C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

S U P E R I O R C O U R T

N° 500-06-

KATHLEEN GAUTHIER, a physical person domiciled and residing at 170, Sorbin Janson, in the City of Mont-Hilaire, judicial district of Ste-Hyacinthe, province of Québec J3H 4E5;

Petitioner

v.

JOHNSON & JOHNSON INC. (CANADA), a legal person established under the *Canadian Business Corporations Act*, and having its registered office at 85 rue Saint Paul O., in the city and judicial district of Montreal, province of Quebec, H2Y 3V4;

and

McNEIL CONSUMER HEALTHCARE GROUP, an operating division of Johnson & Johnson, a legal person established under the *Canadian Business Corporations Act*, and having its registered office at 85 rue Saint Paul O., in the city and judicial district of Montreal, province of Quebec, H2Y 3V4;

Defendants

MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION
(Arts. 571 ff. C.C.P.)

IN SUPPORT OF ITS MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION, THE PETITIONER ALLEGES AS FOLLOWS:

1. During the proposed class period, medications containing acetyl-para-aminophenol ("**APAP**"), more commonly known as acetaminophen or paracetamol were manufactured and sold by Johnson & Johnson Inc. Canada or McNeil Consumer Healthcare (the "**Defendants**") and marketed under the well-known brand name Tylenol (the "**Tylenol Products**").

2. During the class period, the sale of these medications was an important component of Defendants' total sales.

3. For purely mercantile reasons and to protect their important market share, the Defendants misled consumers by omitting to disclose and properly caution against serious risks and major side effects related to these products, up to and including risk of death or acute liver failure requiring a liver transplant.

4. These omissions are particularly unconscionable given that these serious dangers were known and had been voluntarily disclosed by Defendant Johnson & Johnson in the United States, by way of warning labels appearing clearly and expressly on the bottles and packaging of equivalent Tylenol products.

5. These deliberate omissions of material facts directly put at risk the lives, physical integrity and health of Canadians, including those of infants and children.

6. Moreover, these deliberate omissions of material facts exploited the informational vulnerability of consumers in the complex scientific domain of pharmaceuticals. This has the unfortunate societal effect of betraying consumer confidence in the medication market.

7. For all of the aforementioned omissions and non-disclosures, as well as those outlined in the below sections of this motion ("**Material Omissions**"), Defendants are in breach of numerous obligations under the *Civil Code of Quebec*, the *Consumer Protection Act* of Quebec and its counterparts in the rest of Canada, and the *Competition Act*, as fully detailed herein.

8. As a self-proclaimed "family company" that prides itself on putting the "needs and well-being of the people we serve first," this deliberate decision on the part of Johnson & Johnson is even more unconscionable.

The Parties

9. McNeil Consumer Healthcare (Canada) ("**McNeil (Canada)**") is a division of Johnson & Johnson Inc. that markets products under the "Tylenol" brand name for sale to the Canadian consumer. They currently sell 31 Tylenol products, with 19 marketed for adults (aged 12 and over) and 12 marketed for infants and children (collectively the "**Tylenol Products**"):

   Adults:

   1) TYLENOL Rapid Release Gels
   2) TYLENOL Extra Strength
   3) TYLENOL Liquid Gels
   4) TYLENOL Regular Strength
   5) TYLENOL Ultra Relief
   6) TYLENOL Muscle Aches & Body Pain
   7) TYLENOL Back Pain
   8) TYLENOL Arthritis Pain
   9) TYLENOL NUIT Extra Fort
   10) TYLENOL Body Pain Night

11) TYLENOL Complete Cold, Cough & Flu
12) TYLENOL Complete Cold, Cough & Flu Plus Mucus Relief Liquid Gels
13) TYLENOL Complete Cold, Cough & Flu Plus Mucus Relief Syrup
14) TYLENOL Complete Cold, Cough & Flu Plus Mucus Relief Nighttime Syrup
15) TYLENOL Cold
16) TYLENOL Cough
17) TYLENOL Flu
18) TYLENOL Cold & Sinus
19) TYLENOL Sinus

Infants and Children:

