CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000831-160

(Class Action)
SUPERIOR COURT

S. SCHEER

Petitioner

-vs.-

BRISTOL-MYERS SQUIBB CANADA CO.
and
OTSUKA CANADA PHARMACEUTICAL INC.

Respondents

FOURTH AMENDED APPLICATION TO AUTHORIZE THE BRINGING OF A CLASS ACTION & TO APPOINT THE PETITIONER AS REPRESENTATIVE PLAINTIFF
(Art. 574 C.C.P and following)

TABLE OF CONTENTS

TO THE HONOURABLE MR. JUSTICE PIERRE-C. GAGNON OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER STATES AS FOLLOWS:

VI. GENERAL PRESENTATION

A) The Action

1. Petitioner wishes to institute a class action on behalf of the following class, of which he is a member, namely:

    - All persons residing in Canada who were prescribed and have ingested and/or used the drug, ABILIFY® (aripiprazole) before February 23, 2017 and who developed one or more of the following impulse control behaviours:

        - pathological gambling (also known as gambling disorder or compulsive gambling)
        - compulsive eating/ binge eating
        - uncontrollable or compulsive shopping or spending, and/or
        - hypersexual behaviours / sexual addiction

        (the "Impulse Control Disorders")

        and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

    (…)

2. "ABILIFY" is the brand name of the atypical antipsychotic[1] medication, aripiprazole, which is prescribed to patients in order to *inter alia* treat symptoms of schizophrenia, to treat manic or mixed episodes in bipolar I disorder (manic depression), and to treat symptoms of major depressive disorder (in combination with antidepressants);

3. The Respondents developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold ABILIFY as safe and/or effective despite a wealth of existing knowledge that the drugs had dangerous side effects including uncontrollable and irrepressible impulses to engage in harmful impulse control behaviours, such as pathological gambling, binge eating, uncontrollable spending or shopping, and hypersexual behaviours/addiction (the "Impulse-Control Disorders");

[1] Antipsychotics also known as neuroleptics or major tranquilizers, are a class of psychiatric medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought), principally in schizophrenia and bipolar disorder – the word atypical indicates that it is a second generation antipsychotic developed to produce less side effects that its predecessors.

4. The Petitioner contends that Respondents represented to the medical and healthcare community, to Health Canada, and to the Class Members that they had developed, designed, manufactured, and tested ABILIFY and that it had been found to be safe and/or effective for its intended uses. In addition, the Respondents concealed their knowledge of ABILIFY's defects from the medical and healthcare community, Health Canada and from Class Members;

5. In short, the Respondents' liability rests on (i) inadequate warning about the risk of developing Impulse-Control Disorders, (ii) failure to notify of the full scope of risks known to be associated with and caused by ABILIFY, and (iii) safety misrepresentations;

6. Respondents continue to market, label, package, promote, advertise, import, distribute, and/or sell ABILIFY throughout Canada, including within the province of Quebec, with inadequate warnings as to its serious and adverse side effect of developing Impulse-Control Disorders;

B) The Respondents

8. Respondent Bristol-Myers Squibb Canada Co. ("Bristol-Myers") is a Canadian pharmaceutical corporation, with its head office in Saint-Laurent, Quebec. Bristol-Myers is and was at all relevant times involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of pharmaceutical products including ABILIFY. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* and from a copy of an extract from Respondent Bristol-Myers' website at www.bmscanada.ca, produced herein *en liasse* as **Exhibit R-1**;

9. Respondent Otsuka Canada Pharmaceutical Inc. ("Otsuka") is a Canadian pharmaceutical corporation, with its head office in Saint-Laurent, Quebec. Otsuka is and was at all relevant times involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of pharmaceutical products including ABILIFY. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises*, produced herein as **Exhibit R-2**;

10. Respondents Otsuka and Bristol-Myers co-promote ABILIFY in Canada; as sponsors for ABILIFY in Canada, they are responsible for the Product Monographs, which are the primary source of information for healthcare professionals and patients, setting out the uses, dosage, and risks associated with the drug, the whole as appears more fully from a copy of an extract from Respondent Otsuka's website at www.otsukacanada.com and from a copy of

Respondent Bristol-Myers' News Release entitled "Newest Treatment for Schizophrenia & Related Psychotic Disorders now Available to all Quebecers" dated October 26, 2010, produced herein *en liasse* as **Exhibit R-3**;

11. (…);

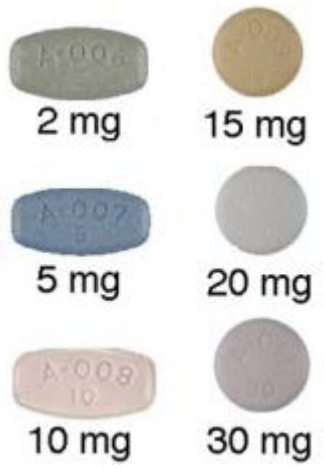
12. (…);

13. (…);

14. All Respondents have either directly or indirectly developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold ABILIFY to distributors and retailers for resale to or, directly to physicians, hospitals, medical practitioners and to the general public throughout Canada, including within the province of Quebec;

15. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other;

C) <u>The Situation</u>



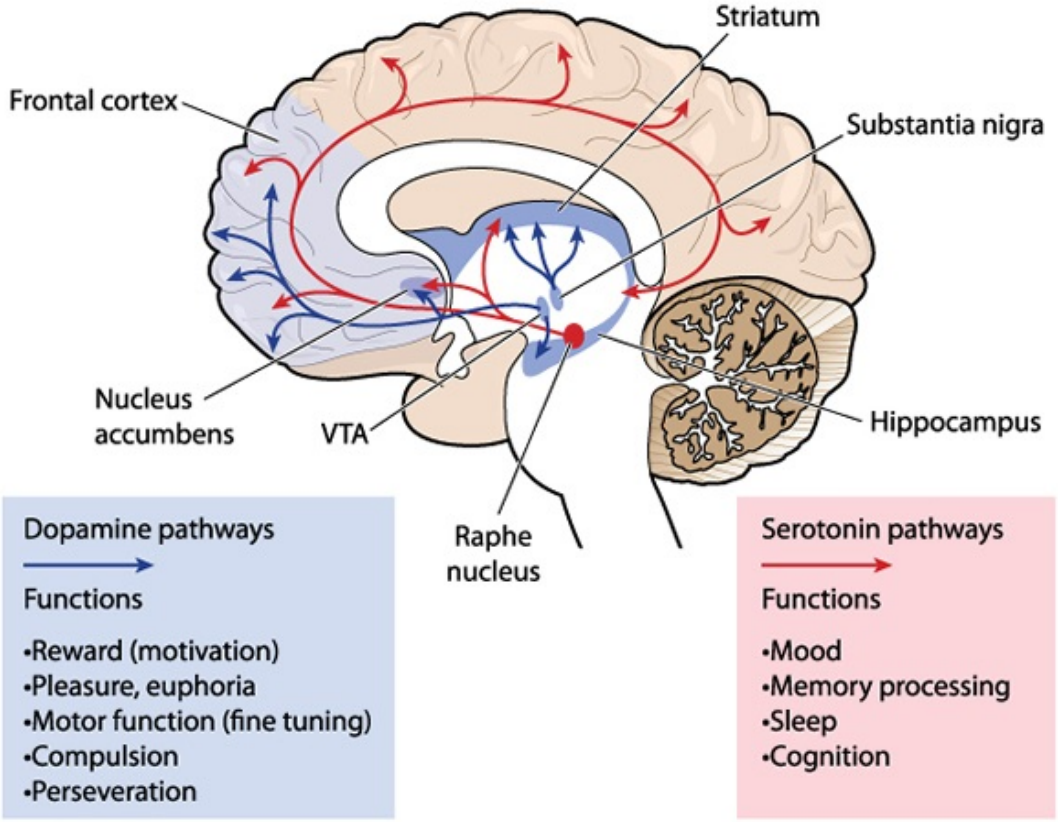
I. <u>What is ABILIFY? What is Dopamine?</u>

16. ABILIFY belongs to a group of medicines called atypical antipsychotics. Atypical antipsychotics (also known as second generation antipsychotics) are a group of antipsychotic drugs used to treat psychiatric conditions. Both generations of medication (typical and atypical antipsychotics) block receptors in the brain's dopamine pathways. Atypicals are less likely to cause extrapyramidal motor control disabilities such as unsteady Parkinson's disease-type movements, body rigidity, and involuntary tremors;

17. Like other atypical antipsychotics, ABILIFY binds to several different neurotransmitter receptors, but unlike others in its class, it doesn't block

dopamine receptors[2] (specifically, dopamine D2 and D3) or serotonin[3] (specifically, 5-HT1A) receptors. Instead, it's a partial agonist[4] at those receptors – it can activate those receptors, but not to the full biological effect. In lay terms, it can both enhance dopamine and serotonin signaling where those transmitters are deficient, and inhibit signaling where they are in excess;

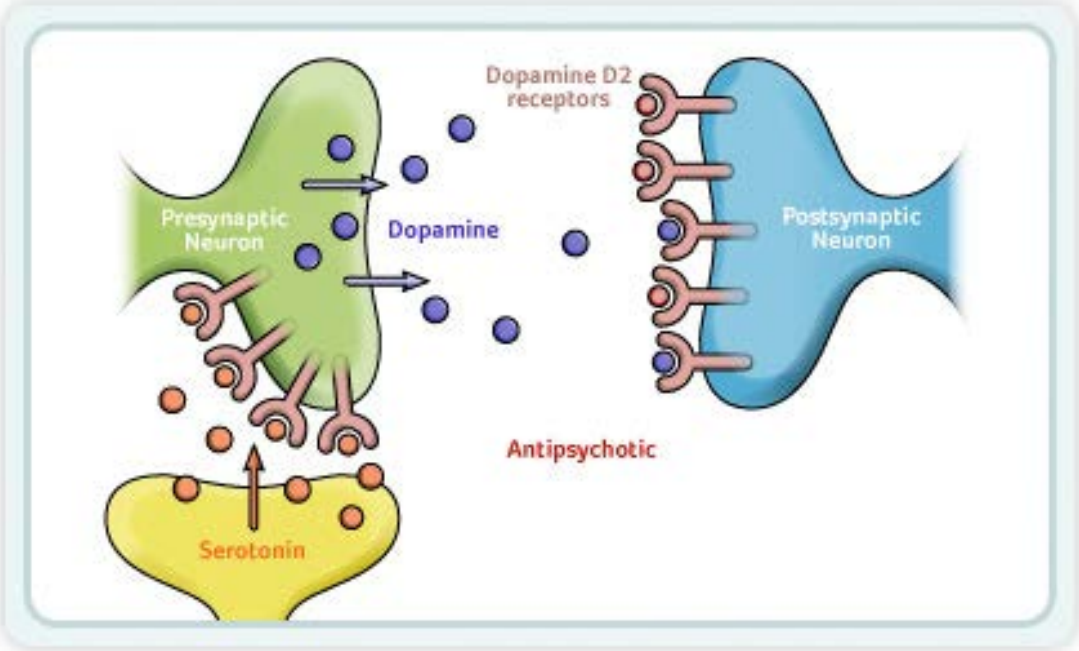
17.1 In this case, the Petitioner's position as to how ABILIFY causes impulse control problems centers on how the drug binds and interacts with two dopamine receptors—D2 and D3—to produce physiological effects in the form of impulsive behaviours;



[2] Dopamine is a compound present in the body as a neurotransmitter and a precursor of other substances including epinephrine. It helps control the brain's reward and pleasure centers and helps regulate movement and emotional responses, and it enables us not only to see rewards, but to take action to move toward them.

