



Court File No.: 50313

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

**BETWEEN:**

ALBAN ALOYSIUS CONLON AND VERNA ANTOINETTE CONLON

Plaintiffs

- and -

BRISTOL-MYERS SQUIBB CANADA CO. AND BRISTOL-MYERS SQUIBB COMPANY

Defendants

Proceeding under the *Class Proceedings Act*, 1992

**STATEMENT OF CLAIM**

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. 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 plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, 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. 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

~~March 8, 2006~~

MAY - 8 2006

Issued by

  
Local registrar

Address of court office Ministry of the Attorney General  
7755 Hurontario St.  
Brampton, Ontario  
L6W 4T6

TO: Bristol-Myers Squibb Canada Co.  
2365 Côte-de-Liesse  
Montréal, Québec  
H4N 2M7

AND TO: Bristol-Myers Squibb Company  
345 Park Avenue  
New York, New York  
USA 10154-0037

## CLAIM

1. The plaintiff, Alban Conlon, claims the following damages on his own behalf and on behalf of all persons similarly situated:
  - (a) general damages in the amount of \$100,000,000;
  - (b) special damages in the amount of \$100,000,000 or such other sum as this Honourable Court deems just;
  - (c) punitive, aggravated, and exemplary damages in the amount of \$10,000,000;
  - (d) the costs of distributing all monies received to the Class;
  - (e) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;
  - (f) costs on a substantial indemnity basis, including plus all applicable taxes; and
  - (g) such further and other relief as this Honourable Court may deem just.
  
2. The plaintiff, Alban Conlon ("Mr. Conlon"), is 70 years old and resides in Etobicoke, Ontario. Mr. Conlon took three doses of Tequin in March 2002 to treat bronchitis. The Tequin was administered orally in accordance with the package label and consumer information pamphlet, and in the manner it was intended to be used. Mr. Conlon reacted negatively to the Tequin, becoming incoherent and falling into a coma. He was hospitalized for seven months during which time he required extensive rehabilitation. Mr. Conlon requires ongoing medical care and will continue to require such care for the rest of his life.
  
3. The plaintiff, Verna Conlon ("Mrs. Conlon") is 68 years old and has been married to Mr. Conlon for fifty years. The Conlons have one son.
  
4. Mrs. Conlon, claims on her own behalf and on behalf of other persons similarly situated in Canada, damages in the amount of \$100,000 for each pursuant to the *Family Law Act*, R.S.O. 1990, c F.3 s.61 and all similar provincial legislation.

5. The defendant Bristol-Myers Squibb Canada Co. is a corporation with its headquarters in Côte-de-Liesse, Montreal, Quebec. Bristol-Myers Squibb Canada Co. is currently involved in and/or responsible for the research, development, manufacturing, sales, distribution and marketing of Tequin. At all material times, Bristol-Myers Squibb Canada Co. was an affiliate of Bristol-Myers Squibb Company.
6. The defendant Bristol-Myers Squibb Company is a U.S. company with its headquarters in New York, New York. Bristol-Myers Squibb Company is currently involved in and/or responsible for the research, development, manufacturing, sales, distribution and/or marketing of Tequin in Canada and elsewhere. At all material times, Tequin was manufactured, marketed, sold and/or distributed in Canada directly or indirectly through an agent, affiliate or subsidiary of Bristol-Myers Squibb Company. References herein to the actions or omissions of the defendants include Bristol-Myers Squibb Company, Bristol-Myers Squibb Canada Co. and the companies for whose actions they are responsible.
7. The business of each of Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Co. (collectively "Bristol-Myers") is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacture, marketing, sale and/or distribution of Tequin in Canada.

#### **THE DRUG**

8. Tequin (gatifloxacin) is a broad-spectrum antibiotic prescribed for the treatment of respiratory infections, urinary tract infections, and sexually transmitted diseases. It is a member of the class of drugs known as fluoroquinolone antibiotics, which are designed to treat bacterial infections.
9. Health Canada approved Tequin for sale in Canada in February, 2001.