20) Infants' TYLENOL Drops
21) Infants' TYLENOL Fever & Sore Throat Pain
22) Children's TYLENOL Liquid
23) Children's TYLENOL Chewables
24) TYLENOL Fièvre et mal de gorge, pour enfants
25) Junior Strength Children's TYLENOL FASTMELTS
26) Children's TYLENOL Cold & Stuffy Nose
27) Children's TYLENOL Cold
28) Children's TYLENOL Cold & Cough Nighttime
29) Children's TYLENOL Cold & Cough
30) Children's TYLENOL Complete Cold Cough & Fever
31) Children's TYLENOL Complete Cold Cough & Fever Nighttime

the whole as appears from their products page on their website, Tylenol.ca/products, communicated herewith as **Exhibit P-1.**

10. Johnson & Johnson Inc. is an American multinational incorporated in the State of New Jersey, USA, whose array of medical devices and products are sold in over 150 countries around the globe.

11. Their Canadian operating arm, Johnson & Johnson Inc. (Canada) provides substantially similar goods and services to the Canadian market. (Both collectively referred to as "**J&J**").

12. In 2014, J&J generated global revenues of more than $70 billion USD and profits over $15 billion USD, according to marketwatch.com, a copy of which is communicated herewith as **Exhibit P-2.**

13. According to the company website, J&J considers itself to be a "family company" holding itself to the highest standards, of putting the "needs and well-being of the people we serve first", behaving as a socially responsible corporate citizen and priding itself to be guided by a "moral compass":

> *The values that guide our decision making are spelled out in Our Credo. Put simply, Our Credo challenges us to put the needs and well-being of the people we serve* first.

> *Robert Wood Johnson, former chairman from 1932 to 1963 and a member of the Company's founding family, crafted Our Credo himself in 1943, just before Johnson & Johnson became a publicly traded company. This was long before anyone ever heard the term "corporate social responsibility." Our Credo is more than just a moral compass. We believe it's a recipe for business success. The fact that Johnson & Johnson is one of only a handful of companies that have flourished through more than a century of change is proof of that.*

The whole, as described on their company website, an extract of which is communicated herewith as **Exhibit P-3.**

Introduction to APAP

14. APAP is both an analgesic and antipyretic, primarily used to fight headaches, pain and fever.

15. To that end, Tylenol Products are used to relieve pain and other symptoms from headaches, backaches, arthritis, coughing, colds, flus, and allergies.

16. These medications have been in regular use in the Canadian market since 1961 and benefit from a widely-held belief of being safe.

17. Despite their toxicity, these medications are readily available over the counter, even to children, without a prescription and without much regulatory control, and are sold everywhere from pharmacies to depanneurs, grocery stores, gas stations and big box stores such as Walmart and Costco.

18. According to Health Canada, more than 4 billion doses of APAP are sold annually in Canada, with 85% of these sales done over-the-counter without prescription.

19. Their unfettered availability, coupled with aggressive and wide-reaching marketing campaigns by J&J, have led consumers to believe that products containing APAP are completely safe. And this to the ultimate advantage of Defendants' bottom line.

The Tylenol Products

20. Of Defendants' products, "Tylenol Extra Strength" and "Tylenol Regular" are the medications most sold in Canada.

21. Tylenol Products contain varying quantities of APAP per dosage. The pills and capsules sold by Defendants range from 325 to 650 mg. They are available for purchase in large containers, sometimes hundreds of pills at a time.

22. The Tylenol Products marketed for use by infants and children are sold in a liquid state. Prior to use, these liquid doses must be precisely calculated in accordance with the child's weight or age, and carefully measured to ensure the exactitude of the dose.

23. As such, Tylenol Products destined for use by infants and children present even greater risks than those Tylenol Products destined for adults, as they require particular care and attention to avoid a toxic overdose.

The Risks associated with APAP

24. Due to its toxicity, APAP is recognized as being the single most dangerous product available over-the-counter in Canada.

25. An accidental overdose of APAP can cause serious liver damage and acute liver failure, that can cause death or necessitate a liver transplant and other serious medical intervention.

26. The risks of accidental overdose are heightened amongst infants and children due to the precise calculations and measurements that are required, as discussed above.

27. APAP is the first cause of acute liver failure in Canada and elsewhere in the world. Thousands of accidental overdoses are reported every year. Even more remain unreported. In Canada, these accidental overdoses require over 800 hospitalisations per year.

