

No.
Vancouver Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

**EVA SZENDE, EXECUTRIX
OF THE ESTATE OF MARGARET SZENDE**

PLAINTIFF

AND:

**BRISTOL-MYERS SQUIBB CANADA CO. and
BRISTOL-MYERS SQUIBB COMPANY**

DEFENDANTS

Brought under the Class Proceedings Act

STATEMENT OF CLAIM

THE PARTIES

1. The Plaintiff is the Executrix of the Estate of Margaret Szende and resides at Suite 1, 2425 Edgemont Boulevard, in the District of North Vancouver, in the Province of British Columbia.
2. The Defendant, Bristol-Myers Squibb Canada Co., is a foreign corporation registered extra-provincially within the Province of British Columbia under number A0059629 and has its registered office at 15th Floor, 1040 West Georgia Street, in the City of Vancouver, in the Province of British Columbia. At all material times, Bristol-Myers Squibb Canada Co. was involved in and/or responsible for the research, development, manufacturing, sales, distribution and/or marketing of Tequin in Canada. At all material times, Bristol-Myers Squibb Canada Co. was an affiliate of Bristol-Myers Squibb Company.

3. The Defendant, Bristol-Myers Squibb Company is a U.S. company with its registered address and main place of business at 345 Park Avenue, New York, New York, U.S.A. At all material times, Bristol-Myers Squibb Company was 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, Bristol-Myers Squibb Company manufactured, marketed, sold and/or distributed Tequin in Canada directly or indirectly through an agent, affiliate or subsidiary.

4. 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 manufacture, marketing, sale and/or distribution of Tequin in Canada.

5. In bringing this action on behalf of a class of people in British Columbia who were prescribed Tequin, to be further defined in a Motion for Certification, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings Act*, R.S.B.C. 1996, c. 50 and amendments thereto.

THE PLAINTIFF

6. This action is brought by the Executrix of the Estate of Margaret Szende for the benefit of the following persons:

- (a) Eva Szende, daughter of Margaret Szende, whose address is #1 – 2425 Edgemont Boulevard, in the District of North Vancouver, in the Province of British Columbia;
- (b) Susana Katz, daughter of Margaret Szende, whose address is 318 East 19th Street, in the City of North Vancouver, in the Province of British Columbia,

- (c) All British Columbians who suffered injury or damage as a result of the ingestion of Tequin.

THE DRUG

7. 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.

8. Health Canada approved Tequin for sale in Canada in February, 2001.

RISKS ASSOCIATED WITH TEQUIN

9. 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.

10. 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 Margaret Szende, 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 Margaret Szende and putative class members or physicians in Canada of those risks.

11. 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.

12. 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.

13. 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".

14. 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.

15. 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.

16. On May 1, 2006, Bristol-Myers Squibb Company confirmed that it would stop making and selling Tequin. Bristol-Myers is returning its rights to the drug to Japan's Kyorin Pharmaceutical Co.

THE EVENT

17. On or about September 11, 2003, Margaret Szende attended her general practitioner as she was not feeling well. Her physician, apparently concerned that she might develop pneumonia, prescribed Tequin.

18. Margaret Szende ingested the Tequin as prescribed from September 12 until September 16, 2003, at which point her health had deteriorated such that she was admitted to the Emergency Department of the Lions Gate Hospital on September 17, 2003.

19. It was determined at that time that her blood glucose levels were extremely abnormal.

20. All efforts to bring her blood glucose under control failed with the result that she died on September 30, 2003.

21. Prior to Margaret Szende's ingestion of Tequin, she had never experienced, nor been treated for, blood glucose abnormalities.

THE CAUSE OF ACTION

22. The Defendants at all material times owed a duty of care to Margaret Szende and putative class members 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 Margaret Szende and putative class members 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.

23. The Defendants negligently breached their duty of care.

24. The Plaintiff states that the death of Margaret Szende and the damages sustained by putative class members 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 Margaret Szende, the putative class, and their respective physicians with any or adequate warnings of the risks associated with Tequin;
- (e) The Defendants failed to warn Margaret Szende, the putative class, 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;

- (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; and
- (m) The Defendants breached other duties of care to Margaret Szende and the putative class, details of which breaches are known only to the Defendants.

25. 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 by Margaret Szende or putative class members. Margaret Szende's death would not have occurred but for the negligence of the Defendants.

DAMAGES

26. The Plaintiff as Executrix of the Estate of Margaret Szende pleads and will rely on the provisions of the *Family Compensation Act* in her claim for damages on her own behalf and on behalf of her sister, Susana Katz, for:

- (a) Medical and hospital expenses which would have been recoverable by Margaret Szende if she had not died;
- (b) Reasonable expenses of the funeral and the disposal of the remains of the deceased person;
- (c) Loss of dependency/support for both past and future;
- (d) Loss of household services; and

(e) Loss of love, guidance and affection.

27. The Plaintiff claims damages on behalf of all those British Columbians who would otherwise be entitled to damages pursuant to the provisions of the *Family Compensation Act* as a result of the death of a family member caused by the negligence of the Defendants or each of them as hereinbefore set out.

PATIENT CLASS

28. The Plaintiff claims damages for all British Columbians who, as a result of the Defendants' negligence, ingested Tequin and, as a result, 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.

29. British Columbians who have ingested Tequin have suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

30. The Plaintiff pleads that the Defendant's 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, willful, in intentional disregard of the safety of Margaret Szende and putative class members, indifferent to the consequences and motivated by economic considerations, such as maintaining cash flow and market share. Such conduct renders the Defendants liable to pay punitive, exemplary and aggravated damages to the Plaintiff and putative class members.

STATUTES

31. The Plaintiff pleads and relies upon the *Sale of Goods Act*, R.S.B.C. 1996, c. 410, the *Class Proceedings Act*, R.S.B.C. 1996, c. 50, the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2 and the *Negligence Act*, R.S.B.C. 1996, c. 333.

PRAYER FOR RELIEF

WHEREFORE the Plaintiff claims, on her own behalf, on behalf of Susana Katz, and on behalf of the putative class, against the Defendants and each of them for the following:

- (a) An Order certifying this proceeding as a Class Proceeding and appointing Eva Szende and her counsel to represent the class and any appropriate subclasses thereof;
- (b) A declaration that the Defendants were negligent in the pre-market research and development , design, testing, manufacture, representations to their regulators, distribution and sale, post-market monitoring recall and warning, as hereinafter described and are liable for the damages described hereunder or the damages to be assessed;
- (c) A declaration that the Defendants are strictly liable to the Plaintiff and other class members for damages caused by the ingestion of Tequin;
- (d) An Order requiring the Defendants to pay for the cost of all medical monitoring and treatment which class members will require as a result of the ingestion of Tequin;
- (e) Damages for innocent misrepresentation;

- (f) Damages for breach of warranty;
- (g) Damages for negligence;
- (h) Damages for negligent misstatements;
- (i) Punitive damages;
- (j) Exemplary damages;
- (k) Pre-judgment interest pursuant to the *Court Order Interest Act*;
- (l) Special costs; and
- (m) Such further and other relief as this Honourable Court may seem just.

PLACE OF TRIAL: Vancouver, British Columbia

DATED:

Solicitor for the Plaintiff

THIS STATEMENT OF CLAIM is filed by **KENNETH J. BAXTER**, of the firm **POYNER BAXTER LLP**, Barristers and Solicitors, whose place of business and address for delivery is 408 – 145 Chadwick Court, North Vancouver, BC V7M 3K1; Telephone: 604-988-6321; Fax: 604-988-3632