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2010

Hfx.No. 327940

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

MARION MICHELLE GOWANLOCK

Plaintiff

- and -

Court Administration

Halifax, N.S.

JANSSEN- ORTHO INC., JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., ORTHO- MCNEIL- JANSSEN PHARMACEUTICALS ,INC., and JOHNSON & JOHNSON, a body corporate

Defendants

NOTICE OF ACTION Amended on this \ day of m--- b -r, 2010 pursuant to Civil Procedure Rule 83.04

Proceeding under the *Class Proceedings Act*, S.N.S 2007,

c.28 TO: JANSSEN – ORTHO INC.

TO: JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C.

TO: ORTHO – MCNEIL – JANSSEN PHARMACEUTICALS

,INC. TO: JOHNSON & JOHNSON

Action has been started against you
The plaintiff takes action against you.

The plaintiff started the action by filing this notice with the court on the date certified by the prothonotary .

The plaintiff claims the relief described in the attached statement of claim. The claim is based on the grounds stated in the statement of claim.

Deadline for defending the action

To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

ï 15 days if delivery is made in Nova Scotia

ï 30 days if delivery is made elsewhere in Canada

ï 45 days if delivery is made anywhere else.

ï **Judgment against you if you do not defend**

ï The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

ï **You may demand notice of steps in the action**

ï If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

ï If you file a demand for notice, the plaintiff must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

ï **Rule 57 - Action for Damages Under \$100,000**

ï Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the plaintiff states the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the plaintiff.

ï This action is not within Rule 57.

ï **Filing and delivering documents**

ï Any documents you file with the court must be filed at the office of the Prothonotary, The Law

ï Courts, 1815 Upper Water Street, Halifax, Nova Scotia (telephone #902-424-4900).

ï When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

ï **Contact information**

ï The plaintiff designates the following address:

ï Wagners
Law Firm
ï 1869 Upper Water
Street Halifax, Nova
Scotia
ï B
3J 1S9

ï Documents delivered to this address are considered received by the plaintiffs on delivery.

ï Further contact information is available from the prothonotary.

Proposed place of trial

The plaintiff proposes that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Sig nature

Signed _____ 1, 2010

[Handwritten signature]

RAYMOND F. WAGNER
Solicitor for Plaintiff

Prothonotary's certificate

I certify that this notice of action, amended on December 1, 2010, including the attached amended statement of claim, was filed with the court on December 1, 2010.

GEORGE GHOSN
Deputy Prothonotary
[Handwritten signature]
Prothonotary

FORM 4.02B

AMENDED STATEMENT OF CLAIM

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

I. OVERVIEW

- 1) Levaquin (Levofloxacin) is a brand-name fluoroquinolone antibiotic prescription drug used in the treatment of certain infections caused by bacteria; namely, sinus infections, skin infections, lung infections, ear infections, bone infections, urinary tract infections, and prostatitis (an infection of the prostate).
- 2) Levaquin was approved by Health Canada in November 1997 for the treatment of bacterial infections in adults.
- 3) During the time that Levaquin has been available for sale in Canada, a total of over 450 reports of injury have been submitted to Health Canada in association with Defendants' product.
- 4) The FDA has reported that Levaquin accounted for 61% of all fluoroquinolone-caused tendon injuries between November 1997 and December 2005.

- 5) In 2007, Levaquin was ranked 37 of the top 200 drugs that were prescribed in the United States.
- 6) In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.
- 7) The sales for Levaquin in 2007 were approximately \$1.6 billion. This accounted for approximately 6.5% of Johnson & Johnson's total revenue, which was an 8% increase over the previous year.
- 8) Levaquin was the most prescribed fluoroquinolone drug in the world in 2007.
- 9) Many pre- and post-label epidemiological studies, adverse event reports from around the world, and early product labels have indicated that Levaquin is associated with an increased risk of tendonitis and tendon rupture, especially
- 10) 11) of the Achilles tendon. In addition, Ruptures have been reported with regard to the peroneous brevis, extensor pollicis longus, adductor longus, long head of the biceps and the rotator cuff tendon.
- 12)
- 13) In July 2008, the FDA released a Black Box warning for Levaquin, as it has been linked to serious side effects including tendon ruptures, injuries, and disorders, which may require surgery to repair.
- 14)
- 15) In January of 2010, an official complaint was filed by the U.S. Justice Department in Boston alleging that Johnson and Johnson illegally paid Omnicare, one of the largest pharmacies in the nation supplying nursing home patients, millions of dollars in kickbacks in exchange for Omnicare increasing its sales of drugs, including Levaquin. Sales of Levaquin increased over other fluoroquinolones over the five year period from 1999 to 2004. Sales of Levaquin dramatically increased despite ever growing reports of the severe adverse reactions in elderly patients.

