CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

No: 500-06-000948-188

SUPERIOR COURT
(Class Action)

[redacted]

Petitioner

v.

OTSUKA PHARMACEUTICAL COMPANY LIMITED a legal person incorporated under the laws of Japan domiciled at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535, Japan

and

OTSUKA CANADA PHARMACEUTICAL INC.
a legal person incorporated under the CBCA, domiciled in the district of Montreal at 2250 Alfred Nobel Blvd., Ste. 301, Saint Laurent, QC H4S 2C9

and

OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC.
a legal person domiciled at 2440 Research Blvd., Rockville, MD, 20850, United States of America

and

H. LUNDBECK A/S
a legal person domiciled at Ottiliavej 9 Copenhagen-Valby, DK-2500, Denmark

and

LUNDBECK CANADA INC.
a legal person incorporated under the Business Corporations Act domiciled at 400-2600 Boul. Alfred-Nobel
St. Laurent QC, H4S 0A9

and

LUNDBECK RESEARCH USA INC.
a legal person domiciled at 1600 Route 23 North, Suite 350, Wayne, NJ, 07410
United States of America

Respondents

MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO OBTAIN THE STATUS OF REPRESENTATIVE
(Article 1002 C.C.P.)

IN SUPPORT OF HIS MOTION, THE PETITIONER RESPECTFULLY SUBMITS AS FOLLOWS:

I. DEFINITIONS

1. In this document, in addition to the terms that are otherwise defined within, the following terms have the following meanings:

   a. **"Abilify"** means aripiprazole tablets sold under the trademark ABILIFY, and depot injections of aripiprazole sold under the trademark ABILIFY MAINTENA;

   b. **"CBCA"** means the *Canada Business Corporations Act,* R.S.C. 1985, c. C-44;

   c. **"CCQ"** means the Civil Code of Québec;

   d. **"Class Period"** means the period starting from February 16, 2017;

   e. **"Compulsive Behaviours"** means, *inter alia*, an uncontrollable impulse to gamble, shop, eat; unusual sexual thoughts, fantasies, desires or behaviours; or any other uncontrollable behaviour that causes harm to the individual or others;

   f. "**Impulse-Control Disorders"** means, *inter alia*, any one or more impulse control disorders, including but not limited to compulsive gambling, hypersexuality, binge eating and compulsive shopping and/or spending;

   g. **"Product Monograph"** means the Canadian product monograph for Rexulti;

   h. **"Rexulti"** means brexpiprazole tablets sold under the trademark Rexulti™;

   i. **"Respondents"** means the Otsuka Pharmaceutical Company Ltd., Otsuka Pharmaceutical Development & Commercialization Inc., Otsuka Canada

Pharmaceutical Inc., H. Lundbeck A/S, Lundbeck Research USA Inc., and Lundbeck Canada Inc.

II. INTRODUCTION

2. This class proceeding arises from the Respondents' failure to warn the Canadian public of the severe side effects of the drug Rexulti. As a result of their misrepresentations and omissions, the Respondents harmed the Class Members.

3. In Canada, Rexulti is indicated for the treatment of schizophrenia. However, it has the undisclosed side effect of causing or materially increasing the risk and severity of Compulsive Behaviours and Impulse Control Disorders, particularly gambling.

4. The Respondents knew or should have known that Rexulti has this severe side effect, because the Respondents intentionally designed Rexulti to be substantially similar to their drug Abilify. Abilify was researched and developed by the Respondents, is indicated for the treatment of schizophrenia, bipolar I disorder and Major Depressive Disorder, and causes or materially increases the risks of Compulsive Behaviours and Impulse Control Disorders. As Rexulti and Abilify are almost identical in their chemical structure and mechanism of action in the brain, the Respondents knew or should have known that Rexulti would also cause or materially contribute to Impulse Control Disorders and Compulsive Behaviours.

5. The increased risk of Compulsive Behaviours and Impulse Control Disorders associated with Abilify became the subject of escalating regulatory intervention in Canada, the United States, and Europe. Regulators compelled the Respondents to revise Abilify's product monographs with increasingly comprehensive warnings, and by 2017, the Canadian product monograph for Abilify featured a lengthy and explicit warning about its risk of Compulsive Behaviours and Impulse Control Disorders.

6. Despite the clear need to label Rexulti with adequate warnings, the Respondents concealed Rexulti's risk of Compulsive Behaviours and Impulse Control Disorders from the Canadian public and their treating physicians. The Product Monograph for Rexulti omits critical information about the full array of the Compulsive Behaviours and Impulse Control Disorders that Rexulti can induce, the causal relationship between with Rexulti and the development of these side effects, the need to discontinue or taper Rexulti if these side effects develop, and the methods for detecting whether a patient is developing these side effects. The Product Monograph also misleadingly implies that only people with a pre-existing history of pathological gambling should be worried about the risk of Compulsive Behaviours and Impulse Control Disorders.

7. Further, despite their significant collective resources and the existence of a large body of scientific evidence demonstrating that Abilify can cause or materially increase the risk of developing Compulsive Behaviours and Impulse Control Disorders, the Respondents failed to conduct any, or any adequate or reasonable, pre- or post-market testing and research to confirm whether Rexulti has the same severe side effects as Abilify.

8. The Petitioner and Class Members would never have been harmed by Rexulti but for the Respondents' failure to warn them about this side effect. This failure to warn was

particularly egregious given the vulnerability of the Petitioner and other Class Members – as individuals with schizophrenia and/or other major mental illnesses, they are particularly affected by the harms of Compulsive Behaviours and Impulse Control Disorders, including social alienation, financial loss, emotional anguish, and humiliation.

III. THE CLASS

9. The Petitioner, [redacted], intends to institute a class action on behalf of the following Class, of which he is a member:

> "All persons who reside or have resided in Canada who were prescribed and ingested the drug REXULTI® during the Class Period and their family members, dependents, heirs and estates" (the "Class" and "Class Members").

IV. PETITIONER'S CIRCUMSTANCES

10. The Petitioner was prescribed 2mg/day of Rexulti on or about May 26, 2018 for the treatment of his Major Depressive Disorder and schizoaffective disorder.

11. The Petitioner had previously been prescribed Abilify to treat these disorders. However, while taking Abilify, he developed a severe gambling addiction. Four months after first being prescribed Abilify, he gambled for the first time in his life. His gambling progressed to 3 to 4 times per week, and ultimately, he lost $15,000 gambling while taking Abilify.

12. As a result of this harmful effect of Abilify, the Petitioner discontinue using this drug. Shortly thereafter, his urge to gamble stopped. However, because Abilify was also treating his depression, discontinuing Abilify made him suicidal, which resulted in his hospitalization for over a month. The Petitioner resumed taking Abilify after his hospitalization.

