C A N A D A

PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

N° 500-06-000473-096

S U P E R I O R C O U R T
(Class action)

DANIEL CLAUDE, residing and domiciled at [redacted]

-and-

SIMON DUNN, residing and domiciled at [redacted]

Petitioners

v.

PFIZER INC., duly constituted corporation, having its head office and principal place of business at 235 East 42nd Street NY, NY 10017

-and-

PFIZER CANADA INC., duly constituted corporation, having its head office and principal place of business at 17300 Trans-Canada Highway, Kirkland (Quebec) H9J 2M5

Respondents

AMENDED MOTION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE
(Articles 1002 etc. C.C.P.)

IN SUPPORT OF THEIR CLAIM, THE PETITIONERS RESPECTFULLY STATE THAT:

INTRODUCTION

1. In 2007, the Respondents introduced a drug into the Canadian market, publicly alleging that it was capable of aiding smokers to quit smoking and this without any serious side effects to their health. Instead, the drug, sold under the trade name Champix, caused serious injury to hundreds of patients throughout Canada, including death. The Respondents breached their obligations toward class members in omitting to inform them of the risks of neuropsychiatric events to which they were exposed in using Champix. Also, Champix is unfit for its intended purpose in that the risks stemming from its use outweigh the possible benefits and this for the great majority of patients to whom Champix was prescribed;

THE PARTIES AND THE PETITIONERS' THEORY OF THE CASE

2. The Petitioners, Daniel Claude and Simon Dunn, propose to institute the present class action on behalf of the following group of which they themselves are members:

> *"All persons residing in Québec, who have purchased or ingested the drug CHAMPIX and the heirs, family members and dependants of said persons"*
>
> *and*
>
> *"All persons residing outside of Québec, who have purchased or ingested the drug CHAMPIX and the heirs, family members and dependants of said persons"*

hereinafter known as "the class";

3. The facts giving rise to an individual action on behalf of the Petitioners are as follows:

3.1 The Respondent, Pfizer Canada Inc. ("Pfizer Canada"), is a corporation incorporated pursuant to the laws of the Dominion of Canada with its registered head office located in the City of Kirkland in the Province of Quebec, the whole as appears from an excerpt from the Quebec Enterprise Register website, filed as **exhibit R-1**;

3.2 The Respondent Pfizer Inc. ("Pfizer") is a corporation incorporated pursuant to the laws of the State of Delaware in the United States

of America with its registered head office located in the City of New York in the State of New York, the whole as appears from an excerpt of the Pfizer U.S. website, filed as **exhibit R-2**;

3.3 Pfizer develops, manufactures, markets and distributes pharmaceuticals throughout the world. Pfizer U.S. operated and acted at all times in Canada through its wholly owned subsidiary Pfizer Canada;

3.4 At all material times, Pfizer and Pfizer Canada, acting in concert, manufactured and distributed throughout Canada a smoking cessation drug known commercially in Canada as CHAMPIX. In the U.S. the drug is sold under the brand name CHANTIX;

3.5 In or about May 2006, CHANTIX was approved for sale by the *Food and Drug Administration* ("FDA") and launched into the market for sale in the United States in or about August 2006;

3.6 In or about February 2007, CHAMPIX was approved for sale by Health Canada and introduced for distribution and sale in the Canadian market in or about April 2007;

3.7 In 2007, Respondent Pfizer's revenues for Chantix/Champix were $883 million, the whole as appears from excerpts of their 2007 Annual Report, filed as **exhibit R-3**;

3.8 CHAMPIX is known generically as varenicline tartrate. It has been indicated for use as an aid to quit smoking;

3.9 Within a year immediately following the introduction of CHAMPIX into the Canadian Market, Health Canada's Canadian Adverse Drug Reaction Monitoring Program reported 226 cases of adverse neuropsychiatric reactions, the whole as appears from a copy of public safety information issued by Health Canada June 2008, filed as **exhibit R-4**. It is commonly accepted that as little as 10% of adverse events are in fact reported;

3.10 An important number of adverse effects were also reported by other regulatory or reporting agencies around the world;

3.11 For instance, in the first quarter of 2008, Champix accounted for 1001 serious injuries or deaths reported in the U.S., that is more than any other prescription drug in this time period. By comparison,

the top 10 brand name drugs combined received 837 adverse report, the whole as appears from page 14 of a copy of a document entitled Quarter Watch: 2008 Quarter 1, dated October 2008 and published by The Institute for Safe Medication Practices, filed as **exhibit R-5;**

3.12 Consumption of CHAMPIX can cause serious health injuries;

3.13 Despite this knowledge, Respondents did not adequately inform class members or health professionals that Champix could cause serious health injuries. On the contrary, Respondents led class members to believe that Champix was safe;

3.14 The Respondents breached their obligations towards class members by selling them a drug without providing adequate information in respect of the health risks associated with the consumption of Champix;

3.15 The Respondents should indemnify all class members who suffered injuries as a result of using CHAMPIX, including being held to pay them punitive and/or exemplary damages. The Respondents are also liable to class members for the collective reimbursement of the cost of prescriptions paid by them, which are not covered by the public drug insurance plan;

