

2007 01T 319/CP

IN THE SUPREME COURT OF NEWFOUNDLAND AND LABRADOR  
TRIAL DIVISION

BETWEEN:

TRAVIS HARRIS

PLAINTIFF

AND:

AMO CANADA COMPANY and ADVANCED  
MEDICAL OPTICS, INC.

DEFENDANTS

Brought under the *Class Actions Act*, SNL 2001, c. C-18.1

STATEMENT OF CLAIM

The Parties

1. The Plaintiff, Travis Harris (“Travis”), is 23 years old. He was born January 9, 1984. He works for Sobeys Inc. at the Ropewalk Lane location in St. John’s, Newfoundland and Labrador. Travis resides at 66 Old Petty Harbour Road, St. John’s, Newfoundland and Labrador, A1G 1H5.
2. The Defendant, AMO Canada Company, (“AMO Canada”) is a company incorporated under the laws of in Nova Scotia that carries on business across Canada, but is not registered to conduct business in Newfoundland and Labrador.
3. The Defendant, Advanced Medical Optics, Inc., (“AMO”) is incorporated in Delaware and has its head office in Santa Ana, California. AMO Canada is a wholly owned subsidiary of AMO.
4. The Defendants individually and jointly researched, developed, tested, manufactured, distributed and sold Complete™ All-In-One MoisturePLUS® contact lens solution, having Drug Identification Number (“D.I.N.”) 02034425, (hereafter the “Contact Lens

Solution”) to residents of Newfoundland and Labrador. The Defendants engaged in a joint enterprise for the promotion and sale of the Contact Lens Solution in Newfoundland and Labrador.

5. In or around December 2003, the Plaintiff purchased several bottles of the Contact Lens Solution. Mr. Harris used the product regularly, and as directed, to clean and disinfect his contact lenses.
6. The Plaintiff brings this action on his own behalf, and on behalf of a class of persons resident in Newfoundland and Labrador (the “Class”).

### **Recall of the Contact Lens Solution**

7. On May 25, 2007, AMO announced a global recall of the Contact Lens Solution. On May 28, 2007, 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.
8. The cause of the recall was that the Contact Lens Solution 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.

9. 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.
10. 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 22 ophthalmology centres across the U.S. By March 2007, the CDC had received data from 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 138 cases of AK in the United States since January 1, 2005.
11. A common feature linking many of these AK cases reported to the CDC was use of the Defendants' Contact Lens Solution. 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.

### **Defendants' Negligence**

12. The Defendants were negligent in the research, development, testing, manufacture, distribution and sale of the Contact Lens Solution. 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

other class members relied on the Defendants' product, and that the Plaintiff and other class members 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 other class members if the Defendants' product was unsafe and ineffective. The Defendants were in such a close and proximate relationship with the Plaintiff and class members as to owe the Plaintiff and class members a duty of care.

13. 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.
14. 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.
15. Particulars of the Defendants' negligence are:
  - (a) failing to adequately test the safety and efficacy of their product before bringing it to market;

- (b) failing to do follow-up studies on the safety and efficacy of their product after bringing it market;
- (c) failing to monitor and follow up on reports of AK infections in users of their product;
- (d) failing to recall the product sooner;
- (e) failing to warn consumers, their health care providers, and Health Canada, of the increased risk of AK infection caused by their product;
- (f) marketing a product which was unsafe, not fit for its intended purpose, and not of merchantable quantity;
- (g) designing, manufacturing and marketing a product which was not reasonably safe and effective in preventing AK in comparison with already available, alternative designs;
- (h) failing to ensure proper concentrations of effective disinfectants in their product during manufacturing, and before shipping it to consumers; and
- (i) failing 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.

### **Plaintiff's Injuries**

16. Travis Harris began using the Contact Lens Solution in December of 2003. He had contacts for approximately five (5) years prior to this, and had previously been using a Bausch & Lomb contact lens solution with no problems. He purchased 2-3 bottles of the Defendants' Contact Lens Solution and used them regularly, as directed.

