Court file # 01-GD-51928

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN

AHMAD SERHAN and BEVERLEY GAGNON

Plaintiffs

and

JOHNSON & JOHNSON,
LIFESCAN CANADA LTD. and LIFESCAN, INC.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

AMENDED

STATEMENT OF CLAIM

TO THE DEFENDANT(S)

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff(s). The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff(s) lawyer(s) or, where the plaintiff(s) do(es) not have a lawyer, serve it on the plaintiff(s), and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure.

Amended this 10th day of December 2003 pursuant to the Rule 26.02(A) registrar at Windsor per.

This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date: AUG - 9 2001

Issued by:

Address of Court

245 Windsor Avenue
Windsor ON N9A 1J2

TO:
JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, New Jersey
08933-7001

AND TO:
LIFESCAN CANADA LTD.
234-4170 Still Creek Drive
Burnaby, British Columbia
V5C 6C6

AND TO:
LIFESCAN, INC.
1000 Gibraltar Drive
Milpitas, California
95035

CLAIM

DEFINED TERMS

1. The following terms used throughout this pleading have the following meanings:

(a) "*Act*" means the *Class Proceedings Act, 1992*, S.O. 1992, c. 6;

(b) **"Associated Paraphernalia"** means the SureStep lancets and control solution sold by the Defendants for use in conjunction with the SureStep Meter and Strips;

(c) **"Class"** means:

(i) all persons in Ontario and elsewhere in Canada, except British Columbia and Quebec, who used a **SureStep Meter** on or after February 1, 1996; and

(ii) all persons in Ontario and elsewhere in Canada, except British Columbia and Quebec, who used a **Strip** on or after February 1, 1996;

(d) **"*Competition Act*"** means the *Competition Act*, R.S.C., 1985, c. C-34, as amended and all regulations thereunder;

(e) **"Defendants"** means, collectively, LifeScan, LifeScan Canada and Johnson & Johnson;

(f) **"Er-1 Defect"** means the software error in the SureStep Meter, as described in paragraph 39;

(g) **"FDA"** means the U.S. Federal Drug Administration;

(h) **"*Food and Drugs Act*"** means the *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended and all regulations thereunder, including the Medical Devices Regulations;

(i) **"Food, Drug and Cosmetic Act"** means the *Food, Drug and Cosmetic Act*, 21 U.S.C., as amended, and all regulations thereunder;

(j) **"Gagnon"** means the plaintiff, Beverley Gagnon;

(k) **"LifeScan"** means LifeScan, Inc.;

(l) **"LifeScan Canada"** means LifeScan Canada Ltd.;

(m) **"MDR"** means the Medical Device Report to the FDA;

(n) **"Partial Strip Insertion Defect"** means the mismatch between the size of the holes in the **Strip** holder and the size of the holes in the **Strip** as described in paragraph 41;

(o) **"Representation"** means the representation made by the Defendants expressly and impliedly that the **SureStep Meter** and the **Strips** were each fit to measure blood glucose levels and free from known defects;

(p) **"Serhan"** means the plaintiff, Ahmad Serhan;

(q) **"Strip"** means a SureStep test strip manufactured before March 1, 1998 and distributed on or after February 1, 1996; and

(r) **"SureStep Meter"** means a SureStep blood glucose meter manufactured before August 1, 1997, bearing a serial number the first five digits of which were in the series L6000 to L7205 or a serial number in the series L7206-GA-00001 to L7206-GA-01128.

RELIEF CLAIMED

2. SERHAN AND GAGNON CLAIM on their own behalf and on behalf of the Class:

(a) an order pursuant to the *Act* certifying this proceeding as a class proceeding and appointing them as representative plaintiffs;

(b) a declaration that the Defendants owed a duty of care to the plaintiffs and to the other Class members;

(c) a declaration that the Defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the SureStep Meter and Strips and are liable for damages;

(d) a declaration that the Defendants made the Representation negligently or fraudulently, knowing it was false and misleading, or recklessly, caring

not whether it was true or false, intending the Class members to rely upon the Representation and they did so to their detriment and that the Defendants are thereby liable for the damages which resulted;

(e) a declaration that the Representation made by the Defendants to the public for the purpose of promoting and selling a product breached s. 52(1) of the *Competition Act* and that the Defendants are thereby liable for damages pursuant to s. 36 of the *Competition Act*;

(f) a declaration that the Defendants' officers, directors, servants, agents and employees conspired among themselves and with others, as hereinafter particularized and that, as a result, the Defendants are liable in damages;

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

(h) a declaration that the Defendants hold all of the revenue generated from the sale of the SureStep Meter and Strips and Associated Paraphernalia in a constructive trust for the benefit of the plaintiffs and the other Class members;

(i) an accounting and an order requiring disgorgement of all revenue derived by the Defendants from the sale of the SureStep Meter, Strips and Associated Paraphernalia;

(j) special damages, general damages and punitive damages, including the costs of administering the plan of distribution of the recovery in this action, in the sum of $500,000,000 or such further sum as this Honourable Court may find appropriate;

(k) a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

(l) prejudgment and postjudgment interest pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C-43, s. 128 and 129;

(m) costs of this action pursuant to the *Act* and to s. 36 of the *Competition Act* as between a solicitor and his own client, including applicable taxes; and

(n) such further and other relief as to this Honourable Court seems just.

THE NATURE OF THIS ACTION

3. The Defendants designed and marketed the SureStep Meter and Strips to be used by diabetics, and specifically the testing challenged users, to accurately monitor their blood glucose levels at home. The Defendants marketed the SureStep Meter and Strips through a distribution network, including pharmacies and hospitals.

4. This action concerns the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the SureStep Meter and Strips, and the failure of the Defendants to report significant defects in the SureStep Meter and Strips to regulatory authorities and to disclose defects known to them to the public.

5. Before marketing the SureStep Meter in February 1996, the Defendants knew that it was materially defective in that a software error in the SureStep Meter caused it to give an "Er-1" or error message instead of a "HI" (high) message when a user's blood glucose level exceeded 500 ~~millimoles~~ milligrams per decilitre ("~~mmol/L~~mg/dL") ~~or 26 milligrams per decilitre ("mg/dL")~~. So, too, the Defendants knew, before marketing the Strips in February 1996, that they were materially defective because a design defect in the Strips generated false low glucose level readings when a Strip was not fully inserted into the SureStep Meter.

6. In the development stage of the SureStep Meter and the Strips, before obtaining regulatory approval and for at least one-and-a-half years after bringing the SureStep Meter and Strips to market, the Defendants intentionally chose not to rectify

the defects. In late July 1997, LifeScan corrected the software defect in the SureStep Meter. Later in 1997, LifeScan also corrected the design flaw that caused the defect in the Strips, but it did not start to manufacture the redesigned Strips until March 1998. The Defendants recalled the SureStep Meters in June 1998 but did not recall the Strips.

7. The Defendants made the Representation that the SureStep Meter and Strips were each fit to measure blood glucose levels and free from known defects. They made this Representation to the FDA and to Health Canada in order to obtain regulatory approval for the SureStep Meter and Strips. They made this Representation knowing it to be false and misleading in a material respect. Having made this Representation to the FDA and Health Canada, the Defendants continued to make it throughout at least 1996, 1997 and 1998 to keep the SureStep Meter and Strips in the marketplace.

8. The Defendants also made the Representation to the plaintiffs and to the other Class members. The Defendants intended to have the Class members rely on the Representation, and the Class members did so to their detriment.

9. Because of the defects present in the SureStep Meter and Strips, their use in measuring diabetics' blood glucose levels could produce grossly inaccurate results. The plaintiffs plead that the SureStep Meter and Strips were dangerously defective devices which could cause personal injury, even death.

THE PLAINTIFFS

10. Serhan is a 53-year-old father of six who resides in the City of Windsor. He is a diabetic. Between October 1997 and 1998 or 1999, he used a SureStep Meter bearing serial number L7111-GA-00871. He also used Strips and Associated Paraphernalia since October 1997.

11. Serhan used the SureStep Meter and Strips to check his blood glucose levels twice daily. By his conduct alone he relied upon the Representation. On at least one occasion, Serhan obtained an Er-1 message when he knew his blood glucose level was high. On many other occasions he obtained low glucose readings at least some of which he later determined to be false on the basis of accurate testing at his physician's office. As a result of the Er-1 messages and low glucose readings, Serhan had to retest, meaning that he had to use additional Strips and Associated Paraphernalia and that he had to repuncture a finger with a lancet to draw additional blood samples, a process which, each time, caused him pain and suffering.

12. Gagnon is 61 and resides in the City of Windsor. She is a diabetic. She began using Strips as well as Associated Paraphernalia in or about 1998. Gagnon used the Strips to check her blood glucose levels twice daily. By her conduct, she too relied upon the Representation. Gagnon experienced false low glucose readings. As a result of these readings, she had to retest, meaning that she had to use additional Strips and Associated Paraphernalia and that she had to repuncture a finger with a lancet to draw additional blood samples, a process which, each time, caused her pain and suffering.

THE DEFENDANTS

13. LifeScan Canada was incorporated under the laws of the Province of British Columbia on November 19, 1982 and has its head office in Burnaby, British Columbia. It is a wholly-owned subsidiary of LifeScan. At all material times, LifeScan Canada advertised, marketed and distributed the SureStep Meter and Strips in Ontario and elsewhere in Canada.

14. LifeScan is incorporated under the laws of the State of California. LifeScan's headquarters and manufacturing facilities are located in Milpitas, California. It is a wholly-owned subsidiary of Johnson & Johnson. At all material times, LifeScan designed, developed, tested, manufactured, licensed, assembled, distributed, marketed and sold the SureStep Meter and Strips in Ontario and elsewhere in Canada.

15. Johnson & Johnson is a corporation organized under the laws of New Jersey, with its headquarters located at One Johnson & Johnson Plaza in New Brunswick, New Jersey. Johnson & Johnson took over LifeScan in 1986 and, since then, has operated it as a wholly-owned subsidiary.

16. Johnson & Johnson and LifeScan are the leading manufacturers of blood glucose monitors in North America. LifeScan is one of Johnson & Johnson's most profitable businesses. It generates over $1 billion US in revenue a year. In 1998,

Johnson & Johnson recorded global sales of $23.7 billion US and net earnings of $3.7 billion US.

17. At all material times, each of the Defendants was the agent of the others and each is vicariously responsible for the acts and omissions of the others as particularized herein.

CORPORATE ORGANIZATION OF THE JOHNSON & JOHNSON FAMILY OF COMPANIES

18. Johnson & Johnson is a conglomerate consisting of almost 200 operating companies manufacturing health products for distribution throughout the world, including Ontario and the rest of Canada. Johnson & Johnson owns, in whole or in part, all of the operating companies and exercises effective and actual control and management of their businesses, including the businesses of LifeScan and LifeScan Canada.