13. In or about April 2018, the Petitioner asked his psychiatrist to replace his Abilify prescription with an efficacious treatment that would not cause him to gamble compulsively.

14. On May 26, 2018, the Petitioner's physician prescribed him Rexulti. The Petitioner's physician advised him that Rexulti would not have the same harmful side effects as Abilify and would not cause him to gamble.

15. Within a month of starting Rexulti, the Petitioner experienced compulsive and unrelenting urges to gamble.

16. The Petitioner's gambling intensified while taking Rexulti. He gambled more frequently and wagered higher amounts than he did on Abilify.

17. The Petitioner discontinued Rexulti on October 2, 2018, after he lost $1,300 gambling in just two days.

18. From May to October 2018, the Petitioner lost approximately $10,000 while gambling compulsively.

19. As a direct result of his use of Rexulti and his compulsive gambling, the Petitioner has endured financial loss, emotional anguish, humiliation, and anxiety. His gambling urges were so severe that he spent all of his money gambling, even if it meant forgoing necessities such as food.

20. Further, the Petitioner borrowed approximately $11,000 from friends to fund his gambling. As a result of his these personal debts and his compulsive gambling, the Petitioner has became estranged from his family and friends. In the past two years he has not spoken to his family or his closest friend.

21. In total, the Petitioner has lost approximately $25,000 gambling.

22. The Petitioner was never advised of the risk of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti.

23. Had the Petitioner been advised that Rexulti had the same serious side effect as Abilify, he would have refused to take Rexulti and would have insisted on a safer alternative treatment.

24. But for the Respondents' breach of their duties to warn the Petitioner of Rexulti's side effects, including the increased risk of Compulsive Behaviours and Impulse Control Disorders, he would not have suffered his injuries and incurred his damages.

25. The Petitioner's damages include pain, suffering, stress, pecuniary losses from gambling, and the loss of care and companionship of his friends and family.

26. The Petitioner also claims punitive from the Respondents for their gross negligence and wanton disregard for his health and safety, as protected by the Charter of Human Rights and Freedoms in an amount to be determined at trial.

27. The Respondents' negligence has also caused harm to the Petitioner's family members and dependents, and to the family members and the dependents of other Class Members, who have suffered pain, stress, and financial losses as a result of the Petitioner's and the other Class Members' compulsive gambling and other harmful Compulsive Behaviours and Impulse Control Disorders.

V. RESPONDENTS' LIABILITY

a. The Respondents

28. At all times material to this action, the Respondents acted in concert in designing, developing, manufacturing, testing, inspecting, marketing, supplying, exporting, importing, and selling Rexulti in Canada, including in the Province of Québec, for profit, and in concealing its risk of Compulsive Behaviours and Impulse Control Disorders from the public.

29. Otsuka Pharmaceutical Company Limited ("Otsuka") is a Japanese corporation with its headquarters in Tokyo, Japan. Otsuka is the owner of the trademark Rexulti™.

Canadian Patent No. 2602247 pertaining to brexpiprazole, the active ingredient in Rexulti, was issued to Otsuka on April 2, 2013, the whole as appears more fully from **Exhibit P-1.**

30. The Product Monograph is purportedly authored by Otsuka. Otsuka oversees worldwide manufacturing, distribution, and marketing of Rexulti in concert with its wholly owned regional subsidiaries.

31. American subsidiary Otsuka Pharmaceutical Development & Commercialization Inc. assisted in the development and commercialization of Rexulti; its employees conducted and published numerous clinical trials and studies relied on by Health Canada in approving Rexulti.

32. In Canada, Otsuka operates through its wholly owned subsidiary Otsuka Canada Pharmaceutical Inc. ("Otsuka Canada"), a corporation incorporated under the *CBCA*, with its head office located in Montreal, Québec. Otsuka Canada uses the trademark Rexulti under license from Otsuka. Otsuka Canada imports and markets Rexulti in Canada.

33. Otsuka pursued these ends as part of a collaborative drug development enterprise with H. Lundbeck A/S, ("Lundbeck") a Danish pharmaceutical company with its headquarters in Valby, Denmark.

34. A November 11, 2011 press release and accompanying slideshow produced by Otsuka details Otsuka's and Lundbeck's agreement to collaborate in respect of "OPC-34712", Otsuka's internal code name for brexpiprazole. The agreement sets out a worldwide revenue sharing arrangement, and provides that Otsuka and Lundbeck will each materially contribute to Rexulti's development and commercialization in the United States, Canada, and select European territories. This press release produced as **Exhibit P-2.**

35. As of September 2018, Otsuka's website identifies Lundbeck as a "global collaborator with whom we have a business alliance" for the "co-development and co-commercialization of brexpiprazole." This web page is produced as **Exhibit P-3.**

36. Like Otsuka, Lundbeck operates globally through its wholly owned regional subsidiaries. Lundbeck Research USA Inc. is a wholly owned subsidiary of Lundbeck; its employees co-authored the clinical trials relied on by Health Canada in approving Rexulti.

37. In Canada, Lundbeck operates through its wholly owned subsidiary Lundbeck Canada Inc., a corporation incorporated under the *CBCA*, with its head office located in Montreal, Québec. With Otuska Canada, Lundbeck Canada imports and markets Rexulti in Canada.

38. As such, the Respondents are solidarily liable to the Petitioner and Class Members because:

    a. They agreed to co-develop and co-commercialize Rexulti in Canada and throughout the world;

b. They actively participated in joint executive governance and operating committees with respect to Rexulti;

c. They mutually provided funding and services including manufacturing, customer management, distribution and pharmacovigilance, for the benefit of their alliance;

d. Their employees and consultants jointly oversaw and authored clinical trials and studies of Rexulti, the results of which formed the basis for Health Canada's approval of Rexulti for the treatment of schizophrenia (the whole as appears more fully from **Exhibits P-4, P-5, P-6, and P-7)**; and,

e. They collectively failed to warn the Petitioner and Class Members of the risks of Compulsive Behaviours and Impulse Control Disorders associated with Rexulti.

b. History of Rexulti and Abilify

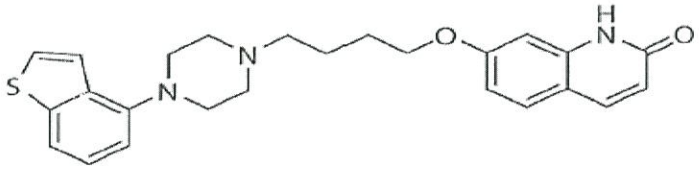
39. Rexulti (brexpiprazole) was approved for sale in Canada on February 16, 2017 to treat schizophrenia in adults, the whole as appears more fully from Health Canada's Regulatory Decision Summary for Rexulti, attached as **Exhibit P-8.**

40. Rexulti is available in oral tablets of 0.25, 0.5, 1, 2, 3 and 4 milligrams.

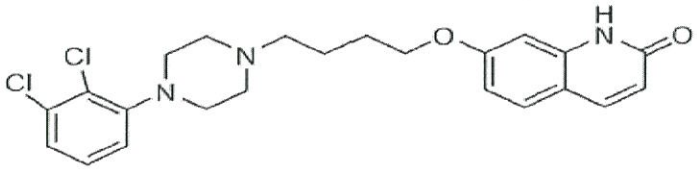
41. Rexulti was previously approved for sale in the United States on July 10, 2015 to treat schizophrenia and as an adjunctive treatment for Major Depressive Disorder, the whole as appears more fully from the U.S. Food and Drug Administration's Approval Letter for Rexulti, attached as **Exhibit P-9.**

42. The active medicinal ingredient in Rexulti, brexpiprazole, belongs to a class of drugs identified alternately in the scientific literature as second-generation and third-generation antipsychotics, the whole as appears more fully from **Exhibit P-10**.