28. APAP was also the leading or contributing cause of over 250 deaths in Canada between 2000-2009.

Media Investigations into the High Risks of APAP

29. The risks of APAP have been heavily investigated and covered in the Canadian and American media.

30. A 2013 ProPublica report entitled "Use Only as Directed" highlighted the risks, amongst others that:

    i. From 2001-2010, annual acetaminophen-related deaths amounted to about twice the number attributed to *all* other over-the-counter pain relievers *combined*. More than 1,500 Americans died in the decade previous to the report's publishing from accidental overdose "of a drug renowned for its safety: acetaminophen, one of the nation's most popular pain relievers";

    ii. For almost every patient interviewed in the report, they said two things: One, the label wasn't clear, and two, they always thought it was a perfectly safe drug;

iii. In the 1990s, McNeil opposed even a modest government campaign to educate the public about acetaminophen's risks, in part because it would harm Tylenol sales.

iv. Lancet, one of the world's most renowned medical journals, stated in a 1975 editorial that if APAP "were discovered today it would not be approved" by British regulators. "It would certainly never be freely available without prescription." It called APAP's apparent safety "deceptive" because "not much more than the recommended maximum daily dosage" can result in liver damage

v. The FDA itself calls deaths and injuries from accidental acetaminophen overdose a "persistent, important public health problem."

vi. The FDA also says APAP carries a special risk because the drug's "narrow safety margin"

vii. The FDA added that such risk does not exist with other over-the-counter pain relievers, such as Aspirin and Advil: "The 4 gram per day recommended dose [for APAP] is also the maximum safe dose, one that must not be exceeded, an unusual situation for any drug, particularly an OTC drug, one placing a large fraction of users close to a toxic dose in the ordinary course of use"

viii. Severe risks exist even *below* the maximum recommended dosage: " A Canadian government study found six people had suffered serious liver damage after taking less than the maximum recommended dose"

As more fully detailed in a copy of the full report, communicated herewith as **Exhibit P-4.**

31. A 2015 Toronto Star piece entitled "The Dark Side of Acetaminophen" highlighted that:

i. A 2013 Health Canada "adverse drug events database" reported a dozen cases where people suffered liver damage after taking acetaminophen for several days - despite taking doses *below* the maximum daily limit;

ii. A 2009 study by Health Canada into the risks of acetaminophen led to the recommendation to change labels to warn of "severe or even fatal LIVER INJURY <u>even at doses less than the maximum recommended dose</u>. However, this language has never appeared on Canadian labels;

iii. More than a third of Canadians misused over-the-counter drugs, according to a 2004 survey commissioned by Health Canada, while seventy-five percent of consumers and even health professionals

considered non-prescription drugs to be "generally, if not completely, safe";

iv. The maximum daily dose is based on an average weight of 70kg for a human male. That does not apply to most people in the marketplace;

v. The suggested solution of every expert interviewed was "to make people aware."

vi. A 2009 Health Canada report indicated that infants and seniors are also at "relatively greatest risk" of being the victims of accidental APAP overdoses.

vii. According to the medical head of the liver transplant unit at London Health Sciences Centre in London, Ontario, if APAP "entered the market today, it probably would not be approved as an over-the-counter drug. Toxicity can result in death or transplant – it's not just fevers or a day off work"

As can be seen from a copy of the full report, communicated herewith as **Exhibit P-5.**

32. It is generally recognized that, at its core, accidental overdoses result from a lack of informational awareness provided to the consumer by the drug manufacturers, and the lack of clarity in the information that is provided concerning the dosage and the risks.

33. It is also generally recognized that to combat fever and pain, other products that are markedly less harmful than APAP are readily available on the market. Examples include acetylsalicylic acid (ASA), which is sold under the commercial brand "Aspirin," and ibuprofen, which is sold under the commercial brands "Advil" and "Motrin."

34. Like analgesics and antipyretics, ASA and ibuprofen are, with few exceptions, perfectly interchangeable - and much safer - substitutes for APAP. As such, producers of ASA and ibuprofen are direct market competitors of Defendants in the pain-reduction arena.

Health Canada's Position

35. The risks and dangers of products containing APAP have not solely been decried by the medical community and the media, but also by Health Canada.