16) **II. REPRESENTATIVE PLAINTIFF AND CLASS**

- 17)
- 18) The Plaintiff, Marion Michelle Gowanlock, resides at 33 Springfield Lake Road, Middle Sackville, Nova Scotia.
- 19)
- 20) The Plaintiff seeks to certify this action as a Class Proceeding and pleads the *Class Proceedings Act*, S.N.S. 2007, c. 28, as providing the basis for such certification. The Plaintiff, as the Representative Plaintiff, does not have any interest adverse to any of the members of the proposed class. The Plaintiff states that there is an identifiable class that would be fairly and adequately represented by the Plaintiff; that the Plaintiff's claims raise common issues; and that a class proceeding would

be the preferable procedure for the resolution of such common issues.

- 21)
- 22) The Plaintiff proposes to bring a ~~common-law~~ class proceeding on behalf of herself and a class of all other Canadian residents who claim to have suffered personal injuries as a result of ingesting were prescribed and ingested the drug at any time from November 1997 to the date of certification of this

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proceeding (the Class Period) Levaquin. The proposed class will be further defined in the Application for Certification.

- 26) In this action, the Plaintiff seeks, on her own behalf and on behalf of the Class:

- (a) compensation for the personal injuries and other costs they have incurred as a result of having taken Levaquin and/or;
- (b) disgorgement of the benefits that accrued to the Defendants as a result of their wrongful acts; and
- (c) damages in the form of total funds required to establish a medical monitoring process for the benefit of the Class Members.

- 27) Class Members have all been prescribed Levaquin.

- 28) Class Members have been harmed by their use of the medication Levaquin as hereinafter described.

- 29) The Plaintiff and Class Members have suffered pain, loss of enjoyment of life, a probable shortening of life, loss of earnings and earning capacity, and therefore, claim both special damages and general damages as a result of ingesting Levaquin

III. DEFENDANTS

- 30) Janssen – Ortho Inc. is an Ontario corporation with its principal place of business located at 19 Green Belt Dr. Toronto, ON M3C 1L9.

- 31) Johnson & Johnson Pharmaceutical Research and Development, L.L.C. is a limited liability company with its principal place of business located at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

- 32) Ortho – McNeil – Janssen Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 1000 Route 202 South, P.O. Box 300,

Raritan, New Jersey 08869.

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33) Johnson and Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

34) Ortho – McNeil – Janssen Pharmaceuticals, Inc.; Johnson & Johnson Pharmaceutical Research and Development, L.L.C.; and Janssen – Ortho Inc. are all members of the Johnson and Johnson “Family of Companies.” As such, Ortho – McNeil – Janssen Pharmaceuticals, Inc.; Johnson & Johnson Pharmaceutical Research and Development, L.L.C.; Janssen – Ortho Inc.; and Johnson and Johnson, all or any one of them, were carrying on business as, inter alia, the researchers, developers, designers, testers, manufacturers, distributors, packagers, promoters, marketers, and sellers of Levaquin in the United States and Canada.

35) ~~Defendants Janssen – Ortho Inc.; Johnson & Johnson Pharmaceutical Research and Development, L.L.C.; Ortho – McNeil – Janssen Pharmaceuticals, Inc.; and Johnson and Johnson shall be referred to herein individually by name or jointly as the “Defendants.”~~

24) ~~25)~~—During the class period, the Defendants were engaged in, involved in, and/or were responsible for the research, development, designing, testing, manufacturing, distributing, packaging, promoting, and/or marketing of Levaquin in the United States and/or Canada.

25) ~~26)~~The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the research, development, designing, testing, manufacturing, distributing, packaging, promoting, and/or marketing and/or selling of Levaquin in the United States and/or Canada.

26) ~~27)~~At all material times, the Defendants, all or any one of them, were carrying on business as, inter alia, the researchers, developers, designers, testers, manufacturers, distributors, packagers, promoters, marketers and/or sellers of Levaquin in the United States and/or Canada.

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IV. NATURE OF THE ACTION

27) ~~28)~~—The Plaintiff and Class Members allege that the Defendants engaged in tortious conduct in the manufacturing, marketing, promotion, distributing and selling of Levaquin in complete disregard for the health and safety of the Plaintiff and Class Members.

