their prescribing physicians.

122. Further, the Plaintiff and BC Class Members had no knowledge that the Defendants were engaged in the wrongdoing alleged herein and because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiff and BC Class Members could not have reasonably discovered the wrongdoing at any time prior thereto.

123. As a result of the Defendants' fraudulent actions, the Plaintiff, BC Class Members and/or their prescribing physicians were unaware and could not have reasonably known or learned through reasonable diligence that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations. The Plaintiff and BC Class Members have been kept ignorant of vital information essential to the pursuit of these class proceedings, without any fault or lack of diligence on their part. The Defendants actively concealed from Plaintiff, BC Class Members and/or their prescribing physicians the true risks associated with the use of the FLQ drugs. The Defendants' acts and omissions included failing to disclose the truth about the safety

and efficacy of their FLQ drugs to the Plaintiff, BC Class Members and/or their prescribing physicians and concealing through misrepresentation the safety and efficacy of their FLQ products. The Plaintiff, BC Class Members and/or their prescribing physicians reasonably relied on the Defendants to disseminate truthful and accurate safety and efficacy information about their drugs and warn of the side effects complained of herein.

124. Although some aspect of the injury may have been known to Plaintiff, BC Class Members and/or their prescribing physicians, due to the Defendants' intentional concealment an essential fact to bring their cause of action was unknown. The Plaintiff and BC Class Members, lacking the reasonable means to discover vital information, reasonably relied on the concealment of essential facts that the Defendants, having actual knowledge of material facts, actively and deliberately concealed with the intent to prevent discovery thereof by others, including the Plaintiff and BC Class Members. As a consequence of the Defendants' conduct, the Plaintiff and BC Class Members were without knowledge of those facts and without means to discover them within the proscriptive periods prescribed by the *Limitation Act*, thereby relying to their detriment on the Defendants' conduct.

125. Furthermore, the Defendants are estopped from relying on the *Limitation Act* as a result of their fraudulent concealment of the defective nature of the FLQs. The Defendants, at all material times hereto, were under a duty to disclose the true character, quality and nature of the FLQs as this was non-public information over which the Defendants had, and continue to have, exclusive control and because the Defendants knew this information was not available to the Plaintiff, BC Class Members and/or their prescribing physicians.

126. The economics of alleged fraud should be considered. The Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, often as a front-line therapy for minor infections, notwithstanding the known or reasonably known risks. The Plaintiff, BC Class Members and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and were forced to rely on only the Defendants' representations. As such, the Defendants are precluded by the applicable discovery rule, the doctrine of fraudulent concealment and/or the doctrine of equitable estoppel from relying upon any limitation defence.

127. Neither the Plaintiff, BC Class Members nor their prescribing physicians were aware of the true risk profile of the Defendants' FLQs before they were injured. The Plaintiff and BC Class Members learned that the Defendants' FLQs might be responsible for their injuries within the proscriptive periods prescribed by the *Limitation Act.*

Part 2: RELIEF SOUGHT

1. The Plaintiff, on his own behalf, and on behalf of the BC Class Members, claims against the Defendants as follows:

(a) an order certifying this action as a class proceeding pursuant to the *Class Proceedings Act*, R.S.B.C. 1996, c.50 and appointing the Plaintiff as the named representative of the class;

(b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, packaging, labeling, warning, marketing, licencing, distribution and/or sale of Avelox, Cipro and/or Levaquin;

(c) a declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees and representatives;

(d) general damages;

(e) punitive, aggravated and/or exemplary damages;

(f) special damages on account of, *inter alia*, all medical and other expenses for treatment, including the subrogated claims of all governmental providers of medical services in British Columbia, in such amount as is proven at trial;

(g) interim, interlocutory and permanent orders, compelling the Defendants to fund a medical monitoring program supervised by the Court for the review and monitoring of the health of the putative class members by medical and other experts and to make recommendations regarding the treatment of the said class members;

(h) in the alternative to the claims for damages, payment of the gross revenues or, in the alternative, the net revenues realized by the Defendants from the sales of Avelox, Cipro and/or Levaquin;

(i) costs on a solicitor/client basis;

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

(k) such further and other relief as to this Honourable Court may seem just.