36. In 2014, Health Canada commissioned a full report on the risks and dangers of acetaminophen use.

37. Following up on this report, Health Canada put out a July 9, 2015 communiqué entitled *"Santé Canada prend de Nouvelles mesures pour améliorer l'innocuité de l'acétaminophène et rappelle aux Canadiens d'utiliser le produit de manière sécuritaire"* :

> « Bien que la grande majorité des consommateurs en fasse un usage sécuritaire, l'acétaminophène, comme la plupart des produits de santé, comporte des risques, surtout si la dose est trop forte ou si la période de la prise est plus longue que celle prescrite. L'acétaminophène peut alors causer des lésions hépatiques et, dans les cas graves, une insuffisance hépatique aiguë, pouvant entraîner la mort. Cette substance est d'ailleurs la principale cause d'atteintes hépatiques graves au Canada et dans d'autres pays, comme les États-Unis, le Royaume-Uni et l'Australie. Plus de 250 cas d'atteinte hépatique grave sont recensés chaque année au Canada, et plus de la moitié d'entre eux sont le résultat d'une surdose accidentelle d'acétaminophène. »

The whole as appears from a copy of the communiqué communicated herewith as **Exhibit P-6.**

38. In September 2016, Health Canada introduced regulatory changes requiring manufacturers of products containing acetaminophen to add stricter warnings and re-assess the maximum daily dosages, following the lead of their American counterparts at the Federal Drug Administration (FDA). The whole, as detailed in a La Presse report from September 15, 2016:

> « Maintenant, l'emballage doit comporter des instructions plus claires », a expliqué Marc Berthiaume, directeur du bureau des produits pharmaceutiques à Santé Canada, au cours d'un exposé technique présenté par le ministère.
>
> « Des instructions (...) qui soulignent l'importance de prendre la dose la plus faible et de s'en tenir à la dose maximale recommandée par jour qui est de 4000 mg pour les adultes, d'utiliser ces produits au plus pour cinq jours en cas de douleur et de trois jours en cas de fièvre », a-t-il détaillé. Ces instructions devront également rappeler de limiter la consommation d'alcool à deux par jour lorsqu'on prend le médicament.
>
> Par ailleurs, la quantité d'acétaminophène contenue dans les produits combinés ne devra pas dépasser les 325 mg. En ce moment, aucun médicament sur ordonnance ne dépasse cette quantité, mais Santé Canada impose cette limite, tout comme l'a fait récemment la Food and Drug Administration (FDA) aux États-Unis.
>
> En plus d'être inspiré par les voisins américains, le ministère fédéral de la Santé dit surveiller l'innocuité de l'acétaminophène « depuis plusieurs années ».
>
> M. Berthiaume cite les mises à jour de l'étiquetage en 2009 et un rapport publié à l'été 2015 qui a conduit aux changements annoncés jeudi matin.

> « Il y a un certain nombre de cas de réactions toxiques du foie à l'acétaminophène qui nous ont conduits à réévaluer les mesures qui étaient en place », a expliqué M. Berthiaume.
>
> Il y a eu discussion avec l'industrie et le milieu médical avant d'annoncer ces changements, a-t-il assuré. Selon lui, les consommateurs et même les médecins sous-estiment les risques associés à l'acétaminophène, particulièrement lorsque le produit est pris en même temps que d'autres médicaments.
>
> « Il y avait un besoin d'améliorer les informations disponibles pour les patients et les professionnels de la santé », a-t-il affirmé.

The whole as appears from a copy of the article, communicated herewith as **Exhibit P-7.**

39. The manufacturers, however, have been given until 2021 to comply. All the while, the serious risks to the consumer - and the shocking and deliberate silence of Defendants - continues.

Disclosure of the risks

40. The relationship between Defendants and the consumers of its products is one of complete trust where the latter relies exclusively upon the instructions, disclosures, and warnings of the drug company.

41. In the United States, J&J implemented two measures to prevent accidental overdoses of its Tylenol Products: dosage reduction and warning information.

42. As far back as 1994, the following two warnings were added to the Tylenol products supplied to the American marketplace:

    a. A warning not to take more than two alcoholic drinks per day while taking a Tylenol product.

    b. A warning not to consume more than one product containing APAP at the same time.