17. Mr. Harris first noticed problems with the Contact Lens Solution on Friday, May 21, 2004. He felt as if there was something in his left eye, and the eye was painful and red. While at work he flushed out the affected eye using the eye wash station there. This wash station was subsequently tested in early July of 2004 for infective agents and came back negative. On Saturday, May 22, 2004, he sought medical treatment at the emergency room of St. Clare's Mercy Hospital in St. John's. He was treated by a Dr. Lane, who diagnosed him with a scratched cornea and prescribed gentamicin eye drops. He used them as instructed, but his eye problems continued to worsen. On Tuesday, May 25, 2004, he went to Dr. David Hart, his family physician, and was given a prescription for Tobradex eye drops. Again he did as instructed, but his eye problems persisted.
18. The Plaintiff went to see Dr. Michael Bense, an optometrist, on Thursday, June 3, 2004 and he was then given a prescription for Viroptic solution. He returned on Monday, June 7, 2004 and was given a prescription for Neosporin drops. That Friday, June 11, 2004 Dr. Bense took corneal scrapings from Travis' left eye. The test for acanthamoeba came back negative. Wednesday, June 23, 2004 Travis got a second opinion from another optometrist, Dr. Brad Murphy, who gave him prescriptions for more Viroptic and more Neosporin. His right eye improved with the drops but his left eye had continued to deteriorate. The Plaintiff then went to Ottawa to see Dr. William Hodge, a corneal specialist on June 25, 2004. He was given a prescription for Pred Forte. These drops did not help. The condition continued to worsen and he began to lose vision in his left eye. Ulcers developed in both eyes, a diagnosis that was confirmed by more corneal scrapings. His eyes became extremely light sensitive causing him to stay in his darkened bedroom for a month. The Plaintiff only came out of his bedroom to eat in the kitchen or to go to an eye appointment, and he would always have a hat pulled down over his eyes when he did so.
19. The Plaintiff continued to be seen by Dr. Bense at the Health Sciences Centre in St. John's, Newfoundland and Labrador. On Friday, July 9, 2004, Dr. Bense suspected he might have AK and put him on Brolene and PHMB in addition to the Neosporin. He was then taking upwards of 45 drops a day in each eye. This led to a dramatic improvement

in the pain in his left eye, however, the vision in that eye remained blurry. The Brolene and PHMB are not available in Canada, and so had to be shipped in from San Jose, California, and the United Kingdom. When the Plaintiff ran out of drops and had to wait for a new shipment to come in, his eyes again got worse.

20. In September of 2004, the Plaintiff had to travel to Halifax to be seen by Dr. Christopher Seamone. Dr. Seamone noted “a lot of scarring on his cornea” and that his symptoms were consistent with interstitial keratitis. He also found it “striking” that the Plaintiff had responded to treatment for acanthamoeba, though he had still not been definitively diagnosed. In late September or early October of 2004, Dr. Bense did a corneal biopsy in an effort to obtain a definitive diagnosis. The results came back negative for AK. Despite this, Dr. Bense decided to treat the problem as AK because the patient had the symptoms associated with AK and the drops for AK had helped his condition.
21. Over the following two (2) years the Plaintiff remained under the care of Dr. Bense. The Brolene, PHMB and Neosporin drops started to take effect and his eyes began to heal. Luckily, Travis is not left with any scarring in his right eye and he now has perfect vision in that eye. However, there was scarring on his left eye that has reduced his vision in that eye to less than 20% of normal. On Thursday, May 4, 2006, the Plaintiff again saw Dr. Seamone in Halifax, who placed him on the donor list for a corneal transplant. He received the transplant on Tuesday, May 23, 2006. The patient’s eye should have healed from this operation within 48 hours, however there was a problem with too much fluid draining from his eye and two and a half weeks later it had still not healed. On Friday, June 9, 2006 two plugs were placed in his left eye to keep the fluid in his eye. These plugs helped tremendously and the very next day the eye started to heal. In June of 2007, he had to have the stitches removed that were used to attach the transplanted cornea. His vision is starting to come back in that eye. The plugs are still in his left eye and he is still taking the eye drops of Neosporin, Brolene and PHMB. Because the latter two are chemicals with no drug identification number, no portion of their cost has been covered by any insurance.

22. The Plaintiff has incurred significant out-of-pocket expenses from travelling to doctor's appointments out of province. He has still not fully recovered use of his left eye. Dr. Bense performed laser surgery on the left eye to correct blurred vision. The procedure was not totally effective and will have to be repeated.
23. The Plaintiff had been attending Memorial University of Newfoundland since September of 2002. He completed two years but was unable to return in September of 2004 because of his eye trouble. Furthermore, just days before his initial eye problems in May of 2004, the Plaintiff had attended an RNC/RCMP seminar with the intention of joining a police force. He took the required applications with the intention of filling them out over the weekend, as they were to be returned the following week. Unfortunately, the Friday of that weekend, May 21, 2004, was when the eye problems began. Not only was he unable to apply to a police force as planned, his current vision problems render him unfit for service in the future.