28) ~~29)~~—The Plaintiff and Class Members further allege that the Defendants were wholly and grossly negligent.

29) ~~30)~~—The Plaintiff and Class Members further allege that the Defendants failed to warn the Plaintiff and Class Members of the serious complications and problems that would ensue with the use of Levaquin. These individuals were not given warning or, in the alternative, clear, complete and current warning of the health risks associated with the ingestion of Levaquin.

30) ~~31)~~—The Plaintiff and Class Members further allege that they and many other individuals have sustained physical, mental, and economic harm through the use of Levaquin as a result of the wholly and grossly negligent actions of the Defendants.

31) ~~32)~~—The Plaintiff and Class Members further allege that the Defendants failed and/or chose not to adequately inform both users of Levaquin and the doctors who prescribed the medication of the very serious risks associated with Levaquin.

32) ~~33)~~—Levaquin has caused damage to the physical and mental health of the Plaintiff and Class Members.

33) ~~34)~~—The Plaintiff alleges on behalf of Class Members that the continued use of Levaquin by Class Members creates ongoing risks to the health of the Class Members.

34) ~~35)~~—During the applicable times within the Class Period while the Defendants were involved with researching, developing, designing, testing, manufacturing, distributing, packaging, promoting, and/or marketing of

Levaquin, they knew or ought to have known of the potential safety risks associated with the drug.

35) ~~36)~~—None of the Defendants took any steps to prevent harm to the Plaintiff and the Class Members or to protect the health and safety of the Plaintiff and Class Members.

~~36)~~ ~~37)~~—Class Members have been prescribed and continue to be prescribed Levaquin.

V. HARM TO THE PLAINTIFF

~~37)~~ ~~38)~~—Marion Michelle Gowanlock was initially prescribed six Levaquin pills by her health care practitioner on February 17, 2003.

~~38)~~ ~~39)~~—Ms. Gowanlock justifiably relied on or was induced by the misrepresentations and active concealment of the Defendants to purchase and consume Levaquin to the detriment of her health and safety.

~~39)~~ ~~40)~~—Beginning on February 17, 2003, Ms. Gowanlock ingested the first of the six pills.

~~40)~~ ~~41)~~—Ms. Gowanlock ingested one pill every twenty-four hours, as was prescribed.

~~41)~~ ~~42)~~—On the fourth day, Ms. Gowanlock ingested the fourth pill; and subsequently, she developed a severe headache.

~~42)~~ ~~43)~~—Ms. Gowanlock immediately discontinued the Levaquin prescription.

~~43)~~ ~~44)~~—Soon thereafter, Ms. Gowanlock began experiencing pains in her right shoulder.

~~44)~~ ~~45)~~—On November 6, 2003, Ms. Gowanlock was diagnosed with rotator cuff tendinitis on the left.

~~45)~~ ~~46)~~—On February 1, 2010, an ultrasound of Ms. Gowanlock's right shoulder revealed an 8 mm tear in Ms. Gowanlock's supraspinatous tendon.

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~~46)~~ ~~47)~~—Ms. Gowanlock claims that the personal injuries were caused or materially contributed to by the use of Levaquin.

~~47)~~ ~~48)~~—The Plaintiff and Class Members have suffered and continue to suffer from anxiety about their own and their family's health because of the effect that Levaquin has had on their lives. The Plaintiff states that all of the Defendants bear the responsibility to, inter alia, create a medical monitoring fund/mechanism as described below.

VI. CAUSES OF ACTION

(A) Conspiracy

48) ~~49)~~ During the class period, the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking bona fides, conspired and agreed together, the one with the other and with persons unknown, as hereinafter set out.

49) ~~50)~~ The Plaintiff pleads that the Defendants' conspiracy involved both lawful and unlawful means with the predominant purpose of causing the Plaintiff and the other Injury Class Members to acquire and ingest Levaquin when they knew or should have known that such use would cause harm to the Injury Class Members and the Family Class Members.

50) ~~51)~~ The Defendants conspired with each other and others to unlawfully market, distribute, advertise and sell Levaquin, intending that their conduct be directed toward the Injury Class Members, when they knew or should have known that in the circumstances, injury and damage to the Injury Class Members and the Family Class Members was likely to result. They derived substantial compensation and revenues from the conspiracy.

51) ~~52)~~ —As a result of the conspiracy, the Plaintiff and the other Injury Class Members have suffered damage and loss, including other side effects as a result of the use of Levaquin.