43. Brexpiprazole is almost chemically identical to aripiprazole. This similarity is apparent on visual comparison of the Lewis structures of aripiprazole and brexpiprazole at Figure 1, inset.



Brexpiprazole



Aripiprazole

[Figure 1]

44. Aripiprazole was researched, developed, designed, tested, manufactured, licensed, marketed, distributed and sold by the Respondents under the brand names ABILIFY© and, as a depot injection, ABILIFY MAINTENA©.

45. The similarity of brexpiprazole to aripiprazole is intentional. Brexpiprazole was developed because aripiprazole lost patent protection in the United States and began to face competition from generic formulations of aripiprazole in 2015.

46. Abilify was a blockbuster drug for the Respondents. In 2014, prior to losing American patent protection, Abilify generated $6.4 billion in global revenues, and was the seventh-best selling drug in the world, as can be seen in Otsuka's Annual Report for Fiscal Year 2014, attached as **Exhibit P-11.**

47. Because of Abilify's success, brexpiprazole was intended to be as functionally similar to aripiprazole as possible while still being chemically distinct enough to attract patent protection of its own. This practice is known as 'evergreening' – extending the monopoly afforded by the patent system by making superficial changes to the chemical structure of an existing drug that do not change its underlying therapeutic properties or side effect profile. Evergreening as an industry practice is discussed in more detail in the *Canadian Medical Association Journal* article attached as **Exhibit P-12.**

48. The Health Canada Summary Basis of Decision for Rexulti observes that brexpiprazole has "a similar chemical structure to the antipsychotic drug aripiprazole (Abilify)", attached as **Exhibit P-13**. A member of Otsuka's advisory board has acknowledged in a scientific publication that brexpiprazole was intended to closely imitate aripiprazole because aripiprazole was losing patent protection. This publication is attached as **Exhibit P-14.**

c. Mechanism of Action

49. Besides chemical similarity, aripiprazole and brexpiprazole share an identical mechanism of action– partial dopamine agonism.

50. Neurons in the brain "activate", or generate an electric signal, when they are exposed to neurotransmitter molecules. Dopamine is a neurotransmitter molecule. It is hypothesized that abnormal patterns of dopaminergic activation cause some of the pathology of schizophrenia.

51. Most antipsychotic drugs used in the treatment of schizophrenia are thought to work by "antagonizing", or blocking, dopamine receptors. This antagonism stops dopamine from binding to the receptor and activating it.

52. Aripiprazole and brexpiprazole are unlike other antipsychotics in that they can both antagonize and agonize, or activate, the brain's dopamine receptors. An agonist that activates a dopamine receptor to the same extent as dopamine itself is a "full" dopamine agonist. Aripiprazole and brexpiprazole are less potent agonists than dopamine, so they are classified as "partial" dopamine agonists.

53. Partial dopamine agonists are thought to have a "buffering" or stabilizing effect on dopamine transmission: they antagonize receptors and reduce transmission when dopamine transmission is high, but agonize receptors and increase transmission when dopamine transmission is low. Their ability to facilitate dopamine transmission may explain their antidepressant properties, while their ability to reduce transmission may explain their antipsychotic properties. This explanation is set out in the article entitled "The ABC's of dopamine receptor partial agonists – aripiprazole, brexpiprazole and cariprazine: the 15-min challenge to sort these agents out", attached as **Exhibit P-15**.

54. Aripiprazole and brexpiprazole have an almost identical propensity, or "affinity", to bind to the same dopamine receptor subtypes and exert this partial agonism effect. This similarity is highlighted in the Product Monograph, attached as **Exhibit P-16,** and in a pair of review articles comparing aripiprazole's and brexpiprazole's mechanisms of action, attached as **Exhibits P-17** and **P-18**.

55. Because dopamine-activated brain circuits also regulate our experience of pleasure and reward, dopamine agonists can cause or exacerbate pleasure- or reward-seeking behaviours, like compulsive gambling, binge eating, or hypersexuality. This side effect of dopamine agonists was known for decades before the development of Abilify and Rexulti.

d. Scientific Evidence that Dopamine Agonists, and Abilify in Particular, Cause Compulsive Behaviours and Impulse-Control Disorders

56. Full dopamine agonists such as Mirapex, Permax and Requip are used in the treatment of Parkinson's disorder and restless leg syndrome, two diseases involving dysfunction of dopaminergic neurons. The product monographs of Mirapex, Permax and Requip were revised in mid-2000 in Canada and the United States to explicitly warn of the risk of compulsive gambling and other Compulsive Behaviours and Impulse-Control Disorders. These revisions were prompted by numerous studies predating or contemporaneous to Abilify's commercialization in the early 2000s, demonstrating that full dopamine agonists cause Compulsive Behaviours and Impulse Control Disorders, particularly compulsive gambling. Some of these studies are reproduced as **Exhibits P-19, P-20, and P-21.** In particular, studies demonstrated that:

a. the onset of compulsive gambling was temporally related to the initiation of, or the increase in dose for, dopamine agonist therapy, per the studies attached as **Exhibits P-22 and P-23**;

b. reductions in dose or discontinuation of dopamine agonist therapy reduced or eliminated the compulsive gambling, per the study attached as **Exhibit P-24**; and

c. adjunctive treatment with dopamine antagonists blocking the D2 receptor subtype (one of the two dopamine receptor subtypes at which aripiprazole and brexpiprazole exert their action) reduces or eliminates dopamine-agonist-caused compulsive gambling, per the study attached as **Exhibit P-25**.

57. It has also been established that Compulsive Behaviours and Impulse Control Disorders are caused by full dopamine agonists in the absence of pre-existing

conditions, risk factors, or dopaminergic pathology, per the study attached as **Exhibit P-26**.