[3] Serotonin is a compound present in blood platelets and serum that constricts the blood vessels and acts as a neurotransmitter. It is thought that *serotonin* can affect mood and social behaviour, appetite and digestion, sleep, memory and sexual desire and function.

[4] In pharmacology, partial agonists are drugs that bind to and activate a given receptor, but have only partial efficacy at the receptor relative to a full agonist.



18. Dopamine's role in compulsive behaviour and pathological gambling is well-known. Dopaminergic reward pathways have frequently been implicated in the etiology of addictive behaviour. Scientific literature has identified dopamine as a potential cause of pathological gambling for years, the whole as appears more fully from a copy of the Frontiers in Behavioral Science article entitled "How central is dopamine to pathological gambling or gambling disorder?" dated December 23, 2013, from a copy of the Frontiers in Behavioral Science article entitled "What motivates gambling behavior? Insight into dopamine's role" dated December 2, 2013, from a copy of the Scientific American article entitled "How the Brain Gets Addicted to Gambling", and from a copy of the Gambling Research Exchange Ontario article entitled "Dopamine release in ventral striatum of pathological gamblers losing money" dated 2010, produced herein *en liasse* as **Exhibit R-6**;

18.1 Dopamine is a neurotransmitter in the central nervous system that is believed to play an integral role in a number of physiological processes, including movement, cognition, emotional stability, and, relevant to this case, reward-motivated behaviors. It acts on five different receptors—D1, D2, D3, D4, and D5—along four major pathways in the brain—the nigrostriatal pathway, the mesocortical pathway, the mesolimbic pathway, the tuberoinfundibular pathway. This case is primarily concerned with the activity of dopamine in the mesolimbic pathway, which regulates pleasure, reward processing, and motivation. Under normal circumstances, the brain responds to rewarding activities or stimuli by releasing dopamine into the mesolimbic pathway, where it binds with dopamine receptors to produce feelings of pleasure. As dopamine levels subside, so do the feelings of pleasure. If the rewarding activity is repeated, then dopamine is again released, and more feelings of pleasure are

produced. The release of dopamine and the resulting pleasurable feelings serve as positive reinforcements that motivate repetition of the pleasure-inducing activity (Exhibit R-62);

19. ABILIFY is available in the oral tablet form in six strengths (2 mg, 5 mg, 10 mg, 20 mg, and 30 mg) usually to be taken daily;

II. The Psychiatric Conditions – Explained

(a) Schizophrenia

20. Schizophrenia is a severe mental disorder characterized by abnormal social behaviour and a failure to comprehend what is real. Common symptoms include false beliefs or suspicions, unclear or confused thinking, hallucinations, delusions, reduced social engagement and emotional expression, and a lack of motivation. People with schizophrenia often have additional mental health problems such as anxiety disorders, major depressive illness, or substance use disorders. Symptoms typically come on gradually, begin in young adulthood, the whole as appears more fully from a copy of the World Health Organization Fact Sheet and from a copy of an extract from the Schizophrenia Society of Canada at www.schizophrenia.ca, produced herein as **Exhibit R-7**;

21. Schizophrenia affects approximately 1 percent of the Canadian Population, the whole as appears more fully from a copy of an extract from the Public Health Agency of Canada - A Report on Mental Illness in Canada: Chapter 3 Schizophrenia and from a copy of the Statistics Canada publication at Section G – Schizophrenia, produced herein *en liasse* as **Exhibit R-8**;

22. Treatment for schizophrenia is antipsychotic medication (such as ABILIFY) along with counselling, job training and social rehabilitation;

(b) Bipolar I Disorder and Depression

23. Bipolar I disorder is a bipolar spectrum disorder characterized by the occurrence of at least one manic or mixed episode[5]. Most patients also, at other times, have one or more depressive episodes, and all experience a hypomanic stage before progressing to full mania, the whole as appears more fully from a copy of the Psych Central article entitled “The Two Types of Bipolar Disorder”, from a copy of the Canadian Mental Health Association article entitled “Bipolar Disorder”, from a copy of the Canadian Mental Health Association brochure for Depression and Bipolar Disorder, dated 2014, and from a copy of the Pubic Health Agency of Canada article entitled “What Should I Know about Bipolar Disorder (Manic-Depression)?” dated April 23, 2009, produced herein *en liasse* as **Exhibit R-9**;

5

24. Approximately 1 percent of Canadians will experience bipolar disorder;

III. Approval of ABILIFY in Canada

25. On July 9, 2009, Respondent Bristol-Myers obtained approval for ABILIFY from Health Canada in the 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg tablet form for the "treatment of schizophrenia and related psychotic disorders" and for the "acute treatment of manic or mixed episodes in Bipolar I Disorder…with lithium or divalproex sodium when there is an insufficient acute response to these agents alone". Thereafter:

(a) On May 12, 2011, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada "[t]o use as cotherapy with lithium or divalproex sodium for maintaining clinical improvement for up to 1 year in patients with manic or mixed episodes associated with Bipolar I Disorder",

(b) On November 21, 2011, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada for the "treatment of schizophrenia in adolescents 15-17 years of age",

(c) On March 13, 2012, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada for the "acute treatment of manic or mixed episodes in bipolar 1 disorder as monotherapy in adolescent patients 13-17 years of age", and

(d) On May 29, 2013, Respondent Bristol-Myers obtained approval from Health Canada to market ABILIFY in Canada for the "use as an adjunct to antidepressants for the treatment of Major Depressinve *[sic]* Disorder (MDD) in adult patients who had an inadequate reponse *[sic]* to prior antidepressant treatments during the current episode",

the whole as appears more fully from copies of the five (5) Notices of Compliance obtained from Respondent Bristol-Myers from Health Canada dated July 9, 2009, May 12, 2011, November 21, 2011, March 13, 2012, and May 29, 2013 and from a copy of the Health Canada Summary Basis of Decision (SBD) for ABILIFY dated July 9, 2009, produced herein *en liasse* as **Exhibit R-10**;

26. Accordingly, ABILIFY was launched in Canada in 2009 in the 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths as a prescription medication;

27. (…);

28. (…);

IV. The U.S. Experience

29. ABILIFY was launched in the United States in or around the fall of 2002;

30. On October 31, 2001, non-party Otsuka Pharmaceutical Co., Ltd. submitted a New Drug Application to the United States Food and Drug Administration ("US FDA") for ABILIFY. Approval was sought to market ABILIFY in 2, 5, 10, 15, 20 and 30 mg tablets as a treatment for schizophrenia. It was approved on November 15, 2002, the whole as appears more fully from a copy of the Approval Letter – Application 21-436, produced herein as **Exhibit R-13**;

31. The US FDA required that the results of Study 138047 to address the longer-term efficacy of ABILIFY in the treatment of adults with schizophrenia be submitted;

32. On December 3, 2002, non-party Otsuka America Pharmaceutical, Inc., submitted a Supplemental New Drug Application (NDA 21-436/S-001) on the longer-term efficacy of ABILIFY in the treatment of schizophrenia. This application was approved on August 28, 2003, the whole as appears more fully from a copy of the Approval Package Application Number NDA 21-436/S-001 dated August 28, 2003, produced herein as **Exhibit R-14**;

33. In June 2003, non-party Otsuka Maryland Research Institute submitted another Supplemental New Drug Application (NDA 21-436/S-002) for ABILIFY tablets as a treatment for bipolar disorder. This application was approved on September 29, 2004, the whole as appears more fully from a copy of the Approval Letter and Package for Application Number NDA 21-436/S-002 dated September 29, 2004, produced herein as **Exhibit R-15**;

34. In May 2007, non-party Otsuka Pharmaceutical Development & Commercialization, Inc., submitted another Supplemental New Drug Application (NDA 21-436/S-018) for ABILIFY tablets as an adjunctive treatment for patients with major depressive disorder. This application was approved on November 16, 2007, the whole as appears more fully from a copy of the Approval Letter from the Department of Health & Human Services dated November 16, 2007, produced herein as **Exhibit R-16**;

35. In Europe, ABILIFY is not indicated to treat depression. The European Medicines Agency declined to approve ABILIFY as an add-on treatment for depression because of concerns about its efficacy for that indication, the whole as appears more fully from a copy of the Withdrawal Assessment Report for ABILIFY dated January 20, 2010, produced herein as **Exhibit R-17**;