CHAMPIX'S LACK OF SAFETY

CHAMPIX'S ACTIVE INGREDIENT AND ITS' PHYSIOLOGICAL EFFECTS ON THE BRAIN

3.16 Smokers receive bursts of nicotine when they inhale tobacco smoke which triggers an immediate increase of dopamine. Dopamine is produced in several areas of the brain and operates as a neurotransmitter. An increase in dopamine creates both the craving and the perceived pleasure from smoking. It is at the core of the addiction problem;

3.17 CHAMPIX is designed to work by specifically inhibiting dopamine receptors in the human brain;

3.18 CHAMPIX is hence supposed to reduce nicotine craving and withdrawal symptoms and the psychological reward associated with smoking;

3.19 Essentially, CHAMPIX regulates dopamine and blocks pleasure sensors to depress the normal flux of emotion experienced by people in daily life;

3.20 According to the current product monograph issued by the Respondents, CHAMPIX works as follows: *varenicline acts as a partial agonist at α4β2 nicotinic acetylcholine receptors. In the absence of nicotine, varenicline's agonist activity is at a significantly lower level than nicotine, but sufficient to activate the central nervous mesolimbic dopamine system, believed to be the neuronal mechanism underlying reinforcement and reward experienced upon smoking. In the presence of nicotine, which competes for the same human α4β2 nicotinic acetylcholine receptor (nAChR) binding site, varenicline prevents nicotine from activating the α4β2 receptor, since it has higher affinity for this site and this prevents full stimulation of the central nervous mesolimbic dopamine system*, the whole as appears from a copy of the current product monograph of Champix last revised in May 2008, filed as **exhibit R-6**;

THE HEALTH RISKS ASSOCIATED WITH THESE PHYSIOLOGICAL EFFECTS

3.21 By regulating and blocking the dopamine sensors, it was to be expected that CHAMPIX could have a negative impact on the reward system and hence logically could cause psychiatric effects including psychological problems and depression. In fact, clinical data, studies and reports published today confirm that CHAMPIX poses a health risk to its users, namely neuropsychiatric in nature;

3.22 As stated above, in the year immediately following the introduction of CHAMPIX into the Canadian Market, Health Canada's Canadian Adverse Drug Reaction Monitoring Program reported 226 cases of adverse neuropsychiatric reactions. Of these reports, at least 46 people described psychiatric cases involving symptoms of amnesia, abnormal dreams, anxiety, insomnia, abnormal thinking, and somnolence, the whole as appears from **exhibit R-4;**

3.23 The number of adverse events reported in Canada was proportionally similar to those reported earlier in the US. In fact on

November 20, 2007, the US regulatory agency, the FDA, indicated in its' *Early Communication about an Ongoing Safety Review Varenicline* that it had received reports of suicidal thoughts and aggressive and erratic behaviour in patients who ingested Chantix. The FDA hence requested that the Respondent Pfizer elevate the prominence of this safety information to the warnings and precautions section of Chantix's prescribing information and labelling, the whole as appears from a copy of a Public Health Advisory on Chantix released by the FDA, on February 1,2008, filed as **exhibit R-7**;

3.24 The European Medicines Agency (EMEA), as part of its' routine pharmacovigilance activities noted receiving "cases of suicidal ideation and suicide" in July, October and November 2007. The following month, the EMEA "concluded that updated warnings to doctors and patients [were necessary] to increase awareness of cases of suicidal ideation and suicide attempts" in patients using varenicline, the whole as appears from an EMEA Press Release dated December 14, 2007, filed as **exhibit R-8**;

3.25 Similarly, a report authored by EMEA involved a 61-year-old man who committed suicide less than a month after he finished taking CHANTIX. The EMEA's report indicates that CHANTIX had approximately six times the number of serious adverse reactions as the smoking cessation drug Zyban® (bupropion), the whole as appears from page 35 of a copy of a document entitled Scientific Discussion taken from the EMEA's website , filed as **exhibit R-9**;

3.26 In the 4th quarter of 2007, varenicline accounted for 988 serious injuries in the U.S. reported to the FDA, more than any other individual drug in this time period. By comparison the FDA received a median of 5 reports of serious injury for 769 different drugs in the 4th quarter. Only 35 drugs accounted for 100 or more reports, the whole as appears from a document entitled "Strong Safety Signal Seen for New Varenicline Risks", dated May 2008, published by The Institute for Safe Medication Practices, filed as **exhibit R-10**;

3.27 From May 2006 through December 2007, the FDA had received 227 domestic reports of suicidal acts, thoughts or behaviors, 397 cases of possible psychosis and 525 reports of hostility or aggression. These totals included 28 cases of suicide and 41 mentions of homicidal ideation, 60 cases of paranoia and 55 cases

of hallucination. The categories were not mutually exclusive, the whole as appears from exhibit **R-10**;

3.28 In the 1st quarter of 2008, varenicline accounted for 1001 serious injuries or deaths in the U.S. reported to the FDA, more than any other prescription drug in this time period. By comparison, the FDA received 837 cases for the top 10 brand name drugs combined, the whole as appears from exhibit **R-5**;

3.29 In the 2nd quarter of 2008, the FDA received 231 possible cases of hostility or aggression, 186 cases of suicidality and 153 cases of possible psychosis associated with the use of varenicline. The total included 12 new cases of completed suicide and 26 suicide attempts, the whole as appears from page 12 of a document entitled Quarter Watch: 2008 Quarter 2, dated January 2009 and published by The Institute for Safe Medications Practices, filed as **exhibit R-11**;