58. Starting in 2007, scientists also began observing this effect in patients prescribed Abilify, a partial (rather than full) dopamine agonist, as seen in the 2007 case report reproduced as **Exhibit P-27.**

59. By 2014, an enormous retrospective analysis of the FDA's Adverse Event Report System from 2003-2012 showed that Abilify had a statistically significant "proportionality reporting ratio" for Compulsive Behaviours and Impulse Control Disorders, like gambling, hypersexuality, shopping and binge eating. This indicated that Abilify causes Compulsive Behaviours and Impulse Control Disorders, and the requirement for a commensurate warning on its packaging. This study is attached as **Exhibit P-28.**

60. These results were replicated by a large 2017 study on the European pharmacovigilance database, which revealed a similarly elevated proportionality reporting ratio for gambling disorders and treatment with Abilify. This study is attached as **Exhibit P-29.**

61. Case studies of Compulsive Behaviours and Impulse Control Disorders in patients prescribed Abilify revealed that these side effects followed a challenge-dechallenge-rechallenge pattern:

    a. The Compulsive Behaviours and Impulse Control Disorders only emerged when the patient was 'challenged' with, or administered, Abilify;

    b. The Compulsive Behaviours and Impulse Control Disorders desisted when the patient was dechallenged, or had their Abilify discontinued; and,

    c. The Compulsive Behaviours and Impulse Control Disorders re-emerged when the patient was "rechallenged" with, or re-administered, Abilify following the dechallenge.

62. This pattern strongly indicates that Abilify causes Compulsive Behaviours and Impulse Control Disorders. A survey of case studies demonstrating this challenge-dechallenge-rechallenge pattern is attached as **Exhibit P-30.**

e. Regulatory Warnings of Abilify's Risk of Compulsive Behaviours and Impulse-Control Disorders

63. Regulatory authorities around the world required the Respondents to provide explicit warnings of Abilify's risks of Compulsive Behaviours and Impulse Control Disorders in its product monographs, as well as detailed information about how to detect and manage these severe side effects.

i. Europe

64. In 2011, Otsuka submitted a "6 Month Periodic Safety Update Report" in respect of Abilify to the European Medicines Agency. The report acknowledged 23 cases of compulsive gambling temporally linked to treatment with Abilify.

65. Following this Safety Update Report, the European Medicines Agency directed Otsuka to warn physicians and consumers of the risk of compulsive gambling associated with Abilify with the following language in the product monograph:

> Pathological Gambling
>
> Post-marketing reports of pathological gambling have been reported among patients prescribed ABILIFY, 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.

66. Further, the European Summary of Product Characteristics for Abilify was updated to list "pathological gambling" as an "undesirable effect." These regulatory interventions are recorded in the European Medicines Agency's summary of procedural steps taken with respect to Abilify, attached as **Exhibit P-31**.

67. In 2017, this warning language in the European product monograph was expanded and strengthened:

> Patients can experience increased urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. Other urges, reported, include: increased sexual urges, compulsive shopping, binge or compulsive eating, and other impulsive and compulsive behaviours. It is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, compulsive shopping, 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, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Impulse control disorders may result in harm to the patient and others if not recognised. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole.

68. The European product monograph is attached as **Exhibit P-32.**

ii. Canada

69. On June 22, 2015, the Canadian product monograph for Abilify was amended for the first time to identify the risk of pathological gambling:

> Pathological Gambling
>
> 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.

70. In September 2015, a similar amendment was made to the Abilify Maintena product monograph. These versions of the product monographs are attached as **Exhibits P-33** and **P-34**

71. On November 2, 2015, Health Canada issued a Summary Safety Review concluding that there is a link between the use of Abilify and an increased risk of compulsive behaviours, particularly pathological gambling and hypersexuality. This Summary Safety Review is attached as **Exhibit P-35.**

72. In October 2016, the Abilify Maintena product monograph was amended to identify pathological gambling and hypersexuality as "Post-Market Adverse Drug Reactions" of "unknown" frequency. This version of the product monograph is attached as **Exhibit P-36**.

73. In December 2016, the Abilify Maintena product monograph was amended again with a revised and expanded "Warning and Precaution", reading as follows:

> **Pathological Gambling and Other Impulse-Control Disorders**
>
> 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 behaviours. Because patients may not recognize these behaviours 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 patient develops such urges while taking aripiprazole.

74. The "Consumer Information" section of the product monograph, a plain language guide intended for patient use, was also amended to include "a history of gambling" as a "Warning and Precaution" to be discussed with the prescribing physician prior to taking Abilify. This version of the product monograph is attached as **Exhibit P-37**.

75. In February 2017, the Abilify product monograph was similarly amended. The Consumer Information "Warning and Precaution" was expanded to include "a history of gambling or impulse control disorders (urge to gamble, spend money, eat or other urges)". This version of the product monograph is attached as **Exhibit P-38**.

iii. The United States

76. In the United States, Otsuka first updated its product monograph for Abilify on January 15, 2016. Under the heading "Postmarketing Experience", it identified "pathological gambling" as an adverse reaction of Abilify. This version of the product monograph is attached as **Exhibit P-39**.

77. On May 3, 2016, the FDA released a Drug Safety Communication about impulse-control problems associated with Abilify. It warned that

    a. the January 15, 2016 labeling change did not "entirely reflect the nature of the impulse-control risk... identified";

    b. anyone taking the medication could be affected by the compulsive behaviours;

    c. the compulsive behaviours stopped when Abilify was discontinued or its dosage reduced;

78. Specifically, of the 184 case reports of impulse control problems associated with Abilify since 2002 reviewed by the FDA, not a single patient had a history of such behaviours before starting Abilify, and all experienced resolution by discontinuing Abilify or reducing their dosage. This Drug Safety Communication is attached as **Exhibit P-40.**

79. In August 2016, the FDA changed Abilify's labeling again to clearly indicate the causal relationship between Abilify and compulsive behaviours. The Product Monograph now had a separate heading for "Pathological Gambling and Other Compulsive Behaviours" under the "Warnings and Precautions" section. It read as follows:

> Post-marketing case reports suggest that patients can experience intense urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. Other compulsive urges, reported less frequently include: sexual urges, shopping, eating or binge eating, and other impulsive or compulsive behaviours. Because patients may not recognize these behaviours as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or intense gambling urges, compulsive sexual urges, compulsive shopping, 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. In some cases, although not all, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Compulsive behaviours may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urge

80. The "Medication Guide", a truncated plain language version of the monograph for the use of patients, was also amended to add warnings about compulsive behaviour for the first time:

> **Unusual urges**. Some people taking ABILIFY have had unusual urges, such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges. If you or your family members notice that you are having unusual urges or behaviours, talk to your healthcare provider.

