ACTION NO. 0901-15719

IN THE COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL DISTRICT OF CALGARY

BETWEEN:

DIANNA CHRISTINE BUSCH as Representative Plaintiff

Plaintiff

-and-

PFIZER CANADA INC. and PFIZER, INC.

Defendants

STATEMENT OF CLAIM

Proceeding under the *Class Proceedings Act*, S.A. 2003, c. C-16.5

Parties and Overview

1. This action concerns Champix (generic name: varenicline). It is a prescription drug sold as a smoking cessation aid. It has been linked to reports of neuropsychiatric adverse events, including depression and suicide.

2. The Plaintiff alleges that the Defendants negligently designed, tested, labeled, manufactured and marketed this drug to Canadians. In particular, the Defendants failed to provide adequate and timely warning to Canadians about the risk of neuropsychiatric adverse events caused by this drug.

3. The Plaintiff, Dianna Christine Busch, resides in Red Deer, Alberta. She was prescribed Champix and took it as directed. She was subsequently hospitalized for a drug induced psychosis. She suffered personal injuries, depression, and near suicide as a result of taking

Champix. She brings this action on her own behalf, and on a behalf of a class of similarly situated persons resident in Alberta and elsewhere in Canada. This class of persons will be more fully defined in the Plaintiff's application for class certification.

4. The Defendant, Pfizer Canada, Inc. ("Pfizer Canada") is incorporated pursuant to the laws of Canada, with registration in Alberta. Its head office is at 17300 Trans Canada Highway, Kirkland, Quebec, H9J 2M5.

5. The Defendant, Pfizer, Inc. ("Pfizer") is a Delaware corporation whose address and principal place of business is 235 East 42nd Street, New York, New York 10017.

6. Pfizer Canada is a subsidiary of Pfizer.

Facts Regarding Champix

7. The Defendants individually and collectively participated in one or more of the following: the development, manufacture, labeling, distribution, marketing, promotion and importation of Champix for sale to Canadians.

8. The Defendants obtained regulatory approval to sell Champix in Canada under the *Food and Drugs Act*, R.S.C. 1985, c.F-27 from Health Canada by Notice of Compliance, dated January 24, 2007, with sales beginning in approximately April 2007 in this country.

9. Pfizer also marketed the drug in the United States and Europe, (U.S. brand name: Chantix) obtaining approval of the U.S. Food and Drug Administration ("FDA") through an accelerated review process on or about May 11, 2006, and from the European Medicines Agency of the European Union ("EMEA") on or about September 29, 2006. Sales of the drug in these jurisdictions preceded sales in Canada by about a year.

10. Champix is designed to work by inhibiting nicotine receptors in the brain. It employs a somewhat novel mechanism of action that is intended to operate as both an "agonist" and "antagonist" to decrease nicotine craving and psychological rewards associated with smokers. As an agonist, Champix is supposed to reduce nicotine craving and withdrawal symptoms. As an antagonist, Champix is supposed to reduce the psychological reward associated with smoking.

11. The receptors in the human brain affected by Champix are controlled by dopamine. This is a neurotransmitter produced by the brain. Smokers receive bursts of nicotine when they inhale which trigger an immediate increase in dopamine, thereby creating the craving and perceived pleasure from smoking.

12. In theory, Champix is supposed to work by blocking dopamine, and thus the cravings for nicotine are diminished and psychological pleasure derived from smoking is reduced. Essentially, Champix regulates and restricts dopamine and blocks pleasure sensors in the brain to depress the normal flux of emotions experienced by humans in daily life.

13. The Defendants negligently failed to properly and fully study and evaluate the mechanism of action and the effects thereof associated with Champix. Neuropsychiatric harm was a foreseeable outcome of this drug, given its intended operation on the brain.

14. The Defendants' failures to conduct adequate studies of Champix include:

(a) intentionally or negligently excluding certain patients from clinical trials. For example, the Defendants excluded patients from clinical trials if they had previous history and/or diagnosis of mental/psychological disorders;

(b) intentionally or negligently ignoring any proper evaluation of depression, aggression, suicide, suicidal ideation, suicidal thoughts, or suicidal tendencies; and

(c) intentionally or negligently failing to determine what other effect Champix has on other receptors in the human brain and body.

15. The Defendants knew or should have known that Champix increased the risk of causing serious injuries and death, including suicide and attempted suicide. The active ingredient in Champix is varenicline tartrate which is derived from cytosine. Cytosine had been used in Europe as a smoking cessation drug. There are reports going back to 1972 linking cytosine to cases of suicide and attempted suicide. The risk of harm with this precursor drug should have alerted the Defendants to the risk of harm with Champix.