3.30 In less than two years since Champix's approval in 2006, the drug has accounted for 3325 reported serious injuries in the United States, including 112 deaths, the whole as appears from page 2 of exhibit **R-11**. Proportionally, this number is comparable to the cases reported in Canada, as indicated by exhibit **R-4**;

3.31 Many of the cases received and reviewed by Health Canada and the FDA were in respect of patients without any prior history of psychiatric illness;

THE RESPONDENTS' KNOWLEDGE

3.32 As manufacturers and distributors of CHAMPIX, the Respondents knew or are legally presumed to have known of the risks associated with the use of CHAMPIX. Without limiting the generality of the foregoing, the Respondents further failed to adequately study or test CHAMPIX to determine the risk of serious injury and/or death associated with its use;

3.33 The Respondents knew of the physiological effects of CHAMPIX in the brain, including its effects on dopamine transmission. They knew or ought to have known that it could cause psychiatric and psychological effects;

3.34 Respondents' knowledge is further confirmed by the fact that the active ingredient in CHAMPIX, varenicline tartrate, is derived from cytosine. Cytosine has been used for decades as a smoking cessation drug in Eastern European Countries. Reports as early as 1972 link cytosine (the derivative of the active ingredient in CHAMPIX) to cases of suicide and attempted suicide;

3.35 Furthermore, Respondents sponsored two clinical trials, prior to introducing CHAMPIX for sale on the Canadian market;

3.36 Contrary to what the Respondents claimed and advertised, when they first sold Champix in Canada, none of these clinical trials could establish the safety of Champix for the general population nor for patients with a prior history of psychiatric problems. Instead, they were designed essentially to assess the efficacy of Champix as a smoking cessation drug;

3.37 However, while sponsoring those clinical trials, the Respondents were made aware of some serious adverse reports, which should have signalled the existence of health risks associated with the consumption of Champix:

3.38 In fact, on July 5, 2006, *The Journal of the American Medical Association* ("JAMA") published the results of a Pfizer sponsored study in which one of the subjects participating in the study committed suicide, the whole as appears from a copy of the article entitled "Effect of Maintenance Therapy with Varenicline on Smoking Cessation", filed as **exhibit R-12**;

3.39 Also on July 5, 2006, JAMA published the results of a randomized controlled trial completed more than a year earlier in March, 2005, which reported cases of serious adverse events associated with varenicline including acute psychosis, emotional liability, insomnia and abnormal dreams, the whole as appears from a copy of the article entitled "Efficacy of Varenicline, an α4β2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Placebo or Sustained-Release Bupropion for Smoking Cessation", filed as **exhibit R-13**;

3.40 Faced with those neuropsychiatric health injuries, Respondents should have investigated and thoroughly studied all health risks associated with the consumption of Champix. They failed to do so;

3.41 The Respondents' failure to conduct proper clinical trials to evaluate the safety of Champix is further evidenced by Respondents' admission that "[p]atients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the controlled clinical trial program", the whole as appears from a copy of the Respondents' statement dated January 18, 2008, filed as **exhibit R-14**;

3.42 The Respondents knew or ought reasonably to have known, when they tested the drug, that the sample group of individuals they chose was not representative of the people they were targeting for consumption of the drug;

3.43 In conclusion, the Respondents breached their obligations by introducing a drug on the market without having first conducted adequate studies to establish its safety and also by:

a) Ignoring the known physiological effects of CHAMPIX on dopamine transmission in the brain;

b) Ignoring any proper evaluation of adverse neuropsychiatric events, namely depression, aggression, suicide, suicidal ideation, suicidal thoughts, suicidal tendencies, etc.

c) Excluding certain patients from clinical trials.

3.44 The Respondents failed to follow basic precautionary principles prior to the marketing of Champix. Unbeknownst to them, Canadian users were *de facto* being used as subjects in a vast clinical trial, which eventually established the lack of safety of CHAMPIX, namely by way of the neuropsychiatric injuries it caused;

CHAMPIX'S LACK OF EFFICACY

3.45 Some clinical trials sponsored by the Respondents suggest that Champix allows certain smokers, in the short term, to be free of their addiction to nicotine. Champix's efficacy as compared with that of placebo does not surpass 15% over 1 year, the whole as appears from exhibit **R-12**;

3.46 Available data suggests that Champix's efficacy is not much higher than that of bupropion, an alternative smoking cessation drug

available on the market. Finally, data suggests that Champix is not more effective than combination nicotine patches, the whole as appears from exhibit **R-12**;

3.47 In fact, at the time of its introduction on the Canadian market, Champix was evaluated by the Patented Medication Price Review Board (PMBRB), an independent organization whose function is to determine whether the price of patented drug entering the market is excessive, the whole as appears from an excerpt of the PMBRB's website regarding its' mandate, filed as **exhibit R-15**;

3.48 The PMBRB concluded that Champix's clinical effectiveness was comparable to other smoking cessation drugs available on the market, the whole as appears from a copy of a document taken from the PMPRB's website, communicated in support of the present motion as **exhibit R-16**;

3.49 However, as explained above, the risks of injury caused by consumption of CHAMPIX are higher than those of comparable drugs;

THE INADEQUACY OF THE INFORMATION PROVIDED BY THE RESPONDENTS

3.50 The information contained in the Champix product monograph or other information packages and labels distributed by the Respondents in Canada contain inadequate warnings of risk for injury and/or death;