81. This version of the product monograph is attached as **Exhibit P-41**.

f. The Respondents' Knowledge of, and Failure to Warn that, Rexulti Causes Compulsive Behaviour and Impulse Control Disorders

82. As the foregoing chronology demonstrates, while the Respondents were developing Rexulti and preparing to bring it to the Canadian market, they were aware that Abilify had the severe side effect of causing Compulsive Behaviours and Impulse Control Disorders, and that extensive warnings were required on Abilify's product monograph and labeling.

83. Having embarked on an enterprise to make a largely identical drug in brexpiprazole, the Respondents knew or should have known that Rexulti also causes or increases the risk of Compulsive Behaviours and Impulse Control Disorders.

84. Despite this knowledge, the Respondents failed to warn the Petitioner and the Class Members of these risks. Instead, the Product Monograph was drafted with cursory, incomplete and inadequate information. The only language pertaining to Compulsive Behaviours and Impulse Control Disorders read and still reads as follows:

> Post-marketing reports of impulse-control disorders including pathological gambling and hypersexuality have been reported in patients treated with another antipsychotic with partial agonist activity at dopamine receptors. Patients with a prior history of impulse-control disorder may be at increased risk and should be monitored carefully.

85. This warning fails to adequately protect the public for the following reasons:

    a. As made clear in this motion, partial dopamine agonists like aripiprazole and brexpiprazole cause or materially contribute to the development of Compulsive Behaviours and Impulse Control Disorders in individuals irrespective of any history of such problems, but this warning implies that only patients with a prior history of such problems are at risk from this side effect;

    b. This warning does not explain the causal relationship between Compulsive Behaviours and Impulse Control Disorders and treatment with Rexulti;

    c. This warning fails to identify the full spectrum of Compulsive Behaviours and Impulse Control Disorders caused or materially contributed to by Rexulti;

    d. This warning fails to advise that Compulsive Behaviours and Impulse Control Disorders frequently desist when Rexulti is discontinued or reduced in dose; and,

    e. This warning provides no guidance as to how to monitor or manage Compulsive Behaviours and Impulse Control Disorders caused by Rexulti.

86. The patient information sheet appended to Rexulti's Canadian monograph contains no information whatsoever about an association between Rexulti and the emergence of Compulsive Behaviours and Impulse Control Disorders so as to allow the Class Members to make an informed decision about using the drug. Instead, it only instructs patients to inform their doctor of a history of "problems with impulse control (i.e. gambling or sex addiction)", without explaining the significance of this caution. It also misleadingly implies that only individuals with such a history are at risk of

developing Compulsive Behaviours and Impulse Control Disorders from treatment with Rexulti.

87. The Canadian labeling for Rexulti stands in sharp contrast to the explicit and detailed warning about compulsive behaviour in the U.S. Rexulti monograph as amended in February 2018:

> Post-marketing case reports suggest that patients can experience intense urges, particularly for gambling, and the inability to control these urges while taking REXULTI. Other compulsive urges, reported less frequently, include: sexual urges, shopping, eating or binge eating, and other impulsive or compulsive behaviours. Because patients may not recognize these behaviours as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or intense gambling urges, compulsive sexual urges, compulsive shopping, binge or compulsive eating, or other urges while being treated with REXULTI. In some cases, although not all, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Compulsive behaviours 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.

88. The February 16, 2018 version of the U.S. product monograph is attached as **Exhibit P-42**.

89. This language is identical to the amendments to the U.S. Abilify product monograph made in August of 2016. For over two years, the Respondents have had an adequate model of how to properly warn the Canadian public about Rexulti's risk of Compulsive Behaviours and Impulse Control Disorders, but have omitted to do so.

90. Additionally, the Respondents have not studied, or have inadequately studied, the risk of Compulsive Behaviours and Impulse Control Disorders associated with brexpiprazole, and have failed to conduct adequate pre- and post-market studies of Rexulti's side effects.

VI. THE RIGHTS OF ACTION

a. Article 1457 of the Civil Code of Québec

91. On behalf of himself and all other Class Members who are residents of Québec, the Petitioner pleads that the Respondents breached their duties to adequately warn the public about the risks of Rexulti.

92. The Respondents designed, developed, tested, manufactured, licensed, distributed, imported and/or exported, marketed, and/or sold Rexulti in Canada. As such, at all material times, the Respondents owed a duty to the Class Members to conduct rigorous scientific studies to assess the risks posed by Rexulti, to carefully monitor the safety and post-market performance of Rexulti and to warn the Class Members, their health care professionals and Canadian regulators of Rexulti's severe side effects, including its propensity to cause or materially contribute to Compulsive Behaviours and Impulse Control Disorders.

93. These duties were enhanced given the Respondents' knowledge of aripiprazole's propensity to cause or exacerbate Compulsive Behaviours, and the Respondents' deliberate scheme to develop, patent and market an evergreened successor drug almost identical to aripiprazole. These duties were also reinforced by the Respondents' knowledge of the Petitioner's and Class Members' vulnerability. As Rexulti is indicated for the treatment of schizophrenia, the Respondents were aware that the users of their drug are particularly vulnerable due to their mental illness and would likely be harmed by Compulsive Behaviours and Impulse Control Disorders.

94. It was reasonably foreseeable that a failure by the Respondents to study Rexulti and warn the public about its risks would cause, materially contribute to, or materially increase injury suffered by the Petitioner and the Class Members in Québec and Canada.

95. The Respondents' breaches of these duties are particularized throughout this motion.

b. Negligence under Common law

96. For those Class Members who are not residents of Québec, the Respondents owed them a duty of care to provide accurate, complete, and timely warnings about any health or safety risk associated with the use of Rexulti.

97. As particularized above, at all material times the Respondents knew, or ought to have known, that the use of Rexulti carries an increased risk of Compulsive Behaviours and Impulse Control Disorders. However, the Product Monograph's warning of this risk was incomplete, inadequate, and inconsistent with the state of science at all relevant times and failed to meet the applicable standard of care.

98. The Respondents further knew, or ought to have known, that the undisclosed risk of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti would not only harm the Petitioner and other users of Rexulti, but also their family members and dependents . In particular, they knew, or ought to have known, that as a result of the compulsive gambling and other harmful Compulsive Behaviours and Impulse Control Disorders caused by Rexulti, their family members and dependents would suffer pain, suffering, stress, and financial losses.

99. Further, despite their significant collective resources and the existence of a large body of scientific evidence highlighting the propensity of dopamine agonists, generally, and aripiprazole specifically, to cause or materially increase the risk of developing Compulsive Behaviours and Impulse Control Disorders, the Respondents failed to conduct any, or any adequate, pre- or post-market testing and research to confirm whether Rexulti had the same severe side effects as Abilify.