43. In 2011, J&J also reduced the maximum daily dosage of its products in order to establish a substantial margin of safety of between 23% and 33.3% (depending on the Tylenol Product) between the maximum dose and the toxicity threshold. In so doing, J&J stated the following with regards to Extra Strength Tylenol :

> *To help encourage the safe use of acetaminophen, the makers of TYLENOL® have lowered the maximum daily dose for single-ingredient Extra Strength TYLENOL® (acetaminophen) products sold in the U.S. from 8 pills per day (4,000*

mg) to 6 pills per day (3,000 mg). The dosing interval has also changed from 2 pills every 4 - 6 hours to 2 pills every 6 hours.[1]

44. As far as the Petitioner is able to ascertain, these preventative measures were implemented by J&J in the USA *voluntarily*, without any obligation imposed upon them by law or regulation.

45. These preventative measures were not implemented in the Canadian market for Canadian consumers.

46. To be clear, the Tylenol Products currently sold in Quebec and the rest of Canada do have warnings: warnings appear on containers' label and on the box in which the container is enclosed, but the warning of the risk of toxicity and its serious health consequences are not expressly or directly associated with this warning, as is the case on their US equivalents.

47. On the box in which the Tylenol Product container in placed (in this example, Tylenol Extra Strength caplets - see **Exhibit P-8**), only the following cautions are provided:

MEDICINAL INGREDIENT	Benefit:
Acetaminophen, 500 mg per caplet	Pain Reliever/ Fever Reducer

TYLENOL® acetaminophen acts quickly to provide effective relief of headache, tension headache, mild to moderate migraine pain; pain of mild to moderate arthritis, minor muscle sprains and strains, menstrual cramps; aches and pains due to cold and flu, and is unlikely to cause stomach upset.

Read inside flaps for important information before use.

DOSAGE: Adult use only (12 years and older): Take 1 caplet every 4-6 hours. If pain or fever does not respond to 1 caplet, take 2 caplets at the next dose. Do not take more than 8 caplets per day.

CAUTION: Keep out of the reach of children. This package contains enough drug to seriously harm a child. **Do not use** with other drugs containing **acetaminophen.** Use the smallest effective dose. **Do not** take more than the maximum daily dose. Overdose may result in **severe or possibly fatal liver damage.** **Consult a doctor if:** you develop allergic wheezing or itching, your symptoms last for more than 5 days, or fever lasts more than 3 days. Very rarely, serious skin reactions with acetaminophen have been reported. Symptoms may include: skin reddening, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away. Ask a doctor or pharmacist before use if you are pregnant or breastfeeding; have chronic alcoholism; have a serious liver or kidney disease; use any other medications including natural health products, prescription drugs, salicylates or other pain and fever relief medications.

NON-MEDICINAL INGREDIENTS: Cellulose, corn starch, hypromellose, magnesium stearate, polyethylene glycol, sodium starch glycolate, water.

WARNING: Do not use if carton is open or if printed bottle neck band or inner foil seal is broken.

Store at room temperature, 15 - 30°C (59 - 86°F).

Prescribing information available to doctors and pharmacists upon request.

48. In addition, an allergy caution and instructions on what to do in case of overdose are literally hidden under the glued flaps at both ends of that box.

49. With respect to the label affixed on the Tylenol Product container itself found inside the box in question, while the "*Caution*" paragraph appearing on the box is repeated on

[1] https://www.tylenol.com/safety-dosing/usage/dosage-for-adults

the container's label, the "*Consult a doctor if*" paragraph is omitted as are the allergy caution and the overdose instructions.

50. Therefore, both on the box in which the Tylenol Product is contained and on the label affixed to the container itself,

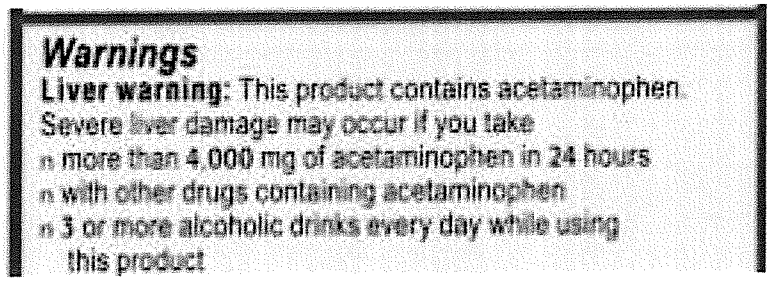
    a. No specific warnings are provided by Defendants stating expressly that severe or possibly fatal liver damage could result from:

        i. Taking other products containing acetaminophen at the same time;

        ii. Taking more than 2 alcoholic drinks per day while taking the Tylenol Product.

    b. Even though the maximum daily dose indicated (i.e. 8 caplets or 4000mg) allows for no margin of safety whatsoever between such dose and the point at which toxicity begins (i.e. 4000mg per day), no clear warning was provided by Defendants that the recommended daily dosage does not contain for a safety margin and that it coincides with the toxicity threshold.