## **RISKS ASSOCIATED WITH TEQUIN**

10. Tequin has been associated with serious risks of dysglycemic effects, including hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar), since its introduction into the U.S. market in 1999.
11. The defendants knew or ought to have known prior to the date upon which Tequin was approved for sale in Canada in 2001, or alternatively, prior to the date upon which Tequin was prescribed to Mr. Conlon, that there were significantly increased risks of serious adverse health complications, including glucose related coma and death, from ingesting Tequin. The defendants failed to properly apprise Mr. Conlon or physicians in Canada of those risks.
12. The defendants purposefully minimized and understated health hazards and risks associated with Tequin. The defendants, through literature and oral statements, deceived potential users of Tequin and their physicians by downplaying the known adverse and serious health effects of the drug. The defendants knowingly withheld relevant information from potential users of Tequin.
13. Between February 21, 2001 and February 28, 2003, Health Canada received 28 reports of abnormal glucose metabolism associated with Tequin, 19 of which were related to hypoglycemia, 7 were related to hyperglycemia and 2 were related to both hypoglycemia and hyperglycemia. All 28 cases were serious with 19 people admitted to hospital, and 2 reported fatalities.
14. In December, 2005, a "Dear Health Care Professional" letter was sent by the defendants advising health care professionals that serious cases of hypoglycemia and hyperglycemia were reported in association with the administration of Tequin and that "[w]hen Tequin is used in diabetic patients, blood glucose should be closely monitored".

15. In February 2006, Health Canada issued an advisory in which it advised diabetic patients not to use Tequin due to concerns about blood glucose disorders. The advisory further indicates that in December 2005 it requested Bristol-Myers Squibb to submit revised product information for Tequin, due to evidence about the possible link between Tequin and blood glucose disorders.
16. In March, 2006, two studies published in the New England Journal of Medicine, concluded that the risk of developing serious hyperglycemia was almost 17 times greater for elderly patients who took Tequin than for those who took another antibiotic. In the same population, those who took Tequin were four times more likely to be hospitalized for hypoglycemia. The results of the studies were published a month ahead of schedule by the New England Journal of Medicine due to the seriousness of the findings.
17. On May 1, 2006, Bristol-Myers Squibb Co. confirmed that it would stop making and selling Tequin. Bristol-Myers is returning its rights to the drug to Japan's Kyorin Pharmaceutical Co.

#### **CAUSE OF ACTION**

18. The defendants at all material times owed a duty of care to the plaintiffs to:
  - (a) ensure that Tequin was fit for its intended or reasonably foreseeable use;
  - (b) conduct appropriate testing to determine whether and to what extent Tequin posed serious health risks, including the risk of significant changes in blood sugar, in particular but not limited to diabetic patients;
  - (c) adequately warn the plaintiffs and their physicians that Tequin carries the risk of hypoglycemia and hyperglycemia, which can be serious and life-threatening;

- (d) ensure that prescribing physicians were kept fully and completely informed of all risks associated with Tequin;
  - (e) monitor, investigate, evaluate and follow up on adverse reactions to the use of Tequin; and
  - (f) properly inform Health Canada and other regulatory agencies of the risks of changes in blood sugar, including coma and death, associated with the use of Tequin.
19. The defendants negligently breached their duty of care.
20. The plaintiffs state that their damages were caused by the negligence of the defendants. Such negligence includes but is not limited to the following:
- (a) The defendants failed to ensure that Tequin was not dangerous to consumers and that the drug was fit for its intended purpose and of merchantable quality;
  - (b) The defendants failed to conduct appropriate testing to determine whether and to what extent the ingestion of Tequin poses serious health risks, including but not limited to changes in blood sugar;
  - (c) The defendants failed to conduct any or adequate follow-up studies on the efficacy and safety of Tequin;
  - (d) The defendants failed to provide Mr. Conlon, the class he seeks to represent, and their respective physicians with any or adequate warnings of the risks associated with Tequin;
  - (e) The defendants failed to warn Mr. Conlon, the class he seeks to represent, and their respective physicians, about the need for comprehensive regular medical

monitoring to ensure early discovery of significant and potentially fatal changes in blood sugar, including hypoglycemia and hyperglycemia;