100. As particularized elsewhere in this pleading, the Respondents breached this duty of care by making misrepresentations and omissions about Rexulti's safety throughout the Class Period

c. Conspiracy

101. At all relevant times, the Respondents, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking *bona fides*, conspired and agreed together, the one with the other, to, among other things, conceal the risk of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti, and to mislead the Petitioner and the Class Members about the health and safety risks associated with the use of the drug.

102. In conspiring to conceal the risk of Compulsive Behaviours and Impulse Control Disorders from the Class Members, the Respondents were motivated predominantly by the following concerns and motivations:

a) to increase or maintain sales volumes of Rexulti;

b) to increase or maintain revenue;

c) to increase or maintain profit;

d) to increase or maintain market share;

e) to avoid negative publicity and preserve public goodwill;

f) to avoid the costs associated with conducting adequate, effective and targeted testing to study the link between the use of Rexulti and the risk of developing Compulsive Behaviours; and

g) to place corporate revenue and profit above the safety of the Class Members.

103. In furtherance of the conspiracy, the Respondents and their employees, servants, and agents, engaged in, *inter alia*, the following acts:

a) they set out not to conduct any or any adequate post-market testing to confirm the existence of a causal relationship between the use of Rexulti and the onset of Impulse Control Behaviours and Compulsive Behaviours;

b) they disregarded or downplayed the existing body of scientific evidence on the risk of Impulse Control Behaviours and Compulsive Behaviours associated with the use of Rexulti;

c) they concealed the result of any clinical trial and other research that they conducted in relation to Rexulti's propensity to cause or materially contribute to Impulse Control Behaviours and Compulsive Behaviours;

d) they knowingly or recklessly represented to the Petitioner and other Class Members that Rexulti was safe for use when they knew or ought to have known that the use of Rexulti is associated with an increased risk of developing Impulse Control Behaviours and Compulsive Behaviours;

e) they continued to distribute Rexulti in the Canadian market without issuing adequate warnings or revisions to the product monograph.

104. The conspiracy was unlawful because the Respondents knowingly or recklessly, directly and indirectly, and in pursuit of their mutual business interests, made representations to the Petitioner, the 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 Rexulti.

105. In the circumstances, the Respondents knew that the conspiracy would, and did, cause the Petitioner and the Class Members to suffer losses as described herein.

VII. THE SITUATION OF THE CLASS MEMBERS

a) Facts Giving Rise to an Individual Action by Each of the Members of the Class

106. The facts giving rise to an individual action on behalf of each Class Member against the Respondents, other than the facts set out above with the necessary adaptations, are as follows:

107. Every Class Member ingested Rexulti in Canada, or is a family member or dependent of a person who ingested Rexulti in Canada;

108. All Class Members will have suffered harm as a result of Rexulti, in particular one or more of pain and suffering, personality change, financial losses, humiliation, psychological and emotional harm, loss of reputation, disruption of personal and professional relationships, and medical and rehabilitation treatment costs for their pathologically compulsive behaviours;

109. None of the Class Members were adequately warned about the increased of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti, and had no actual or constructive knowledge of its risks;

110. None of the Class Members and Family Class Members would have suffered their injuries but for the acts and omissions of the Respondents;

111. All Class Members are entitled to claim from the Respondents damages for personal injuries, pain, suffering, loss of companionship or consortium and financial losses;

112. In addition, all Class Members are entitled to claim from the Respondents moral and punitive damages in an amount to be determined by the Court for their gross negligence and complete disregard for the life, health, safety and bodily integrity of the Petitioner and other Class Members, rights protected under art. 1 of the *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12.

b) The Composition of the Class makes the application of articles 59 and 67 C.C.P. difficult or impractical

113. Rexulti was approved for sale in Canada on or about February 16, 2017 and continues to be sold in Canada, including in Québec;

114. The Class is comprised of numerous persons geographically dispersed throughout Canada, including Québec;

115. Prescriptions for Rexulti are not funded by provincial health insurance schemes, including the RAMQ, so it is difficult to know how many persons throughout Canada and Québec have purchased or used Rexulti;

116. The names and addresses of the members of the Class are not known to the Petitioner;

117. Given the costs and risk inherent in an individual action, many Class Members would otherwise hesitate to assert their rights against the Respondents if not for a class action.

VIII. IDENTICAL, SIMILAR OR RELATED QUESTIONS OF FACT AND LAW

118. The identical, similar or related questions of fact and law between each Class Member, Family Class Member and the Respondents which the Petitioner wishes to have decided by the class action are as follows:

i. Does Rexulti cause and/or materially contribute to the development of Compulsive Behaviours and Impulse Control Disorders?

ii. Did the Respondents know or should they have known of the risks of Compulsive Behaviours associated with the use of Rexulti? If so, when?

iii. Were the Respondents at fault in failing to conduct adequate clinical trials and studies about the increased risk of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti prior to introducing Rexulti to the Canadian market?

iv. Did the Respondents fail in their duty to adequately warn the Petitioner and the Class Members of the risks of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti and/or did they knowingly and recklessly misrepresent such risk to physicians and Class Members?

v. Did the Respondents conspire to conceal the risks associated with the use of Rexulti from the Class Members, and if so, for how long and what harm to the Class Members was caused by this conspiracy?

vi. If any breach of duty to the Class Members is identified, are the Respondents solidarily liable to the Petitioner and the Class Members for that breach of duty?

vii. Are the Petitioner and the Class Members entitled to claim aggravated, moral, compensatory, special and/or punitive damages from the

Respondents, and if so, what amount of such damages are they entitled to recover?

IX. INDIVIDUAL QUESTIONS

119. The only individual questions of fact and law that remain after the resolution of the common issues are the nature of' harm suffered by, and the quantum of damages of, each member of the Class.

X. THE NATURE OF THE RECOURSE

120. The nature of the recourse which the Petitioner wishes to advance on behalf of the Class Members is a civil liability damages action.

XI. THE CONCLUSIONS

121. The conclusions sought by the Petitioner are:

GRANT the class action of the Petitioner and the Class Members against the Respondents;

DECLARE that the Respondents failed to warn the Petitioner and the Class Members and/or made misrepresentations about Rexulti's propensity to cause, materially contribute to, or exacerbate Compulsive Behaviours and Impulse Control Disorders;

CONDEMN the Respondents solidarily to pay to the Petitioner and the Class Members the total damages awarded by the court for their physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents solidarily to pay to the Petitioner and the Class Members punitive damages in an amount determined by the Court, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

ORDER the collective recovery of damages of the Class Members;

CONDEMN the Respondents solidarily to pay such other amounts and grant the Class Members such further relief as this Honourable Court may determine as being just and proper; and

THE WHOLE with costs, including the costs of all exhibits, experts and publication notices.