51. In contrast, on the Tylenol Products sold in the USA, such warnings concerning the risks of severe liver damage are clearly indicated and readily visible, legible and comprehensible (See **Exhibit P-9** for a picture of the box) :



52. In summary, Defendants *voluntarily* implemented several *years ago*, for the benefit and safety of American consumers, the following precautionary measures to ensure a safer use of APAP specifically aimed at reducing the risk and number of accidental overdoses causing death, acute liver failure and other severe health problems, but deliberately chose *not* to implement the same measures for the benefit and safety of Canadian consumers:

    a. Reducing from 4000mg to 3000mg (or 3250mg depending on the Tylenol Product) in the USA the maximum daily recommended dosage of APAP in order to create a substantial safety margin between a safe use of the Tylenol Products and the risk of toxicity (which begins at 4000mg per period of 24 hours) in order to both diminish the risk of accidental overdose and allow for the safe use of acetaminophen.

For Canadian consumers, no such lowering of the recommended daily dosage to increase the margin of safety was implemented with the result that the maximum recommended daily dose of 4000mg also coincides with the starting point of toxicity. In addition, no specific warning was given to Canadian consumers that the recommended daily dosage does not provide for a safety margin and that it coincides with the toxicity threshold.

b. Expressly warning the American consumers that taking more than 2 alcoholic beverages per day while using a Tylenol Product can cause severe liver damage (which can result in death or require a liver transplant).

   No such warning is given to Canadian consumers on the label affixed to the Tylenol Product containers nor on the box in which the container is enclosed. The only indication given to Canadian consumers concerning alcohol consumption is to consult a doctor or a pharmacist before taking a Tylenol Product if they suffer from "*chronic alcoholism*".

c. Expressly warning the American consumers that taking a Tylenol Product with any other product containing acetaminophen can cause severe liver damage (which can result in death or require a liver transplant).

   No such clear warning is given to Canadian consumers on the label affixed to the Tylenol Product containers nor on the box in which the container is enclosed. Both Canadians and Americans are advised not to use a Tylenol Product with any other product containing acetaminophen, but *only* the American consumers are specifically warned, in a clear, *separate and additional* warning, of the potentially severe consequences of doing so, namely severe liver damage (which can result in death or require a liver transplant).

53. The level of detail, as well as the presentation of the warning and risk information, is markedly more clear, detailed, effective and forthcoming on the Tylenol Products sold in the USA than those sold in Canada.

54. It is therefore clear that Defendants have all the tools available to them to adequately divulge and inform the Canadian consumer. However, they have deliberately chosen to remain silent and to hide the serious risks and dangers of their products from the Canadian market.

55. This is particularly unconscionable, given the major health risks involved (including death and liver damage) and the intense reliance by consumers upon Defendants for information.

56. Even if the divulgation of information was initially mandated by some American law or FDA regulation (which was not the case), it is unthinkable that this information would not subsequently be voluntarily divulged to Defendants' Canadian consumers.

57. After all, these are matters of life and death.

The Causes of Action

58. Over and beyond the Defendants' basic informational obligations under federal health laws and regulations or administrative directives from Health Canada, the Defendants are bound by additional legal obligations under the Québec *Consumer Protection Act*, the *Competition Act* and the *Civil Code of Québec* to disclose the major risks mentioned above, especially given the fact that the Defendants were fully aware of them, chose to *voluntarily* divulge them to consumers in the USA but, at the same time, chose, for mercantile reasons, to deliberately withhold them from, and not disclose them to, consumers in Canada. In so doing, the Defendants purposely, knowingly, recklessly and negligently imperiled the lives, physical integrity and health of Canadians, including those of infants and children.

59. Petitioner does not lay claim to any personalized injury or death flowing from the use of the Tylenol Products.

60. Defendants knowingly and deliberately omitted to disclose material facts regarding the major health risks and dangers associated with the use of their Tylenol Products.