Subrogated Claims

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

3. The Plaintiff and BC Class Members required health services as a result of the conduct of the Defendants as alleged herein.

4. The Province of British Columbia will continue to provide treatment in the future to the Plaintiff and BC Class Members.

5. The subrogated interest of the Province of British Columbia includes the cost of all past and future insured services for the benefit of the Plaintiff and BC Class Members.

6. The cost of the purchase of the FLQs by the Plaintiff and BC Class members was covered, in whole or in part, individually or by third parties including private or group health insurers and private drug benefit plans, or by provincial health insurers and public drug benefit plans.

7. BC Class Members who paid for their own FLQs seek full indemnification of the purchase price. Third Party payors have a subrogated interest in their expenditures for FLQs on behalf of the Plaintiff and BC Class Members and they seek a full indemnification of the purchase price.

8. The Plaintiff and BC Class Members state that they would not have used the FLQs if the Defendants had acted reasonably and responsibly.

9. The Plaintiff and BC Class Members are entitled to recover from the Defendants as special damages the cost of purchasing the FLQs . But for the Defendants wrongdoing as alleged herein, the Plaintiff and BC Class Members would not have incurred the expense of purchasing the FLQs.

Part 3: LEGAL BASIS

A. Jurisdiction

1. There is a real and substantial connection between British Columbia and the facts alleged in this proceeding. The Plaintiff and the BC Class Members plead and rely upon the *Court Jurisdiction and Proceedings Transfer Act,* R.S.B.C. 2003, c.28 (the *"CJPTA"*) in respect of these Defendants. Without limiting the foregoing, a real and substantial connection between British Columbia and the facts alleged in this proceeding exists pursuant to sections 10 (f) and (g) of the *CJPTA* because this proceeding:

   (f) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia; and

   (g) concerns a tort committed in British Columbia.

B. Causes of Action

Product Liability – Failure to Warn

2. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full.

3. The Defendants have engaged in the business of manufacturing, marketing, promoting, selling, distributing and/or supplying the FLQ drugs and, through that conduct, have

knowingly and intentionally placed such drug products into the stream of commerce with full knowledge that the FLQ drug products reached consumers such as Plaintiff and BC Class Members who ingested them.

4. The Defendants did in fact manufacture, market, promote, sell, distribute and/or supply the FLQ drugs to the Plaintiff, BC Class Members and/or their prescribing physicians. Further, the Defendants expected the drugs they were manufacturing, marketing, promoting, selling, distributing and/or supplying to reach the Plaintiff, BC Class Members and/or their prescribing physicians, without any substantial change in the condition from when they were initially distributed by Defendants.

5. At all material times to the cause of action herein, the Defendants' FLQ drugs were defective and unsafe in manufacture such that they were unreasonably dangerous to the user and were so at the time they were distributed by the Defendants and ingested by the Plaintiff and BC Class Members. The defective condition of such drugs was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia*, aortic dissection, as a result of their use.

6. This defect caused serious injuries to the Plaintiff and BC Class Members who used the Defendants' FLQs in their intended and foreseeable manner.

7. At all material times to the cause of action herein, the Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and/or take such steps to ensure that their drug products did not cause users to suffer from unreasonable and dangerous side effects.

8. The Defendants so negligently and recklessly labeled, promoted and/or distributed the aforesaid drug products that they were dangerous and unsafe for the use and purpose for which they were intended.

9. The Defendants breached their duty of care to the Plaintiff and the BC Class Members, the particulars, *inter alia*, of which are:

(a) failing to warn them and/or their prescribing physician that ingestion of the FLQs carried the risk of irreversible peripheral neuropathy and other serious bodily injuries, including, *inter alia*, aortic dissection;

(b) failing to ensure that prescribing physicians and other healthcare professions were apprised and fully and regularly informed of the risk of irreversible peripheral neuropathy and other serious bodily injuries, including, *inter alia*, aortic dissection with ingesting the FLQ drugs;

(c) failing to inform Health Canada and/or the FDA fully, properly and in a timely manner of the risk of irreversible peripheral neuropathy and other serious bodily injuries, including, *inter alia*, aortic dissection with ingesting the FLQ drugs;