19. Johnson & Johnson is a household name in Ontario and the rest of Canada in the area of health care and related products. Products manufactured by Johnson & Johnson and/or its subsidiaries are sold in Ontario and elsewhere in Canada. Consumers in Ontario purchase products associated with the name Johnson & Johnson because Johnson & Johnson has substantial brand-name recognition in Ontario and elsewhere in Canada.

20. Johnson & Johnson has subsidiaries in Ontario, including DePuy Canada Ltd., Mississauga; Janssen-Ortho Inc., North York; McNeil Consumer Products, Guelph; and Ortho-Chemical Diagnostics, Mississauga. Johnson & Johnson receives dividend income from Ontario, owns patents for products sold in Ontario, and advertises in Ontario.

21. Johnson & Johnson is organized in such a way that the Defendants function as an ongoing, organized and continuing business unit sharing common purposes and objectives.

22. Since its takeover of LifeScan in 1986, Johnson & Johnson has operated LifeScan as if it were not a separate corporation but rather as if it were functionally part of Johnson & Johnson. Johnson & Johnson has directly controlled the day-to-day operations of LifeScan through the direction of its Executive Committee and its Professional Group Operating Committee (the "Professional Group"). The Executive Committee is the principal management group of Johnson & Johnson. The Professional Group is comprised of managers who represent, oversee, direct, manage and coordinate key operations within the professional segment of Johnson & Johnson's business including the businesses of LifeScan and LifeScan Canada. The professional segment includes medical equipment and devices, including LifeScan's blood glucose monitoring systems.

23. The president of LifeScan Canada reports directly to the management of LifeScan. In turn, the president of LifeScan reports directly to the Chairman of the

Professional Group who is employed by Johnson & Johnson and who sits on the Executive Committee. As a result of this relationship, LifeScan reported to and took direction from Johnson & Johnson on all matters relating to the SureStep Meter and Strips.

24. At all material times, LifeScan Canada, LifeScan and Johnson & Johnson shared the common purpose of designing, developing, testing, manufacturing, licensing, assembling, distributing, marketing and selling blood glucose monitoring systems for profit. In particular:

(a) Johnson & Johnson provided executive services to its co-Defendants such as a preferred rate mortgage program and relocation services;

(b) a representative from the Johnson & Johnson law department met with the FDA with respect to interpretation of MDR regulations, among other matters;

(c) Johnson & Johnson's corporate counsel was copied on LifeScan correspondence with the FDA;

(d) Johnson & Johnson's regulatory lawyers were involved in deciding whether MDR's should be filed and in deciding not to file MDRs relating to the SureStep Meter and Strips;

(e) Johnson & Johnson established a council of research directors of its companies which met at least once a year; and

(f) Johnson & Johnson's legal department reviewed all labeling changes and were involved in advertising approval for LifeScan products.

25. LifeScan Canada, LifeScan and Johnson & Johnson also shared the common purpose of concealing the defects of the SureStep Meter and Strips from both regulatory authorities and Class members. Pursuant to the organizational structure described above, employees of LifeScan Canada reported the defects in the SureStep

Meter and Strips to LifeScan, and employees of LifeScan reported the defects to Johnson & Johnson, which directed, acquiesced in and approved LifeScan's decision to conceal the defects, to refrain from correcting the defects in a timely manner and to make the Representation. For example, Johnson & Johnson's corporate attorney and a member of its regulatory staff participated in LifeScan's regulatory action committee meetings held in July and October of 1997 when, on both occasions, a decision was made not to initiate a voluntary recall of the SureStep Meter.

26. Johnson & Johnson, therefore, is liable for the acts and omissions of its subsidiaries, LifeScan and LifeScan Canada, because:

(a) it operated itself, LifeScan and LifeScan Canada as a single entity;

(b) it prepared its financial statements on a consolidated basis and reported profits from the sale of the SureStep Meter and Strips;

(c) it associated its name with the SureStep Meter and Strips on all packaging and in all promotional material;

(d) it owns the SureStep trademark;

(e) it controlled, through the Professional Group and Executive Committee, the day-to-day operations of LifeScan and LifeScan Canada;

(f) the employees, officers and directors of LifeScan Canada and LifeScan reported consumer complaints and the defects with the SureStep Meter and Strips to Johnson & Johnson and looked to Johnson & Johnson to give them directions and Johnson & Johnson gave them directions to make the Representation; and

(g) it conspired with LifeScan and LifeScan Canada as particularized herein.

27. LifeScan is liable for the acts and omissions of its subsidiary, LifeScan Canada, because:

(a) LifeScan Canada's president reported directly to LifeScan management;

(b) LifeScan Canada's employees, officers and directors reported Canadian consumer complaints and defects with the SureStep Meter and Strips to LifeScan;

(c) LifeScan owns the patent rights to various material elements of the SureStep Meter and Strips; and

(d) it conspired with LifeScan Canada and Johnson & Johnson to market the SureStep Meter and Strips and to make the Representation.

DIABETES–THE DISEASE AND ITS MANAGEMENT

28. Diabetes is the seventh leading cause of death in Canada.

29. According to the Canadian Diabetes Association, approximately 2,000,000 Canadians are afflicted with the disease. Although the elderly comprise the largest proportion of the diabetic population, approximately 10% of diabetics are children and adolescents and that number is growing.

30. Diabetes is a chronic disorder in which the body fails to keep blood sugar, glucose, at normal levels because the body lacks the hormone insulin or because it is unable to use it correctly. The build-up of glucose in the blood produces diabetes. As glucose levels rise, so too do the immediate dangers of hyperglycemia, high blood sugar, and ketoacidosis, a build-up of ketones in blood that can lead to diabetic coma, even sudden death.

31. Over the long term, consistently high glucose levels can harm many organs and cause hypertension, blood vessel disorders, cardiovascular disease, blindness, kidney failure, and death.

32. Diabetes has no cure. So frequent self-monitoring of glucose levels and tight glucose control are essential to the management of the disease and to the lessening of its attendant health risks. By tracking their glucose levels throughout the day, diabetics know when to give themselves insulin and in what amounts. They rely heavily, therefore, on home glucose monitors for the effective management of their disease and the avoidance of potentially life threatening diabetes-related health complications. The consequences to diabetics of inaccurate blood glucose level readings can be lethal.

HOME GLUCOSE MONITORS

33. Before the invention of blood glucose meters, diabetics tested their blood glucose levels by taking urine samples and wetting strips of chemically treated paper. The method was not only inconvenient, but it also produced inconsistent, inaccurate results.

34. With the introduction of glucose meters, however, self-monitoring was revolutionized. Using a lancet, diabetics draw a drop of blood and apply it to a chemically treated melinex test strip. The diabetic then inserts the test strip into the meter, which displays the glucose level reading on a liquid crystal display. The glucose

levels can be measured either in millimoles per liter (mmol/L) or in milligrams per deciliter (mg/dL) units of measurement.

35. LifeScan pioneered a new era of blood glucose monitoring with the introduction of technology that eliminated the need to wipe blood on a strip and to time the procedure. LifeScan is a world leader in blood glucose monitoring and marketed itself as the brand most recommended by doctors, hospitals and diabetic counsellors.

36. In February 1996, the Defendants launched the SureStep Meter and Strips in Canada. The Defendants participated in the preparation, approval and dissemination of the regulatory submissions, product packaging, promotional and advertising material, all of which contained the Representation that the SureStep Meter and Strips were each fit to measure blood glucose levels and free from known defects.

37. The Defendants designed, developed, tested, manufactured, licensed, assembled, distributed, marketed and sold millions of test Strips and hundreds of thousands of SureStep Meters under or in conjunction with:

(a) the name "SureStep";
(b) the name "LifeScan, a Johnson & Johnson company"; and
(c) the trademark SureStep which is owned by Johnson & Johnson.

THE DEFECTS IN THE SURESTEP METER AND STRIPS

38. From their inception, the SureStep Meter and Strips were materially defective.

39. The defect in the SureStep Meter involved a software error that caused an incorrect "Er-1" error message, instead of a "HI" high message, to appear on the SureStep Meter when the user's blood glucose level:

(a) was between 500 and 600 mg/dL with a low hematocrit;

(b) was over 600 mg/dL regardless of hematocrit; and

(c) was over 400 mg/dL and the Strip was inserted more than 90 seconds after the application of blood to the Strip. The labeling stated that the user had up to 2 minutes to insert the Strip.

According to the owner's manual, an "Er-1" reading signified an improper sample application but not a high glucose level. A person with blood glucose levels in the range of 500 mg/dL or higher is in a severe hyperglycemic state, and requires immediate lowering of glucose levels. Failing such corrective action, users are at risk of ~~diabetic coma, renal failure and toxic shock~~ diabetic ketoacidosis or hyperglycemic-hyperosmoler non-ketosis. The risk of death from the former is 5-10% and from the latter is 16-60%.

40. *Approximately* ~~290,000~~ 300.000 *SureStep Meters with the Er-1 Defect* were manufactured and distributed by the Defendants in the U.S., Canada and elsewhere.

41. The defect in the Strips was the result of a design flaw, namely, a mismatch between the size of the holes in the Strip holder and the size of the holes in the Strip. The defect manifested itself when a Strip was not fully inserted into the SureStep Meter. According to the owner's manual, the SureStep Meter is supposed to warn the

user when he or she has not completely inserted the test Strip. The warning is necessary because diabetics, particularly the elderly, often suffer afflictions—shaky hands, blurred vision, or some other physical impairment—which make it difficult for them to insert the Strip fully. In fact, the SureStep Meter and Strips issued no such warning. Instead, when a Strip was partially inserted, the SureStep Meter merely displayed a false low glucose level, a reading which could be as low as 20% of the "true" value at high glucose levels. The Partial Strip Insertion Defect was potentially dangerous to users because it meant that a diabetic with high glucose levels would be unaware, having received a false low glucose reading, that corrective action should be taken immediately, and might even be led to increase his or her glucose levels.

42. Prior to the launch of the SureStep Meter, research and development scientists at LifeScan suggested that the Partial Strip Insertion Defect could be fixed by retooling the SureStep Meter. This fix was never implemented because the time needed to fix the problem would delay the launch of the product. Before March 1998, the Defendants manufactured millions of Strips with the Partial Strip Insertion Defect and distributed them throughout the U.S., Canada and elsewhere.

43. As early as 1993, the Defendants knew about the Er-1 Defect, and as early as May, 1994 they knew about the Partial Strip Insertion Defect. ~~for at least~~Therefore, the Defendants knew about the defects ~~several~~ years before they marketed the SureStep Meter and Strips and certainly before they applied to the FDA and to Health Canada for medical device approval. The Defendants knew that both defects could result in serious injury and death. LifeScan's own employees warned

management that incorrect readings had "the potential to create a life-threatening failure." and could potentially lead to an FDA-directed Class I recall of the SureStep product. Despite this knowledge and for purely economic reasons, the Defendants rejected the option of delaying introduction of the SureStep Meter and Strips. Had these defects been disclosed, the SureStep Meter and Strips could not and would not have been marketed.