V. Impulse-Control Disorders: Pathological/ Compulsive Gambling and Dopamine

35.1 Broadly defined, Impulse-Control Disorders are a group of psychiatric disorders that involve problems with behavioural self-control resulting in harm to oneself or to others. Core characteristics of Impulse-Control Disorders include: (1) a behaviour that is repetitive or compulsive, despite adverse consequences; (2) an inability to stop the harmful behavior; (3) an urge or craving to engage in the harmful behavior; and (4) a pleasurable ("hedonic") quality to the harmful behavior. Impulse-Control Disorders are also termed behaviour addictions, due to increasing recognition of similarities between Impulse-Control Disorders and alcohol and drug addiction in terms of clinical features, cognitive changes, treatment, and underlying neurobiological processes. For example, people with a gambling disorder exhibit cravings, tolerance through a need to increase betting, euphoric "highs," and even withdrawal symptoms similar to what people with a drug addiction experience, the whole as appears more fully from a copy of the Frontiers in Psychiatry review article entitled "Impulse control disorders: updated review of clinical characteristics and pharmacological management" dated February 21, 2011 and from a copy of the Science Magazine article entitled "'Behavioral' Addictions: Do They Exist?" dated November 2, 2001, produced herein *en liasse* as **Exhibit R-54**;

35.2 Examples of specific Impulse-Control Disorders include, but are not limited to, pathological gambling (also known as gambling disorder or compulsive gambling), compulsive sexual behaviour (i.e. hypersexuality or sexual addiction), compulsive buying/shopping (i.e. shopping addiction), and compulsive eating (i.e. binge eating) (Exhibit R-B). Many psychiatric conditions feature impulsive-compulsive behaviours, such as attention-deficit/hyperactivity disorder, mania, and substance use disorders, although they are not formally labeled as an Impulse-Control Disorder. The classification of a specific disorder as an Impulse-Control Disorder, and the very definition of an Impulse-Control Disorder, is an evolving field of psychiatry, the whole as appears more fully from a copy of the Neuron Review article entitled "Impulsivity, compulsivity, and top-down cognitive control" dated February 24, 2011, produced herein as **Exhibit R-55**;

36. Pathological gambling is a major psychiatric disorder and is considered to be the most extreme form of "disordered gambling". It may be defined as an addictive urge to gamble continuously despite harmful negative consequences or a desire to stop, the whole as appears more fully from a copy of the Journal of Gambling Studies article entitled "Pathologic Gambling and Impulse Control Disorders" dated March 2005, produced herein as **Exhibit R-18**;

37. Dopamine's role in compulsive behaviour and pathological gambling is well-known. Dopaminergic reward pathways have frequently been implicated in the cause of addictive behaviour. Scientific literature has identified dopamine as a potential cause of pathological gambling for years (as appears in the proceeding section);

38. ABILIFY is a dopamine agonist that has been scientifically linked to a higher chance of compulsive behaviours like binge-eating, hypersexuality, compulsive spending or shopping, and gambling;

39. Bristol-Myers Squibb Company's September 2011 6-Month Periodic Safety Update Report submitted to the European Medicines Agency acknowledges a plausible mechanism for pathological gambling. The Report states that an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric Disorders* (Exhibit R-21), "does suggest a possible mechanism by which drugs that act on dopamine neurons, like aripiprazole, might possibly have some effect on behavior related to reward", the whole as appears more fully from a copy of Bristol-Myers Squibb Company's September 1, 2011 6-Month Periodic Safety Update Report dated September 1, 2011, produced herein as **Exhibit R-19**;

40. The Safety Update Report (Exhibit R-19) acknowledged seven serious reports of pathological gambling, three in the medical literature and four spontaneous reports. The report also noted sixteen cases of pathological gambling in the Bristol-Myers Squibb company safety database;

41. The Medical Assessment of the pathological gambling cases in Respondents' Safety Update Report (Exhibit R-19) did not exclude ABILIFY as the cause of the compulsive gambling adverse events. The Respondents concluded that "a causal role of aripiprazole could not be excluded" or that "aripriprazole was suggested by the temporal relationship";

42. The European Final Assessment Report of the Safety Update Report (Exhibit R-19) concluded that with regard to compulsive gambling "in all of the reported cases we have a (+) temporal; (+) dechallenge and in one case a (+) rechallenge", the whole as appears more fully from a copy of the Final Assessment Report on the 15th Periodic Safety Update Report dated December 5, 2011, produced herein as **Exhibit R-20**;

VI. <u>The Scientific Studies Behind the Drug</u>

43. ABILIFY emulates dopamine, a chemical that is critical for controlling the pleasure and reward centers in the brain. It is also a chemical that has often been implicated in relation to addiction. Researchers argue that dopamine has two key effects on patients: (i) it can impair decision-making and (ii) create urges that must be rewarded. The drug can minimize cognitive control while, at the same time stimulate the brain's reward system. The studies and case reports that follow demonstrate that ingesting and/or injecting ABILIFY causes an increased risk of compulsive or pathological gambling;

44. In 2004, the complex nature of reward processing in the brain and the role of the brain's reward circuitry in several psychiatric disorders including substance use disorders, schizophrenia, pathologic gambling, major depressive disorder, and attention-deficit/hyperactivity disorder was investigated. The report concluded that more research would be beneficial on the relationship between dopamine and various disorders including pathological gambling, the whole as appears more fully from a copy of the Current Psychiatry Reports report entitled "The neural circuitry of reward and its relevance to psychiatric disorders" dated November 2004, produced herein as **Exhibit R-21**;

45. In April 2007, a case report was published detailing the exacerbation of obsessive-compulsive disorder (OCD) during treatment with atypical antipsychotics (such as ABILIFY), the whole as appears more fully from a copy of the Journal of Clinical Psychopharmacology Letters to the Editors entitled "Worsening of Obsessive-Compulsive Symptoms After Treatment With Aripiprazole" dated April 2007, produced herein as **Exhibit R-22**;

46. In October 2008, a case report was published detailing an uncontrollable increase in sexual desire following the ingestion of aripiprazole (ABILIFY). ABILIFY'S dopaminergic activity at the mesolimbic circuit, especially at the nucleus accumbens, was associated with compulsive behaviour, the whole as appears more fully from a copy of the Journal of Clinical Psychopharmacology Letters to the Editors entitled "Aripiprazole Induced Hypersexuality in a 24-Year-Old Female Patient With Schizoaffective Disorder?" dated October 2008, produced herein as **Exhibit R-23**;

47. In March 2010, an article was published detailing the experience of a 64-year old woman who after being prescribed aripiprazole, she experienced an irresistible urge to gamble and compulsion to eat – these urges stopped one month after switching medications, the whole as appears more fully from a copy of the Australian & New Zealand Journal of Psychiatry correspondence entitled "Pathological Gambling and Compulsive Eating Associated with Aripiprazole" dated March 2010, produced herein as **Exhibit R-24**;

48. In November 2010, a case report was published in which two patients with schizophrenia, previously treated with anti-psychotic drugs and no history of pathological gambling, who within a short time after starting aripiprazole, developed pathological gambling symptoms and criminal behaviour, which totally resolved after stopping the drug, the whole as appears more fully from a copy of the Journal of Forensic Sciences article Case Report entitled "Partial Agonist Therapy in Schizophrenia: Relevance to Diminished Criminal Responsibility" dated November 2010, produced herein as **Exhibit R-25**;

49. In 2010, two case reports were published in which two patients experienced adverse behavioural changes related to impulse control and addictions such as hypersexuality and excessive shopping after administration of aripiprazole, the

whole as appears more fully from a copy of the International Journal of Neuropsychopharmacology Letter to the Editor entitled “Aripiprazole-induced behavioural disturbance related to impulse control in a clinical setting” dated 2010, produced herein as **Exhibit R-26**;

50. In 2011, three case reports were published that suggested that pathological gambling may have been caused following treatment with aripiprazole. All three subjects reported an escalation of gambling and uncontrollable urges upon being administered ABILIFY and all three reported these urges normalizing upon cessation of the drug, the whole as appears more fully from a copy of report from the British Journal of Psychiatry entitled “Pathological gambling and the treatment of psychosis with aripiprazole: case reports” dated 2011, produced herein as **Exhibit R-27**;

51. In 2011, three cases of pathological gambling induced by Aripiprazole were reported whereby there was no prior history of pathological gambling and they started gambling after initiating treatment with Aripiprazole. The pathological behaviour disappeared when the medication ended, the whole as appears more fully from a copy the Current Drug Safety article entitled “Aripiprazole-Induced Pathological Gambling: A Report of 3 Cases” dated 2011, produced herein as **Exhibit R-28**;

52. In 2013, two cases of hypersexuality were reported in patients receiving treatment with aripiprazole, the whole as appears more fully from a copy of the Case Report entitled “Two Cases of Hypersexuality Probably Associated with Aripiprazole” dated 2013, produced herein as **Exhibit R-29**;

53. In December 2014, a study was published that analyzed the records of 1,580 patients who had reported adverse drug effects involving compulsive gambling and other impulse behaviour issues. The researchers conducting the study reported that they found a “significant” link between use of ABILIFY and gambling, the whole as appears more fully from a copy of the JAMA Internal Medicine article entitled “Reports of Pathological Gambling, Hypersexuality, and Compulsive Shopping Associated With Dopamine Receptor Agonist Drugs” dated 2014, produced herein as **Exhibit R-30**;

54. In March 2014, a study was published that involved eight people who were being treated for compulsive gambling. A direct link between the use of aripiprazole and the disorder was present in 7 of the patients. The researchers reported those patients could once again control their impulse to gamble after they were taken off of the medication, the whole as appears more fully from a copy of the Addictive Behaviors “Aripiprazole: a new risk factor for pathological gambling? A report of 8 case reports” dated March 2014, produced herein as **Exhibit R-31**;

54.1 In February 2016, a study was published which compared the characteristics of possibly medication-induced (iatrogenic) problem gambling in patients taking ABILIFY with the characteristics of such gambling in patients taking a full dopamine replacement therapy. The authors of the study concluded that it was possible that the gambling behaviour in 16 of the 17 cases was "actually due to" ABILIFY, but cautioned that more research would be necessary to definitively establish that ABILIFY causes compulsive gambling, the whole as appears more fully from a copy of the Journal of Clinical Psychopharmacology review article entitled "Pathological Gambling Associated with Aripiprazole or Dopamine Replacement Therapy: Do Patients Share the Same Features? A Review" dated February 2016, produced herein as **Exhibit R-56**;

54.2 In February 2017, an epidemiological study was published in which a statistically significant association was found to exist between ABILIFY and Impulse-Control Disorder and between ABILIFY and gambling disorder (the "Etminan Study"), the whole as appears more fully from a copy of the Journal of Clinical Psychopharmacology brief report entitled "Risk of Gambling Disorder and Impulse Control Disorder With Aripiprazole, Pramipexole, and Ropinirole" dated February 2017, produced herein as **Exhibit R-57**;

