ORIGINATING NOTICE (ACTION)

2007 S.H. No. 287972

IN THE SUPREME COURT OF NOVA SCOTIA

Prothonotary's Administration
NOV - 8 2007
Halifax, N.S.

BETWEEN:

DONALD STEVEN MACKAY

Plaintiff

- and -

AMO CANADA COMPANY and **ADVANCED MEDICAL OPTICS, INC.**

Defendants

TO THE DEFENDANTS:

TAKE NOTICE that this proceeding has been brought by the Plaintiff against you, the Defendants, in respect of the claim set out in the Statement of Claim annexed to this notice.

AND TAKE NOTICE that the Plaintiff may enter judgment against you on the claim, without further notice to you, unless within TWENTY days after the service of this Originating Notice upon you, excluding the day of service, you or your solicitor cause your Defence to be delivered by mail or personal delivery to,

(a) the office of the Prothonotary at 1815 Upper Water Street in Halifax, Nova Scotia, and

(b) to the address given below for service of documents on the Plaintiff:

provided that if the claim is for a debt or other liquidated demand and you pay the amount claimed in the Statement of Claim and the sum of $ (or such sum as may be allowed on taxation) for costs to the plaintiff or his solicitor within six days from the service of this notice on you, then this proceeding will be stayed.

ISSUED the 8TH day of November, A.D., 2007.

RAYMOND F. WAGNER
Solicitor for the Plaintiff
whose address for service
is 1869 Upper Water Street
Halifax, Nova Scotia
B3J 1S9

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IN THE SUPREME COURT OF NOVA SCOTIA

B E T W E E N:

DONALD STEVEN MACKAY

Plaintiff

- and -

AMO CANADA COMPANY and **ADVANCED MEDICAL OPTICS, INC.**

Defendants

STATEMENT OF CLAIM
(Proposed Common Law Class Proceeding)

I. REPRESENTATIVE PLAINTIFF AND CLASS

1. The Plaintiff, Donald Steven MacKay resides in Sydney, Nova Scotia.

2. The Plaintiff proposes to bring a common law class proceeding on behalf of himself and a class of other individual residents of Nova Scotia ("the Class") who have suffered personal injuries and other damages as a result of having used Complete All-In-One MoisturePLUS contact lens solution ("the Product"). The proposed Class will be further defined in the Application for Certification.

3. The Plaintiff seeks to certify this action as a class proceeding, and pleads the Supreme Court of Canada's decision in *Western Canadian Shopping Centers Inc. v. Dutton*, [2001] 2 S.C.R. 534, and Rule 5.09 of Nova Scotia's *Civil Procedure Rules*, as providing the basis for such certification. The Plaintiff, as the Representative Plaintiff, does not have any interest adverse to any of the members of the proposed class. The Plaintiff states that there is an identifiable class that would be fairly and adequately represented by the Plaintiff; that the Plaintiff's claims raise common issues; and that a class proceeding would be the preferable procedure for the resolution of such common issues.

4. The Plaintiff and Class have been continuously harmed by their use of the Product as hereinafter described.

5. On or about August 14, 2006, the Plaintiff purchased the Product. The Plaintiff used the Product regularly, and as directed, to clean and disinfect his contact lenses.

II. DEFENDANTS

Advanced Medical Optics, Inc.

6. The Defendant, Advanced Medical Optics, Inc., ("AMO"), is incorporated in the State of Delaware and has its head office in Santa Ana, California.

AMO Canada Company

7. The Defendant, AMO Canada Company, ("AMO Canada"), is a company incorporated under the laws of Nova Scotia and carries on business in Canada from its offices in Markham, Ontario. AMO Canada is a wholly owned subsidiary of AMO.

8. The Defendants individually and jointly researched, developed, tested, manufactured, distributed and sold the Product to residents of Nova Scotia. The Defendants engaged in a joint enterprise for the promotion and sale of the Product in Nova Scotia.

III. RECALL OF THE CONTACT LENS SOLUTION

9. On May 25, 2007, the Defendant AMO announced a global recall of the Product. On May 28, 2007, the Defendant AMO Canada sent out an "Urgent Recall Notice" to Canadian health care professionals, advising them of the recall. On May 30, 2007, Health Canada issued a public health advisory concerning the recall.