44. Internal clinical tests by LifeScan in 1997 confirmed the existence of the Er-1 Defect and the Partial Strip Insertion Defect in the SureStep Meter and Strips. The Defendants failed to warn consumers and failed to report the defects to the FDA and to Health Canada in accordance with their statutory obligations. The Defendants rejected the option of recalling the defective SureStep Meters and Strips. Throughout, the Defendants were motivated solely by economic self-interest.

THE GUILTY PLEAS

45. On April 2, 1998, forty U.S. Federal agents raided and seized records from LifeScan's headquarters in Milpitas, California. Thereafter, for 2.5 years, the FDA, the Federal Bureau of Investigation, the Department of Health and Human Services, the Department of Justice and other U.S. Federal agencies investigated LifeScan.

46. On December 15, 2000, the U.S. government and LifeScan entered into a settlement agreement. LifeScan pleaded guilty to a number of criminal or quasi-criminal

or regulatory charges, including failure and refusal to furnish appropriate notifications and information to the FDA, and to the introduction into interstate commerce of a misbranded medical device. Pursuant to the settlement, LifeScan agreed, among other things, to pay $60 million US in criminal and civil fines for selling the defective SureStep Meter and Strips and for submitting false information about the defects to the FDA.

47. On December 15, 2000, LifeScan signed a plea agreement. Under the plea agreement, LifeScan admitted the following facts to be true:

(a) In or about 1993, it learned that its SureStep Meter and Strips were defective because the Meter sometimes displayed an "Er-1" message instead of a "HI" message if the user's blood glucose level exceeded 500 mg/dL and because partially inserted Strips would produce inaccurate low blood glucose readings;

(b) On or about May 23, 1994, LifeScan submitted an application to the FDA for approval to market the SureStep Meter and Strips to the public. In this application, LifeScan submitted labeling and supporting material that stated the SureStep Meter would display a "HI" message when blood glucose levels were above 500 mg/dL. The materials did not disclose that the SureStep Meter could generate an "Er-1" message at high glucose levels or false low readings if the Strips were not fully inserted;

(c) At the time that LifeScan began marketing the SureStep Meter and Strips in Canada in February 1996, it did not disclose the Er-1 Defect or the Partial Strip Insertion Defect to consumers in any of its packaging, labeling, manuals, advertisements or other material;

(d) In or about February 1997, LifeScan's Japanese affiliate notified LifeScan that consumers in Japan were receiving "Er-1" messages instead of "HI" messages at high blood glucose levels. LifeScan informed its Japanese affiliate that it did not consider this problem to constitute a health risk and would not recall the SureStep Meters;

(e) It was not until late July 1997 that LifeScan corrected the Er-1 Defect in all SureStep Meters manufactured after July 27, 1997. It was not until November 1997 that LifeScan began to include an explanatory insert in Strip packages which advised users that an "Er-1" message could indicate blood glucose levels exceeding 500 mg/dL. Consumers would

not have received this notice until they bought new Strips, and merchants continued selling old inventories of Strips as LifeScan intended;

(f) LifeScan did not recall the defective SureStep Meters until June 1998;

(g) LifeScan addressed the Partial Strip Insertion Defect in late 1997 by redesigning the Strips. The corrected strips were manufactured in March 1998 and thereafter, but LifeScan chose not to recall any of the older version of Strips and did not notify the FDA or consumers that incomplete strip insertion could generate false low readings;

(h) During 1996, 1997 and 1998, LifeScan received over 2,000 complaints of inaccurate low readings by its SureStep Meters, some of which were attributable to partial strip insertion, and over 700 complaints regarding "Er-1" readings, some of which were attributable to high blood glucose. LifeScan failed to report these complaints fully, truthfully and/or accurately to the FDA and dishonestly attributed failures of the SureStep Meter and Strips to users themselves who had suffered serious injury;

(i) LifeScan failed to file MDRs when it should have and knowingly submitted false, incomplete and/or misleading information in the reports it did file; and

(j) In May 1997, LifeScan's Director of Clinical Evaluations, a medical doctor, reviewed several consumer complaints received by LifeScan and advised his employer that the SureStep Meters should be immediately recalled because they posed an unacceptable risk of harm to the public. LifeScan rejected the Director's recommendation.

48. The plaintiffs plead that as a result of the admissions of LifeScan documented in the December 15, 2000 plea agreement, the Defendants are estopped in this action from challenging any of the facts admitted therein.

LIFESCAN CANADA'S ACTIONABLE CONDUCT

49. LifeScan Canada knew that the design of the SureStep Meter and Strips was flawed before it applied for a Medical Device Licence from Health Canada. Before it introduced the SureStep Meter and Strips to Canada in February 1996, LifeScan

Canada knew of both the Er-1 Defect and Partial Strip Insertion Defect but chose nevertheless to market and sell the SureStep Meter and Strips rather than delay their introduction in Ontario and elsewhere in Canada.

50. The Defendants marketed the SureStep Meter and Strips from their inception to the testing challenged users, namely, to children, to the elderly and to first-time users of blood glucose monitors.

51. Between 1996 and June 1998, LifeScan Canada received complaints from Canadian consumers about the Er-1 Defect and the Partial Strip Insertion Defect. In breach of its statutory obligations, LifeScan Canada failed to report these complaints to Health Canada. LifeScan Canada did not remedy the defects, or recall the SureStep Meter and Strips or warn Canadian consumers about the defects.

THE SALE AND RECALL OF THE SURESTEP METER AND STRIPS

52. The Defendants sold, delivered or caused to be delivered a SureStep Meter to the plaintiffs and to every other Class member in Ontario and elsewhere in Canada.

53. The Defendants sold Strips to the plaintiffs and to every other Class member in Ontario and elsewhere in Canada.

54. In or about June 1998, under the guise of a product replacement program, the Defendants initiated a North America-wide recall of the SureStep Meter because of the Er-1 Defect, thereby, by conduct, admitting that the SureStep Meters were defective.

55. This recall of the SureStep Meter was misleading because some diabetics, wholesalers and distributors did not realize that the product replacement was for a serious malfunction.

56. The FDA properly classified the recall of the SureStep Meters as Class I, the most serious and urgent type of recall, for situations in which there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

57. In the December 15, 2000 plea agreement, LifeScan admitted that the Strips manufactured before March 1998 were defective, yet it did not recall them.

THE CONSPIRACY

58. During the period from on or about January 1, 1993 to on or about June 30, 1998, at Burnaby, British Columbia; New Brunswick, New Jersey, Milpitas, California and elsewhere, 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 to:

(a) submit false, inaccurate and misleading information to Health Canada for the purpose of obtaining a Medical Device License in respect of the SureStep Meter and Strips;

(b) conceal the defects of the SureStep Meter and Strips, namely the Er-1 Defect and the Partial Strip Insertion Defect from the FDA, Health Canada and Class members;

(c) mislead Class members and others about the features, efficacy, safety and accuracy of the SureStep Meter and Strips;

(d) make the Representation to Class members and others that the SureStep Meter and Strips were each fit to measure blood glucose levels and free from known defects with the intent of inducing them to purchase, use and rely upon the SureStep Meter and Strips;

(e) delay the correction of the defects;

(f) hide the true causes of the Er-1 Defect and false low blood glucose readings;

(g) submit inaccurate, incomplete, false and/or misleading MDRs to the FDA and inaccurate, incomplete, false and/or misleading reports to Health Canada;

(h) delay the recall of the SureStep Meter;

(i) reject the recommendations of medical advisers employed by the Defendants and others to recall the SureStep Meter in 1996 and 1997;

(j) refuse to recall the defective Strips even after LifeScan had publicly acknowledged that they were defective; ~~and~~

(k) breach the provisions of the *Competition Act*, the *Food and Drugs Act*, and the *Food, Drug and Cosmetic Act*; and~~.~~

(l) to receive revenue from distributors who would sell or distribute SureStep Meters and Strips to Class members.

59. The Defendants were motivated to conspire and their predominant purposes and predominant concerns were:

(a) to increase their sales to distributors and profits arising from their distribution network's sales of SureStrip Meters and Strips to the Class members;

(b) to increase or hold their market share;

(c) to avoid adverse publicity;

(d) to place corporate profits above the safety of the Class members and others;

(e) to save the expense consequent upon the recall of the SureStep Meter and Strips in the hands of Class members of retooling manufacturing equipment to correct the defects and of recalling defective inventory from retailers.;

(f) to maintain and expand upon worldwide leadership in blood glucose monitoring;

(g) to leverage costs, expenses, alliances and its market leadership position to create a sustainable competitive advantage to offset the narrowing technology gap with its competitors;

(h) to maintain brand trust and corporate image;

(i) to reduce the number of MDR's filed with the FDA in order to:

(i) reduce the exposure to liability from lawyers seeking class action lawsuits; and

(ii) reduce the competitive disadvantage created by having more MDR's than its main competitor highlighted in trade publications;

(j) to avoid alerting their competitors to the defects; and

(k) to cause the Class members to purchase or acquire the SureStep Meter and purchase Strips.

60. The conspiracy was unlawful because the Defendants knowingly caused dangerously defective products to be marketed, failed to file timely or adequate MDRs with the FDA and engaged in the practice of false advertising.

61. The conspiracy was directed towards diabetics and potential users of the SureStep Meter and Strips, including the plaintiffs and the other Class members. The

Defendants knew in the circumstances that the conspiracy would likely cause injury and loss to the plaintiffs and the other Class members. The conspiracy caused injury and loss to the plaintiffs and the other Class members.

62. The acts particularized and alleged in this claim to have been done by each of the Defendants were authorized, ordered and done by each ~~d~~Defendant's officers, directors, agents, employees and representatives while engaged in the management, direction, control and transaction of its business affairs and are therefore acts and omissions for which the Defendants are vicariously liable.

THE DEFENDANTS' NEGLIGENCE

63. The Defendants owed a duty of care to the plaintiffs and the other Class members and breached the requisite standard of conduct expected of them in the circumstances.