54.3 The authors of the Etminan Study (Exhibit R-57) analyzed medical and pharmaceutical billing information for over 6 million individuals, drawn from a large insurance claims database known as LifeLink[6]. The database included, *inter alia*, patients' diagnoses and all prescriptions they filled between 2006 and 2014. Within this data, the authors first identified all individuals whose insurance records reflected a diagnostic code for either pathological gambling or impulse control disorder. These individuals served as the Etminan Study's "case" group. Next, from the same data, the authors drew a random sample of similar individuals whose records contained neither diagnostic code. These individuals served as "controls." The authors then compared the cases (individuals diagnosed with pathological gambling or impulse control disorders) to the controls (individuals with no such diagnoses) based on the prevalence of exposure to ABILIFY in each group. Exposure to Abilify was defined for the cases as one prescription for ABILIFY having been filled during the year before the pathological gambling or impulse control disorder diagnosis, and in corresponding calendar time for the controls. The study found that individuals exposed to Abilify had a statistically significant higher incidence of pathological gambling and impulse control disorder diagnoses than did unexposed individuals;

[6] The purpose of an epidemiological case-control study is to determine whether exposure to a drug is associated with a particular outcome (i.e., a disease or adverse effect). Researchers identify a group of individuals who have a disease ("cases") and a group of similar individuals who do not have the disease ("controls"). See id. Then, they compare the two groups in terms of past exposure to the drug. See id. If individuals in the case group are found to have a higher proportion of past exposure than the controls, then an association is said to exist between exposure and the disease.

55. Several of these studies demonstrate what is known as a challenge, de-challenge, and re-challenge (see, for example, Exhibits R-21, R-26, and R-27):

    (a) Challenge is the administration of a suspect product by any route,

    (b) De-challenge is the withdrawal of the suspected product from the patient's therapeutic regime. A positive de-challenge is the partial or complete disappearance of an adverse experience after withdrawal of the suspect product. For example, a positive de-challenge occurs when a patient ceases use of ABILIFY and pathological gambling behaviours cease,

    (c) Re-challenge is defined as a reintroduction of a product suspected of having caused an adverse experience following a positive de-challenge. A positive re-challenge occurs when similar signs and symptoms reoccur upon reintroduction of the suspect product. For example, a positive re-challenge occurs when a patient reintroduces ABILIFY into her treatment regime and pathological gambling behaviour reoccurs in a similar manner as such behaviours had existed when the patient previously used ABILIFY,

    The whole as appears more fully from a copy of the US FDA draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biologic Products Including Vaccines dated 2001, produced herein as **Exhibit R-32**;

56. A positive de-challenge is considered evidence that a drug caused a particular effect, as is a positive re-challenge, the whole as appears more fully from a copy of the US FDA Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment dated March 2005 and from a copy of the Federal Judicial Center's Reference Manual on Scientific Evidence – Third Edition, dated 2011, produced herein *en liasse* as **Exhibit R-33**;

57. These studies serve to indicate the importance of informing both patients and healthcare professionals of these adverse side-effects so that they may make informed decisions regarding this medication. In addition, should the patient make an informed decision to take ABILIFY in spite of the serious risks, knowledge of these risks would have allowed them to, at the very least, know what was causing their pathological behaviours;

58. The Respondents, in failing to advise doctors and patients of the increased risks associated with ABILIFY, effectively usurped their ability to make informed decisions regarding its use and removed their ability to limit and/or control the risk through engaging in precautionary monitoring measures;

59. On November 19, 2009, the first adverse event was reported to Health Canada, whereby a 56-year-old female suffered palpitations while taking ABILIFY. Thereafter, 995 adverse events have been reported up until November 30, 2018 (including this first report), the whole as appears from a copy of Health Canada's

adverse reaction reports from January 1, 1965 to June 30, 2016, produced herein as **Exhibit R-34** and from a copy of Health Canada's adverse reaction reports from June 30, 2016 to November 30, 2018, produced herein as **Exhibit R-34B**;

60. Of these adverse events reported, in terms of the Impulse-Control Disorders:

- 35 include "gambling" and/or "gambling disorder", the first adverse event having been reported to Health Canada on August 25, 2014, the whole as appears more fully from a copy of Health Canada's list of adverse reaction reports and from a copy of the actual reports, produced herein *en liasse* as **Exhibit R-35B**;

- 7 include "compulsive shopping", the first adverse event having been reported to Health Canada on September 12, 2017, the whole as appears more fully from a copy of Health Canada's list of adverse reaction reports and from a copy of the actual reports, produced herein *en liasse* as **Exhibit R-35C**;

- 14 include "compulsive sexual behaviour", "hypersexuality", "sexual activity increased", sexual transmission of infection", "sexually inappropriate behaviour", and/or "sexually transmitted disease", the first having been reported to Health Canada on October 17, 2014, the whole as appears more fully from a copy of Health Canada's list of adverse reaction reports and from a copy of the actual reports, produced herein *en liasse* as **Exhibit R-35D**;

61. In the United States, from May 1, 2009 to May 1, 2011, the US FDA received thousands of serious adverse event[7] reports concerning ABILIFY (n=4599), including over two-thousand serious adverse drug experiences of which 193 involved children (0-16 years old), the whole as appears more fully from a copy of the slides from the US FDA "Pediatric Focused Safety Review: Abilify® (aripiprazole) to May 1, 2011" dated September 22, 2011, produced herein as **Exhibit R-36**;

61.1 On March 10, 2016, the US FDA conducted a Pharmacovigilance Review on the subject of ABILIFY and Impulse-Control Disorders through an evaluation of the cases identified in the US FDA Adverse Event Reporting System database and the published medical literature for an association between aripiprazole and impulse-control disorders and related disorders. The US FDA identified an association between ABILIFY and the following Impulse-Control Disorders: pathological gambling, compulsive sexual behaviours, compulsive buying, compulsive eating, and a multiple of these disorders, the whole as appears more fully from a copy of the Pharmacovigilance Review dated March 10, 2016, produced herein as **Exhibit R-58**;

[7] Serious adverse events are drug experiences including the outcomes of death, life-threatening events, hospitalization, disability, congenital abnormality, and other harmful medical events.

61.2 Based on the data analyzed (being 184 case reports), the US FDA recommended that the following warnings/statements be added in 2 places to the ABILIFY product labelling:

> Pathological Gambling and Impulse-Control Disorders Case reports suggest that patients can experience intense urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. Other urges, reported less frequently than gambling, include: sexual urges, uncontrolled spending, binge or compulsive eating, and other urges with impulsive and compulsive features. These urges were reported to have stopped when the dose was reduced or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while being treated with aripiprazole. If left unrecognized, these urges may result in harm to the patient and to others. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole,

In addition, the US FDA recommended that a Drug Safety Communication be issued containing the above warning information (Exhibit R-58);

62. Since its introduction in the U.S. in November 2002 until mid-January 2016,184 case reports were identified indicating an association between ABILIFY and impulse-control problems. The specific impulse-control problems reported include: pathological gambling (n=164); compulsive sexual behaviour (n=9); compulsive buying (n=4); compulsive eating (n=3); and multiple impulse-control problems (n=4). These urges began only after starting to take ABILIFY and were resolved after reducing the dosage or discontinuing the treatment altogether, the whole as appears more fully from a copy of the US FDA Drug Safety Communications Safety Announcement entitled “FDA Drug Safety Communication: FDA warns about new impulse-control problems associated with mental health drug aripiprazole (Abilify, Abilify Maintena, Aristada)” dated May 3, 2016, produced herein as **Exhibit R-37**;

62.1 The US FDA Drug Safety Communication (Exhibit R-37) stated the following:

> “compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics)”;

63. A disproportionality study of the US FDA Adverse Event Reporting System showed a proportional reporting ratio for compulsivity of 8.6 for ABILIFY (Exhibit

R-30). A ratio of more than three indicates a signal of an adverse event, the whole as appears more fully from a copy of the International Journal of Medical Sciences article entitled "Data Mining of the Public Version of the FDA Adverse Event Reporting System" dated April 25, 2013, produced herein as **Exhibit R-38**;

63.1 On March 28, 2019, Dr. Alain Dagher, neurologist, wrote an expert report concerning the mechanism of action and clinical indications of ABILIFY, along with its link to behavioural addictions such as problem gambling. Dr. Dagher opined the following:

> In sum, it is my opinion that the use of aripiprazole can materially contribute to an elevated risk of developing a behavioural addiction. The medical literature implicates aripiprazole in several forms of impulse control disorder, including cases of problem gambling, hypersexuality, compulsive eating, and compulsive shopping. While certainly individuals are at greater underlying risk than others, it can be stated that it is the drug itself rather than the pre-existing psychopathology or personality that is the direct cause of impulse control disorders in the cases described.

The whole as appears more fully from a copy of the Expert Report of Dr. Alain Dagher dated March 28, 2019, produced herein as **Exhibit R-73**;

VII. Governmental Regulation of ABILIFY

64. In October 2012, following a safety review of ABILIFY, the European Medicines Agency[8] required that the Respondents warn patients and the medical community in Europe of the risk of pathological gambling associated with the use of ABILIFY, the whole as appears more fully from a copy of the European Medicines Agency document for ABILIFY and from a copy of the European Medicines Agency's Annex I – Summary of Product Characteristics, produced herein *en liasse* as **Exhibit R-39**;

65. Specifically, the European Medicines Agency required the following labelling change in Europe in the "Special warnings and precautions" for use section of the label:

> Pathological gambling
> Post-marketing reports of pathological gambling have been reported among patients prescribed aripiprazole, regardless of whether these patients had a prior history of gambling. Patients with a prior history of pathological gambling may be at increased risk and should be monitored carefully (see section 4.8),

[8] The European Medicines Agency is an international public health agency charged with the scientific evaluation, supervision and safety monitoring of medicines for the European Union.