3.51 Firstly, prior to May of 2008, CHAMPIX's product monograph did not contain any warning whatsoever in respect of the neuropsychiatric health risks associated with the consumption of Champix;

3.52 In May 2008, the Respondents modified CHAMPIX's product monograph distributed in Canada. to include, namely, the following warnings : "*There have been rare post-marketing reports of serious neuropsychiatric symptoms with CHAMPIX, including depressed mood, agitation, hostility, changes in behaviour, suicidal ideation and suicide, as well as worsening of pre-existing psychiatric illness (previously diagnosed or not)"*, the whole as appears from page 4 of **exhibit R-6**;

3.53 The information contained in the Champix product monograph is still insufficient for many reasons, including but not limited to the following as it fails to explicitly warn consumers of : a) the importance of a close follow-up by doctors of patients taking Champix b) the real number and frequency of serious adverse injuries c) the severity of such serious injuries and d) the appropriate action to be taken if certain adverse events are experienced;

3.54 Moreover, the Respondents did not adequately inform health care professionals of the risks associated with the ingestion of Champix;

THE RESPONDENTS' BEHAVIOR TOWARDS THE DISCLOSURE OF THE RISKS OF CHAMPIX AND PUNITIVE AND/OR EXEMPLARY DAMAGES

3.55 Smoking causes death and serious health injuries. Smoking kills thousands of Canadians per year. Smoking is considered one of the most important public health issues in the country, the whole as appears from an excerpt of Physicians for a Smoke Free Canada's website, filed as **exhibit R-17**;

3.56 Smoking creates a strong physiological dependence;

3.57 The effectiveness of any smoking cessation drug must be assessed against its' risks;

3.58 As stated above, the efficacy of Champix as a smoking cessation drug, compared to placebo, was determined to be roughly 13% over a period of 52 weeks. Canadians spent several tens of millions of dollars on prescriptions for Champix in 2008 alone. Yet Champix caused a large number of serious health injuries, which would have been avoided if proper warnings had been given by the Respondents;

3.59 These serious adverse reports occurred immediately after the introduction of Champix into the market. The Respondents had knowledge of those adverse reports. They also knew the number of reported events represented a small portion of the adverse effects actually caused by the ingestion of Champix. However, the Respondents made no attempt to communicate them immediately and effectively to the class members or their health professionals;

3.60 Instead of adopting basic precautionary measures to protect the safety of those Canadians, the Respondents denied and continue to deny the mounting scientific evidence linking CHAMPIX to serious injury and death including certain psychiatric side effects and adverse events such as suicide, attempted suicide, and erratic and aggressive behaviour;

3.61 In their press release dated January 18, 2008, the Respondents stated: "A causal relationship between CHANTIX and these reported symptoms has not been established. In some reports, however, an association could not be excluded.", the whole as appears from exhibit **R-14**;

3.62 The FDA and Health Canada had to take positive steps to force the Respondents to communicate to class members the risks of serious health injuries which were caused by the consumption of Champix;

3.63 The Respondents should have voluntarily strengthened the warning label for CHAMPIX prior to Health Canada's intervention;

3.64 The Respondents should have notified consumers of any potential problems at the first reports of adverse reactions - particularly life-threatening reactions such as the risk of serious injury and death, instead of delaying said changes to the warning label and product monograph;

3.65 The Respondents widely and successfully marketed Champix throughout Canada by many means including, inter alia, media advertisements, and statements contained in sales literature, the whole as appears from documentation taken from the Champix website as well as a press release from the Respondent Pfizer Canada, filed as **exhibit R-18**;

3.66 The Respondents misrepresented the safety of Champix. They led the consumer to believe that Champix was safe. The lack of clear and adequate warnings allowed Champix's market share to expand and it eventually became the leading smoking cessation drug in Canada. In particular, the lack of adequate warning permitted the Respondents to create an edge over their competitors, such as Bupropion, whose product monographs already included warnings on the risks associated with their use;

3.67 The Respondents knew that if such health risks stemming from the use of Champix, the actual efficacy of their product and the need for an extensive medical follow-up of patients taking Champix were appropriately disclosed to class members and health care professionals, Champix would not be prescribed as extensively;

THE RESPONDENTS' NEGLIGENCE

3.68 The Respondents breached the obligations incumbent upon them with respect to the civil law regime in Québec as well as the common law regime in the Canadian common law provinces. They are therefore liable, pursuant to these regimes, to compensate class members for the damages caused to them. Without limiting the generality of the foregoing, the Respondents breached the following obligations:

i. They failed to ensure that Champix was fit for its' intended purpose;

ii. They failed to conduct appropriate testing to determine the existence and nature of the health risks associated with the ingestion of Champix;

iii. They failed to conduct adequate clinical studies to ensure the safety of Champix, namely they failed to propose a clinical research protocol with a representative sample of eventual consumers of Champix;

iv. They failed to adequately test Champix so that its' risks and adverse effects be known and communicated in an efficient and constant manner;

v. They failed to conduct clinical studies after the sale of Champix with regard to its' efficacy and safety;

vi. They failed to provide the Petitioners, class members and their health care professionals with any or adequate warnings of the inherent risks associated with CHAMPIX, including any or adequate updated and current information regarding the risks and effects of CHAMPIX immediately as such information became available;

vii. They failed to warn, or to effectively warn, the Petitioners, class members and their health care professionals about the need for comprehensive regular medical monitoring to ensure early discovery of potentially adverse events, namely by way of “black box warnings”;

viii. They failed to put into place efficient and adequate procedures in order to inform health care professionals of the risks associated with the use of Champix;

ix. They failed to avoid representing Champix as a drug without risks;

x. They failed to rapidly and efficiently evaluate and investigate adverse event reports;

xi. They failed to avoid falsely overstating the benefits of Champix while at the same time failing to communicate the risks associated with its’ use;