64. The Defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the SureStep Meter and Strips. Particulars of some of the acts of negligence follow:

(a) they knew, from internal testing, as early as 1993—three years before marketing the SureStep Meter and Strips—of the Er-1 Defect and took no steps to remedy the defect;

(b) they knew, from internal testing, years before marketing the SureStep Meter and Strips of the Partial Strip Insertion Defect and took ~~no~~ steps to remedy it but did not implement the remedy prior to launch;

(c) they wrongfully and intentionally accepted the known risk of injury to a Class member as a result of the SureStep Meter's software problem, the Er-1 Defect and the Strip's design flaw, the Partial Strip Insertion Defect;

(d) they knew that the Er-1 Defect would occur when a Class member's blood glucose level: ~~exceeded 500 mg/dL~~

(i) was between 500 and 600 mg/dL with a low hematocrit;

(ii) was over 600 mg/dL regardless of hematocrit; and

(iii) was over 400 mg/dL and the Strip was inserted more than 90 seconds after the application of blood to the Strip.

and that, in such an event, the Class member would be misled as to his or her true glucose level and might fail to take immediate and appropriate corrective action;

(e) they failed to remedy the Er-1 Defect to eliminate this known risk and consciously accepted the risk of the Er-1 Defect occurring because they wrongfully concluded that the health risk associated with the defect was not severe enough to warrant a change in the software;

(f) they knew that the Partial Strip Insertion Defect would occur whenever a Class member incompletely inserted a Strip and that, in such an event, the Class member would be misled as to his or her true glucose level and might fail to take immediate or appropriate corrective action or might even take actions, such as ingesting food or taking insulin, that would elevate his or her already dangerously high blood glucose;

(g) they failed to remedy the design flaw that caused the Partial Strip Insertion Defect in spite of the foreseeable risks and consciously accepted the risks because they did not want to alert competitors to the defect by redesigning the Strips and because they wrongly concluded that the health risks associated with the defect were insufficient to warrant a change in the design of the Strips;

(h) they knew or ought to have known that the two defects in the SureStep Meter and Strips were hazardous to Class members because pre-market testing confirmed the software problem and design flaw, and their own medical experts warned of the potential catastrophic consequences to Class members;

(i) they failed to design a software program that would ensure blood glucose levels exceeding ~~5~~400 mg/dL generated a "HI" message and not an "Er-1" message;

(j) they failed to design a Strip that when partially inserted caused an insertion error message and not a false low blood glucose reading;

(k) they manufactured, licensed, assembled, distributed, marketed and sold the SureStep Meter and Strips knowing that they suffered from the defects described herein;

(l) they designed, developed, tested, manufactured, licensed, assembled, distributed, marketed and sold a defective SureStep Meter and Strips;

(m) they failed to warn the Class members of the dangers associated with the use of the SureStep Meter and Strips;

(n) they failed to warn Class members that an "Er-1" message could mean a blood glucose level of ~~5~~400 mg/dL or higher;

(o) they failed to warn Class members that partial strip insertion could generate a false low blood glucose level reading;

(p) they falsely represented that a "HI" message would appear when a user's blood glucose level was 500 mg/dL or higher and that an incomplete Strip insertion symbol would appear when a test Strip was partially inserted;

(q) they failed to change the design of the SureStep Meter's software and the design flaw of the Strip when they knew or ought to have known of the Er-1 Defect and the Partial Strip Insertion Defect;

(r) they failed to change their design, manufacturing and assembly process of the SureStep Meters and Strips in a reasonable and timely manner;

(s) they failed to include a warning that described the two defects on the SureStep Meter packaging, on the Strips packaging or in the owner's booklet;

(t) they failed to instruct their HelpLine employees to properly evaluate, record and advise on complaints of the defects;

(u) they encouraged their HelpLine employees to conceal the true causes of an "Er-1" message or a false low glucose level reading when communicating with Class members and others;

(v) they failed to accurately, candidly, promptly and truthfully disclose consumer complaints and SureStep Meter and Strips defects to Health Canada;

(w) they failed to initiate timely review, evaluation and investigation of the Er-1 Defect and the Partial Strip Insertion Defect following complaints of injury or death or hazard to safety;

(x) they failed to properly assess and investigate complaints adequately when they received them;

(y) they refrained from reporting the two defects to the FDA, Health Canada and Class members in order to maximize profits and retain market share;

(z) they refrained from recalling the Strips at the time of the SureStep Meter recall in order to use up existing inventory and thereby maximize profits and retain market share;

(aa) they failed to change the design, manufacture and assembly process of the Strip in a reasonable and timely manner because they required a compatible Strip to ensure continued sales of the SureStep Meter and replacement meters and because the greatest portion of their profits were derived from the sale of the Strips;

(bb) they failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and the *Food, Drug and Cosmetic Act*;

(cc) they hired incompetent personnel and appointed incompetent officers and directors;

(dd) they failed to instruct their servants, agents, officers and directors to act ethically and responsibly;

(ee) they failed to properly supervise their employees, their subsidiaries and affiliated corporations;

(ff) they encouraged their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and diabetic counsellors of the two defects; ~~and~~

(gg) they failed to recall the SureStep Meter and/or the Strips in a timely manner or at all because of the cost and the negative publicity~~.~~;

(hh) they failed to perform validation testing of the SureStep Meter before launch;

(ii) they categorized the Er-1 Defect as a low priority issue;

(jj) they knew that the low blood glucose readings caused by the Partial Insertion Defect were easily repeatable with certain techniques of strip insertion such as slower insertion rates, hesitant insertion, wet fingers and

a weak grip on the strip, all characteristics of the targeted consumer group of the testing challenged;

(kk) they rejected test data showing erroneous low blood glucose readings on the basis that the readings were due solely to user technique error and not a defect;

(ll) they failed to implement the modified software in the SureStep Meters when it became available in or about May, 1997;

(mm) they decided to exhaust the inventory of Strips prior to shipping modified strips;

(nn) they knew that while the probability of occurrence of the Partial Strip Insertion Defect might be low, the severity of the result was potentially very high; and

(oo) they knewwhen they inserted the explanatory insert about the Er-1 message in Strip packages that it could be as long as six months before some diabetics would need to purchase new Strips and would not become aware of the problem until that time had elapsed.

65. The plaintiffs plead that, by virtue of the acts described, the Defendants are liable in damages to them and to the Class members who used the SureStep Meter and/or Strips and that each defendant is responsible for the acts and omissions of the other Defendants for the following reasons:

(a) each was the agent of the other;

(b) each company's business was operated so that it was inextricably interwoven with the business of the other as particularized in paragraphs 21 to 25;

(c) each company entered into a common advertising and business plan to distribute and sell blood glucose monitoring systems, including the SureStep Meter and Strips, in association with the names Johnson & Johnson and LifeScan and as particularized in paragraph 37;

(d) each defendant owed a duty to the other and to each Class member by virtue of the common business plan to distribute and sell medical devices;

(e) the Defendants intended that their businesses be run as one global business organization; and

(f) the Defendants established a financial management system whereby a member of Johnson & Johnson's Executive Committee would sit as Chairman of the Professional Group, the group principally responsible for the coordination, management and operation of the medical devices business, including LifeScan and LifeScan Canada.

NEGLIGENT AND FRAUDULENT MISREPRESENTATION

66. As pleaded in subparagraph 1(o), "Representation" means the representation made expressly and impliedly that the SureStep Meter and the Strips were each fit to measure blood glucose levels and free from known defects.

67. Beginning in February 1996, the Defendants made the Representation to the Class members and others. The Defendants made the Representation directly to each Class member by the use of the name SureStep and by the product itself and, in particular, through the owner's booklet and the labelling on the package. They also made the Representation in their print and electronic advertising, in their brochures and in their point-of-purchase displays. They made the Representation repeatedly and in all manner of ways, including the following:

(a) by their conduct in seeking approval from Health Canada and in offering the SureStep Meters and the Strips for sale and/or use by the Class members; and

(b) by their express words, stating that the SureStep Meter and Strips:

(i) were "simple and accurate";

(ii) were "sure at every step";

(iii) would "do everything possible to make testing sure at every step of the way";

(iv) would "help patients get accurate results";

(v) were "accurate, reliable and easy to use";

(vi) were "getting accurate test results – every step of the way";

(vii) would give "accurate results in as little as 15 seconds";

(viii) were "unique" and would "actually 'forgive' poor technique";

(ix) were "specifically designed to make self-monitoring easy for millions of people with diabetes who suffer from a wide range of physical limitations," including trembling hands and visual impairment; and that

(x) the Strips were unique, provided increased confidence that users were testing properly, and minimized wasted Strips and repeated tests.

68. Each plaintiff and each other Class member relied on the Representation.

69. The reliance upon the Representation by each plaintiff and every other Class member is established by his or her purchase and/or use of a SureStep Meter and/or Strips. Had each plaintiff and each other Class member known that the Representation was false and misleading, he or she would not have purchased and/or used the SureStep Meter and/or Strips.

70. The Defendants made the Representation negligently or fraudulently, knowing it was false and misleading or, recklessly caring not whether it was true or false, intending that each Class member rely upon the Representation, intending that each Class member would acquire the SureStep Meter and/or purchase Strips from

pharmacies or other distributors and each Class member did rely upon this Representation to his or her detriment by using the SureStep Meter and/or Strips and, in so doing, increased the Defendants' revenues from their distribution network.

BREACH OF SECTION 52 OF THE *COMPETITION ACT*

71. The Defendants made the Representation to the public as particularized in paragraph 67. In so doing, the Defendants breached s. 52 of the *Competition Act* because the Representation:

(a) was made for the purpose of promoting the business interests of the Defendants;

(b) was made to the public;

(c) was false and misleading in a material respect; and

(d) stated a level of performance of the SureStep Meter and Strips that was not based on an adequate and proper test.

72. The plaintiffs and every other Class member relied upon the Representation by using the SureStep Meter and/or Strips and suffered damages and loss.

73. Pursuant to s. 36 of the *Competition Act*, the Defendants are liable to pay the damages which resulted from the breach of s. 52.

CONSTRUCTIVE TRUST

74. The plaintiffs and the other Class members trusted and relied upon the Defendants, because of their reputation in the marketing of medical devices and health care products, to produce a meter and strips each fit to measure blood glucose levels and free from known defects. The Defendants profited from that trust by receiving increased revenue which is directly attributable to the conspiracy and false Representation.

75. The plaintiffs plead that good conscience requires the Defendants to hold in trust for the plaintiffs and the other Class members all the revenue they received in Ontario and elsewhere in Canada from the sale of the SureStep Meters, the Strips and the Associated Paraphernalia and to disgorge this revenue.

76. The Defendants are constituted as constructive trustees in favour of the Class members for all the revenue from the sale of the SureStep Meters, Strips and Associated Paraphernalia because, among other reasons:

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

(b) justice and good conscience require the imposition of a constructive trust;

(c) the integrity of the medical devices regulations and the marketplace would be undermined if the court did not impose a constructive trust;

(d) the Class members have suffered a loss and the Defendants have been unjustly enriched; ~~and~~

(e) the Strips and the Associated Paraphernalia could not have been marketed and the Defendants would not have received any revenue from the sale of these items absent the conspiracy pleaded above, absent the Representation and absent the Defendants' marketing of the SureStep Meter ~~and Strips.~~;

(f) the Defendants engaged in wrongful conduct in putting into the marketplace a medical device that they knew was defective giving rise to potentially life threatening consequences, particularly so for the testing challenged users;

(g) the Defendants had an obligation to the Class members to refrain from marketing a knowingly defective medical device or, in the alternative, to warn the user of the defect and its potential consequences; and

(h) there are no factors which render the imposition of a constructive trust unjust in this case.