66. In addition, the risk of pathological gambling was included in the section entitled "Undesirable effects" along with agitation, nervousness, suicide attempt, suicidal ideation, and completed suicide;

67. On November 2, 2015, Health Canada concluded that there is "a link between the use of aripiprazole and a possible risk of pathological gambling or hypersexuality" and found an increased risk of pathological (uncontrollable) gambling and hypersexuality with the use of ABILIFY, the whole as appears more fully from a copy of the Health Canada Information Update entitled "Safety information for antipsychotic drug Abilify and risk of certain impulse-control behaviours" dated November 2, 2015, from a copy of the Health Canada Summary Safety Review - ABILIFY and ABILIFY MAINTENA (aripiprazole) - Evaluating the Risk of Certain Impulse Control Behaviours" dated November 2, 2015, and from a copy of the CTV News article entitled "Health Canada updates list of possible side effects for 2 antipsychotic drugs" dated November 2, 2015, produced herein *en liasse* as **Exhibit R-40**;

68. It was not until June 22, 2015 that the Respondents finally did include pathological gambling as a potential side effect of ingesting and/or injecting ABILIFY on the Product Monograph (as will be outlined in more detail below);

VIII. <u>The Respondents' Marketing Practices</u>

69. Despite the risks of serious adverse events, and the lack of adequate testing, that Respondents aggressively promoted ABILIFY, including illegal promotion for off-label use. In the United States, in 2007, Bristol-Myers reportedly paid $515 million to settle federal and state investigations into off-label marketing of Abilify for pediatric use and to treat dementia-related psychosis. Otsuka American Pharmaceutical, Inc., later paid more than $4 million to resolve the allegations, the whole as appears more fully from a copy of the United States Department of Justice Press Release entitled "Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing" dated September 28, 2007 and from a copy of the United States Department of Justice Press Release entitled "Otsuka to Pay More than $4 Million to Resolve off-label Marketing Allegations Involving Abilify" dated March 27, 2008, produced herein *en liasse* as **Exhibit R-41**;

70. The US FDA issued a letter dated April 17, 2015 finding ABILIFY promotional material "false or misleading because it makes misleading claims and presentations about the drug." The US FDA found the material "misleading because it implies that Abilify offers advantages over other currently approved treatments for bipolar disorder or MDD when this has not been demonstrated." The US FDA also found the cited references "not sufficient to support claims and presentations suggesting that Abilify has been demonstrated to modulate dopaminergic and serotonergic activity, or modulate neuronal activity in both

hypoactive and hyperactive environments in humans", the whole as appears more fully from a copy of the letter from the US FDA Department of Health & Human Services to Otsuka Pharmaceutical Development & Commercialization, Inc. dated April 17, 2015 and from a copy of the PLoS Medicine article entitled "Questionable Advertising of Psychotropic Medications and Disease Mongering" dated July 2006, produced herein *en liasse* as **Exhibit R-42**;

71. The Respondents have invested millions of dollars in teams of pharmaceutical sales representatives who visit and contact members of the medical community, including prescribing doctors, purporting to "educate" them about ABILIFY. These pharmaceutical sales representatives have not notified patients, the medical community, or prescribers that ABILIFY use causes, is linked to, or might be associated with compulsive gambling, pathological gambling, or gambling addiction;

72. The Respondents have made payments to doctors to promote ABILIFY. For example, from August 2013 to December 2014, $10.6 million in payments relating to ABILIFY were made to 21,155 physicians in the United States, the whole as appears more fully from a copy of the Pro Publica webpage entitled "Has Your Doctor Received Drug or Device Company Money?" for ABILIFY, produced herein as **Exhibit R-43**;

73. ABILIFY generated $5.501 billion in sales worldwide in 2013, being the tenth best-selling drug worldwide, the whole as appears more fully from a copy of an extract from the FiercePharma article for ABILIFY, produced herein as **Exhibit R-44**;

74. Bristol-Myers touted ABILFY as its "largest-selling product" in 2012, 2013 and 2014, the whole as appears more fully from copies of extracts from Bristol-Myers website at www.bms.com, produced herein *en liasse* as **Exhibit R-45**;

75. Bristol-Myers reported worldwide revenues from sales of ABILIFY of $2.020 billion in 2014, $2.289 billion in 2013, $2.827 in 2012, and $2.758 in 2011, the whole as appears more fully from a copy of Bristol-Myers' Annual Reports dated 2014 and 2013, produced herein *en liasse* as **Exhibit R-46**;

76. (…);

77. According to Otsuka's Annual Report for the year 2014, sales of their "top-selling pharmaceutical product ABILIFY constitute approximately 40% of [their] total consolidated net sales". In 2013, Otsuka reported that it constituted over 30% of sales, the whole as appears more fully from copies of Otsuka's Annual Reports dated 2013 and dated 2014, produced herein *en liasse* as **Exhibit R-48**;

78. As stated above in the section entitled “B) The Respondents”, Respondent Bristol-Myers and Otsuka entered into an agreement to co-market and promote ABILIFY in Canada (Exhibit R-3). Under the terms of this agreement, ABILIFY was to be marketed by Bristol-Myers under license by non-party Otsuka Pharmaceutical Co., Ltd. This agreement was originally formed for the marketing of ABILIFY in the U.S. in 1999 whereby it was agreed that Bristol-Myers and Otsuka would collaborate to complete clinical studies for schizophrenia, and that Bristol-Myers would conduct additional studies for new dosage forms and new indications, the whole as appears more fully from a copy of the Press Release entitled “Bristol-Myers Squibb And Otsuka Announce Commercialization Agreement For Aripiprazole” dated September 21, 1999, produced herein as **Exhibit R-49**;

79. In spite of the strong indication that ABILIFY was causing pathological gambling and other pathological behaviours, the Respondents failed to timely inform consumers, health care professionals, Health Canada and the scientific community and they failed to perform further investigation into its safety;

80. This important information is hardly present in the eighty-four-page Product Monograph of ABILIFY at present as it is only mentioned three times; one in the “Warnings and Precautions” section as follows:

> Post-marketing reports of pathological gambling have been reported in patients treated with ABILIFY. In relation to pathological gambling, patients with a prior history of gambling disorder may be at increased risk and should be monitored carefully.

Under the section entitled “Post-Market Adverse Drug Reactions” the word “gambling” again appears as follows: “*Unknown*: Pathological gambling, Hypersexuality” and lastly in the Consumer Information section for ABILIFY, “an urge to gamble” appears under “side effects and what to do about them”,

The whole as appears more fully from a copy of the Product Monograph for ABILIFY last revised on June 22, 2015, produced herein as **Exhibit R-50**;

80.1 The product monograph for ABILIFY was revised again on November 30, 2017 to include *inter alia* the following (the portion in italics appeared in the June 22, 2015 revision (Exhibit R-50):

> *Post-marketing reports of pathological gambling have been reported in patients treated with aripiprazole.* These reports suggest that patients can experience increased urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. With regards to pathological gambling, *patients with a prior history of gambling disorder may be at*

> *increased risk and should be monitored carefully*. Other urges, reported very rarely, include: increased sexual urges, compulsive spending, binge or compulsive eating, and other impulsive and compulsive behaviors. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, compulsive spending, binge or compulsive eating, or other urges while being treated with aripiprazole. It should be noted that impulse-control symptoms can be associated with the underlying disorder; however, in some cases, although not all, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Although impulse-control disorders have been reported very rarely, impulse-control disorders may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole.

This is the first time that Impulse-Control Disorders are mentioned in a product monograph, the whole as appears more fully from a copy of the Product Monograph for ABILIFY last revised on November 30, 2017, produced herein as **Exhibit R-59**;

81. Previous versions of the Product Monographs for ABILIFY, which make no mention whatsoever about gambling or Impulse-Control Disorders, pathological or otherwise, are produced herein *en liasse* as **Exhibit R-51**;

82. There are many feasible alternatives to ABILIFY in the form of antipsychotics and/or atypical antipsychotics which do not cause uncontrollable impulses such as compulsive or pathological gambling. The serious side effects of ABILIFY rendered their design defective, which was a substantial factor in causing the Petitioner's and Class Members' injuries;

83. Despite various warning changes, the Respondents' marketing of ABILIFY continues to fail to adequately warn consumers, healthcare professionals and the public of the serious risk of experiencing uncontrollable urges including compulsive or pathological gambling;

IX. <u>The Respondents' Liability</u>

84. The Respondents have either not adequately studied ABILIFY or have failed to make public the results of any studies or investigations that they might have conducted. A review of all the randomized clinical trials comparing ABILIFY to other schizophrenia drugs concluded that the information on comparisons was of limited quality, incomplete, and problematic to apply clinically, the whole as appears more fully from a copy of the Cochrane Library Database of Systematic

Reviews article entitled “Aripiprazole versus other atypical antipsychotics for schizophrenia (Review)” dated 2016, produced herein as **Exhibit R-52**;

85. Despite evidence that ABILIFY causes Impulse-Control Disorders such as pathological gambling and calls from the medical community to conduct further research and warn patients about this possible effect of ABILIFY, the Respondents have either failed to investigate or conduct any studies on the compulsive behaviour side effects of ABILIFY and/or failed to make public the results of any studies or investigations that they might have conducted;

86. A reasonably prudent drug developer, designer, manufacturer, tester, marketer, labeller, packager, promotor, advertiser, distributer, and/or seller in the Respondents’ positions would have adequately warned both doctors and patients of the risks associated with the use of ABILIFY;

87. Despite a clear signal, the Respondents failed to either alert the public and the scientific and medical community or to perform further investigation into the safety of ABILIFY;