3.69 The Superior Court of Québec has jurisdiction to entertain a national class action filed on behalf of all users of Champix in Canada. Attorneys for the Petitioners are working with the firm of McPhadden Samac Merner Tuovi who have filed a class action in Ontario on behalf of users of Champix;

3.70 The Petitioners rely on the legislation listed in Appendix A in support of the claims of members residing in the Canadian common law provinces;

THE PETITIONER – DANIEL CLAUDE

3.71 The Petitioner, Daniel Claude, is a member of the class described above;

3.72 He has been a smoker since 1973;

3.73 Daniel Claude unsuccessfully tried to quit smoking on two occasions, once in 1988 and once in 2000, before trying for a third time with Champix;

3.74 Daniel Claude decided to attempt to quit smoking for a third time and was prescribed the drug Champix in August 2008;

3.75 Approximately two days after initiating consumption of the drug Champix, the Petitioner experienced adverse effects, namely high fever and vomiting;

3.76 One week later, on or around August 17, 2008, Daniel Claude phoned the Respondent, Pfizer Canada's, information center about these adverse effects and was informed that said adverse effects were rare but not unknown;

3.77 The Petitioner continued taking Champix;

3.78 Approximately 10 days later, on or around August 24, 2008, the Petitioner attempted to commit suicide;

3.79 The Petitioner had no previous history of suicidal behaviour or tendencies;

3.80 Daniel Claude was hospitalized for several days and was treated in a center for approximately two weeks;

3.81 After his treatment was completed, Daniel Claude reported the adverse events he experienced to the Respondents, the whole as appears from a copy of the adverse event form completed by the Petitioner, filed as **exhibit R-19**;

3.82 The Petitioner then received a response letter from the Respondents, a copy of which is filed as **exhibit R-20**;

3.83 The Petitioner also reported his adverse events to Health Canada's Canada Vigilance Program, the whole as appears from a copy of the response letter received by the Petitioner from Health Canada, filed as **exhibit R-21**;

3.84 Following those events, the Petitioner sought to understand the factors that lead him to attempt to commit suicide;

3.85 The Petitioner then began searching for information on the Internet and was astonished to learn that other people reported having developed suicidal behaviours following their consumption of the drug Champix;

3.86 The Petitioner was at no point in time before or during his consumption of the drug Champix informed that it could cause psychiatric and psychological problems or that it caused several people to develop suicidal behaviors, thoughts or tendencies;

3.87 The Petitioner was at no point in time before or during his consumption of the drug Champix informed that several adverse events, including suicidal behavior were reported regarding the use of this drug and that a close medical follow-up would have been required;

3.88 If the Petitioner had known of such adverse effects, he would not have used CHAMPIX and would not have attempted to commit suicide;

3.89 Since his attempted suicide, the Petitioner has personally made several inquiries in respect of the nature and extent of the adverse effects associated with using CHAMPIX that were experienced by class members;

THE PETITIONER – SIMON DUNN

3.90 The Petitioner, Simon Dunn, is a member of the class described above;

3.91 He is a 42 year old college instructor and has been employed in post secondary education for eleven years;

3.92 He has been a smoker since 1985;

3.93 Simon Dunn unsuccessfully tried to quit smoking on three occasions once in 1999, once in 2002 using Zyban and once in November 2007 using Champix;

3.94 Approximately three days after starting the course of Champix, the Petitioner experienced adverse effects, namely bizarre violent dreams and restlessness. These symptoms disappeared thereafter;

3.95 The Petitioner continued to take the medication until January 21st, 2008. At this time the Petitioner experienced a severe change in behaviour for the first time in his life;

3.96 For reasons unknown to him and beyond his control, the Petitioner experienced an uncontrollable onset of profound rage which led him to assault his family members and to then attempt suicide;

3.97 The Petitioner contacted his family doctor who advised him to stop taking the medication Champix;

3.98 The Petitioner had continued suicidal feelings for approximately one week after he stopped using Champix;

3.99 The Petitioner has no personal memory of the events of January 21st 2008;

3.100 The Petitioner had no previous history of suicidal behaviour or tendencies nor violent behaviour prior to taking Champix;

3.101 The Petitioner was at no point in time before and during his consumption of the drug Champix informed that it could cause psychiatric and psychological problems or that it caused several people to develop suicidal behaviors, thoughts or tendencies;

3.102 The Petitioner was at no point in time before and during his consumption of the drug Champix informed that several adverse events, including suicidal behavior were reported regarding the use of this drug and that a close medical follow-up would have been required;

3.103 If the Petitioner had known of such adverse effects, he would not have used CHAMPIX and would not have attempted to commit suicide;

3.104 The Petitioners suffered direct damages in relation to their ingestion of Champix;

3.105 The Petitioners have the right to hold the Respondents liable for these damages due to their faults, breaches and omissions;