(d) failing to provide truthful and complete information when submitting New Drug Submission for the FLQ drugs to Health Canada and/or the FDA;

(e) failing to provide complete and accurate clinical and non-clinical data to Health Canada, and/or the FDA, throughout the approval process for the FLQ drugs and thereafter;

(f) failing to promptly report to Health Canada, and/or the FDA, all adverse events that came to be reported to them with regards to the FLQ drugs subsequent to its approval for sale in North America;

(g) failing to issue prompt, up-to-date and accurate Health Professional Communications and Public Communications, which are the modes of communication through which manufacturers are required to communicate with healthcare professionals and the public regarding the safety concerns affecting a drug product;

(h) failing to provide truthful and complete information in warning labels, product monographs and/or prescribing information for the FLQ drugs which are directed to healthcare professionals and patients; and

(i) failing to disclose, adequately or at all, in the warning label, product monograph and/or prescribing information of the risk of irreversible peripheral neuropathy and other serious bodily injuries, including, *inter alia*, aortic dissection with ingesting the FLQ drugs.

10. The Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that the Defendants knew, or ought to have known, that the FLQ drugs caused serious bodily injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy and/or aortic dissection from their use, even though these side effects were known or reasonably scientifically knowable at the time of their initial marketing and/or distribution. The Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, the Defendants acted with a conscious disregard for the safety of Plaintiff and BC Class Members.

11. The Plaintiff and BC Class Members could not have discovered any defect in the subject drug products through the exercise of reasonable care.

12. The Defendants, as the manufacturers and/or distributors of the FLQ drugs, are held to the level of knowledge of experts in the field.

13. The Plaintiff and BC Class members reasonably relied upon the skill, superior knowledge and judgment of Defendants.

14. Had the Defendants properly disclosed the risks associated with the FLQ drugs, the Plaintiff and BC Class Members would have avoided the risk of irreversible peripheral neuropathy and/or other serious bodily injuries including, *inter alia,* aortic dissection, by not ingesting the FLQ drugs.

15. As a direct and proximate result of the negligence, recklessness and/or gross negligence of Defendants as alleged herein, the subject drug products caused the Plaintiff and BC Class Members to suffer injuries as alleged herein.

Negligence

16. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full.

17. At all times material to the cause of action herein, the Defendants had a duty to exercise reasonable care to consumers, including the Plaintiff and BC Class Members, in the design, development, testing, manufacture, inspection, packaging, labeling, promotion, marketing, distribution and/or sale of the FLQ drugs.

18. The Defendants breached their duty of care to the Plaintiff and BC Class Members in that they negligently promoted, marketed, labeled and/or distributed the FLQ drugs.

19. The Plaintiff's and BC Class Members' injuries and damages as alleged herein were, and are, the direct and proximate result of the negligence of Defendants, the particulars, *inter alia*, of which are:

(a) failing to design, develop, research, test, manufacture, package, label, promote, market, distribute and/or sell the FLQ drugs in accordance with the *Food and Drugs Act*, RSC, 1985, c. F-27 and the Regulations thereto;

(b) failing to warn or instruct and/or adequately warn or instruct, users of the subject drug products, including the Plaintiff and BC Class Members, of the dangerous and defective characteristics of the FLQ drugs;

(c) in the design, development, implementation, administration, supervision and/or monitoring of clinical trials for the FLQ drugs;

(d) in promoting the FLQ drugs in an overly aggressive, deceitful and fraudulent manner, including as a first-line therapy to treat infections for which they were not required despite evidence as to the drugs defective and dangerous characteristics due to their propensity to cause irreversible peripheral neuropathy and/or other serious bodily injuries, including, *inter alia*, aortic dissection;

(e) in representing that the FLQ drugs were safe for their intended use when, in fact, the drug products were unsafe for their intended use;

(f) failing to perform appropriate pre-market testing of the FLQ drugs;

(g) failing to perform appropriate post-market monitoring and/or surveillance of the FLQ drugs;

(h) failing to adequately and properly test the FLQ drugs before and after placing them on the market;

(i) failing to conduct sufficient testing on the FLQ drugs which, if properly performed, would have shown that it had serious side effects of causing irreversible peripheral neuropathy and/or other serious bodily injuries including, *inter alia*, aortic dissection;