DAMAGES

77. The plaintiffs plead that Class members would not have used the SureStep Meter and/or Strips if the Defendants had acted reasonably and responsibly.

78. As a result of the Defendants' negligence, conspiracy, fraudulent or negligent misrepresentation and breach of section 52 of the *Competition Act*, the plaintiffs and other Class members who received and used a SureStep Meter and/or Strips ~~suffered damages and loss, including~~:

(a) suffered damages because he or she was at risk, which damages include:

(i) the amounts paid for the SureStep Meter and/or Strips;

(ii) out-of-pocket expenses incurred by the Class members for their benefit, such as the costs to return the SureStep Meters;

(b) also suffered damages and loss, including:

(i) personal injury, including pain and suffering from repuncturing fingers to draw additional blood samples as a result of erroneous readings;

~~(a)~~(ii) diabetic shock; and

(iii) loss of income.

~~(b)the amounts paid for the SureStep Meter and/or Strips;~~

~~(c)out-of-pocket expenses incurred by the Class members or for their benefit such as the costs to return the SureStep Meters; and~~

~~(e)~~(c) ~~oss of income.~~

THE CLAIM FOR COSTS, INCLUDING THE COSTS OF INVESTIGATION

79. Pursuant to s. 36 of the *Competition Act*, the plaintiffs and the other Class members are entitled to recover their full costs of investigation and their solicitor-client costs paid in accordance with the *Act*.

80. The plaintiffs and the other Class members are also entitled to recover as damages or costs in accordance with the *Act*, the costs of administering the plan to distribute the recovery in this action and the costs to determine the damages of each Class member which administration costs probably will exceed $5,000,000.

PUNITIVE DAMAGES

81. The plaintiffs plead that the Defendants' conduct in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing, sale, instruction and promotion of the SureStep Meter and Strips, the delayed recall and/or the failure to recall, the conspiracy and the misrepresentation as pleaded above, was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, wilful, in intentional disregard of the plaintiffs' rights and safety and the rights and safety of the other Class members, indifferent to the consequences which

were potentially life-threatening and motivated by economic considerations such as the maintaining of cash flow and market share. Such conduct renders the Defendants liable to pay punitive damages.

LEGISLATION

82. The plaintiffs plead and rely upon the *Act,* the *Negligence Act*, R.S.O. 1990, c.N-1, the *Competition Act,* the *Food and Drugs Act* and the *Food, Drug and Cosmetics Act*, all as amended and the regulations made thereunder.

83. The plaintiffs propose that this action be tried in the City of Windsor, in the County of Essex, in the Province of Ontario.

SERVICE OUTSIDE OF ONTARIO

84. This originating process may be served without court order outside Ontario in that the claim is:

(a) in respect of personal property in Ontario (rule 17.02(a));

(b) in respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (rule 17.02(b));

(c) in respect of a tort committed in Ontario (rule 17.02(g));

(d) against a person carrying on business in Ontario (rule 17.02(p)); and

(e) authorized by statute, the *Competition Act*, to be made against a person outside Ontario by a proceeding commenced in Ontario (rule 17.02(n)).

Date: August 9, 2001

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105942

AHMAD SERHAN ET AL. vs. JOHNSON & JOHNSON ET AL.

Plaintiffs Defendants

Court File No. 01-GD-51928

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDINGS COMMENCED AT WINDSOR

AMENDED STATEMENT OF CLAIM

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FILE: 60-900-000
REF: HTS/ba

CLAIM

DEFINED TERMS

1. The following terms used throughout this pleading have the following meanings:

(a) **"*Act*"** means the *Class Proceedings Act, 1992*, S.O. 1992, c. 6;

(b) **"Associated Paraphernalia"** means the SureStep lancets and control solution sold by the Defendants for use in conjunction with the SureStep Meter and Strips;

(c) **"Class"** means:

(i) all persons in Ontario and elsewhere in Canada who used a **SureStep Meter** on or after February 1, 1996; and

(ii) all persons in Ontario and elsewhere in Canada who used a **Strip** on or after February 1, 1996;

(d) **"*Competition Act*"** means the *Competition Act*, R.S.C., 1985, c. C-34, as amended and all regulations thereunder;

(e) **"Defendants"** means, collectively, LifeScan, LifeScan Canada and Johnson & Johnson;

(f) **"Er-1 Defect"** means the software error in the SureStep Meter, as described in paragraph 39;

(g) **"FDA"** means the U.S. Federal Drug Administration;

(h) **"*Food and Drugs Act*"** means the *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended and all regulations thereunder, including the Medical Devices Regulations;

(i) **"Food, Drug and Cosmetic Act"** means the *Food, Drug and Cosmetic Act*, 21 U.S.C., as amended, and all regulations thereunder;

(j) **"Gagnon"** means the plaintiff, Beverley Gagnon;

(k) **"LifeScan"** means LifeScan, Inc.;

(l) **"LifeScan Canada"** means LifeScan Canada Ltd.;

(m) **"MDR"** means the Medical Device Report to the FDA;

(n) **"Partial Strip Insertion Defect"** means the mismatch between the size of the holes in the **Strip** holder and the size of the holes in the **Strip** as described in paragraph 41;

(o) **"Representation"** means the representation made by the Defendants expressly and impliedly that the **SureStep Meter** and the **Strips** were each fit to measure blood glucose levels and free from known defects;

(p) **"Serhan"** means the plaintiff, Ahmad Serhan;

(q) **"Strip"** means a SureStep test strip manufactured before March 1, 1998 and distributed on or after February 1, 1996; and

(r) **"SureStep Meter"** means a SureStep blood glucose meter manufactured before August 1, 1997, bearing a serial number the first five digits of which were in the series L6000 to L7205 or a serial number in the series L7206-GA-00001 to L7206-GA-01128.

RELIEF CLAIMED

2. SERHAN AND GAGNON CLAIM on their own behalf and on behalf of the Class:

(a) an order pursuant to the *Act* certifying this proceeding as a class proceeding and appointing them as representative plaintiffs;

(b) a declaration that the Defendants owed a duty of care to the plaintiffs and to the other Class members;

(c) a declaration that the Defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the SureStep Meter and Strips and are liable for damages;

(d) a declaration that the Defendants made the Representation negligently or fraudulently, knowing it was false and misleading, or recklessly, caring not whether it was true or false, intending the Class members to rely upon

the Representation and they did so to their detriment and that the Defendants are thereby liable for the damages which resulted;

(e) a declaration that the Representation made by the Defendants to the public for the purpose of promoting and selling a product breached s. 52(1) of the *Competition Act* and that the Defendants are thereby liable for damages pursuant to s. 36 of the *Competition Act*;

(f) a declaration that the Defendants' officers, directors, servants, agents and employees conspired among themselves and with others, as hereinafter particularized and that, as a result, the Defendants are liable in damages;

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

(h) a declaration that the Defendants hold all of the revenue generated from the sale of the SureStep Meter and Strips and Associated Paraphernalia in a constructive trust for the benefit of the plaintiffs and the other Class members;

(i) an accounting and an order requiring disgorgement of all revenue derived by the Defendants from the sale of the SureStep Meter, Strips and Associated Paraphernalia;

(j) special damages, general damages and punitive damages, including the costs of administering the plan of distribution of the recovery in this action, in the sum of $500,000,000 or such further sum as this Honourable Court may find appropriate;

(k) a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

(l) prejudgment and postjudgment interest pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C-43, s. 128 and 129;

(m) costs of this action pursuant to the *Act* and to s. 36 of the *Competition Act* as between a solicitor and his own client, including applicable taxes; and

(n) such further and other relief as to this Honourable Court seems just.

THE NATURE OF THIS ACTION

3. The Defendants designed and marketed the SureStep Meter and Strips to be used by diabetics to accurately monitor their blood glucose levels at home.

4. This action concerns the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the SureStep Meter and Strips, and the failure of the Defendants to report significant defects in the SureStep Meter and Strips to regulatory authorities and to disclose defects known to them to the public.

5. Before marketing the SureStep Meter in February 1996, the Defendants knew that it was materially defective in that a software error in the SureStep Meter caused it to give an "Er-1" or error message instead of a "HI" (high) message when a user's blood glucose level exceeded 500 millimoles per litre ("mmol/L") or 26 milligrams per decilitre ("mg/dL"). So, too, the Defendants knew, before marketing the Strips in February 1996, that they were materially defective because a design defect in the Strips generated false low glucose level readings when a Strip was not fully inserted into the SureStep Meter.

6. In the development stage of the SureStep Meter and the Strips, before obtaining regulatory approval and for at least one-and-a-half years after bringing the SureStep Meter and Strips to market, the Defendants intentionally chose not to rectify the defects. In late July 1997, LifeScan corrected the software defect in the SureStep Meter. Later in 1997, LifeScan also corrected the design flaw that caused the defect in

the Strips, but it did not start to manufacture the redesigned Strips until March 1998. The Defendants recalled the SureStep Meters in June 1998 but did not recall the Strips.

7. The Defendants made the Representation that the SureStep Meter and Strips were each fit to measure blood glucose levels and free from known defects. They made this Representation to the FDA and to Health Canada in order to obtain regulatory approval for the SureStep Meter and Strips. They made this Representation knowing it to be false and misleading in a material respect. Having made this Representation to the FDA and Health Canada, the Defendants continued to make it throughout at least 1996, 1997 and 1998 to keep the SureStep Meter and Strips in the marketplace.

8. The Defendants also made the Representation to the plaintiffs and to the other Class members. The Defendants intended to have the Class members rely on the Representation, and the Class members did so to their detriment.

9. Because of the defects present in the SureStep Meter and Strips, their use in measuring diabetics' blood glucose levels could produce grossly inaccurate results. The plaintiffs plead that the SureStep Meter and Strips were dangerously defective devices which could cause personal injury, even death.

THE PLAINTIFFS

10. Serhan is a 53-year-old father of six who resides in the City of Windsor. He is a diabetic. Between October 1997 and 1998 or 1999, he used a SureStep Meter

bearing serial number L7111-GA-00871. He also used Strips and Associated Paraphernalia since October 1997.

11. Serhan used the SureStep Meter and Strips to check his blood glucose levels twice daily. By his conduct alone he relied upon the Representation. On at least one occasion, Serhan obtained an Er-1 message when he knew his blood glucose level was high. On many other occasions he obtained low glucose readings at least some of which he later determined to be false on the basis of accurate testing at his physician's office. As a result of the Er-1 messages and low glucose readings, Serhan had to retest, meaning that he had to use additional Strips and Associated Paraphernalia and that he had to repuncture a finger with a lancet to draw additional blood samples, a process which, each time, caused him pain and suffering.