3.106 The Petitioners evaluate the amount to which they are entitled as compensation of the physical, psychological and moral damages caused by the ingestion of Champix at least $100,000 each, which can be adjusted, and reserve the right to claim for other types of pecuniary damages as they manifest themselves;

3.107 The Petitioners also evaluate the amount of punitive and/or exemplary damages to which they are entitled at $10 000 each, which can be adjusted;

3.108 The Petitioners also seek the reimbursement of the portion of the cost of Champix that is not covered by the public prescription drug insurance plan for themselves and for class members;

3.109 From April 2007 to April 2008, Champix was the object of more than 708 534 prescriptions in Canada, the whole as appears from a Health Canada's Public Communication dated June 13, 2008, filed as **exhibit R-4**;

3.110 The cost of the indicated 12-week Champix treatment, namely 165 tablets, is $278.025 at $1.685 per tablet, the whole as appears from exhibit **R-16**;

4. The facts giving rise to an individual action on behalf of each class member against the Respondents, other than the facts set out in paragraph 3 with the necessary adaptations, are the following:

- Each class member purchased or ingested the drug Champix in Canada;

- Each class member suffered damages in relation to the purchase or ingestion of Champix;

5. The composition of the class renders the application of articles 59 or 67 C.C.P. difficult or impracticable in that :

5.1 The drug Champix was put on the market in Canada in or about April 2007;

5.2 From April 2007 to April 2008, Champix was the object of more than 708 534 prescriptions in Canada, as appears from **exhibit R-4**;

5.3 Moreover, as of April 2008, there were 226 neuropsychiatric adverse events associated or caused by the ingestion of Champix, as appears from exhibit **R-4**;

5.4 It is commonly accepted that there is substantial underreporting of adverse effects. In the United States, the most current data on the issue indicates that no more than 10% and sometimes as little as 1-

2% of adverse events are reported, the whole as appears from page 7 of exhibit **R-5.** The same rate of underreporting should apply in Canada;

5.5 Therefore, the number of persons in Canada who have had psychiatric or psychological adverse events caused by Champix, exceeds by many times the number of neuropsychiatric adverse events reported in Canada which, between April 2007 and April 2008, total 226 events.

5.6 Due to the confidentiality of medical records, it is impossible to know the identity of the persons having ingested this drug;

5.7 Consequently, the composition of the class renders the application of articles 59 C.C.P. or 67 C.C.P.

6. The questions of fact and of law, that are identical, similar or related and bind each class member to the Respondents (…) are:

6.1 What are the health risks associated or caused by the use of Champix?

6.2 Can the use of Champix cause neuropsychiatric or psychological problems?

6.3 Does Champix have a higher efficacy than that of the other smoking cessation drugs available on the market?

6.4 Is Champix fit for its intended purpose?

6.5 Did the Respondents adequately and sufficiently warn the class members of the health risks associated with the use of Champix ?

6.6 Did the Respondents know or ought to have known of the risks of injury associated with the use of Champix?

6.7 Did the Respondents fail to conduct adequate clinical trials prior to sale of CHAMPIX in Canada?

6.8 Did the Respondents commit a fault calling into play their civil liability, pursuant to the applicable civil law rules in Québec?

6.9 With respect to common law, do the Respondents owe a duty of care to the class members?

6.10 With respect to common law, did the Respondents breach their duty of care towards the class members?

6.11 What is the nature and scope of the class members' rights and the Respondents' obligations stemming from the Québec *Consumer Protection Act*?

6.12 What is the nature and scope of the class members' rights and the Respondents' obligations stemming from the various consumer protection legislation in the common law provinces?

6.13 With respect to civil law, are the Respondents liable to pay punitive and/or exemplary damages to each class member?

6.14 With respect to common law, are the Respondents liable to pay punitive and/or exemplary damages to each class member?

6.15 Can the class members seek collective recovery of the cost of acquisition of Champix, or of any other damages?

6.16 With respect to common law, does the waiver of torts entitle class members to seek the reimbursement of the cost of acquisition of Champix or the profits generated by the sale of Champix?

7. The questions of fact and of law particular to each class member consist of :

7.1 The gravity of the damages suffered;

7.2 The amount of damages each can claim from the Respondents;

8. It is opportune to grant the class action for the benefit of the class members;

9. The nature of the action your Petitioners intend to bring on behalf of the class members is:

An action in damages based on manufacturers' liability and on consumer protection legislation;

10. The conclusions your Petitioners seek are:

GRANT the class action of the Petitioners and the class members against the Respondents;

CONDEMN the Respondents jointly and severally, to pay to the Petitioner, Daniel Claude, the amount of $100,000 for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents jointly and severally, to pay to the Petitioner, Simon Dunn, the amount of $ 100, 000 for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents jointly and severally, to pay to each class member an amount to be determined as compensation for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate, plus the additional indemnity provided by the law, to accrue from the date of service;

CONDEMN the Respondents jointly and severally to pay to the Petitioners the amount of $10 000 each in punitive and/or exemplary damages with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents jointly and severally to pay to each class member the amount of $10,000 in punitive and/or exemplary damages with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents to reimburse the portion of the cost of Champix that is not covered by the public prescription drug insurance plan to the Petitioners and the class members;

ORDER the collective recovery of member claims for the non-pecuniary damages if the proof allows for it;

ORDER the collective recovery of member claims for punitive and/or exemplary damages;