- (f) The defendants falsely stated and/or implied that Tequin was safe and fit for its intended purpose when they knew or ought to have known that these representations were false;
- (g) The defendants disregarded reports of glysemic effects, including serious reports of hypoglycemia and hyperglycemia among patients who ingested Tequin in Canada and elsewhere;
- (h) The defendants misstated the state of research, opinion and medical literature pertaining to the purported benefits of Tequin and its associated risks;
- (i) The defendants failed to timely cease the manufacture and/or distribution of Tequin when they knew or ought to have known that this drug caused or could cause significant injury;
- (j) The defendants failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of Tequin and the risks associated with the drug;
- (k) The defendants encouraged their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the increased risks, including hypoglycemia and hyperglycemia, associated with Tequin; and
- (l) The defendants knew or ought to have known that there were safe and effective alternatives to Tequin and they failed to take any or appropriate steps to encourage dispensation of same;



(m) The defendants breached other duties of care to the plaintiffs, and the classes they seek to represent, details of which breaches are known only to the defendants.

21. The risks associated with Tequin, including hypoglycemia and hyperglycemia were in the exclusive knowledge and control of the defendants. The extent of the risks was not known and could not have been known to the plaintiffs. The plaintiffs' injuries would not have occurred but for the negligence of the defendants.

### **DAMAGES**

22. The plaintiffs injuries and damages were caused by the negligence of the defendants, their servants and agents.

23. As a result of the defendants' negligence, Mr. Conlon, and the class of persons he seeks to represent, have suffered and continue to suffer serious personal injuries and pain and suffering. Additionally, they have suffered and will continue to suffer damages including out-of-pocket expenses incurred including those in relation to medical treatment and medication, costs of future care and future services, loss of employment in some instances, loss of income and benefits and loss of future income, in addition to other special damages and expenses.

24. As a result of the conduct of the defendants, Mr. Conlon and the class of persons he seeks to represent, have suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

25. The expenses related to the medical treatment that Mr. Conlon and the persons he seeks to represent, have undergone, and will continue to undergo, have been borne by the various provincial health insurers including the Ontario Health Insurance Plan ("OHIP"). As a result of the negligence of the defendants, the various provincial health

insurers have suffered and will continue to suffer damages. The plaintiffs plead and maintain this action on behalf of all Provincial Health Insurers.

26. The plaintiffs plead that the defendants' conduct, in the design, development, testing, manufacturing, licensing, distribution, marketing, sale, and promotion of Tequin and the delayed warning and/or failure to recall was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, wilful, in intentional disregard of the safety of the plaintiffs, 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, exemplary and aggravated damages to the plaintiffs.
27. The plaintiffs plead and rely upon the provisions the *Class Proceedings Act*, 1992, S.O. 1992, c.6, the *Competition Act*, R.S.C. 1985, c. C-34, the *Food and Drugs Act*, R.S.C. 1985, c. F.27, and the *Negligence Act*, R.S.O. 1990, c. N-1, as amended, and regulations thereunder.

#### **SERVICE OUTSIDE OF ONTARIO**

28. The plaintiffs plead and rely on section 17 (g), (h), (o) and (p) of the Rules of Civil Procedure, allowing for service *ex juris* of the foreign defendants. Specifically, this originating process may be served without court order outside Ontario in that the claim is:
- (a) in respect of a tort committed in Ontario (rule 17.02(g));
  - (b) in respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed (rule 17.02(h));

- (c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and
- (d) against a person carrying on business in Ontario (rule 17.02(p)).

**PLACE OF TRIAL**

29. The plaintiffs propose that this action be tried in Brampton, Ontario.

~~April~~, 2006

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