88. The Respondents were negligent (at both civil and common law) in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, distribution, and/or sale of ABILIFY in one or more of the following respects:

    a. They knew or should have known that ABILIFY increased the risk of the adverse side effect of uncontrollable impulses including compulsive and/or pathological gambling;

    b. They failed to ensure that ABILIFY was not dangerous to consumers;

    c. They failed to conduct appropriate testing to determine whether and to what extent the ingestion and/or use of ABILIFY poses serious risks, including the uncontrollable impulses of compulsive and/or pathological gambling;

    d. They failed to adequately test the products prior to placing them on the market;

    e. They failed to adequately test ABILIFY in a manner that would fully disclose the side effect of uncontrollable impulses including compulsive and/or pathological gambling;

    f. They failed to use care in developing, designing and manufacturing their products so as to avoid posing unnecessary health risks to users of such product;

g. They failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the drug;

h. They failed to advise that the ingestion and/or use of ABILIFY could result in severe side effects, including but not limited to, uncontrollable impulses including compulsive and/or pathological gambling;

i. They failed to advise the medical and scientific communities of the potential to increase the risk of uncontrollable impulses including compulsive and/or pathological gambling;

j. They failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks associated with the use of ABILIFY;

k. They failed to provide Class Members and their physicians with adequate warnings or sufficient indications of inherent risks associated with ABILIFY;

l. They failed to provide adequate warnings regarding the need to assess impulse control and gambling activity prior to starting a patient on ABILIFY and to continue with periodic testing and monitoring while the patient is taking ABILIFY;

m. They failed to provide adequate updated and current information to Class Members and their physicians respecting the risks of ABILIFY as such information became available;

n. They failed to provide prompt warnings of potential hazards of ABILIFY in the product monographs and in the product labelling;

o. They failed to warn that Class Members and their physicians that the risks associated ABILIFY would exceed the risks of other available antipsychotic and atypical antipsychotic medications;

p. After receiving actual or constructive notice of the problems associated with ABILIFY, they failed to issue adequate warnings, to publicize the problem and otherwise act properly and in a timely manner to alert the public, the Class Members and their physicians, of the drugs' inherent dangers;

q. They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the risks associated with the drugs;

r. They falsely stated and/or implied that ABILIFY was safe when they knew or ought to have known that this representation was false;

r.1 They failed to ensure that ABILIFY was safe for use by Class Members, fit for its intended purpose and of merchandise quality;

s. They disregarded reports of uncontrollable impulses including compulsive and/or pathological gambling among patients;

t. They failed to accurately and promptly disclose to Health Canada information relating to uncontrollable impulses including compulsive and/or pathological gambling associated with ABILIFY and to modify ABILIFY' product monographs and product labelling accordingly in a timely manner;

u. They failed to monitor and to initiate a timely review, evaluation and investigation of reports of uncontrollable impulses including compulsive and/or pathological gambling associated with ABILIFY in Canada and around the world;

v. They failed to properly investigate cases of uncontrollable impulses including compulsive and/or pathological gambling caused by ABILIFY;

w. They deprived patients of a chance for safe, effective and/or successful alternative treatments; and

x. In all circumstances of this case, they applied callous and reckless disregard for the health and safety of their consumers;

89. Despite the vast availability of knowledge clearly indicating that ABILIFY use is causally-related to uncontrollable impulses including compulsive and/or pathological gambling, the Respondents not only failed to provide adequate labelling to warn Class Members of the risks associated with the use of ABILIFY, but instead incongruously promoted and marketed ABILIFY as a safe and effective drug, effectively appropriating the ability of doctors and patients to make informed decisions regarding their health;

90. The Respondents concealed and failed to completely disclose their knowledge that ABILIFY were associated with or could cause uncontrollable impulses including compulsive and/or pathological gambling as well as their knowledge that they had failed to fully test or study said risk;

91. The Respondents ignored the association between the use of ABILIFY and the risk of uncontrollable impulses including compulsive and/or pathological gambling;

92. The Respondents' failure to disclose information that they possessed regarding the failure to adequately test and study ABILIFY for uncontrollable impulses including compulsive and/or pathological gambling risk further rendered warnings for this medication inadequate;

92.1 The Defendants' negligence involved both lawful and unlawful means with the predominant purpose of causing Class Members to acquire and use ABILIFY when they knew or should have known that such use would cause harm to the Class Members and their family members;

92.2 The Defendants further acted in concert to conceal the risk of Impulse Control Disorders associated with the use of ABILIFY;

92.3 At all relevant times, Otsuka and Bristol-Myers, by their directors, officers, servants and agents wrongfully, unlawfully, maliciously and lacking bona fides, conspired and agreed together, to, among other things, conceal the risk of Impulse Control Disorders associated with the use of ABILIFY, and to mislead Class Members about the health and safety risks associated with the use of the drug;

92.4 The Defendants' conduct as described herein was unlawful and constituted material and misleading information in breach of sections 36 and 52 of the Competition Act;

92.5 In conspiring to conceal the risk of Impulse Control Disorders from the Class Members, each of the Defendants was motivated, among other things:

a) to increase or maintain sales volumes of ABILIFY;

b) to increase or maintain revenue;

c) to increase or maintain profit;

d) to increase of maintain market share; and

e) to avoid negative publicity and preserve public goodwill;

92.6 The conspiracy was unlawful because the Defendants knowingly or recklessly, directly and indirectly, and in pursuit of their mutual business interests, made representations to Class Members and the public which were false or misleading in a material respect and which deceived them as to the health and safety risks associated with the use of Abilify. In making the misrepresentations as described herein, the Defendants breached sections 36 and 52 of the *Competition Act*;

92.7 In the circumstances, the Defendants knew that the conspiracy would, and did, cause the Class Members to suffer damages as described herein;

X. The U.S. Litigation

92.8 On October 3, 2016, the U.S. Judicial Panel on Multidistrict Litigation ("JPML") consolidated pretrial proceedings for *in Re: Abilify (Aripiprazole) Products Liability Litigation*, MDL No. 2734 in the United States District Court for the Northern District of Florida (the "U.S. MDL Court"), the whole as appears more fully from a copy of the Transfer Order dated October 3, 2016, produced herein as **Exhibit R-60**;

92.9 On December 2, 2016, a Master Long Form Complaint and Jury Demand was filed in the U.S. MDL Court, the whole as appears more fully from a copy of the Master Long Form Complaint and Jury Demand dated December 2, 2016, produced herein as **Exhibit R-61**;

92.10 On March 15, 2018, in ruling on the defendants' motion for summary judgment on the issue of general causation, the U.S. court adjudged that "that Plaintiffs have satisfied their burden to demonstrate that a genuine dispute of material fact exists as to whether Abilify can cause uncontrollable impulsive behaviors in individuals taking the drug", the whole as appears more fully from a copy of the Amended Order dated March 15, 2018, produced herein as **Exhibit R-62**;

92.11 On April 28, 2018, after a successfully mediation, 4 individual cases from the MDL were settled with full releases, the whole as appears more fully from a copy of the Order dated April 28, 2018, produced herein as **Exhibit R-63**;

92.12 As of the date of the filing of the Third Amended Application, over 2,100 cases had been consolidated in the MDL;

92.13 On May 2, 2018, the U.S. court ordered the U.S. parties to create a global settlement framework addressing the remaining ABILIFY lawsuits in the MDL – a confidential global settlement was reached on February 15, 2019, the whole as appears more fully from a copy of the Global Settlement Order No. 1, dated May 2, 2018 and from a copy of the Joint Notice of Proposed Settlement Program dated February 15, 2019, produced herein *en liasse* as **Exhibit R-64**;

VII. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

92.14 In spring of 2013, the Petitioner studied for and passed his General Education Diploma (GED)[9] in order to apply to West Island Career Centre

[9] The GED is the High School Equivalency Certificate.

(WICC), at 13700 Pierrefonds Blvd., in Pierrefonds, Quebec, in the Automobile Mechanics program. The Petitioner was interested in the CPA certification course to eventually take the CPA certification exam and begin his career in auto mechanics. The Petitioner was placed onto the wait list for admission;

92.15 In the end of October-beginning of November 2013, the Petitioner's physician gave him several sample boxes of ABILIFY in the 2-mg dosage and directed him to take half of a pill every morning, which was intended to treat his severe anxiety associated with his obsessive-compulsive disorder (OCD), and to prevent depressive episodes;

92.16 By December 3, 2013, the Petitioner noticed that his casual gambling was turning into uncontrollable urges/ compulsions and that he was gambling more and more money, so he sought help from *Centre de réadaptation en dépendence Foster*[10] ("CRD Foster") on December 5, 2013 and he began CRD Foster's out-patient program on December 6, 2013 on their recommendation, the whole as appears more fully from a copy of the Petitioner's file from *Centre de réadaptation en dépendence Foster*, produced herein under seal as **Exhibit R-66**;

92.17 By December 20, 2013, the Petitioner was spending 5 to 7 hours per day, everyday, gambling at bars, exclusively playing video lottery machines (referred to as VLT in the Petitioner's medical files);

92.18 Over the Christmas holidays of 2013, the Petitioner's gambling became more and more uncontrollable and irrepressible;

93. On January 3, 2014 (…), the Petitioner was prescribed ABILIFY by his physician in the 10-mg dosage[11] (…);

94. The Petitioner filled his prescription at the Thi Yen Nguyen Phaman affiliated pharmacy – Uniprix located at 5443 Rue Bannantyne, in Verdun, Quebec and he continued to take the medication as directed, namely, once daily in the mornings. Thereafter, he switched pharmacies several times depending on where he was living, the whole as appears more fully from a copy of the Petitioner's file from the Uniprix pharmacy in Verdun and from a copy of the Petitioner's file from the Brunet in Chateauguay, produced herein under seal and *en liasse* as **Exhibit R-67**;

94.1 The *fiche conseil* that was given to the Petitioner when he was first dispensed ABILIFY (Exhibit R-67) did not mention the possibility of developing any

[10] *Centre de réadaptation en dépendence Foster*, has since been renamed as *Centre Intégré de santé et de services sociaux de la Montérégie Ouest-département de santé mentale et dépendance*.
[11] The Petitioner was weaned onto the medication, starting first with a lower dose of 2-mgs for a few months.