12. Gagnon is 61 and resides in the City of Windsor. She is a diabetic. She began using Strips as well as Associated Paraphernalia in or about 1998. Gagnon used the Strips to check her blood glucose levels twice daily. By her conduct, she too relied upon the Representation. Gagnon experienced false low glucose readings. As a result of these readings, she had to retest, meaning that she had to use additional Strips and Associated Paraphernalia and that she had to repuncture a finger with a lancet to draw additional blood samples, a process which, each time, caused her pain and suffering.

THE DEFENDANTS

13. LifeScan Canada was incorporated under the laws of the Province of British Columbia on November 19, 1982 and has its head office in Burnaby, British Columbia. It is a wholly-owned subsidiary of LifeScan. At all material times, LifeScan Canada advertised, marketed and distributed the SureStep Meter and Strips in Ontario and elsewhere in Canada.

14. LifeScan is incorporated under the laws of the State of California. LifeScan's headquarters and manufacturing facilities are located in Milpitas, California. It is a wholly-owned subsidiary of Johnson & Johnson. At all material times, LifeScan designed, developed, tested, manufactured, licensed, assembled, distributed, marketed and sold the SureStep Meter and Strips in Ontario and elsewhere in Canada.

15. Johnson & Johnson is a corporation organized under the laws of New Jersey, with its headquarters located at One Johnson & Johnson Plaza in New Brunswick, New Jersey. Johnson & Johnson took over LifeScan in 1986 and, since then, has operated it as a wholly-owned subsidiary.

16. Johnson & Johnson and LifeScan are the leading manufacturers of blood glucose monitors in North America. LifeScan is one of Johnson & Johnson's most profitable businesses. It generates over $1 billion US in revenue a year. In 1998, Johnson & Johnson recorded global sales of $23.7 billion US and net earnings of $3.7 billion US.

17. At all material times, each of the Defendants was the agent of the others and each is vicariously responsible for the acts and omissions of the others as particularized herein.

CORPORATE ORGANIZATION OF THE JOHNSON & JOHNSON FAMILY OF COMPANIES

18. Johnson & Johnson is a conglomerate consisting of almost 200 operating companies manufacturing health products for distribution throughout the world, including Ontario and the rest of Canada. Johnson & Johnson owns, in whole or in part, all of the operating companies and exercises effective and actual control and management of their businesses, including the businesses of LifeScan and LifeScan Canada.

19. Johnson & Johnson is a household name in Ontario and the rest of Canada in the area of health care and related products. Products manufactured by Johnson & Johnson and/or its subsidiaries are sold in Ontario and elsewhere in Canada. Consumers in Ontario purchase products associated with the name Johnson & Johnson because Johnson & Johnson has substantial brand-name recognition in Ontario and elsewhere in Canada.

20. Johnson & Johnson has subsidiaries in Ontario, including DePuy Canada Ltd., Mississauga; Janssen-Ortho Inc., North York; McNeil Consumer Products, Guelph; and Ortho-Chemical Diagnostics, Mississauga. Johnson & Johnson receives dividend

income from Ontario, owns patents for products sold in Ontario, and advertises in Ontario.

21. Johnson & Johnson is organized in such a way that the Defendants function as an ongoing, organized and continuing business unit sharing common purposes and objectives.

22. Since its takeover of LifeScan in 1986, Johnson & Johnson has operated LifeScan as if it were not a separate corporation but rather as if it were functionally part of Johnson & Johnson. Johnson & Johnson has directly controlled the day-to-day operations of LifeScan through the direction of its Executive Committee and its Professional Group Operating Committee (the "Professional Group"). The Executive Committee is the principal management group of Johnson & Johnson. The Professional Group is comprised of managers who represent, oversee, direct, manage and coordinate key operations within the professional segment of Johnson & Johnson's business including the businesses of LifeScan and LifeScan Canada. The professional segment includes medical equipment and devices, including LifeScan's blood glucose monitoring systems.

23. The president of LifeScan Canada reports directly to the management of LifeScan. In turn, the president of LifeScan reports directly to the Chairman of the Professional Group who is employed by Johnson & Johnson and who sits on the Executive Committee. As a result of this relationship, LifeScan reported to and took

direction from Johnson & Johnson on all matters relating to the SureStep Meter and Strips.

24. At all material times, LifeScan Canada, LifeScan and Johnson & Johnson shared the common purpose of designing, developing, testing, manufacturing, licensing, assembling, distributing, marketing and selling blood glucose monitoring systems for profit.

25. LifeScan Canada, LifeScan and Johnson & Johnson also shared the common purpose of concealing the defects of the SureStep Meter and Strips from both regulatory authorities and Class members. Pursuant to the organizational structure described above, employees of LifeScan Canada reported the defects in the SureStep Meter and Strips to LifeScan, and employees of LifeScan reported the defects to Johnson & Johnson, which directed, acquiesced in and approved LifeScan's decision to conceal the defects, to refrain from correcting the defects in a timely manner and to make the Representation.

26. Johnson & Johnson, therefore, is liable for the acts and omissions of its subsidiaries, LifeScan and LifeScan Canada, because:

(a) it operated itself, LifeScan and LifeScan Canada as a single entity;

(b) it prepared its financial statements on a consolidated basis and reported profits from the sale of the SureStep Meter and Strips;

(c) it associated its name with the SureStep Meter and Strips on all packaging and in all promotional material;

(d) it owns the SureStep trademark;

(e) it controlled, through the Professional Group and Executive Committee, the day-to-day operations of LifeScan and LifeScan Canada;

(f) the employees, officers and directors of LifeScan Canada and LifeScan reported consumer complaints and the defects with the SureStep Meter and Strips to Johnson & Johnson and looked to Johnson & Johnson to give them directions and Johnson & Johnson gave them directions to make the Representation; and

(g) it conspired with LifeScan and LifeScan Canada as particularized herein.

27. LifeScan is liable for the acts and omissions of its subsidiary, LifeScan Canada, because:

(a) LifeScan Canada's president reported directly to LifeScan management;

(b) LifeScan Canada's employees, officers and directors reported Canadian consumer complaints and defects with the SureStep Meter and Strips to LifeScan;

(c) LifeScan owns the patent rights to various material elements of the SureStep Meter and Strips; and

(d) it conspired with LifeScan Canada and Johnson & Johnson to market the SureStep Meter and Strips and to make the Representation.

DIABETES–THE DISEASE AND ITS MANAGEMENT

28. Diabetes is the seventh leading cause of death in Canada.

29. According to the Canadian Diabetes Association, approximately 2,000,000 Canadians are afflicted with the disease. Although the elderly comprise the largest proportion of the diabetic population, approximately 10% of diabetics are children and adolescents and that number is growing.

30. Diabetes is a chronic disorder in which the body fails to keep blood sugar, glucose, at normal levels because the body lacks the hormone insulin or because it is unable to use it correctly. The build-up of glucose in the blood produces diabetes. As glucose levels rise, so too do the immediate dangers of hyperglycemia, high blood sugar, and ketoacidosis, a build-up of ketones in blood that can lead to diabetic coma, even sudden death.

31. Over the long term, consistently high glucose levels can harm many organs and cause hypertension, blood vessel disorders, cardiovascular disease, blindness, kidney failure, and death.

32. Diabetes has no cure. So frequent self-monitoring of glucose levels and tight glucose control are essential to the management of the disease and to the lessening of its attendant health risks. By tracking their glucose levels throughout the day, diabetics know when to give themselves insulin and in what amounts. They rely heavily, therefore, on home glucose monitors for the effective management of their disease and the avoidance of potentially life threatening diabetes-related health complications. The consequences to diabetics of inaccurate blood glucose level readings can be lethal.

HOME GLUCOSE MONITORS

33. Before the invention of blood glucose meters, diabetics tested their blood glucose levels by taking urine samples and wetting strips of chemically treated paper. The method was not only inconvenient, but it also produced inconsistent, inaccurate results.

34. With the introduction of glucose meters, however, self-monitoring was revolutionized. Using a lancet, diabetics draw a drop of blood and apply it to a chemically treated melinex test strip. The diabetic then inserts the test strip into the meter, which displays the glucose level reading on a liquid crystal display. The glucose levels can be measured either in millimoles per liter (mmol/L) or in milligrams per deciliter (mg/dL) units of measurement.

35. LifeScan pioneered a new era of blood glucose monitoring with the introduction of technology that eliminated the need to wipe blood on a strip and to time the procedure. LifeScan is a world leader in blood glucose monitoring and marketed itself as the brand most recommended by doctors, hospitals and diabetic counsellors.

36. In February 1996, the Defendants launched the SureStep Meter and Strips in Canada. The Defendants participated in the preparation, approval and dissemination of the regulatory submissions, product packaging, promotional and advertising material, all of which contained the Representation that the SureStep Meter and Strips were each fit to measure blood glucose levels and free from known defects.

37. The Defendants designed, developed, tested, manufactured, licensed, assembled, distributed, marketed and sold millions of test Strips and hundreds of thousands of SureStep Meters under or in conjunction with:

(a) the name "SureStep";
(b) the name "LifeScan, a Johnson & Johnson company"; and
(c) the trademark SureStep which is owned by Johnson & Johnson.

THE DEFECTS IN THE SURESTEP METER AND STRIPS

38. From their inception, the SureStep Meter and Strips were materially defective.

39. The defect in the SureStep Meter involved a software error that caused an incorrect "Er-1" error message, instead of a "HI" high message, to appear on the SureStep Meter when the user's blood glucose level was 500 mg/dL or higher. According to the owner's manual, an "Er-1" reading signified an improper sample application but not a high glucose level. A person with blood glucose levels of 500 mg/dL is in a severe hyperglycemic state, and requires immediate lowering of glucose levels. Failing such corrective action, users are at risk of diabetic coma, renal failure and toxic shock.

40. Approximately 290,000 SureStep Meters with the Er-1 Defect were manufactured and distributed by the Defendants in the U.S., Canada and elsewhere.

41. The defect in the Strips was the result of a design flaw, namely, a mismatch between the size of the holes in the Strip holder and the size of the holes in the Strip. The defect manifested itself when a Strip was not fully inserted into the SureStep Meter. According to the owner's manual, the SureStep Meter is supposed to warn the user when he or she has not completely inserted the test Strip. The warning is necessary because diabetics, particularly the elderly, often suffer afflictions—shaky hands, blurred vision, or some other physical impairment—which make it difficult for them to insert the Strip fully. In fact, the SureStep Meter and Strips issued no such warning. Instead, when a Strip was partially inserted, the SureStep Meter merely displayed a false low glucose level. The Partial Strip Insertion Defect was potentially dangerous to users because it meant that a diabetic with high glucose levels would be unaware, having received a false low glucose reading, that corrective action should be taken immediately, and might even be led to increase his or her glucose levels.

42. Before March 1998, the Defendants manufactured millions of Strips with the Partial Strip Insertion Defect and distributed them throughout the U.S., Canada and elsewhere.