XII. REPRESENTATIVE STATUS

122. The Petitioner requests that he be ascribed the status of representative of the Class for the following reasons:

i. he is a Class Member;

ii. he is well informed of the facts alleged in this motion;

iii. he has all the required time, determination and energy to bring this matter to a conclusion and adequately represent the Class Members;

iv. he cooperates with his attorneys and responds diligently and articulately to requests they make and he fully comprehends the nature of the class proceedings; and

v. he is not aware of any conflict of interest with other Class Members;

123. The Petitioner communicates herewith a draft notice to members (art. 1006 C.C.P.) complying with Form IV of the Rules of Practice of the Superior Court;

124. The Petitioner and the Respondents Otsuka Canada and Lundbeck Canada Inc. are domiciled in the District of Montreal and the District of Montreal;

125. The present motion is well-founded in fact and in law;

WHEREFORE, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the institution of a class action as follows:

A civil liability action for damages;

GRANT the status of representative to [redacted] for bringing the said class action for the benefit of the Class described as follows:

"All persons who reside or have resided in Canada who were prescribed and ingested the drug REXULTI®, and their family members, dependents, heirs and estates" ("Class" or "Class Members")

ORDER THAT the principal questions of fact and law to be determined collectively are as follows:

i. Does Rexulti cause, materially contribute to the development of Compulsive Behaviours and Impulse Control Disorders?

ii. Did the Respondents know or should they have known of the risks of Compulsive Behaviours associated with the use of Rexulti? If so, when?

iii. Were the Respondents at fault in failing to conduct adequate clinical trials and studies about the increased risk of Compulsive Behaviours and

Impulse Control Disorders associated with the use of Rexulti prior to introducing Rexulti to the Canadian market?

iv. Did the Respondents fail in their duty to adequately warn the Petitioner and the Class Members of the risks of Compulsive Behaviours and Impulse Control Disorders associated with the use of Rexulti and/or did they knowingly and recklessly misrepresent such risk to physicians and Class Members?

v. Did the Respondents conspire to conceal the risks associated with the use of Rexulti from the Class Members, and if so, what harm to the Class Members was caused by this conspiracy?

vi. If any breach of duty to the Class Members is identified, are the Respondents solidarily liable to the Petitioner and the Class Members for that breach of duty?

vii. Are the Petitioner and the Class Members entitled to claim aggravated, moral, compensatory, special and/or punitive damages from the Respondents, and if so, what amount of such damages are they entitled to recover?

ORDER THAT the conclusions sought with respect to such questions be identified as follows:

GRANT the class action of the Petitioner and the Class Members against the Respondents;

DECLARE that the Respondents failed to warn the Petitioner and Class Members and/or made misrepresentations about Rexulti's propensity to cause, materially contribute to, or exacerbate Compulsive Behaviours and Impulse Control Disorders;

CONDEMN the Respondents solidarily to pay to the Petitioner the Class Members the total damages awarded by the court for their physical, psychological and moral damages incurred as well as for loss of income and past and future care costs, with interest at the legal rate and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

CONDEMN the Respondents solidarily to pay to the Petitioner and the Class Members punitive damages in an amount determined by the Court, with interest and additional indemnity pursuant to Article 1619 of the *Civil Code of Québec*, as of and from the date of service;

ORDER the collective recovery of damages of Class Members;

CONDEMN the Respondents solidarily to pay such other amounts and grant the Class Members such further relief as this Honourable Court may determine as being just and proper;

THE WHOLE with costs, including the costs of all notices and expert fees, and publication notices;

DECLARE THAT any Class Member who has not opted out of the Class be bound by any judgment to be rendered on the class action in accordance with the *Code of Civil Procedure*;

ORDER THAT the deadline for opting out be fixed at sixty (60) days from notice to Class Members and that at the expiry of the deadline, any Class Member who has not opted out be bound by any such judgment;

ORDER THAT a notice to the members of the Class be published, in the form substantially similar to the draft notice to members communicated herewith as **Exhibit P-17**, to be published once in the daily newspapers *La Presse*, *The Gazette* and any other newspaper as ordered by the Court;

ORDER THAT the Respondents and counsel for the Petitioner publish the notice to the members of the Class, in French and in English on a website to be determined;

ORDER THAT the Respondents be ordered to pay the translation and publication costs of the notice to the Class;

ORDER THAT the deadline for publishing the notice to the Class be thirty (30) days from the date of final judgment on the present motion;

ORDER THAT the record be referred to the Chief Justice so that he may fix the district wherein the class action is to be brought and the judge before whom it will be heard;

THE WHOLE with costs, including the expert fees and costs of all publication notices.

Montréal, October 9, 2018

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NOTICE OF PRESENTATION

To:

OTSUKA PHARMACEUTICAL COMPANY LIMITED, 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535, Japan

OTSUKA CANADA PHARMACEUTICAL INC.
2250 Alfred Nobel Blvd., Ste. 301
Saint Laurent, QC H4S 2C9
Canada

OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC.
2440 Research Blvd.,
Rockville, MD, 20850, United States of America

H. LUNDBECK A/S
Ottiliavej 9, 2500
Valby, Denmark

LUNDBECK CANADA INC.
400-2600 Boul. Alfred-Nobel
St. Laurent QB, H4S 0A9

LUNDBECK RESEARCH USA INC.
1600 Route 23 North, Suite 350
Wayne, NJ, 07410
United States of America

PLEASE BE ADVISED that the foregoing *Motion to institute a class action and to obtain the status of representative* will be presented as directed by the Honourable Chantal Châtelain, j.c.s., Coordinating judge of the Class Actions Division.

DO GOVERN YOURSELVES ACCORDINGLY.

Montréal, October 9, 2018

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SUMMONS
(Articles 145 and following C.c.p.)

Take notice that the plaintiff has filed this originating application in the office of the Superior court in the judicial district of Laval.

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1, Notre-Dame Street, Montreal, Quebec H2Y 1B6 within 15 days of service of the application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the plaintiff's lawyer or, if the plaintiff is not represented, to the plaintiff.