Impulse-Control Disorders and contained only the following disclosure of "possible side effects":

> "In addition to its desired action, this medication may cause some side effects, notably:
>
> - it may cause headaches;
> - it may cause drowsiness or dizziness -- use caution if driving;
> - it may cause unusual tiredness;
> - it may cause nausea and vomiting";

95. Within a few months' time, the Petitioner began experiencing increasingly uncontrollable and irrepressible urges to gamble (…). In approximately July 2013, he had (…) gambled a few times with small sums of money in video lottery machines with colleagues at various bars. At first, he would gamble once a week with $20.00, then with $50.00, but beginning in December 2013 and continuing into January 2014, the urges escalated, rapidly becoming uncontrollable and he began regularly gambling at the video lottery machines, losing thousands of dollars within a short period of time;

96. The Petitioner's gambling became so uncontrollable and compulsive that he would to do anything he could to find cash to gamble at the slot machines including, but not limited to the following:

(a) Withdrawing his RRSPs at the Laurentian Bank in the amount of $2,500.00,

(b) Selling his 2006 Pontiac G6 GT Coupe for $850.00 (approximately 10 to 15 percent of its worth at the time),

(c) Selling his Canada Goose jacket in the middle of winter for $60.00 (approximately 10 percent of its worth at the time),

(d) Accruing liabilities on various credit cards (owned by himself and by close friends and family) by purchasing new merchandise from stores on credit and then pawning them at pawn shops for a fraction of their value, and

(e) Pawning all the gold he could find, including sentimental family pieces;

96.1 In the end of January 2014, the Petitioner received a phone call from WICC informing him that he had been admitted to the Automobile Mechanics program; however, at this point in time, his compulsive gambling had taken over his life and he had no interest in anything other than playing the video lottery machines and in figuring out how to get money in order to do so. He never accepted the admission or attended the program;

97. The Petitioner's anxiety about his irrepressible and uncontrollable urges and about where he was going to find money to gamble with became unbearable. He lost interest in everything except gambling and he could not stop the cravings and urges. His therapist at CRD Foster had been recommending in-patient care (IPC) and informed him that a bed would be available on January 29, 2014. On January 29, 2014, the Petitioner (…) checked himself into the in-patient rehab centre of CRD Foster, at 6 Rue Foucreault, in Saint-Philippe, Quebec;

98. He stayed at the rehab centre on two occasions; the first being from January 29, 2014 to February 26, 2014 (a 28-day period), where he received individual and group therapy. During this first stay at the rehab centre the Petitioner remained abstinent until his final weekend out when he lost $400 gambling. The Petitioner was referred to "Recovery Management" groups on Friday mornings at CRD Foster's outpatient centre. Immediately after being released, the Petitioner had a gambling relapse and he readmitted himself to the rehab centre a second time. He remained in rehab from March 31, 2014 to April 16, 2014 (a 17-day period) (…). was administered ABILIFY everyday while at the rehab centre, but when he was released, he would continue compulsively gambling;

99. His urges and compulsions, and the accompanying anxiety, became so bad that on July 13, 2014, at approximately 11:15 pm, he attempted suicide by taking all the medication that he found in his mother's medicine cabinet (including 12-18 sertralines/ Zolofts). He was taken by ambulance to the Hôpital de Verdun at 4000 Boulevard LaSalle, in Verdun, Quebec, where, at approximately 12:30 am, he was administered charcoal to make him throw up the medications that he had taken, the whole as appears more fully from a copy of the Petitioner's file from Hôpital de Verdun, produced herein under seal as **Exhibit R-68**;

100. Following the suicide attempt, on July 22, 2014, Mr. Scheer registered with another rehab centre, Portage Quebec Adult Day Centre Montreal, at 1640, rue Saint-Antoine West, in Montreal, Quebec, where he was accepted as an out-patient on Tuesdays, Wednesdays, and Thursdays from 10:00 A.M. to 4:00 P.M. The idea was to wait for an opening at their in-patient facility at 1790 chemin du Lac Écho, in Prévost, Quebec, the whole as appears more fully from a copy of the Petitioner's file from Portage, produced herein under seal as **Exhibit R-69**;

101. Throughout this time period, the Petitioner would continue to compulsively gamble, including on the way to and from the rehab centre;

102. On (…) September 2, 2014, the Petitioner was admitted to the Portage Quebec in-patient centre in Prévost, Quebec where he was administered ABILIFY daily and where his uncontrollable and unbearable gambling urges continued;

103. The Petitioner's urges to gamble became so intense that by November 18, 2014, he had to check himself out of the rehab centre (…) to gamble – after temporarily satiating his urges, the Petitioner checked himself back into the rehab centre the following week on November 25, 2014;

104. The Petitioner's gambling compulsions continued unabated for another approximate three months while at the rehab centre until his cravings again and his intense anxiety and aggression related thereto forced him to check himself out again on March 4, 2015, at which point he travelled directly to the Casino de Montreal to gamble all the money in his bank account at the time;

105. The Petitioner continued gambling five to six days a week and losing approximately $1,000.00 to $1,500.00 each time;

106. This dismal situation continued until in or about August 2016 when his girlfriend's sister saw a commercial about ABILIFY and how it may cause gambling problems. The Petitioner stopped taking ABILIFY immediately upon learning that his compulsive gambling may be related to the medication that he was taking;

107. About one month after stopping to take ABILIFY, the Petitioner's compulsive gambling problems were completely gone, what remained was an intense fear of relapse, the whole as appears more fully from a copy of the Petitioner's file from Jacqueline Aubie M.A., O.P.Q., produced herein under seal as **Exhibit R-70**;

108. The Petitioner lost between $50,000.00 and $60,000.00 while taking ABILIFY over the course of approximately five years;

109. The Petitioner had no gambling problems prior to taking ABILIFY and his gambling problems ended upon stopping to take ABILIFY;

110. At no time was the Petitioner made aware of the risks of suffering from uncontrollable impulses including compulsive and/or pathological gambling associated with taking ABILIFY;

111. Had the Respondents properly disclosed the risks associated with ABILIFY, Petitioner would have avoided the risk of suffering from uncontrollable impulses, including compulsive and/or pathological gambling by not ingesting ABILIFY at all. Further, had the Petitioner been made aware of the risks of suffering from uncontrollable impulses, including compulsive and/or pathological gambling, he would not have had to suffer injury for five long years without any explanation of the cause, and instead would have simply discontinued his use of ABILIFY at the first sign of the uncontrollable urges;

112. Petitioner is aware that several lawsuits were filed in the United States due to the defects associated with ABILIFY and due to the Respondents' conduct related thereto, as appears more fully from a copy of the U.S. Complaints, produced herein *en liasse* as **Exhibit R-53**;

112.1 On April 1, 2019, Dr. Evan Brahm, psychiatrist, wrote an expert report that concluded the following:

> While Mr. Scheer is a young male with a previous alcohol use problem and a family history of addiction (his father's alcohol use issues), he never manifested any problem with gambling prior to starting Abilify and in my opinion, the fact that he has had no craving to gamble and no problem prudently managing his finances for 2.5 years since discontinuing Abilify, without the need for further addiction treatment, strongly suggests that Abilify either solely caused his compulsive gambling or markedly exacerbated any potential for addictive or compulsive behaviour that he already had. His compulsive gambling from the end of 2013 to August 2016 coincides exactly with his taking Abilify and ceased quickly when he discontinued taking Abilify.
>
> Even acknowledging the known risk factors and, despite Mr. Scheer having those that I cite, the clinical evidence is that both prior to being on Abilify and since he stopped, until the present, he has not manifested any symptoms of pathological gambling and his capacity to stop gambling so quickly after discontinuing is demonstrative of Abilify being the cause of him having developed the Gambling Disorder (as defined in the DSM-5). In my opinion, there is no evidence of any likelihood that this would have occurred had he not taken Abilify.

The whole as appears more fully from a copy of the Expert Report of Dr. Brahm dated April 1, 2018, produced herein as **Exhibit R-74**;

112.2 In his Expert Report (Exhibit R-73), Dr. Dagher opined the following:

> The strongest evidence linking the medication to the gambling disorder in this case is the very strong time-locked relationship between the medication and the gambling urges. The description by Mr. Scheer of a spontaneous resolution of gambling urges following discontinuation of the medication is consistent with the medical literature and strongly supportive of a causal relationship between aripiprazole and gambling in this case;

113. As a result of the Respondents' conduct, the Petitioner suffered damages including, but not limited to physical and mental/emotional injuries, including pain, suffering, anxiety (the very problem he was trying to resolve), fear

(including fear of relapse), loss of quality and enjoyment of life, damage to or loss of reputation, extensive financial losses (including the loss of sentimental family jewelry pieces), loss of income, expenses relating to his treatment in the rehab centres, and the apportioned cost of ABILIFY;

114. Petitioner's damages are a direct and proximate result of his use of the drug ABILIFY, Respondents' negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of ABILIFY;

115. In consequence of the foregoing, the Petitioner is justified in claiming damages;

VIII. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

116. Every member of the Class has purchased and/or ingested/injected ABILIFY or is the successor, family member, assign, and/or dependant of a person who purchased, ingested, and/or used ABILIFY;

117. The Class Members' damages would not have occurred, but for the acts, omissions and/or negligence of the Respondents in failing to ensure that ABILIFY was safe to use, for failing to provide adequate warning of the unreasonable risks associated with using the drug, for false or misleading representations and for omitting to disclose important information to Class Members, to their physicians, and to Health Canada;

118. In consequence of the foregoing, each member of the Class is justified in claiming at least one or more of the following as damages:

a. Physical and mental/emotional injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, increased risk of mental problems, damage to and/or loss of reputation;

b. Out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of the compulsive behaviours;

c. Extensive financial losses (such as from gambling or spending) and out-of-pocket expenses, including loss of income and loss of future income;

d. Refund of the purchase price of ABILIFY or alternatively, the incremental costs of ABILIFY as paid for by the Class Members and/or by the *Régie de l'assurance maladie du Québec*, the Ontario Health Insurance Plan, and other provincial health insurers; and

e. Punitive damages;

119. As a direct result of the Respondents' conduct, the users' family members and dependants have, had, and/or will suffer damages and loss including:

a. Out-of-pocket expenses, including debts accrued and/or paying or providing nursing, housekeeping and other services;

b. Loss of income and loss of future income; and

c. Loss of support, guidance, care, consortium, and companionship that they might reasonably have expected to receive if the injuries had not occurred;

119.1 The Class Members plead and rely upon, *inter alia*, the following provincial statutes (all as amended):

a. *Tort-Feasors Act*, R.S.A. 2000, c. T-5

b. *Fatal Accidents Act*, R.S.A. 2000 c. F-8

c. *Family Compensation Act*, R.S.B.C. 1996 c. 126

d. *Fatal Accidents Act*, C.C.S.M. c. F50

e. *Fatal Accidents Act*, R.S.N.B. 2012, c. 104

f. *Fatal Accidents Act*, R.S.N.L. 1990, c.F-6

g. *Fatal Injuries Act*, R.S.N.S. 1989. c.163

h. *Family Law Act*, R.S.O. 1990, c. F.3

i. *Fatal Accidents Act*, R.S.P.E.I. 1988, c.F-5

j. *Fatal Accidents Act*, R.S.S. 1978, c.F-11

120. All of these damages to the Class Members are a direct and proximate result of the use of ABILIFY and the Respondents' conduct, negligence (at common law or civil law) and reckless failure to adequately disclose necessary information and the risks associated with the drug;