52) ~~53)~~ As a further result of the conspiracy, Family Class Members have suffered damages and loss, and continue to suffer damages and loss, including actual

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expenses reasonably incurred for the benefit of the Injury Class Member, a reasonable allowance for loss of income or the value of services provided to the Injury Class Member and an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Injury Class Member.

53) ~~54)~~ —Some, but not all, of the Defendants' concerns, motivations and intentions in engaging in the conspiracy were to:

- (a) increase the sales of Levaquin and their profits;
- (b) increase or hold their market share;

- (c) avoid adverse publicity;
- (d) place their profits above the safety of Injury Class Members and others;
- (e) maintain brand trust and corporate image;
- (f) avoid alerting the Injury Class Members, Health Canada, the FDA, health practitioners, the public and their competitors to the dangerous properties and effects of Levaquin; and
- (g) cause the Injury Class Members to ingest and continue to ingest Levaquin and thereby suffer harm.

In furtherance of the conspiracy, the following are some, but not all, of the acts carried out by the Defendants or one or some of them:

- (a) they submitted false, inaccurate and/or misleading information to Health Canada for the purpose of obtaining approval to market Levaquin in Canada;
- (b) they concealed and disguised information about the dangerous properties and effect of Levaquin from Health Canada, from health practitioners and from Injury Class Members;

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- (c) they misled Injury Class Members, health practitioners and others about the safety and effect of Levaquin;
- (d) they refused to issue correcting information or to stop selling Levaquin even after its harmful effects became manifest;
- (e) they decided not to warn Class Members and others in Canada of the dangers of taking Levaquin; and
- (f) they developed and used marketing and promotional strategies that covered up the truth about Levaquin's dangerous properties and effect.

(B) Negligence

54) ~~55)~~ Each of the Defendants owed a duty of care to the Plaintiff and Class

Members and breached the requisite standard of conduct expected of them in the circumstances.

55) ~~56)~~The Defendants negligently breached their duty of care in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that they, directly and indirectly, advertised, marketed and promoted Levaquin for the treatment of bacterial infections, even though Levaquin, in fact, was a danger to the public. Furthermore, the Defendants failed to adequately warn of the increased risk of serious injury, which the Defendants knew or should have known about.

56) ~~57)~~The Plaintiff and Class Members state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following, that the Defendants jointly and severally:

(a) chose not to ensure that Levaquin was not dangerous to recipients during the course of its use and that the drug was fit for its intended or reasonably foreseeable use;

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(b) chose to inadequately test Levaquin in a manner that concealed the magnitude of the risks associated with its use, including but not limited to the risk of serious tendon ruptures;

(c) misinformed Health Canada by providing it with incomplete and/or inaccurate information;

(d) conducted inadequate or no follow-up studies on the efficacy and safety of Levaquin;

(e) concealed and mislead the Plaintiff, Class Members and their physicians with inadequate and/or incomplete warning of the risks associated with ingesting Levaquin;

(f) provided the Plaintiff, Class Members and their physicians with inadequate or incomplete or no information and warnings respecting the correct usage of Levaquin;

(g) provided inadequate or incomplete or no updated and current

information to the Plaintiff, Class Members and their physicians respecting the risks of Levaquin as it came available from time to time;

- (h) chose not to provide clear and adequate warnings of the potential hazards of ingesting Levaquin on package labels and by other means;
- (i) chose not to provide clear and adequate warnings of the risks associated with Levaquin on the customer information pamphlets in Canada;
- (j) chose not to warn the Plaintiff, Class Members, and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of serious problems from the use of Levaquin;
- (k) after noticing problems with Levaquin, chose not to issue adequate warnings, recall the drug in a timely manner, publicize the problem

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and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff, Class Members and their physicians of the drug's inherent dangers;

- (l) engaged in a system of improper and inadequate direction to their sales representatives and prescribing physicians respecting the correct usage of Levaquin and the risks associated with the drug;
- (m) represented that Levaquin was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
- (n) misrepresented the state of research, opinion, and medical literature pertaining to the purported benefits of Levaquin and its associated risks;
- (o) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known to the Defendants;
- (p) continued to manufacture, market, and promote the selling and/or distribution of Levaquin when they knew or ought to have known that this drug caused or could cause serious problems;

- (q) actively encouraged aggressive dispensation of Levaquin;
- (r) breached other duties of care to the Plaintiff and the Class Members, details of which breaches are known only to the Defendants.