10. The cause of the recall was that the Product has been linked to a markedly increased risk for contact lens wearers of developing *Acanthamoeba* keratitis ("AK"). AK is an extremely painful and debilitating eye infection which can result in blindness. *Acanthamoeba* are protozoa which can invade and attack the

cornea if introduced into the eye. Symptoms of AK include eye pain, redness, blurred vision, light sensitivity, tearing, and the sensation of something being in the eye. In its early stages, AK may be confused with less serious eye conditions, such as “pink eye”. To confirm a diagnosis of AK it may be necessary to take corneal scrapings from the patient, to permit stain and culture of the sample. If caught early enough, AK may be treated with a regime of drugs and anti-amoebal toxins including biguanides, chlorhexidine, propamidine, antiglycoside neomycin, and the antifungal clotrimazole. Both the diagnostic procedures used, and the treatment regime of repeatedly applying toxins to the eye in an effort to kill the *Acanthamoeba* infection, can be very painful. The treatment regime may be prolonged, with lingering uncertainty as to whether the infection has been truly eradicated.

11. In advanced cases, surgery may be required in the form of a penetrating keratoplasty (corneal transplant). This procedure has risks of complications, including reduced structural integrity to the eye, and there is a high probability of recurrence and graft failure if the infection has not already been thoroughly eliminated from the eye at the time of the procedure.

12. AK is ordinarily an extremely rare condition in humans. The baseline incidence for this infection has been estimated at only one or two cases per million individuals per year. In 2006, the University of Illinois at Chicago observed an unusual increase in reported cases of AK in Illinois. In January 2007, the U.S. Centres for Disease Control and Prevention (the “CDC”), initiated a retrospective study of twenty-two (22) ophthalmology centres across the U.S. By March 2007, the CDC had received data from thirteen (13) of these centres, showing a marked increase in AK in the U.S. since 2004 over a wide geographic area. By May 24, 2007, the CDC had gathered data showing at least one hundred and thirty-eight (138) cases of AK in the United States since January 1, 2005.

13. A common feature linking many of these AK cases reported to the CDC was use of the Defendants’ Product. The CDC found that contact lens wearers using the Defendants’ Product were more than seven (7) times more likely to develop AK than contact lens wearers using other products.

IV. HARM TO THE PLAINTIFF

14. The Plaintiff began using the Product in August 2006. At that time he purchased a cleaning kit which included two (2) large bottles and one (1) small bottle of the Product. The Plaintiff used the Product regularly, as directed until approximately April 1, 2007.

15. The Plaintiff first noticed problems with his left eye at the end of March or the beginning of April 2007.

16. During the period of March 31 - April 6, 2007, the Plaintiff started experiencing symptoms similar to pink eye or conjunctivitis in his left eye. At that time the white of his left eye became slightly pink in color with a watery discharge. His left eye was also itchy and slightly irritated.

17. On or about April 6, 2007, the Plaintiff went to the emergency department at the New Waterford Hospital and saw the doctor on-call, who diagnosed conjunctivitis. A bacterial swab of the lining of the Plaintiff's eyelid was taken and sent to the lab. The Plaintiff was not prescribed any medication at this time pending the results of the swab. The results of the swab were negative for conjunctivitis.

18. During the period of April 7 - 15, 2007, the Plaintiff waited for the results of the swab taken at the New Waterford Hospital. The Plaintiff's symptoms in his left eye persisted and he made an appointment to see his optometrist, Dr. Flemming at the earliest opportunity on April 25, 2007.

19. On April 25, 2007, Dr. Flemming examined the Plaintiff's left eye and decided to refer the Plaintiff to the ophthalmologist on call that same day. The Plaintiff received a referral letter from Dr. Flemming on April 25, 2007 to see Dr. Carrillo.

20. Dr. Carrillo prescribed a course of treatment that ultimately proved to be unsuccessful. Dr. Carillo referred the Plaintiff to Dr. Stan George, a cornea specialist, in Halifax. The Plaintiff saw Dr. Stan George on June 6, 2007.