(j) failing to adequately warn the Plaintiff, BC Class Members and their prescribing physicians that the use of the FLQ drugs carried a risk of developing irreversible peripheral neuropathy and/or other serious bodily injuries including, *inter alia*, aortic dissection;

(k) failing to provide adequate post-marketing warnings or instructions after the Defendants knew, or ought have known, of the significant risk of irreversible peripheral neuropathy and aortic dissection associated with the use of the FLQ drugs;

(l) failing to include a "boxed warning" about the significant risk of developing irreversible peripheral neuropathy and/or other serious bodily injuries including, *inter alia*, aortic dissection, with the use of the FLQ drugs;

(m) failing to adequately and timely inform the Plaintiff, BC Class Members and/or their prescribing physicians of the risk of serious bodily injuries, in particular, irreversible peripheral neuropathy and/or other serious bodily injuries including *inter alia*, aortic dissection, from ingestion of the FLQ drugs as described herein; and.

(n) failing to promptly report to Health Canada, and/or the FDA, all adverse events that came to be reported to them with regards to the FLQ drugs subsequent to its approval for sale in North America;

20. The Defendants knew, or ought to have known, that consumers such as Plaintiff and BC Class Members would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

21. As a direct and proximate result of Defendants' negligence, the Plaintiff and BC Class Members suffered severe and permanent physical and emotional injuries including, but not limited to, irreversible peripheral neuropathy and/or aortic dissection.

Breach of Express Warranty

22. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full

23. Before the Plaintiff and BC Class Members were first prescribed the FLQ drugs and during the period in which they used the drugs, the Defendants expressly warranted that their FLQs were safe.

24. The Defendants' FLQ drugs did not conform to their express representations because their drugs were not safe and had an increased risk of serious side effects including, *inter alia*, irreversible peripheral neuropathy and aortic dissection, whether taken individually or in conjunction with other therapies.

25. As a direct and proximate result of this wrongful conduct, the Plaintiff and BC Class Members were injured as alleged herein.

Breach of Implied Warranty of Merchantability

26. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full.

27. At all material times to the cause of action herein, the Defendants manufactured, compounded, packaged, labeled, distributed, recommended, merchandised, advertised, promoted, supplied and/or sold the FLQ drugs, and before such drugs were prescribed to the Plaintiff and BC Class Members, the Defendants impliedly warranted to the Plaintiff and BC Class Members that these drugs were of merchantable quality and safe and fit for the use for which they were intended pursuant to the *Sale of Goods Act*, RSBC 1996, c.410.

28. The Plaintiff and BC Class Members, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

29. The Plaintiff and BC Class Members were prescribed, purchased and used the subject drug products for their intended purpose.

30. As a result of the Defendants' wrongful conduct as alleged herein, the Plaintiff and BC Class Members could not have known about the nature of the risks and side effects associated with the subject drug products until after they used them.

31. Contrary to the implied warranty for the subject drug products, the Defendants' FLQ drugs were not of merchantable quality nor were they safe or fit for their intended uses and purposes, as alleged herein.

32. As a direct and proximate result of the Defendants' breach of implied warranty, the Plaintiff and BC Class Members suffered severe and permanent physical and emotional injuries including, *inter alia*, irreversible peripheral neuropathy and/or aortic dissection

33. The Plaintiff and BC Class Members further plead and rely on the *Competition Act*, RSC, 1985, c C-34.

34. The Defendants' claims regarding the safety and effectiveness of the FLQ drugs, as compared to other similar fluoroquinolones, were representations made for the purpose of promoting the business interests of the Defendants and promoting the FLQ drugs. There representations were made to the public, including the Plaintiff and BC Class Members. They were false and misleading in a material respect and were made by the Defendants

knowingly and recklessly.

35. As such, the Defendants breached section 52 of the *Competition Act*, in knowingly or recklessly making false and/or misleading representations to the public and are liable for damages, the costs of investigating and pursing this proposed class proceeding.