ORDER the collective recovery of member claims for the pecuniary damages if the proof allows for it and alternatively, order the individual recovery of member claims;

THE WHOLE with costs, including notice and experts costs;

11. Your Petitioners, Daniel Claude and Simon Dunn, ask that the status of representatives of the class be ascribed to them;

12. Your Petitioners are in a position to represent the class members adequately and this for the following reasons :

12.1 Your Petitioners are disposed to invest the necessary resources and time towards the accomplishment of all formalities and tasks necessary for the bringing of the present class action and they are committed to collaborate fully with their attorneys;

12.2 Your Petitioners are capable of providing their attorneys with the information useful to the bringing of the present class action;

12.3 Your Petitioners act in good faith with the only goal of obtaining justice for themselves and each class member;

12.4 Your Petitioners have already made several inquiries in respect of the nature and extent of the adverse effects associated with using CHAMPIX that were experienced by class members and intend to continue doing so;

12.5 (…)

13. Your Petitioners propose that the class action be carried out before the Superior Court of the district of Montreal for the following reasons:

13.1 The Respondent Pfizer Canada has a place of business and a head office in Montreal;

13.2 Attorneys for the Petitioners have their offices in Montreal;

13.3 A large number of the class members reside in the district of Montreal and its surroundings;

FOR THESE REASONS, THE COURT:

GRANTS the motion of the Petitioners;

GRANTS the following action in damages by way of a class action:

> An action in damages based on manufacturers' liability and on consumer protection legislation

ASCRIBES the status of representatives to Daniel Claude and Simon Dunn, on behalf of the class described hereafter:

> *"All persons residing in Québec who have purchased or ingested the drug CHAMPIX and the heirs, family members and dependants of said persons"*
>
> *and*
>
> *"All persons residing outside of Québec, who have purchased or ingested the drug CHAMPIX and the heirs, family members and dependants of said persons"*

IDENTIFIES the principal questions of fact and law to be determined collectively as follows:

> What are the health risks associated or caused by the use of Champix?
>
> Can the use of Champix cause neuropsychiatric or psychological problems?
>
> Does Champix have a higher efficacy than that of the other smoking cessation drugs available on the market?
>
> Is Champix fit for its intended purpose?
>
> Did the Respondents adequately and sufficiently warn the class members of the health risks associated with the use of Champix ?
>
> Did the Respondents know or ought to have known of the risks of injury associated with the use of Champix?

Did the Respondents fail to conduct adequate clinical trials prior to sale of CHAMPIX in Canada?

Did the Respondents commit a fault calling into play their civil liability, pursuant to the applicable civil law rules in Québec?

With respect to common law, do the Respondents owe a duty of care to the class members?

With respect to common law, did the Respondents breach their duty of care towards the class members?

What is the nature and scope of the class members' rights and the Respondents' obligations stemming from the Québec *Consumer Protection Act*?

What is the nature and scope of the class members' rights and the Respondents' obligations stemming from the various consumer protection legislation in the common law provinces?

With respect to civil law, are the Respondents liable to pay punitive and/or exemplary damages to each class member?

With respect to common law, are the Respondents liable to pay punitive and/or exemplary damages to each class member?

Can the class members seek collective recovery of the cost of acquisition of Champix, or of any other damages?

With respect to common law, does the waiver of torts entitle class members to seek the reimbursement of the cost of acquisition of Champix or the profits generated by the sale of Champix?

IDENTIFIES as follows the sought conclusions:

GRANT the class action of the Petitioners and the class members against the Respondents;

CONDEMN the Respondents jointly and severally, to pay to the Petitioner, Daniel Claude, the amount of $100,000 for the physical, psychological and moral damages incurred as well as for loss of

income and past and future care costs, with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents jointly and severally, to pay to the Petitioner, Simon Dunn, the amount of $100, 000 for the physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents, jointly and severally, to pay to each group member an amount to be determined as compensation for the physical, psychological and moral damages, as well as for loss of income and past and future care costs incurred, with interest at the legal rate, plus the additional indemnity provided by the law, to accrue from the date of service;

CONDEMN the Respondents jointly and severally to pay to the Petitioners the amount of $10,000 each in punitive and/or exemplary damages with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents jointly and severally to pay to each class member the amount of $10,000 in punitive and/or exemplary damages with interest at the legal rate, plus the additional indemnity provided by law, as of and from the date of service, which can be adjusted;

CONDEMN the Respondents to reimburse the portion of the cost of Champix that is not covered by the public prescription drug insurance plan to the Petitioners and the class members;

ORDER the collective recovery of member claims for the non-pecuniary damages if the proof allows for it;

ORDER the collective recovery of member claims for punitive and/or exemplary damages;

ORDER the collective recovery of member claims for the pecuniary damages if the proof allows for it and alternatively, order the individual recovery of member claims;

THE WHOLE with costs, including notice and expertise costs;

DECLARES that, unless exclusion, the class members will be bound by all judgments to intervene on the class action in the manner provided by the law;

SETS the deadline for opting-out to thirty (30) days from the publication of the notice to members, after which the class members who will not have prevailed themselves of the means of exclusion will be bound by any judgement to intervene;

ORDERS the publication of a notice to the class members, according to the terms set forth in the form of the Rules of practice of the Superior Court of Quebec in civil matters, to be published once in the daily newspaper La Presse, The Gazette, The Globe and Mail and any other newspaper as ordered by the Court;

ORDERS the Respondents and counsel for the Petitioners to publish the notices to the members, in French and in English, on their websites;

SETS the deadline provided for the publishing of the notice to members at thirty (30) days of the final judgment to intervene on the present motion;

TRANSMITS the file to the Chief Justice for the determination of the district in which the class action will have to be instituted and the designation of a judge for the hearing;

ORDERS the clerk of this Court, in the case that the class action must to be instituted in another district, to transmit the file, as of the decision of the Chief Justice, to the clerk of this other district;

THE WHOLE with costs, including the costs of notice.