21. Within five to ten minutes, and virtually upon visual inspection, Dr. George said he was 90% sure that the Plaintiff was infected with *Acanthamoeba.*

22. The Plaintiff was admitted to the VG Hospital that day for observation and to have the required cornea scrapings and cultures prepared.

23. The Plaintiff was required to stay in the hospital until a positive culture was obtained. The *Acanthamoeba* could take from three to ten days to show a positive result. On Sunday, June 10, 2007, the results came back from the lab as positive for *Acanthamoeba.* The Plaintiff's left eye was therefore infected with *AK.*

24. From June 7, 2007, to the present time the Plaintiff has been under the primary care of Dr. George in Halifax.

25. The Plaintiff was unable to work for approximately four months.

26. The Plaintiff has been prescribed and continues to take multiple medications to try to clear up the AK in his left eye.

27. It will take approximately a further six months before the Plaintiff will know if the AK infection has been eliminated. The Plaintiff may require a corneal transplant because of lesions on his cornea created by the AK infection.

28. The Plaintiff has incurred significant out-of-pocket expenses from travelling to doctor's appointments. He still has not fully recovered use of his left eye and does not know if his vision in his left eye will be fully restored.

29. In addition, the Plaintiff and the Class have suffered and continue to suffer from anxiety about their health because of the effect that the Product has had on their lives. The Plaintiff states that all of the Defendants bear the responsibility to, *inter alia*, create a medical monitoring fund/mechanism as described below that would give him and the Class access to experts who could address their health concerns.

V. CAUSES OF ACTION

(a) Defendant's Negligence

30. The Defendants were negligent in the research, development, testing, manufacture, distribution and sale of the Product. Use of contact lenses is a known method for potentially transmitting *Acanthamoeba* to the eye. It is critical therefore that a contact lens cleaner be safe and effective in killing *Acanthamoeba*, thereby preventing transmission of AK. The Defendants knew or should have known that the Plaintiff and the Class relied on the Defendants' Product, and that the Plaintiff and the Class would have no way of determining or inspecting the safety and efficacy of the Product on their own. The Defendants knew or should have known that damages were reasonably foreseeable to the Plaintiff and the Class if the Defendants' Product was unsafe and ineffective. The Defendants were in such a close and proximate relationship with the Plaintiff and the Class as to owe the Plaintiff and the Class a duty of care.

31. The Defendants developed and marketed their Product as a new and improved, "no rub", multi-purpose solution. Before the marketing of multi-purpose solutions, hydrogen peroxide was used to sterilize contact lenses, killing *Acanthamoeba* and other pathogens. Hydrogen peroxide however could be irritating to the eye if it was not fully neutralized through use of a separate solution or chemical tablet during cleaning. Multi-purpose solutions were then developed, combining a detergent with a chemical disinfectant to clean the lenses and kill pathogens. These products are less irritating but they require the consumer to actively rinse and thoroughly rub the lens, to ensure adequate distribution and effectiveness of the disinfectant on the lens.

32. The Defendants' Product labelling did not require any rubbing by the consumer, but rather promoted the Product as "no rub". To achieve this, it was vitally important that the Product contain and deliver adequate concentrations of effective disinfectant to the lens. The Defendants failed in this regard. Their Product did not deliver adequate concentrations of disinfectant to the lens to prevent AK. The Product they had designed, tested, manufactured and promoted was not an improvement over conventional multi-purpose solutions, but rather,

carried a significantly higher risk of AK infection than other lens solutions already on the market.

33. Particulars of the Defendants' negligence are:

(a) chose not to adequately test the safety and efficacy of their Product before bringing it to market;

(b) chose not to do follow-up studies on the safety and efficacy of their Product after bringing it market;

(c) chose not to monitor and follow up on reports of AK infections in users of their Product;

(d) chose not to recall the Product sooner;

(e) chose not to properly train and monitor their work force and quality control personnel so as to prevent or detect contamination of their Product;

(f) chose not to warn consumers, their health care providers, and Health Canada, of the increased risk of AK infection cased by their Product;

(g) marketing the Product which was unsafe, not fit for its intended purpose, and not of merchantable quantity;

(h) designing, manufacturing and marketing the Product which was not reasonably safe and effective in preventing AK in comparison with already available, alternative designs;

(i) chose not to ensure proper concentrations of effective disinfectants in their Product during manufacturing, and before shipping it to consumers;

(j) chose not to take adequate steps to correct production problems in the manufacture of their Product when they discovered contamination;

(k) delaying and/or denying responsibility for the incidence of AK infections so as to maintain their profits;

(l) chose not to adequately test and determine the continued efficacy of the disinfectants in the Product consistent with the Defendants' recommended shelf-life and storage conditions for the Product; and

(m) such further and other negligence as may appear.