36. The Plaintiff and BC Class Members plead and rely upon the *Food and Drugs Act*. Contrary to section 9 of the *Food and Drugs Act*, the Defendants labeled, packaged, advertised and/or sold the FLQ drugs in an manner that was false, misleading, deceptive and/or was likely to create an erroneous impression regarding its character, value, composition, merit and/or safety.

Fraud

37. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full.

38. The Defendants having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and/or sell their FLQs, owed a duty to provide accurate and complete information regarding their drugs.

39. The Defendants' advertising, marketing and educational programs by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the FLQ drugs was safe for human use, had no unacceptable side effects and would not interfere with daily life.

40. The Defendants did not properly study nor report accurately the results of their studies in terms of risks and benefits of its FLQ drugs.

41. The Defendants purposefully concealed, failed to disclose, misstated, downplayed and/or understated the health hazards and risks associated with the use of their FLQ drugs. The Defendants published inaccurate and misleading scientific articles for the purpose of creating confusion so as to pollute existing scientific and medical knowledge pertaining to

the risk of developing permanent peripheral neuropathy from use of the FLQ drugs. The Defendants then used and relied on these inaccurate and fraudulently prepared scientific papers to defend and justify the marketing, promotion and labeling of their FLQ drugs. At all material times, the Defendants knew that what they were publishing or having published was inaccurate and that this information would mislead the members of the medical and scientific communities who were studying, or more importantly, prescribing FLQs.

42. The Defendants, through the publication of medical literature, deceived potential users and prescribers of the FLQs by relaying only allegedly positive information while concealing, misstating and/or downplaying the known adverse and serious health effects including, *inter alia*, irreversible peripheral neuropathy and/or aortic dissection.

43. The Defendants similarly used promotional practices to deceive potential users and prescribers of the FLQs by relaying only allegedly positive information while concealing, misstating and/or downplaying the known adverse and serious health effects including, *inter alia*, irreversible peripheral neuropathy and/or aortic dissection.

44. The Defendants also failed to disclose relevant information from potential fluoroquinolone users and minimized prescriber concerns regarding the safety and efficacy of the FLQs. Despite learning as early as 1988 that there was an association of a serious hazard with its FLQ drugs, the Defendants intentionally withheld this information from physicians and patients until the labeling for the FLQ drugs was changed to reflect any risk of developing neuropathy. Even then, however, the Defendants sought to minimize the frequency and permanency of these serious events by indicating that they were "rare". The Defendants knew these labeling statements were false and misleading because they knew as early as the 1990s that CNS related effects were more common with quinolones than with other antimicrobial classes of drugs and the onset of events like peripheral neuropathy could be rapid and irreversible.

45. The Defendants intentionally misrepresented that irreversible neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. More specifically, the warning labels, product monographs and/or prescribing information for the FLQ drugs specifically stated that the drugs should be "discontinued if the patient experiences symptoms of

neuropathy...in order to prevent the development of an irreversible condition."

46. Further, the scientific and medical communities were misled as to the true nature of the risk and benefits of the Defendants' FLQ drugs, in particular, as to the treatment needs and options for patients in need of antibiotic therapy

47. The misconceptions as to the true risks and benefits of the Defendants' FLQ drugs were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants which included, *inter alia*, the following:

(a) the publication of fraudulent scientific papers in scientific and medical literature;

(b) providing false and misleading information to physicians during sales and detailing calls at the physician's offices or at medical or scientific conferences and meetings;

(c) funding and sponsoring physicians, consultants and/or key opinion leaders to disseminate false and misleading scientific and medical information through medical journals and publications;

(d) funding third party companies to disseminate false and misleading scientific and medical information through their publications and members to physicians and patients;

(e) funding continuing medical education to disseminate false and misleading information to physicians;

(f) paying specialists in the field to meet with prescribing physicians for the purpose of disseminating false and misleading information about the risks and benefits of the FLQ drugs; and

(g) disseminating direct to consumers advertising to drive patients to their physicians offices to ask for their FLQ drugs based on false and misleading information regarding the risks and benefits of the drugs.