Montreal, November 23, 2009

LAUZON BÉLANGER INC.
Counsel for the Petitioners

C A N A D A

PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

N° 500-06-000473-096

SUPERIOR COURT
(Class action)

DANIEL CLAUDE
-and-
SIMON DUNN

Petitioners

v.

PFIZER INC.
-and-

PFIZER CANADA INC.

Respondents

LIST OF EXHIBITS

R-1 Excerpt from the Quebec Enterprise Register website (Pfizer Canada);

R-2 Excerpt from the Respondent, Pfizer's, website;

R-3 Excerpt from the 2007 Annual Rapport;

R-4 Copy of a public safety information issued by Health Canada in June 2008;

R-5 Document entitled Quarter Watch: 2008 Quarter 1, dated October 2008 and published by The Institute for Safe Medication Practices;

R-6 Copy of the current version of Champix's product monograph, last revised in May 2008;

R-7 Copy of the Public Health Advisory on Chantix issued by the FDA on February 1, 2008;

R-8 Press release issued by the EMEA dated December 14, 2007;

R-9 Copy of a document entitled Scientific Discussion taken from the EMEA's website;

R-10 Document entitled Strong Safety Signal Seen for New Varenicline Risks, dated May 2008 and published by The Institute for Safe Medication Practices;

R-11 Document entitled Quarter Watch: 2008 Quarter 2, dated January 2009 and published by The Institute for Safe Medication Practices;

R-12 Copy of an article entitled Effect of Maintenance Therapy with Varenicline on Smoking Cessation published on July 5, 2006 in The Journal of the American Medical Association;

R-13 Copy of an article entitled Efficacy of Varenicline, an α4β2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Placebo or Sustained-Release Bupropion for Smoking Cessation published on July 5, 2006 in The Journal of the American Medical Association;

R-14 Copy of a statement made by the Respondents dated January 18, 2008;

R-15 Excerpt from the PMPRB's website regarding its' mandate;

R-16 Copy of a document taken from the PMPRB's website;

R-17 Excerpt from Physicians for a Smoke Free Canada's website;

R-18 Copy of documentation on Champix accessible on Champix's website as well as press release from the Respondent Pfizer Canada;

R-19 Copy of the adverse event form completed by the Petitioner, Daniel Claude;

R-20 Copy of the response letter sent to the Petitioner Daniel Claude by the Respondents;

R-21 Copy of the letter received by the Petitioner Daniel Claude from Health Canada;

Montreal, November 23, 2009

LAUZON BÉLANGER INC.
Counsel for the Petitioners

APPENDIX A

- *Consumer Protection Act*, 2002 S.O. 2002, CHAPTER 30 Schedule A
- *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2
- *Fair Trading Act*, R.S.A. 2000, c. F-2
- *Consumer Protection Act,* S.S. 1996, c. C-30.1
- *Consumer Product Warranty and Liability Act*, S.N.B. 1978, c. C-18.1
- *Consumer Protection Act*, C.C.S.M. c. C200
- *Consumer Protection Act*, R.S.N.S. 1989, c. 92
- *Sale of Goods Act*, R.S.P.E.I. 1988, c. S-1
- *Sale of Goods Act*, R.S.N.L. 1990, c. S-6
- *Sale of Goods Act*, R.S.Y. 2002, c. 198
- *Sale of Goods Act*, R.S.O. 1990, c. S.1
- *Fatal Accident Act,* R.S.N.L. 1990, c. F.6, s. 2 and 4;
- *Fatal Accidents Act*, C.C.S.M. c.F.50, s.1 and 3.1(1);
- *Fatal Accidents Act,* R.S.A. 2000, c. F-8, s.1 and 3(1) ;
- *Fatal Accidents Act,* R.S.N.B. 1973, c.F-7, s.1;
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3, s.1 and 3(1)(a);
- *Fatal Accidents Act,* R.S.P.E.I. 1988, c. F-5, s.1 and 2(1);
- *Fatal Accidents Act*, R.S.S. 1978, c.F-11, s.2, 4(1) and 8(1);
- *Fatal Accidents Act*, R.S.Y. 2002, c.86, s.1 and 3(1);
- *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, s.2;

- *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197. s.18;
- *Health Services Insurance Act,* C.C.S.M., C.1135, s. 97(2);
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8, s.14(1);
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990, c.H-7, s.5;
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3, s.19(1) and (2), s.20(1);
- *Hospital Insurance Services Act*, R.S.Y. 2002, c. 112, s.10-11;
- *Hospital Services Act,* R.S.N.B. 1973, c. H-9, s.10(1) and (2);
- *Hospitals Act*, R.S.A. 2000, c. H-12, s.62(1);
- *Trustee Act*, C.C.S.M. c. T160, s.53(3);