(C) Strict Liability

57) ~~58)~~—The Defendants are strictly liable for some or all of the damages suffered by the Plaintiff and other Class Members in that:

- (a) the Defendants manufactured Levaquin;
- (b) Levaquin is a prescription drug that is considered to be inherently dangerous;

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(c) the Plaintiff and other Class Members had no opportunity to inspect or test Levaquin to ensure its safety; and

(d) Levaquin was used by the Plaintiff and other Class Members.

(D) Breach of Warranty

58) ~~59)~~—The Defendants warranted to the Plaintiff and the Class Members that Levaquin was of merchantable quality and fit for use and safe for human consumption. The Defendants breached the warranty to the Plaintiff and the Class Members by researching, developing, designing, testing, manufacturing, distributing, packaging, promoting, marketing and/or selling Levaquin which was inherently dangerous to users and which the Defendants knew or ought to have known would lead to serious injuries.

(E) Waiver of Tort

59) ~~60)~~—As a result of the Defendants' conduct described herein, the Plaintiff and Class Members reserve the right to elect at the trial of the common issues to waive the torts and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, or the net income received by the Defendants or a percent of the proceeds from the sale of Levaquin as a result of the Defendants' conduct.

60) ~~61)~~—The Plaintiff and Class Members claim that such an election is appropriate for the following reasons, among others:

- (a) revenue was acquired in a manner in which 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) absent the Defendants' tortious conduct, Levaquin could not have been marketed nor would the Defendants have received any revenue from its sale in Canada; and

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- (d) the Defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the potential to cause serious risk of injury.

(F) Breach of Section 52 of the *Competition Act*, R.S. 1985, c. C-34

~~61) 62)~~—The Defendants knowingly or recklessly made material false representations to the Plaintiff and Class Members for the purposes of promotion the supply and use of Levaquin.

(G) Breach of the Food and Drugs Act, R.S. 1985, c. F-27

~~62) 68)~~The Defendants engaged in unfair trade practices and specifically declared unlawful under ss. 3 and 9 of the FDA. Such practices included making false or misleading representations or advertisements, knowingly or with reason to know, as to the characteristics of Levaquin.

(H) Unjust Enrichment

~~63) 69)~~—The Defendants voluntarily accepted and retained profits and benefits, derived from the Plaintiff and Class Members, with full knowledge and awareness that, as a result of their conscious and intentional wrongdoings, Plaintiff and Class Members did not receive a product of the quality, nature or fitness that had been represented by the Defendants or that Plaintiff and Class Members, as a reasonable consumer, expected.

~~64) 70)~~—By virtue of the conscious wrongdoings alleged, the Defendants have been unjustly enriched at the expense of the Plaintiff and Class Members.

VII. DAMAGES

~~65) 71)~~The Plaintiff's and Class Members' injuries and damages were caused by the

Defendants, their servants, and agents.

~~66) 72)~~The Defendants have caused injury to the Plaintiff and to the Class Members including:

(a) a reduced standard of living as a result of injury;

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(b) the cost of treatment to combat the adverse health effects caused by their use of Levaquin; and

(c) an enhanced risk of future problems attributable to the use of Levaquin.

~~67) 73)~~As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiff and Class Members have been placed in a position where they have sustained or will sustain serious personal injuries and damages.

~~68) 74)~~As a result of the conduct of the Defendants, the Plaintiff, and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

~~69) 75)~~Some of the expenses related to the medical treatment that the Plaintiff and Class Members have undergone, and will continue to undergo have been borne by provincial health insurer including the Nova Scotia Medical Services Insurance Plan. As a result of the negligence of the Defendants, the provincial health insurer has suffered and will continue to suffer damages.

(A) Manifest Harm and Injuries:

~~70) 76)~~In addition, the past and ongoing use of Levaquin has resulted in the Plaintiff and Class Members' physical and mental health injuries pleaded above, and has further led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, and out of pocket expenses.

~~71) 77)~~The Plaintiff and Class Members assert a claim for each of the types of damages listed above.

(B) Medical Monitoring: Responding To Material Risk Of Illness

72) ~~78)~~ Further, the past and ongoing use of Levaquin has also caused or materially contributed to increased health risks to the Plaintiff and other Class Members. As a result of the use, the Plaintiff and Class Members have

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already and will continue to experience illness, anxiety, loss of amenities and enjoyment of life.

73) ~~79)~~ There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will detect at an early stage the serious problems which may result from the use of Levaquin by the Class Members. However, not all of these tests are generally available or being administered to the Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm therefrom.