IX. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

A) The composition of the Class makes it difficult or impracticable to apply the rules for mandates to sue on behalf of others or for consolidation of proceedings

120.1 Both Defendants maintain head offices and do business in Quebec, making a national class action appropriate for authorization;

121. The Petitioner is unaware of the specific number of persons who ingested, injected and/or purchased ABILIFY, which information is confidential; however, it is safe to estimate that it is in the hundreds of thousands;

122. Class Members are numerous and are scattered across the entire province and country;

123. In addition, given the costs and risks inherent in an action before the courts, many people will hesitate to institute an individual action against the Respondents. Even if the Class Members themselves could afford such individual litigation, it would place an unjustifiable burden on the courts. Furthermore, individual litigation of the factual and legal issues raised by the conduct of the Respondents would increase delay and expense to all parties and to the court system;

124. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory judgments on questions of fact and law that are similar or related to all members of the Class;

125. These facts demonstrate that it would be impractical, if not impossible, to contact each and every member of the Class to obtain mandates and to join them in one action;

126. In these circumstances, a class action is the only appropriate procedure for all of the members of the Class to effectively pursue their respective rights and have access to justice;

126.1 Where, as indicated above, both Defendants are domiciled in Quebec, there is nothing to preclude the Courts of Quebec from applying the common law and the statutes of other provinces to the claim of the Class Members;

B) The claims of the members of the Class raise identical, similar or related issues of law or fact

127. Individual issues, if any, pale by comparison to the numerous common issues that are significant to the outcome of the litigation;

128. The damages sustained by the Class Members flow, in each instance, from a common nucleus of operative facts, namely, Respondents' misconduct;

129. The claims of the members raise identical, similar or related issues of fact or law, namely:

a) Does ABILIFY cause, exacerbate or contribute to an increased risk of dangerous side effects including having uncontrollable and irrepressible impulses to engage in harmful impulse control behaviours such as:

- pathological gambling (also known as gambling disorder or compulsive gambling)
- compulsive eating/ binge eating
- uncontrollable or compulsive shopping or spending, and/or
- hypersexual behaviours / sexual addiction

(the "Impulse Control Disorders")?

a.1) In the affirmative, did the Defendants know or should they have known about the risks of Impulse Control Disorders associated with the use of ABILIFY?

b) Did the Defendants breach the applicable standard of care in failing to adequately test ABILIFY both before and/or after placing it on the market?

b.1) Did the Defendants have a duty to warn Class Members of the risk of Impulse Control Disorders associated with the use of Abilify?

c) Did the Defendants adequately and sufficiently advise/warn the Class Members, Health Canada, and/or their physicians about the risks of experiencing the Impulse Control Disorders associated with the use of ABILIFY?

d) (…)

d.1) Are the Defendants, or some of them, liable for conspiracy to promote, market, and distribute Abilify in Canada without adequate and timely warnings about the risk of Impulse Control Disorders and, if so, over what period of time?

d.2) Can causality be determined on a collective basis and, if so, can Class Members rely on a presumption to establish causation?

e) In the affirmative to any of the above questions, did the Defendants' conduct engage their solidary liability toward some or all of the Class Members?

f) Are the Defendants liable to pay compensatory damages to some or all of the Class Members?

f.1) In the affirmative, can the compensatory damages payable to Class Members be determined and recovered on a collective basis?

g) Are the Defendants liable to pay aggravated or punitive damages and, if so, in what amount?

130. The interests of justice favour that this application be granted in accordance with its conclusions;

X. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

131. The action that the Petitioner wishes to institute on behalf of the members of the Class is an action in damages (…);

132. The conclusions that the Petitioner wishes to introduce by way of an application to institute proceedings are:

GRANT the class action of the Plaintiff and each of the members of the Class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of ABILIFY;

RESERVE the right of each of the members of the Class to claim future damages related to the use of ABILIFY;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the Class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the application to authorize a class action;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

A) <u>The Petitioner requests that he be attributed the status of representative of the Class</u>

133. Petitioner is a member of the Class;

134. Petitioner is ready and available to manage and direct the present action in the interest of the members of the Class that he wishes to represent and is determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the Class, as well as, to dedicate the time necessary for the present action before the Courts and the *Fonds d'aide aux actions collectives*, as the case may be, and to collaborate with his attorneys;

135. Petitioner has the capacity and interest to fairly, properly, and adequately protect and represent the interest of the members of the Class;

136. Petitioner has given the mandate to his attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

137. Petitioner, with the assistance of his attorneys, is ready and available to dedicate the time necessary for this action and to collaborate with other members of the Class and to keep them informed;

138. Petitioner has given instructions to his attorneys to put information about this class action on its website and to collect the coordinates of those Class Members that wish to be kept informed and participate in any resolution of the present matter, the whole as will be shown at the hearing, the whole as appears more fully from a copy of a redacted chart of potential Class Members who have inputted their information through the CLG webpage, produced herein as **Exhibit R-65**;

139. Petitioner is in good faith and has instituted this action for the sole goal of having his rights, as well as the rights of other Class Members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Respondents' conduct;

140. Petitioner understands the nature of the action;

141. Petitioner's interests are not antagonistic to those of other members of the Class;

142. Petitioner is prepared to be examined out-of-court on his allegations (as may be authorized by the Court) and to be present for Court hearings, as may be required and necessary;

143. Petitioner has spent time researching this issue on the internet and meeting with his attorneys to prepare this file. In so doing, he is convinced that the problem is widespread;

B) The Petitioner suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal

144. A great number of the members of the Cass reside in the judicial district of Montreal and in the appeal district of Montreal;

145. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

146. The present application is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present application;

AUTHORIZE the bringing of a class action in the form of an application to institute proceedings in damages (…);

ASCRIBE the Petitioner the status of representative of the persons included in the class herein described as:

- All persons residing in Canada who were prescribed and have ingested and/or used the drug, ABILIFY® (aripiprazole) before February 23, 2017 and who developed one or more of the following impulse control behaviours:

  - pathological gambling (also known as gambling disorder or compulsive gambling)
  - compulsive eating/ binge eating
  - uncontrollable or compulsive shopping or spending, and/or
  - hypersexual behaviours / sexual addiction

  (the "Impulse Control Disorders")

and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

(…)

IDENTIFY the principle issues of fact and law to be treated collectively as the following:

a) Does ABILIFY cause, exacerbate or contribute to an increased risk of dangerous side effects including having uncontrollable and irrepressible impulses to engage in harmful impulse control behaviours such as:

- pathological gambling (also known as gambling disorder or compulsive gambling)
- compulsive eating/ binge eating
- uncontrollable or compulsive shopping or spending, and/or
- hypersexual behaviours / sexual addiction

(the "Impulse Control Disorders")?

a.1) In the affirmative, did the Defendants know or should they have known about the risks of Impulse Control Disorders associated with the use of ABILIFY?

b) Did the Defendants breach the applicable standard of care in failing to adequately test ABILIFY both before and/or after placing it on the market?

b.1) Did the Defendants have a duty to warn Class Members of the risk of Impulse Control Disorders associated with the use of Abilify?

c) Did the Defendants adequately and sufficiently advise/warn the Class Members, Health Canada, and/or their physicians about the risks of experiencing the Impulse Control Disorders associated with the use of ABILIFY?

d) (…)

d.1) Are the Defendants, or some of them, liable for conspiracy to promote, market, and distribute Abilify in Canada without adequate and timely warnings about the risk of Impulse Control Disorders and, if so, over what period of time?

d.2) Can causality be determined on a collective basis and, if so, can Class Members rely on a presumption to establish causation?

e) In the affirmative to any of the above questions, did the Defendants' conduct engage their solidary liability toward some or all of the Class Members?

f) Are the Defendants liable to pay compensatory damages to some or all of the Class Members?

f.1) In the affirmative, can the compensatory damages payable to Class Members be determined and recovered on a collective basis?

g) Are the Defendants liable to pay aggravated or punitive damages and, if so, in what amount?

IDENTIFY the conclusions sought by the class action to be instituted as being the following:

GRANT the class action of the Plaintiff and each of the members of the Class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of ABILIFY;

RESERVE the right of each of the members of the Class to claim future damages related to the use of ABILIFY;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the Class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the application to authorize a class action;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

DECLARE that all members of the Class that have not requested their exclusion, be bound by any judgment to be rendered on the class action to be instituted in the manner provided for by the law;

FIX the delay of exclusion at sixty (60) days from the date of the publication of the notice to the Class Members, date upon which the members of the Class that have not exercised their means of exclusion will be bound by any judgment to be rendered herein;

ORDER the parties to provide the Court with draft notices to the Class Members in English and in French within thirty (30) days hereof;

RECONVENE the parties to a case management conference at a date to be determined based on the availability of the Court to rule on the text of the notices and the notice plan;

(…)

(…)

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

THE WHOLE with costs, including all publication fees.

Montreal, November 5, 2019

Andrea Grass

_____

CONSUMER LAW GROUP INC.
Per: Me Andrea Grass
Attorneys for the Petitioner

CONSUMER LAW GROUP INC.
1030 rue Berri, Suite 102
Montréal, Québec, H2L 4C3
Telephone: (514) 266-7863
Telecopier: (514) 868-9690
Email: agrass@clg.org

Nº: 500-06-000831-160

(Class Action)
SUPERIOR COURT
DISTRICT OF MONTREAL

S. SCHEER

Petitioner

-vs.-

BRISTOL-MYERS SQUIBB CANADA CO. *et al.*

Respondents

FOURTH AMENDED APPLICATION TO AUTHORIZE THE BRINGING OF A CLASS ACTION & TO APPOINT THE PETITIONER AS REPRESENTATIVE PLAINTIFF
(Art. 574 C.C.P and following)

COPY

Me Jeff Orenstein, Ext. 2
Me Andrea Grass, Ext. 3
CONSUMER LAW GROUP INC.
1030 rue Berri, Suite 102
Montreal, Quebec, H2L 4C3
Telephone: (514) 266-7863
Telecopier: (514) 868-9690
Email: jorenstein@clg.org
agrass@clg.org

BC 4013

Consumer Law Group