### **Trade Practices Act**

24. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the Contact Lens Solution for personal use by the Plaintiff and by class members were "consumer transactions" within the meaning of the *Trade Practices Act*, R.S.N.L. 1990, c. T-7 ("TPA"). With respect to those transactions, the Plaintiff and class members who purchased and/or used the Contact Lens Solution for personal use are "consumers" and the Defendants are "suppliers" within the meaning of the TPA.
25. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of the Contact Lens Solution, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of the Contact Lens Solution. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of the Contact Lens Solution were "unfair trade practices" within the meaning of s.5 of the TPA and contrary to s.7 of the TPA. The

Defendants' unfair trade practices included the Defendants' failure to properly disclose all material facts regarding the safety and efficacy of the Contact Lens Solution.

26. As a result of the Defendants' unfair trade practices, the Plaintiff and class members have suffered loss and damages. The Plaintiff seeks damages and statutory compensation pursuant to s.14 of the TPA on her own behalf and on behalf of class members who purchased and/or used the Contact Lens Solution for their personal use, including disgorgement of any revenue or profits obtained by the Defendants from the sale of the Contact Lens Solution.
27. It is not necessary for the Plaintiff and class members to establish reliance on the Defendants' deceptive acts or practices in order to establish breach of the TPA and a remedy for that breach. In the alternative, if reliance is required to establish statutory breach and/or remedy, such reliance may be assumed or inferred on the facts of this case. In the further alternative, there was actual reliance by the Plaintiff and class members on the Defendants' deceptive acts and practices.
28. As a result of the Defendants' negligence and the Defendants' deceptive acts and practices, the Plaintiff and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendant. Particulars of the loss and damage suffered by the Plaintiff and class members 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.
29. The Defendants knew of the connection between the contact lens solution 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.

30. The Plaintiff pleads that the Statement of Claim in this action may be served outside of Newfoundland and Labrador and relies on sections 6.07 (1) (f), (g), (i) and (j) and 6.07 (2) of the *Rules of the Supreme Court, 1986*.

### **Relief Sought**

31. The Plaintiff claims, on his own behalf, and on behalf of a class of similarly situated persons resident in Newfoundland and Labrador:
- (a) an order certifying this action as a class proceeding;
  - (b) general damages;
  - (c) special damages;
  - (d) punitive damages;
  - (e) damages and statutory compensation available under the *Trade Practices Act*;
  - (f) pre-judgment interest;
  - (g) costs; and
  - (h) such further and other relief as this Honourable Court may deem just.

**DATED** at the City of St. John's, in the Province of Newfoundland and Labrador, this 26<sup>th</sup> day of July, 2007.

CHES CROSBIE BARRISTERS  
Solicitors for the Plaintiff, whose  
address for service is:  
169 Water Street, 4<sup>th</sup> Floor  
St. John's, NL A1C 1B1  
*Per: Chesley F. Crosbie, Q.C.*

**TO: THE DEFENDANTS**  
AMO Company Canada  
Halifax, Nova Scotia

Advanced Medical Optics, Inc.  
Santa Ana, California

**ISSUED** at the City of St. John's, in the Province of Newfoundland and Labrador, this <sup>26</sup> day of July, 2007.

Sgt. Michael D. Sullivan  
Court Officer

2007 01T CP

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TRIAL DIVISION

**BETWEEN:**

TRAVIS HARRIS

PLAINTIFF

**AND:**

AMO CANADA COMPANY and ADVANCED  
MEDICAL OPTICS, INC.

DEFENDANTS

Brought under the *Class Actions Act*, SNL 2001, c. C-18.1

**NOTICE TO DEFENDANT(S)**

You are hereby notified that the Plaintiff may enter judgement in accordance with the Statement of Claim or such order as, according to the practice of the Court, the Plaintiff is entitled to, without any further notice to you unless within 10 days, after service hereof upon you, you cause to be filed in the Registry of the Supreme Court of Newfoundland and Labrador at St. John's a defence and unless within the same time a copy of your defence is served upon the Plaintiff or the Plaintiff's Solicitor at the Plaintiff's Solicitors stated address for service.

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 the Plaintiff's Solicitor within 10 days from the service of this notice upon you, then proceeding will be stayed.

**TO: THE DEFENDANTS**  
AMO Company Canada  
Halifax, Nova Scotia

Advanced Medical Optics, Inc.  
Santa Ana, California