16. The Defendants also should have known of the potential risks of serious injury and death related to Champix because of experience with other drugs with similar mechanisms of action on dopamine, including Zoloft.

17. Further, there was evidence that arose during the Defendants' clinical trials which demonstrated risk of injury due to Champix. The Defendants failed to properly consider and follow up on this evidence. In a clinical study completed by the Defendants in February 2004, one of the subjects participating in the study committed suicide. In a second study completed by the Defendants in March 2005, there were multiple reports of adverse psychiatric effects among test subjects, including cases of acute psychosis.

18. In clinical trials, the efficacy of Champix has been shown to be limited, at best. In a head to head study comparing Champix against the nicotine patch, published on February 8, 2008, the benefits of using Champix over the patch were found to be marginal and not statistically significant. Unlike Champix however, the nicotine patch does not present a risk of serious injury, death or suicide. Given its limited benefit, and its apparent risk, the Defendants ought to have proceeded more cautiously, and ought to have conducted more testing before bringing the product to market in Canada and elsewhere.

19. The Defendants disregarded such concerns in favour of profits. After its launch, Champix quickly became one of the Defendants' best selling new drugs in Canada and elsewhere. The Defendants sold over 700,000 prescriptions of Champix to Canadians in the first year the product was on the market in this country, earning substantial revenues and profits.

Regulatory Events

20. Beginning in 2006, the EMEA began to receive reports of neuropsychiatric adverse events in patients taking Champix in Europe. It conducted follow up investigations into cases of suicide and suicide ideation in July, October, and November, 2007. Similar reports were received by the FDA in the United States during 2006 and 2007.

21. Thus, before the Defendants even began to sell Champix in Canada, they were already aware of reports of adverse events received by regulators in the United States and Europe.

22. In November 2007, the United States FDA issued an advisory concerning the drug, noting a possible association between suicide and attempted suicide within days to weeks of initiating treatment with the drug. On November 20, 2007, the U.S. regulator issued a directive to Pfizer requiring "Modification of the patient package insert to address possible drug adverse effects [including] depression, agitation, suicidal thoughts..."

23. In Europe, the EMEA issued a press release on December 14, 2007, in which it "concluded that updated warnings are needed to increase awareness of cases of suicidal ideation and suicide attempts reported in patients taking Champix".

24. In Canada, the label was updated in December 2007, and again on May 15, 2008. However, these warnings were inadequate, and were not quickly, properly and thoroughly disseminated by the Defendants. The Defendants failed to take adequate or prompt steps to bring these changes to the attention of Canadian doctors and patients. Letters were not promptly sent to doctors and pharmacies alerting them to the change in labeling, nor did the Defendants' sales personnel immediately telephone or meet with doctors and pharmacists to advise them of this new safety information. Existing product on store shelves, which contained prior labeling, was not replaced with new product, with updated labels.

25. The 2008 edition of the *Compendium of Pharmaceutical Specialties*, the desk reference commonly used by Canadian doctors and pharmacists as an encyclopedia of drug labels, contained Champix's original product label from January 23, 2007. It did not contain updated safety information, including a warning about neuropsychiatric adverse events. The Defendants' updated warning label from May 15, 2008, was included in the 2009 edition of the *Compendium of Pharmaceutical Specialties*.

26. In April 2008, Health Canada issued an advisory that it had received 46 reports of adverse psychiatric effects in Canadians taking Champix.

27. On June 13, 2008, Pfizer Canada issued a letter to Canadian doctors advising them of the risk of psychiatric illness associated with the drug. The letter stated that between April 2007 and April 30, 2008, a total of 226 Canadian cases of neuropsychiatric adverse events had been reported.

28. On January 6, 2009, Health Canada issued a reminder to Canadians of the risks of Champix, and that the label would need to be further updated. It noted that "[t]his update is the result of continuing reports, in Canada and internationally, of serious psychiatric symptoms associated with the use of Champix, and is intended to increase awareness of this risk."

The Plaintiff's Particulars

29. The Plaintiff, Ms. Busch, was prescribed Champix by her family physician in February 2008. She took the drug regularly and as directed.

30. Neither Ms. Busch, nor her doctor, had received any warning from the Defendants about the risk of neuropsychiatric injury at the time the drug was prescribed. The package insert that Ms. Busch received at the pharmacy when she purchased Champix had not been updated by the Defendants.