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the cases required by the Code, cooperate with the plaintiff in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Québec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

You may ask the court to refer the originating application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the plaintiff.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

In support of the originating application, the plaintiff intends to use the following exhibits:

P-1. Form IV: Patent List for Patent Number 2602247 (brexpiprazole), issued by Health Canada on 2013-04-02

P-2. Press release issued by Otsuka entitled "OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S Sign Historic Agreement to Deliver Innovative Medicines with Focus on Psychiatric Disorders Worldwide", dated November 11, 2011

P-3. Web page https://www.otsuka.co.jp/en/company/global-collaborators/ , "Global Collaborators" by Otsuka, dated October 1, 2018

P-4. Correll CU, Skuban A, Ouyang J, Hobart M, Pfister S, McQuade RD, et al. "Efficacy and safety of brexpiprazole for the treatment of acute schizophrenia: a 6-week randomized, double-blind, placebo-controlled trial." American Journal of Psychiatry. 2015; 172(9):870-880

P-5. Fleischhacker WW, Hobart M, Ouyang J, Forbes A, Pfister S, McQuade RD, et al. "Efficacy and Safety of Brexpiprazole (OPC-34712) as Maintenance Treatment in Adults with Schizophrenia: a Randomized, Double-Blind, Placebo-Controlled Study." International Journal of Neuropsychopharmacology. 2016; 20(1): 11–21

P-6. Maeda K, Sugino H, Akazawa H, Amada N, Shimada J, Futamura T et al, "Brexpiprazole I: in vitro and in vivo characterization of a novel serotonin-dopamine activity modulator." Journal of Pharmacology and Experimental Therapeutics. 2014; 350(3): 589–604

P-7. Maeda K, Lerdrup L, Sugino H, Akazawa H, Amada N, McQuade RD et al. "Brexpiprazole II: antipsychotic-like and procognitive effects of a novel serotonin-dopamine activity modulator." Journal of Pharmacology and Experimental Therapeutics. 2014; 350(3):605-614

P-8. Regulatory Decision Summary for REXULTI, issued by Health Canada, issued on 2017-02-16

P-9. Food and Drug Administration "Approval Letter" for Rexulti, July 2015.

P-10. Mailman, Richard B., and Vishakantha Murthy. "Third Generation Antipsychotic Drugs: Partial Agonism or Receptor Functional Selectivity?" Current pharmaceutical design. 2010; 16(5): 488–501.

P-11. Otsuka, Annual Report for FY 2014

P-12. Collier, Roger. "Drug Patents: The Evergreening Problem." CMAJ : Canadian Medical Association Journal. 2013; 185(9): E385–E386.

P-13. Summary Basis of Decision for Rexulti, by Health Canada, updated May 9, 2018

P-14. Das S, Barnwal P, Winston A B, Mondal S, Saha I. "Brexpiprazole: so far so good." Therapeutic Advances in Psychopharmacology. 2016; 6(1):39-54.

P-15. Citrome, L. "The ABC's of dopamine partial agonists – aripiprazole, brexpiprazole and cariprazine: the 15 minute challenge to sort these agents out." International Journal of Clinical Practice. 2015; 69(11): 1211–1220

P-16. Rexulti Product Monograph, dated February 16, 2017

P-17. Stahl S. "Mechanism of action of brexpiprazole: comparison with aripiprazole." CNS Spectrums. 2016; 21(1): 1-16

P-18. Frankel J, Schwartz T, "Brexpiprazole and cariprazine: distinguishing two new atypical antipsychotics from the original dopamine stabilizer aripiprazole", Therapeutic Advances in Psychopharmacology. 2017; 7(1): 29–41

P-19. Avanzi M, Baratti M, Cabrini S, Uber E, Brighetti G, Bonfa F. Prevalence of pathological gambling in patients with Parkinson's disease. Movement Disorders. 2006; 21(12): 2068-2072

P-20. Weintraub D, Siderowf AD, Potenza MN, Goveas J, Morales KH, Duda JE, et al. Association of dopamine agonist use with impulse control disorders in Parkinson disease. Archives of Neurology. 2006; 63(7): 969-973

P-21. Grosset KA, Macphee G, Pal G, Stewart D, Watt A, Davie J, et al. Problematic gambling on dopamine agonists: not such a rarity. Movement Disorders. 2006; 21(12): 2206-2208

P-22. Dodd ML, Klos KJ, Bower JH, Geda YE, Josephs KA, Ahlskog JE. Pathological gambling caused by drugs used to treat Parkinson disease. Archives of Neurology. 2005; 62(9): 1377-1381

P-23. Voon V, Hassan K, Zurowski M, de SM, Thomsen T, Fox S, et al. Prevalence of repetitive and reward-seeking behaviours in Parkinson disease. Neurology. 2006; 67(7): 1254-125

P-24. Driver-Dunckley E, Samanta J, Stacy M. Pathological gambling associated with dopamine agonist therapy in Parkinson's disease. Neurology. 2003; 61(3): 422-423

P-25. Seedat S, Kesler S, Niehaus DJ, Stein DJ (2000). Pathological gambling behaviour: emergence secondary to treatment of Parkinson's disease with dopaminergic agents. Depress Anxiety. 2000; 11(4): 185-186

P-26. Campbell-Meiklejohn D, Wakeley J, Herbert V, Cook J, Scollo P, Ray MK, et al. Serotonin and dopamine play complementary roles in gambling to recover losses. Neuropsychopharmacology. 2011; 36(2): 402-410

P-27. Mouaffak F, Gallarda T, Bayle FJ, Olie JP, Baup N. Worsening of obsessive-compulsive symptoms after treatment with aripiprazole. J Clin Psychopharmacol. 2007; 27(2): 237-238

P-28. Moore TJ, Glenmullen J, Mattison DR. Reports of pathological gambling, hypersexuality, and compulsive shopping associated with dopamine receptor agonist drugs. 2014; JAMA Intern Med 174(12): 1930-1933

P-29. Etminan M, Sodhi M, Samii A, Procyshyn RM, Guo M, Carleton BC. Risk of gambling disorder and impulse control disorder with aripiprazole, pramipexole, and ropinirole: a pharmacoepidemiologic study. J Clin Psychopharmacol. 2017; 37(1): 102-104

P-30. Seedat, Soraya, Simon Kesler, Dana J. H. Niehaus, and Dan J. Stein. "Pathological Gambling Behaviour: Emergence Secondary to Treatment of Parkinson's Disease with Dopaminergic Agents." Depression and Anxiety. 2000: 11 (4): 185-186

P-31. Copy of "Abilify: Procedural steps taken and scientific information after the authorisation" [sic], European Medicines Agency, updated October 26, 2017

P-32. Abilify: European Public Assessment Report – Product Information, European Medicines Agency, updated April 9, 2018

P-33. Abilify Product Monograph, June 22, 2015 revision

P-34. Abilify Maintena Product Monograph, September 15, 2015 revision

P-35. Summary Safety Review, Health Canada, November 2, 2015

P-36. Abilify Maintena Product Monograph, October 4, 2016 revision

P-37. Abilify Maintena Product Monograph, December 13, 2016 revision

P-38. Abilify Product Monograph, February 23, 2017 revision

P-39. Abilify U.S. Product Monograph, January 15, 2016 revision

P-40. Drug Safety Communication, U.S. Food and Drug Administration, May 3, 2016

P-41. Abilify U.S. Product Monograph, August 18, 2016 revision

P-42. Rexulti U.S. Product Monograph, February 2, 2018 revision

These exhibits are available upon request.

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

Montréal, October 9, 2018

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Montréal, October 9, 2018

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