48. The Defendants falsely and deceptively misrepresented material facts regarding the safety and effectiveness of their FLQ drugs and fraudulently, intentionally and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of their drug products, including by concealing the following information:

(a) that there was evidence of peripheral paraesthesia associated with FLQ therapy as early as 1988;

(b) that there was evidence demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as the mid-1990s;

(c) that cases of paraesthesia were frequently reported adverse events related to the CNS;

(d) that the FLQ drugs were not fully and adequately tested by the Defendants for the risk of developing irreversible peripheral neuropathy and/or other serious bodily injuries including, *inter alia*, aortic dissection;

(e) the severity, frequency, rapid onset and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) the wide range of injuries caused by the FLQ drugs to multiple body systems including, *inter alia* musculoskeletal, neuropsychiatric, peripheral nervous system, sensory, skin and cardiovascular; and

(g) that the FLQ drugs should not be used as a first-line therapy to treat infections for which they are not required.

49. The misrepresentations and/or active concealment was perpetuated directly and/or indirectly by the Defendants. Moreover, as a result of these efforts it was accepted by the medical and scientific communities that the FLQs had a certain risk benefit profile that was shown to be completely false by independent studies, case series, post-marketing experience and adverse event reports.

50. The Defendants were in possession of evidence demonstrating that the FLQs caused serious and debilitating side effects, including irreversible peripheral neuropathy and/or aortic dissection. Nevertheless, the Defendants continued to market such drug products by providing false and misleading information with regard to their safety and efficacy to the Plaintiff, BC Class Members and their prescribing physicians.

51. The Defendants knew, or ought to have known, that these representations were false and made the representations with the intent or purpose of deceiving the Plaintiff, BC Class Members, prescribing physicians and/or the healthcare industry.

52. The Defendants made these false representations with the intent or purpose that the Plaintiff, BC Class Members, their prescribing physicians and/or the healthcare industry would rely on them, leading to the widespread use of the FLQ drugs by the Plaintiff, BC Class Members and the general public.

53. At all material times to the cause of herein, neither the Plaintiff, BC Class Members nor their prescribing physicians were aware of the falsity or incompleteness of the statements being made by the Defendants and believed them to be true. The Plaintiff and BC Class Members say that had they been aware of these facts, they would not have been prescribed the FLQ drugs by their physicians.

54. The Plaintiff, BC Class Members, their prescribing physicians and/or the healthcare industry justifiably relied on and/or were induced by the Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of the FLQ drugs that the Defendants did suppress, conceal or fail to disclose to the Plaintiff's and BC Class Members' detriment.

55. The Plaintiff and BC Class Members justifiably relied, directly or indirectly, on the Defendants' misrepresentations and/or active concealment regarding the true dangers of the FLQ drugs. Based on the nature of the physician-patient relationship, the Defendants had reason to expect that Plaintiff and BC Class Members would indirectly rely on the Defendants' misrepresentations and/or active concealment. As a result of the concealment and/or suppression of the material facts set forth above, the Plaintiff and BC Class Members

ingested the Defendants FLQ drugs and suffered injuries as alleged herein.

Negligent Misrepresentation

56. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full.

57. The Defendants negligently and/or recklessly misrepresented to the Plaintiff, BC Class Members, their prescribing physicians and/or the healthcare industry the safety and effectiveness of the FLQ drugs and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness and dangers posed by the FLQs.

58. The Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when the Defendants knew, or ought to have known, that the FLQ drugs had defects, dangers and characteristics that were other than what the Defendants had represented to Plaintiff, BC Class Members, their prescribing physicians and/or the healthcare industry. Specifically, the Defendants negligently or recklessly concealed from the Plaintiff, BC Class Members, their prescribing physicians, the health care industry and/or the general public the following:

(a) that there was evidence of peripheral paraesthesia associated with FLQ therapy (ciprofloxacin) as early as 1988;

(b) that there was evidence demonstrating that the FLQs increased the risk of irreversible peripheral neuropathy;

(c) that paraesthesia was one of the most frequently reported adverse events related to CNS;

(d) that the FLQ drugs were not fully and adequately tested by the Defendants for the risk of developing irreversible peripheral neuropathy and/or other serious bodily injuries including, *inter alia*, aortic dissection;

(e) the severity, frequency, rapid onset and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) the wide range of injuries caused by the FLQ drugs to multiple body systems including, *inter alia,* musculoskeletal, neuropsychiatric, peripheral nervous system, sensory, skin and cardiovascular; and

(g) that the FLQ drugs should not be used as a first-line therapy for minor or uncomplicated infections.