34. As a result of the Defendants' negligence, the Plaintiff and the Class have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage suffered by the Plaintiff and the Class which were caused or materially contributed to by the aforementioned acts of the Defendants include:

(a) pain, suffering, loss of quality and enjoyment of life;

(b) damages for past and future loss of income; and

(c) special damages and expenses including medical expenses.

(b) Waiver of Tort

35. As a result of the Defendants' conduct described herein, the Plaintiff and some or all of the Class reserve to themselves the right to elect before judgment to waive the tort of negligence and to have their damages assessed in an amount equal to the gross revenues received by the Defendants, or alternatively, the net income received by the Defendants as a result of selling the Product which was subject to the recall.

36. The Plaintiffs and the Class claim that such an election is appropriate for the following reasons, among others:

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

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

(c) absent the Defendants' tortious conduct the Product could not have been marketed nor would the Defendants have received any revenue from its sale in Nova Scotia; and

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

VI. PUNITIVE DAMAGES

37. The Defendants knew of the connection between the Product and AK for years before the May 2007 recall. The Defendants' conduct was reprehensible and departed to a marked degree from ordinary standards of decent behaviour. The Defendants' reckless disregard for public safety is deserving of punishment and condemnation by means of an award of punitive damages. This case raises issues of general deterrence. A punitive damage award in this case is necessary to express society's condemnation of conduct such as the Defendants', to advance public safety and to achieve the goal of both specific and general deterrence.

VII. MEDICAL MONITORING: RESPONDING TO MATERIAL RISK OF ILLNESS

38. Further, the use of the Product has also caused or materially contributed to increased health risks to the Plaintiff and the Class. As a result of its use, the Plaintiff and the Class have already and will continue to experience illness, anxiety, loss of amenities and enjoyment of life.

39. There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will protect the health of the Plaintiff and the Class. However, not all of these tests are generally available or being administered to the Plaintiff and the Class despite their elevated risk. The early detection of these conditions will significantly reduce the harm therefrom.

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

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

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

VIII. GENERAL

43. The Plaintiff pleads the *Sale of Goods Act,* R.S.N.S, c. 408, s. 1 and the *Consumer Protection Act,* R.S.N.S., c. 92, s. 1.

44. The Plaintiff pleads the doctrine of *respondeat superior* and state that the Defendants are vicariously liable to the Plaintiff and the Class for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.

IX. RELIEF SOUGHT

45. The Plaintiff repeats the foregoing paragraphs and state that the Defendants are jointly and severally liable for the following:

(a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;

(b) general damages, including aggravated damages for personal injuries;

(c) special damages for medical expenses and other expenses related to the use of the Product;

(d) aggravated, punitive and exemplary damages;

(e) further or alternatively the Plaintiff claims, on his own behalf and on behalf of the Class:

(i) a declaration that the benefits which accrued to the Defendants as a result of their negligence and failure to warn unjustly enriched the Defendants;

(ii) an accounting of the benefits which accrued to the Defendants as a result of their negligence and/or failure to warn;

(iii) a declaration that the Defendants hold in trust for the Plaintiff and the Class the benefits which accrued to the Defendants as a result of their negligence and/or failure to warn;

(iv) disgorgement of the benefits which accrued to the Defendants as a result of their negligence and/or failure to warn;

(f) damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Plaintiff and the Class, and to make recommendations about their treatment;

(g) subrogated claims on behalf of Provincial providers of medical services;

(h) interest pursuant to the *Judicature Act*;

(i) costs; and

(j) such further and other relief as this Honourable Court deems just.

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Halifax, Nova Scotia this 8TH day of November, 2007.

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