31. Had Ms. Busch been warned of the risks of neuropsychiatric injury prior to taking the drug, she would not have taken it.

32. Soon after Ms. Busch started taking the drug, she experienced adverse psychiatric effects. She suffered auditory and visual hallucinations. Her thoughts turned to suicide. She suffered unusual and unexplained changes in emotion which she found difficult to control. She found herself engaging in non-sensical and irrational behaviour. She cut off all of her hair, even though she had previously been very fond of her long hair. She gave away nearly all of her possessions, even possessions of great personal and sentimental value. Ms. Busch had never before experienced such difficulties. Her behaviour was completely out of character for her, and was very upsetting to her and to her family.

33. Ms. Busch continued taking Champix until March 5, 2008 when she went to see her doctor to complain about the distressing symptoms she was experiencing. He promptly took her off Champix.

34. The symptoms continued. On April 2, 2008, she carved marks into her wrists in an attempt at suicide. Her husband took her to emergency department at Red Deer Regional Hospital. She was admitted and hospitalized for three weeks for treatment.

35. Ms. Busch suffered personal injury as a result of her taking Champix. The drug diminished her quality and enjoyment of life. She missed work as a result of her hospitalization, and subsequently lost employment. Her personal confidence and mental state has not returned to what it was before she took the drug, and her condition continues to be monitored by her doctor.

Negligence and Failure to Warn

36. As the manufacturers, marketers, developers, distributors, labellers and/or importers of Champix, the Defendants were in such a close and proximate relationship to the Plaintiff, and other class members, as to owe them a duty of care. They caused the drug to be introduced into the stream of commerce in Canada, and they knew that any dangers or adverse effects related to the drug would cause foreseeable injury to the Plaintiff and class members.

37. The Defendants owed a duty to the Plaintiff and class members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, distributing, importing, and selling Champix.

38. In particular, the Defendants owed a duty to the Plaintiff and class members to warn of dangers and adverse side effects of the product. Such warning must be prompt, clear and accurate. It must be appropriate to the seriousness of the risk of injury presented by the drug. The Defendants must take appropriate steps to ensure that such warning is actually received by the Plaintiff, other class members, and their health care providers.

39. The Defendants failed to exercise the due care expected of a reasonable pharmaceutical manufacturer under the circumstances, and they breached their duty to the Plaintiff and class members. They failed to provide an adequate, timely warning as to the risk of serious injury and death related to their product. Particulars of their negligence are:

(a) failing to test Champix properly and thoroughly before releasing the drug to market;

(b) intentionally excluding from such testing those patients who might be vulnerable to Champix's adverse effects, thereby achieving a safety profile in clinical testing that was unrealistic;

(c) failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of Champix, including reports of suicide and neuropsychiatric adverse events in subjects on Champix during actual clinical trials;

(d) failing to consider the risks posed by Champix given reports of suicide in cytosine, the drug from which Champix is derived;

(e) failing to consider the risks posed by Champix given the clinical experience with other drugs, with similar mechanisms of action on dopamine receptors in the brain, such as Zoloft;

(f) failing to disclose to regulators, the medical community, and the general public, data from its pre- and post-marketing tests of Champix which indicated risks associated with its use;

(g) failing to conduct an adequate and timely analysis of adverse event reports;

(h) marketing the drug in Canada after already receiving sufficient reports of adverse effects among patients in the United States and Europe as to alert the Defendants to the serious risks of injury presented by Champix;

(i) failing to provide adequate and timely warning of the significant risks of injury and death presented by Champix;

(j) failing to promptly and adequately draw the attention of doctors, pharmacists and patients to changes in the product's labeling;

(k) failing to promptly call or write doctors and pharmacists to alert them to changes in labeling;

(l) failing to replace existing packaging on store shelves with updated labeling;

(m) failing to educate healthcare providers about the safest use of the drug;

(n) failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient;

(o) failing to design and implement an appropriate post-marketing surveillance system to monitor and quickly identify adverse risks among vulnerable patient populations, particularly in circumstances where the Defendants had deliberately excluded such populations from pre-clinical testing; and

(p) negligently continuing to manufacture and market Champix after the Defendants knew or should have known of the risk of serious injury and death associated with using this drug.

Damages

40. As a result of the negligence of the Defendants, the Plaintiff and other Class Members have suffered the following damages:

(a) personal injury;

(b) special damages for out of pocket expenses and loss of property;

(c) loss of income; and

(d) cost of future care.