59. The negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by the Defendants.

60. The Defendants ought to have known through the exercise of due care that these representations were false and made the representations without the exercise of due care leading to the deception of the Plaintiff, BC Class Members, their prescribing physicians, and/or the healthcare industry.

61. The Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that the Plaintiff, BC Class Members, their prescribing physicians and/or the healthcare industry would rely on them, leading to the use of the FLQs by the Plaintiff, BC Class Members and/or the general public.

62. At all material times to the cause of action herein, neither the Plaintiff, BC Class Members nor their prescribing physicians were aware of the falsity or incompleteness of the statements being made by the Defendants and believed them to be true. The Plaintiff and BC Class Members say that had they been aware of said facts, their physicians would not have prescribed and the Plaintiff and BC Class Members would not have taken the FLQ drugs.

63. The Plaintiff and BC Class Members justifiably relied on and/or were induced by the Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of the Defendants' FLQ drugs and relied on the absence of

information regarding the dangers of these drugs which the Defendants negligently or recklessly suppressed, concealed or failed to disclose to the Plaintiff and BC Class Members detriment.

64. The Defendants had a post-sale duty to warn the Plaintiff, BC Class Members, their prescribing physicians and/or the general public about the potential risks and complications associated with the FLQ drugs in a timely manner.

65. The Defendants made the representations and actively concealed information about the defects and dangers of the FLQ drugs with the absence of due care such that the Plaintiff's and BC Class Members' prescribing physicians and/or the general public would rely on such information, or the absence of information, in selecting the FLQs as a treatment.

66. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, the Plaintiff and BC Class Members ingested the Defendants' FLQ drugs and suffered injuries as alleged herein.

Fraudulent Concealment

67. The Plaintiff re-alleges all prior paragraphs of the Notice of Civil Claim as if set out here in full.

68. The Defendants are estopped from asserting a limitation defense because they fraudulently concealed their wrongful conduct from the Plaintiff and BC Class Members with the intent that the Plaintiff, BC Class Members and/or their prescribing physicians would rely on such material representations. First, the Defendants had actual knowledge of the defective and dangerous nature of their FLQ drugs. Second, the Defendants failed to conduct adequate testing on their FLQ drugs to establish safety and efficacy. Third, the Defendants had actual knowledge of their misrepresentations, negligence, breach of warranties and false, misleading, deceptive and unconscionable conduct. Despite that, the Defendants continued to perpetuate their wrongful conduct with the intent and fixed purpose of concealing their wrongs from the Plaintiff, BC Class Members and/or the general public.

69. The Plaintiff, BC Class Members and /or their prescribing physicians were unaware of the falsity of these representations, acted in actual and justifiable reliance on such material misrepresentations and were injured as a direct and proximate result thereof.

70. Further, the Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform the Plaintiff, BC Class Members, their prescribing physicians and/or the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact with the intent that the Plaintiff, BC Class Members and/or their prescribing physicians would rely on the Defendants' misrepresentations. The Plaintiff, BC Class Members and/or their prescribing physicians did, in fact, act in actual and justifiable reliance on the Defendants' representations and the Plaintiff and BC Class Members were injured as a result thereof.

71. The Defendants, as the manufacturers and/or distributors of the FLQ drugs, were in a position of superior knowledge and judgment regarding any potential risks associated with their drugs.

72. The Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to the Plaintiff and BC Class Members relating to the FLQ drugs at issue in this proposed class proceeding, said breach or breaches constituting fraud because of its propensity to deceive others or constitute an injury to public interests or public policy.

73. In breaching their duties to the Plaintiff and BC Class Members, the Defendants used their position of trust as the manufacturers and/or distributors of FLQ drugs to increase sales of the drugs at the expense of informing the Plaintiff and BC Class Members that, by ingesting these drugs, they were placing themselves at a significantly-increased risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems , including, *inter alia*, musculoskeletal, neuropsychiatric, sensory, skin and cardiovascular.