43. As early as 1993, the Defendants knew about the Er-1 Defect, and they knew about the Partial Strip Insertion Defect for at least several years before they marketed the SureStep Meter and Strips and certainly before they applied to the FDA and to Health Canada for medical device approval. The Defendants knew that both defects could result in serious injury and death. LifeScan's own employees warned management that incorrect readings had "the potential to create a life-threatening

failure." Despite this knowledge and for purely economic reasons, the Defendants rejected the option of delaying introduction of the SureStep Meter and Strips.

44. Internal clinical tests by LifeScan in 1997 confirmed the existence of the Er-1 Defect and the Partial Strip Insertion Defect in the SureStep Meter and Strips. The Defendants failed to warn consumers and failed to report the defects to the FDA and to Health Canada in accordance with their statutory obligations. The Defendants rejected the option of recalling the defective SureStep Meters and Strips. Throughout, the Defendants were motivated solely by economic self-interest.

THE GUILTY PLEAS

45. On April 2, 1998, forty U.S. Federal agents raided and seized records from LifeScan's headquarters in Milpitas, California. Thereafter, for 2.5 years, the FDA, the Federal Bureau of Investigation, the Department of Health and Human Services, the Department of Justice and other U.S. Federal agencies investigated LifeScan.

46. On December 15, 2000, the U.S. government and LifeScan entered into a settlement agreement. LifeScan pleaded guilty to a number of criminal charges, including failure and refusal to furnish appropriate notifications and information to the FDA, and to the introduction into interstate commerce of a misbranded medical device. Pursuant to the settlement, LifeScan agreed, among other things, to pay $60 million US

in criminal and civil fines for selling the defective SureStep Meter and Strips and for submitting false information about the defects to the FDA.

47. On December 15, 2000, LifeScan signed a plea agreement. Under the plea agreement, LifeScan admitted the following facts to be true:

(a) In or about 1993, it learned that its SureStep Meter and Strips were defective because the Meter sometimes displayed an "Er-1" message instead of a "HI" message if the user's blood glucose level exceeded 500 mg/dL and because partially inserted Strips would produce inaccurate low blood glucose readings;

(b) On or about May 23, 1994, LifeScan submitted an application to the FDA for approval to market the SureStep Meter and Strips to the public. In this application, LifeScan submitted labeling and supporting material that stated the SureStep Meter would display a "HI" message when blood glucose levels were above 500 mg/dL. The materials did not disclose that the SureStep Meter could generate an "Er-1" message at high glucose levels or false low readings if the Strips were not fully inserted;

(c) At the time that LifeScan began marketing the SureStep Meter and Strips in Canada in February 1996, it did not disclose the Er-1 Defect or the Partial Strip Insertion Defect to consumers in any of its packaging, labeling, manuals, advertisements or other material;

(d) In or about February 1997, LifeScan's Japanese affiliate notified LifeScan that consumers in Japan were receiving "Er-1" messages instead of "HI" messages at high blood glucose levels. LifeScan informed its Japanese affiliate that it did not consider this problem to constitute a health risk and would not recall the SureStep Meters;

(e) It was not until late July 1997 that LifeScan corrected the Er-1 Defect in all SureStep Meters manufactured after July 27, 1997. It was not until November 1997 that LifeScan began to include an explanatory insert in Strip packages which advised users that an "Er-1" message could indicate blood glucose levels exceeding 500 mg/dL. Consumers would not have received this notice until they bought new Strips, and merchants continued selling old inventories of Strips as LifeScan intended;

(f) LifeScan did not recall the defective SureStep Meters until June 1998;

(g) LifeScan addressed the Partial Strip Insertion Defect in late 1997 by redesigning the Strips. The corrected strips were manufactured in March 1998 and thereafter, but LifeScan chose not to recall any of the older

version of Strips and did not notify the FDA or consumers that incomplete strip insertion could generate false low readings;

(h) During 1996, 1997 and 1998, LifeScan received over 2,000 complaints of inaccurate low readings by its SureStep Meters, some of which were attributable to partial strip insertion, and over 700 complaints regarding "Er-1" readings, some of which were attributable to high blood glucose. LifeScan failed to report these complaints fully, truthfully and/or accurately to the FDA and dishonestly attributed failures of the SureStep Meter and Strips to users themselves who had suffered serious injury;

(i) LifeScan failed to file MDRs when it should have and knowingly submitted false, incomplete and/or misleading information in the reports it did file; and

(j) In May 1997, LifeScan's Director of Clinical Evaluations, a medical doctor, reviewed several consumer complaints received by LifeScan and advised his employer that the SureStep Meters should be immediately recalled because they posed an unacceptable risk of harm to the public. LifeScan rejected the Director's recommendation.

48. The plaintiffs plead that as a result of the admissions of LifeScan documented in the December 15, 2000 plea agreement, the Defendants are estopped in this action from challenging any of the facts admitted therein.

LIFESCAN CANADA'S ACTIONABLE CONDUCT

49. LifeScan Canada knew that the design of the SureStep Meter and Strips was flawed before it applied for a Medical Device Licence from Health Canada. Before it introduced the SureStep Meter and Strips to Canada in February 1996, LifeScan Canada knew of both the Er-1 Defect and Partial Strip Insertion Defect but chose nevertheless to market and sell the SureStep Meter and Strips rather than delay their introduction in Ontario and elsewhere in Canada.

50. The Defendants marketed the SureStep Meter and Strips from their inception to children, to the elderly and to first-time users of blood glucose monitors.

51. Between 1996 and June 1998, LifeScan Canada received complaints from Canadian consumers about the Er-1 Defect and the Partial Strip Insertion Defect. In breach of its statutory obligations, LifeScan Canada failed to report these complaints to Health Canada. LifeScan Canada did not remedy the defects, or recall the SureStep Meter and Strips or warn Canadian consumers about the defects.

THE SALE AND RECALL OF THE SURESTEP METER AND STRIPS

52. The Defendants sold, delivered or caused to be delivered a SureStep Meter to the plaintiffs and to every other Class member in Ontario and elsewhere in Canada.

53. The Defendants sold Strips to the plaintiffs and to every other Class member in Ontario and elsewhere in Canada.

54. In or about June 1998, under the guise of a product replacement program, the Defendants initiated a North America-wide recall of the SureStep Meter because of the Er-1 Defect, thereby, by conduct, admitting that the SureStep Meters were defective.

55. This recall of the SureStep Meter was misleading because some diabetics, wholesalers and distributors did not realize that the product replacement was for a serious malfunction.

56. The FDA properly classified the recall of the SureStep Meters as Class I, the most serious and urgent type of recall, for situations in which there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

57. In the December 15, 2000 plea agreement, LifeScan admitted that the Strips manufactured before March 1998 were defective, yet it did not recall them.

THE CONSPIRACY

58. During the period from on or about January 1, 1993 to on or about June 30, 1998, at Burnaby, British Columbia; New Brunswick, New Jersey, Milpitas, California and elsewhere, 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 to:

(a) submit false, inaccurate and misleading information to Health Canada for the purpose of obtaining a Medical Device License in respect of the SureStep Meter and Strips;

(b) conceal the defects of the SureStep Meter and Strips, namely the Er-1 Defect and the Partial Strip Insertion Defect from the FDA, Health Canada and Class members;

(c) mislead Class members and others about the features, efficacy, safety and accuracy of the SureStep Meter and Strips;

(d) make the Representation to Class members and others that the SureStep Meter and Strips were each fit to measure blood glucose levels and free from known defects with the intent of inducing them to purchase, use and rely upon the SureStep Meter and Strips;

(e) delay the correction of the defects;

(f) hide the true causes of the Er-1 Defect and false low blood glucose readings;

(g) submit inaccurate, incomplete, false and/or misleading MDRs to the FDA and inaccurate, incomplete, false and/or misleading reports to Health Canada;

(h) delay the recall of the SureStep Meter;

(i) reject the recommendations of medical advisers employed by the Defendants and others to recall the SureStep Meter in 1996 and 1997;

(j) refuse to recall the defective Strips even after LifeScan had publicly acknowledged that they were defective; and

(k) breach the provisions of the *Competition Act*, the *Food and Drugs Act*, and the *Food, Drug and Cosmetic Act*.

59. The Defendants were motivated to conspire and their predominant purposes and predominant concerns were:

(a) to increase their sales and profits;

(b) to increase or hold their market share;

(c) to avoid adverse publicity;

(d) to place corporate profits above the safety of the Class members and others; and

(e) to save the expense consequent upon the recall of the SureStep Meter and Strips in the hands of Class members of retooling manufacturing equipment to correct the defects and of recalling defective inventory from retailers.

60. The conspiracy was unlawful because the Defendants knowingly caused dangerously defective products to be marketed, failed to file timely or adequate MDRs with the FDA and engaged in the practice of false advertising.

61. The conspiracy was directed towards diabetics and potential users of the SureStep Meter and Strips, including the plaintiffs and the other Class members. The Defendants knew in the circumstances that the conspiracy would likely cause injury and loss to the plaintiffs and the other Class members. The conspiracy caused injury and loss to the plaintiffs and the other Class members.

62. The acts particularized and alleged in this claim to have been done by each of the Defendants were authorized, ordered and done by each defendant's officers, directors, agents, employees and representatives while engaged in the management, direction, control and transaction of its business affairs and are therefore acts and omissions for which the Defendants are vicariously liable.

THE DEFENDANTS' NEGLIGENCE

63. The Defendants owed a duty of care to the plaintiffs and the other Class members and breached the requisite standard of conduct expected of them in the circumstances.