41. The conduct of the Defendants warrants a claim for punitive damages. They have conducted themselves in a high-handed, wanton and reckless manner, and without regard to public safety. Particularly egregious was the Defendants' maintenance of Champix in the Canadian marketplace and continued marketing of the product as safe and effective when they knew or should have known of the risks associated with its use.

Real and Substantial Connection

42. There is a real and substantial connection between the subject matter of this action and the Province of Alberta for the following reasons:

(a) the Defendants marketed and sold Champix in Alberta;

(b) the Plaintiff purchased and used Champix in Alberta;

(c) the Plaintiff resides in Alberta;

(d) the Plaintiff's damages, and those of other Class Members resident in Alberta, were sustained in Alberta.

Venue and Trial Duration

43. The Plaintiff proposes that this action be tried at the City of Calgary, in the Province of Alberta.

44. The Plaintiff anticipates that the trial will take in excess of 25 days.

Claim

45. WHEREAS the Plaintiff claims:

(a) An order certifying this action as a class proceeding under the *Class Proceedings Act*, S.A. 2003, c. C-16.5, and appointing the Plaintiff as Representative Plaintiff for the Class proposed above;

(b) General damages;

(c) Special damages;

(d) Punitive damages;

(e) Judgment interest pursuant to the *Judgment Interest Act*, R.S.A. 2000, c. J-1;

(f) Costs of this action on a substantial indemnity basis and GST thereon; and

(g) Such further and other relief as this Honourable Court finds just.

DATED at the City of Calgary in the Province of Alberta, this 20th day of October, 2009, **AND DELIVERED** by DOCKEN & COMPANY, #900, 800-6th Avenue S.W. Calgary, Alberta T2P 3G3, telephone (403) 269-3612, Attention: Clint Docken, and by KLEIN LYONS, Barristers & Solicitors, Suite 1100, 1333 West Broadway, Vancouver, British Columbia, V6H 4C1, Attention: David A. Klein, Solicitors for the Plaintiffs, whose address for service is in care of the said Solicitors.

ISSUED out of the Office of the Clerk of the Court of Queen's Bench of Alberta, Judicial District of Calgary, Alberta, this 20 day of October, 2009.

K. McAUSLAND COURT SEAL

CLERK OF THE COURT

Action No: 0901-15719 2009

IN THE COURT OF QUEEN'S BENCH OF ALBERTA JUDICIAL DISTRICT OF CALGARY

BETWEEN:

DIANNA CHRISTINE BUSCH as Representative Plaintiff

Plaintiff

-and-

PFIZER CANADA INC. and PFIZER, INC.

Defendants

STATEMENT OF CLAIM

This Statement of Claim is issued by
Docken & Company
Solicitor for the Plaintiff who resides in Red Deer, AB, and whose address for service is in care of said Solicitor at
900, 800-6th Avenue SW
Calgary, AB T2P 3G3

And is addressed to the Defendants whose places of business as far as known to the Plaintiff are:

Pfizer Canada, Inc.
17300 Trans Canada Highway
Kirkland, Quebec H9J 2M5

Pfizer, Inc.
235 East 42nd Street
New York, New York 10017.

File No. 7813

CLERK OF THE COURT
OCT 20 2009
CALGARY, ALBERTA

NOTICE TO THE DEFENDANTS

TO: PFIZER CANADA INC. AND PFIZER, INC.

You have been sued. You are the Defendant. You have only 15 days to file and serve a Statement of Defence or Demand of Notice. You or your lawyer must file your Statement of Defence or Demand of Notice in the office of the Clerk of the Court of Queen's Bench in Calgary, Alberta. You or your lawyer must also leave a copy of your Statement of Defence or Demand of Notice at the address for service for the Plaintiff named in this Statement of Claim.

WARNING: If you do not do both things within 15 days, you may automatically lose the law suit. The Plaintiff may get a Court judgment against you if you do not file, or do not give a copy to the Plaintiff, or do either thing late.

This Statement of Claim is filed by:

Docken & Company
Barristers and Solicitors
900, 800-6th Avenue SW
Calgary, AB T2P 3G3

Clint Docken
Phone: (403) 269-3612
Fax: (780) 269-8246

Klein Lyons
Barristers & Solicitors
Suite 1100, 1333 West Broadway
Vancouver, B.C. V6H 4C1

Solicitors for the Plaintiff, who resides in Red Deer, AB.

And whose address for service is in care of the said Solicitors and is addressed to the Defendants.

The Defendant carry on business in Calgary and elsewhere in the Province of Alberta.