Unjust Enrichment

74. The Defendants voluntarily accepted and retained profits and benefits derived from the

Plaintiff and BC Class Members. The Defendants did so with full knowledge that, as a result of the Defendants' intentional wrongdoing, the Plaintiff and BC Class members did not receive a product of the quality, nature or fitness that had been represented by the Defendants or reasonably expected by the Plaintiff and BC Class Members.

75. The Plaintiff and BC Class members have suffered a loss corresponding to the benefit received by the Defendants.

76. There is no juristic reason for the Defendants' enrichment.

77. By virtue of the wrongdoing alleged herein, the Defendants have been unjustly enriched at the expense of harm to the Plaintiff and BC Class Members.

Waiver of Tort

78. The Plaintiff and BC Class Members are entitled to waive the tort and require the Defendants to account for all of the revenue they received from the sale of the FLQs in British Columbia.

79. The Plaintiff and BC Class Members plead that waiver of tort may be appropriate for, *inter alia*, the following reasons:

(a) such revenue was acquired in such circumstances that the Defendants cannot in good conscience retain it;

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

(c) the FLQs could not have been marketed, and the Defendants would not have received any revenue from their sale in British Columbia, absent the Defendants' egregious conduct;

(d) the Defendants engaged in wrongful conduct by putting into the marketplace a

pharmaceutical drug product which caused or has the potential to cause increased risk of serious bodily injuries; and

(e) the Defendants would be unjustly enriched if they were permitted to retain revenues realized from the sale of the FLQs.

Plaintiff's(s') address for service:

Garcha & Company
Barristers & Solicitors
#405 - 4603 Kingsway
Burnaby, BC V5H 4M4

Fax number address for service (if any):

604-435-4944

E-mail address for service (if any):

none

Place of trial:

Vancouver, BC

The address of the registry is:

800 Smithe Street
Vancouver, BC V6Z 2E1

Dated: August 30, 2016

Signature of K.S. Garcha
lawyer for plaintiff(s)

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

There is a real and substantial connection between British Columbia and the facts alleged in this proceeding. The Plaintiff and the Class Members plead and rely upon the *Court Jurisdiction and Proceedings Transfer Act* R.S.B.C. 2003 c.28 (the *"CJPTA"*) in respect of these Defendants. Without limiting the foregoing, a real and substantial connection between British Columbia and the facts alleged in this proceeding exists pursuant to sections 10(f) and (g) of the *CJPTA* because this proceeding:

(f) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia; and

(g) concerns a tort committed in British Columbia.

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

[The following information is provided for data collection purposes only and is of no legal effect.]

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This is a proposed product liability class action in respect to the pharmaceutical drugs Cipro, Avelox and Levaquin. The Plaintiff seeks monetary damages on behalf of the proposed class.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:
[ ] motor vehicle accident
[ ] medical malpractice
[ ] another cause

A dispute concerning:
[ ] contaminated sites
[ ] construction defects
[ ] real property (real estate)
[ ] personal property
[ ] the provision of goods or services or other general commercial matters
[ ] investment losses
[ ] the lending of money
[ ] an employment relationship
[ ] a will or other issues concerning the probate of an estate
[x] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[x] a class action
[ ] maritime law
[ ] aboriginal law
[ ] constitutional law
[ ] conflict of laws
[ ] none of the above
[ ] do not know

Part 4:

1. *Class Proceedings Act*, R.S.B.C. 1996, c.50
2. *Court Jurisdiction and Proceedings Transfer Act* R.S.B.C. 2003 c.28
3. *Business Practices and Consumer Protection Act,* S.B.C. 2004 ;
4. *Sale of Goods Act*, R.S.B.C 1996, c.410
5. *Negligence Act,*R.S.B.C. 1996, c.333
6. *Hospital Insurance Act*, R.S.B.C. 1996, c.204
7. *Health Care Costs Recovery Act*, S.B.C. 2008, c.27
8. *Family Compensation Act*, R.S.B.C. 1996, c.126
9. *Competition Act*, R.S.C. 1985, C-34
10. *Food and Drugs Act,* R.S.C. 1985, F-27
11. *Limitations Act*, R.S.B.C., 1996 c.266
12. *Court Order Interest Act*, R.S.B.C., c. 79