74) ~~80)~~ The Class Members seek to recover damages in the form of the total funds required to establish a 'medical monitoring' process to be made available to the Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Class Members.

75) ~~81)~~ The damages referred to above may have been incurred directly by the Plaintiff and Class Members, or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.

76) ~~82)~~ The Plaintiff further allege that the establishment of a medical monitoring process is a necessary and appropriate step for all of the Defendants to take in the course of fulfilling their obligation to minimize the damages suffered by Class Members.

VIII. AGGRAVATED, PUNITIVE AND EXEMPLARY DAMAGES

77) ~~83)~~ The Defendants designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labelled, and sold Levaquin with full knowledge of the fact that they were adversely impacting the physical and psychological health of the Plaintiff and the Class Members. Knowledge of the risks associated with the use of Levaquin was not released to the Plaintiff and Class Members. Despite having specific information that the Plaintiff and Class Members were at risk of serious problems associated with the use of Levaquin, the Defendants

continued or permitted the continuation of the designing, developing, manufacturing, testing, packaging, promoting,

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marketing, distributing, labelling, and selling of Levaquin without any or reasonable controls.

78) ~~84)~~—These activities were carried out with reckless, callous, and wanton disregard for the health, safety and pecuniary interests of the Plaintiff and other Class Members. The Defendants knowingly compromised the interests of the Plaintiff and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that Levaquin posed to the Plaintiff and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.

79) ~~85)~~—The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety or welfare of the Plaintiff and Class Members.

80) ~~86)~~—Consequently, the Plaintiff and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.

81) ~~87)~~—The Plaintiff and Class Members plead that, by virtue of the acts described herein, the Defendants are liable to them in damages. Each of the Defendants is vicariously liable for the acts and omissions of the others for the following reasons:

- (a) each was the agent of the other;
- (b) each Defendants' business was operated so that it was inextricably interwoven with the business of the other;
- (c) each Defendant entered into a common advertising and business plan with the other to distribute and sell Levaquin;
- (d) each Defendant owed a duty to the other and to the Plaintiff and Class Members by virtue of the common business plan to distribute and sell Levaquin; and

- (e) each Defendant intended that the businesses be run as one global business organization.

IX. GENERAL PROVISIONS

~~82)~~ ~~88)~~—The Plaintiff states that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiff and other Class Members.

~~83)~~ ~~89)~~—The Plaintiff pleads the doctrine of respondeat superior and states that the Defendants are vicariously liable to the Plaintiff and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub- contractors, agents, servants, employees, assigns, appointees and partners.

~~84)~~ ~~90)~~—The Plaintiff pleads and relies on the Canada *Food and Drugs Act*, R.S. 1985, c. F-27, the Canada *Competition Act*, R.S., 1985, c. C-34, s. 1; R.S., 1985, c. 19 (2nd Supp.), s. 19, the Nova Scotia *Tortfeasors Act*, R.S.N.S., c. 471, the Nova Scotia *Sale of Goods Act*, R.S., c. 408, s. 1, the Nova Scotia *Consumer Protection Act*, R.S., c. 92, s. 1.

X. RELIEF SOUGHT

~~85)~~ ~~91)~~—The Plaintiff repeats the foregoing paragraphs and states that the Defendants are jointly and severally liable for the following:

- (a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;
- (b) general damages, including aggravated damages for personal injuries;
- (c) special damages for medical expenses and other expenses related to the use of Levaquin;
- (d) aggravated, punitive and exemplary damages;
- (e) further or alternatively the Plaintiff claims, on her own behalf and on behalf of the Class Members:

- (i) a declaration that the benefits which accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;
 - (ii) an accounting of the benefits which accrued to the Defendants as a result of their wrongful acts;
 - (iii) a declaration that the Defendants hold in trust for the Class the benefits which accrued to the Defendants as a result of their wrongful acts;
 - (iv) disgorgement of the benefits which accrued to the Defendants as a result of their wrongful acts;
 - (f) damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Class Members, and to make recommendations about their treatment;
 - (g) subrogated claims on behalf of the Provincial providers of medical services;
 - (h) interest pursuant to the Judicature Act;
 - (i) costs; and
- (j) such further and other relief as this Honourable Court deems just. PLACE OF TRIAL:

Halifax, Nova Scotia

DATED at Halifax, Nova Scotia this day of , 2010.



RAYMOND F. WAGNER
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