64. The Defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the SureStep Meter and Strips. Particulars of some of the acts of negligence follow:

(a) they knew, from internal testing, as early as 1993—three years before marketing the SureStep Meter and Strips—of the Er-1 Defect and took no steps to remedy the defect;

(b) they knew, from internal testing, years before marketing the SureStep Meter and Strips of the Partial Strip Insertion Defect and took no steps to remedy it;

(c) they wrongfully and intentionally accepted the known risk of injury to a Class member as a result of the SureStep Meter's software problem, the Er-1 Defect and the Strip's design flaw, the Partial Strip Insertion Defect;

(d) they knew that the Er-1 Defect would occur when a Class member's blood glucose level exceeded 500 mg/dL and that, in such an event, the Class member would be misled as to his or her true glucose level and might fail to take immediate and appropriate corrective action;

(e) they failed to remedy the Er-1 Defect to eliminate this known risk and consciously accepted the risk of the Er-1 Defect occurring because they wrongfully concluded that the health risk associated with the defect was not severe enough to warrant a change in the software;

(f) they knew that the Partial Strip Insertion Defect would occur whenever a Class member incompletely inserted a Strip and that, in such an event, the Class member would be misled as to his or her true glucose level and might fail to take immediate or appropriate corrective action or might even take actions, such as ingesting food or taking insulin, that would elevate his or her already dangerously high blood glucose;

(g) they failed to remedy the design flaw that caused the Partial Strip Insertion Defect in spite of the foreseeable risks and consciously accepted the risks because they did not want to alert competitors to the defect by redesigning the Strips and because they wrongly concluded that the health risks associated with the defect were insufficient to warrant a change in the design of the Strips;

(h) they knew or ought to have known that the two defects in the SureStep Meter and Strips were hazardous to Class members because pre-market testing confirmed the software problem and design flaw, and their own medical experts warned of the potential catastrophic consequences to Class members;

(i) they failed to design a software program that would ensure blood glucose levels exceeding 500 mg/dL generated a "HI" message and not an "Er-1" message;

(j) they failed to design a Strip that when partially inserted caused an insertion error message and not a false low blood glucose reading;

(k) they manufactured, licensed, assembled, distributed, marketed and sold the SureStep Meter and Strips knowing that they suffered from the defects described herein;

(l) they designed, developed, tested, manufactured, licensed, assembled, distributed, marketed and sold a defective SureStep Meter and Strips;

(m) they failed to warn the Class members of the dangers associated with the use of the SureStep Meter and Strips;

(n) they failed to warn Class members that an "Er-1" message could mean a blood glucose level of 500 mg/dL or higher;

(o) they failed to warn Class members that partial strip insertion could generate a false low blood glucose level reading;

(p) they falsely represented that a "HI" message would appear when a user's blood glucose level was 500 mg/dL or higher and that an incomplete Strip insertion symbol would appear when a test Strip was partially inserted;

(q) they failed to change the design of the SureStep Meter's software and the design flaw of the Strip when they knew or ought to have known of the Er-1 Defect and the Partial Strip Insertion Defect;

(r) they failed to change their design, manufacturing and assembly process of the SureStep Meters and Strips in a reasonable and timely manner;

(s) they failed to include a warning that described the two defects on the SureStep Meter packaging, on the Strips packaging or in the owner's booklet;

(t) they failed to instruct their HelpLine employees to properly evaluate, record and advise on complaints of the defects;

(u) they encouraged their HelpLine employees to conceal the true causes of an "Er-1" message or a false low glucose level reading when communicating with Class members and others;

(v) they failed to accurately, candidly, promptly and truthfully disclose consumer complaints and SureStep Meter and Strips defects to Health Canada;

(w) they failed to initiate timely review, evaluation and investigation of the Er-1 Defect and the Partial Strip Insertion Defect following complaints of injury or death or hazard to safety;

(x) they failed to properly assess and investigate complaints adequately when they received them;

(y) they refrained from reporting the two defects to the FDA, Health Canada and Class members in order to maximize profits and retain market share;

(z) they refrained from recalling the Strips at the time of the SureStep Meter recall in order to use up existing inventory and thereby maximize profits and retain market share;

(aa) they failed to change the design, manufacture and assembly process of the Strip in a reasonable and timely manner because they required a compatible Strip to ensure continued sales of the SureStep Meter and replacement meters and because the greatest portion of their profits were derived from the sale of the Strips;

(bb) they failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and the *Food, Drug and Cosmetic Act*;

(cc) they hired incompetent personnel and appointed incompetent officers and directors;

(dd) they failed to instruct their servants, agents, officers and directors to act ethically and responsibly;

(ee) they failed to properly supervise their employees, their subsidiaries and affiliated corporations;

(ff) they encouraged their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and diabetic counsellors of the two defects; and

(gg) they failed to recall the SureStep Meter and/or the Strips in a timely manner or at all because of the cost and the negative publicity.

65. The plaintiffs plead that, by virtue of the acts described, the Defendants are liable in damages to them and to the Class members who used the SureStep Meter and/or Strips and that each defendant is responsible for the acts and omissions of the other Defendants for the following reasons:

(a) each was the agent of the other;

(b) each company's business was operated so that it was inextricably interwoven with the business of the other;

(c) each company entered into a common advertising and business plan to distribute and sell blood glucose monitoring systems, including the SureStep Meter and Strips, in association with the names Johnson & Johnson and LifeScan and as particularized in paragraph 37;

(d) each defendant owed a duty to the other and to each Class member by virtue of the common business plan to distribute and sell medical devices;

(e) the Defendants intended that their businesses be run as one global business organization; and

(f) the Defendants established a financial management system whereby a member of Johnson & Johnson's Executive Committee would sit as Chairman of the Professional Group, the group principally responsible for the coordination, management and operation of the medical devices business, including LifeScan and LifeScan Canada.

NEGLIGENT AND FRAUDULENT MISREPRESENTATION

66. As pleaded in subparagraph 1(o), "Representation" means the representation made expressly and impliedly that the SureStep Meter and the Strips were each fit to measure blood glucose levels and free from known defects.

67. Beginning in February 1996, the Defendants made the Representation to the Class members and others. The Defendants made the Representation in their print

and electronic advertising, in their brochures, in their point-of-purchase displays and in their product packaging. They made the Representation repeatedly and in all manner of ways, including the following:

(a) by their conduct in seeking approval from Health Canada and in offering the SureStep Meters and the Strips for sale and/or use by the Class members; and

(b) by their express words, stating that the SureStep Meter and Strips:

(i) were "simple and accurate";

(ii) were "sure at every step";

(iii) would "do everything possible to make testing sure at every step of the way";

(iv) would "help patients get accurate results";

(v) were "accurate, reliable and easy to use";

(vi) were "getting accurate test results – every step of the way";

(vii) would give "accurate results in as little as 15 seconds";

(viii) were "unique" and would "actually 'forgive' poor technique";

(ix) were "specifically designed to make self-monitoring easy for millions of people with diabetes who suffer from a wide range of physical limitations," including trembling hands and visual impairment; and that

(x) the Strips were unique, provided increased confidence that users were testing properly, and minimized wasted Strips and repeated tests.

68. Each plaintiff and each other Class member relied on the Representation.

69. The reliance upon the Representation by each plaintiff and every other Class member is established by his or her use of a SureStep Meter and/or Strips. Had

each plaintiff and each other Class member known that the Representation was false and misleading, he or she would not have used the SureStep Meter and/or Strips.

70. The Defendants made the Representation negligently or fraudulently, knowing it was false and misleading or, recklessly caring not whether it was true or false, intending that each Class member rely upon the Representation and each Class member did rely upon this Representation to his or her detriment by using the SureStep Meter and/or Strips.

BREACH OF SECTION 52 OF THE *COMPETITION ACT*

71. The Defendants made the Representation to the public as particularized in paragraph 67. In so doing, the Defendants breached s. 52 of the *Competition Act* because the Representation:

(a) was made for the purpose of promoting the business interests of the Defendants;

(b) was made to the public;

(c) was false and misleading in a material respect; and

(d) stated a level of performance of the SureStep Meter and Strips that was not based on an adequate and proper test.

72. The plaintiffs and every other Class member relied upon the Representation by using the SureStep Meter and/or Strips and suffered damages and loss.

73. Pursuant to s. 36 of the *Competition Act*, the Defendants are liable to pay the damages which resulted from the breach of s. 52.

CONSTRUCTIVE TRUST

74. The plaintiffs and the other Class members trusted and relied upon the Defendants, because of their reputation in the marketing of medical devices and health care products, to produce a meter and strips each fit to measure blood glucose levels and free from known defects. The Defendants profited from that trust.

75. The plaintiffs plead that good conscience requires the Defendants to hold in trust for the plaintiffs and the other Class members all the revenue they received in Ontario and elsewhere in Canada from the sale of the SureStep Meters, the Strips and the Associated Paraphernalia and to disgorge this revenue.

76. The Defendants are constituted as constructive trustees in favour of the Class members for all the revenue from the sale of the SureStep Meters, Strips and Associated Paraphernalia because, among other reasons:

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

(b) justice and good conscience require the imposition of a constructive trust;

(c) the integrity of the medical devices regulations and the marketplace would be undermined if the court did not impose a constructive trust;

(d) the Class members have suffered a loss and the Defendants have been unjustly enriched; and

(e) the Associated Paraphernalia could not have been marketed absent the Representation and absent the Defendants' marketing of the SureStep Meter and Strips.

DAMAGES

77. The plaintiffs plead that Class members would not have used the SureStep Meter and/or Strips if the Defendants had acted reasonably and responsibly.

78. As a result of the Defendants' negligence, conspiracy, fraudulent or negligent misrepresentation and breach of section 52 of the *Competition Act*, the plaintiffs and other Class members suffered damages and loss, including:

(a) personal injury, including pain and suffering from repuncturing fingers to draw additional blood samples as a result of erroneous readings;

(b) diabetic shock;

(c) the amounts paid for the SureStep Meter and/or Strips;

(d) out-of-pocket expenses incurred by the Class members or for their benefit such as the costs to return the SureStep Meters; and

(e) loss of income.

THE CLAIM FOR COSTS, INCLUDING THE COSTS OF INVESTIGATION

79. Pursuant to s. 36 of the *Competition Act*, the plaintiffs and the other Class members are entitled to recover their full costs of investigation and their solicitor-client costs paid in accordance with the *Act*.

80. The plaintiffs and the other Class members are also entitled to recover as damages or costs in accordance with the *Act*, the costs of administering the plan to distribute the recovery in this action and the costs to determine the damages of each Class member which administration costs probably will exceed $5,000,000.

PUNITIVE DAMAGES

81. The plaintiffs plead that the Defendants' conduct in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing, sale, instruction and promotion of the SureStep Meter and Strips, the delayed recall and/or the failure to recall, the conspiracy and the misrepresentation as pleaded above, was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, wilful, in intentional disregard of the plaintiffs' rights and safety and the rights and safety of the other Class members, indifferent to the consequences and motivated by economic considerations such as the maintaining of cash flow and market share. Such conduct renders the Defendants liable to pay punitive damages.

LEGISLATION

82. The plaintiffs plead and rely upon the *Act,* the *Negligence Act*, R.S.O. 1990, c.N-1, the *Competition Act,* the *Food and Drugs Act* and the *Food, Drug and Cosmetics Act*, all as amended and the regulations made thereunder.

83. The plaintiffs propose that this action be tried in the City of Windsor, in the County of Essex, in the Province of Ontario.

SERVICE OUTSIDE OF ONTARIO

84. This originating process may be served without court order outside Ontario in that the claim is:

(a) in respect of personal property in Ontario (rule 17.02(a));

(b) in respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (rule 17.02(b));

(c) in respect of a tort committed in Ontario (rule 17.02(g));

(d) against a person carrying on business in Ontario (rule 17.02(p)); and

(e) authorized by statute, the *Competition Act*, to be made against a person outside Ontario by a proceeding commenced in Ontario (rule 17.02(n)).

Date: August 9, 2001

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AHMAD SERHAN ET AL. vs. JOHNSON & JOHNSON ET AL.

Plaintiffs Defendants

Court File No. 01-GD-51928

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDINGS COMMENCED AT WINDSOR

AMENDED

STATEMENT OF CLAIM

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FILE: 60-900-000
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