61. Accordingly, Petitioner seeks to enforce Defendants' duties to inform and positive obligations of good faith in contracting with the consumer in the marketplace.

A. *Illegal Practices under the Consumer Protection Act* ("**C.P.A.**") *as regards the Québec Subclass*

62. The Material Omissions of fact by Defendants, as previously described, constitute illegal practices under Title II of the C.P.A.

63. In particular, a violation of Art. 228 C.P.A., for remaining deliberately silent as to important facts in their consumer marketing:

> **228.** No merchant, manufacturer or advertiser may fail to mention an important fact in any representation made to a consumer.

64. This behaviour also constitutes a violation of Art. 219 C.P.A. for making false and misleading representations by omission by virtue of Art. 216 C.P.A.:

> **216.** For the purposes of this title, representation includes an affirmation, a behaviour or *an omission*.

> **219.** No merchant, manufacturer or advertiser may, by any means whatever, make false or misleading representations to a consumer.

65. Accordingly, the following claims may be levied against Defendants pursuant to Art. 272 C.P.A.:

    a. A reduction of obligations (equal to the entirety or a portion of the profits generated by Defendants by the sale of the Tylenol Products);

    b. Compensatory damages

    c. Punitive damages

66. Our courts have been clear that even in the absence of direct injury flowing from a breach of one of the imposed obligations under the C.P.A., the consumer benefits from a presumption of absolute prejudice in this regard.

67. The mere existence of a prohibited practice under the C.P.A. constitutes on its own "un dol" under Art. 1401 C.C.Q.

B. *Illegal Practices under the Consumer Protection Acts* in the other Canadian jurisdictions *as regards the ROC Subclass*

68. Petitioner reserves its right to amend the present proceedings to invoke the relevant provisions of the Consumer Protection Acts from the other Canadian provinces and territories in support of its action, if necessary;

C. *Illegal Practices under the Competition Act* (the "**Act**") *as regards both the Québec Subclass and the ROC Subclass*

69. The aforementioned Material Omissions also constitute false and misleading information provided to the public on material points that should have been disclosed. This, in contravention of Art. 52 of the Act:

> **52(1).** No person shall, for the purpose of promoting, directly or indirectly, the supply or use of a product for the purpose of promoting, directly or indirectly, any business interest, by an means whatever, knowingly or recklessly make a representation to the public that is false or misleading in a material respect.

70. Similarly to the burden imposed upon the Defendants to divulge important information under the CPA, there is similarly no requirement that proof of actual deception occurred. Proof of the contravening conduct is sufficient:

> **52 (4)** For greater certainty, in establishing that any of subsections (1) to (3) was contravened, it is not necessary to prove that any person was deceived or misled.

71. Accordingly, the following civil claims may be levied against Defendants pursuant to Art. 36 of the Act, in additional to any penal penalties that the appropriate authorities might seek, or this Honourable Court might levy:

a. Compensatory damages

b. Supplementary amounts to cover costs, as this Honourable Court may reasonably determine, in reimbursement of all investigations and proceedings instituted in relation to the contravention of the Act;

D. *Contraventions of the Civil Code of Quebec* (**"C.C.Q."**) *as regards the Québec Subclass*

72. The Material Omissions constitute a fault pursuant to Art. 1401 C.C.Q. by Defendants, vitiating the consent of the Class of consumers, who were prevented from giving an informed consent as a direct result of the Material Omissions committed by the Defendants.:

> **1401.** Error on the part of one party induced by fraud committed by the other party or with his knowledge vitiates consent whenever, but for that error, the party would not have contracted, or would have contracted on different terms.
>
> Fraud may result from silence or concealment.

73. In addition, the Material Omissions constitute an inexcusable violation of Defendants' positive obligations of good faith, including the obligation to adequately inform their co-contractants (the consumers of their products) in contravention of Articles 6, 7, and 1375 C.C.Q.:

> **6.** Every person is bound to exercise his civil rights in accordance with the requirements of good faith.
>
> **7.** No right may be exercised with the intent of injuring another or in an excessive and unreasonable manner, and therefore contrary to the requirements of good faith.

1375. The parties shall conduct themselves in good faith both at the time the obligation arises and at the time it is performed or extinguished.

74. Defendants violated their positive obligation to inform by deliberately omitting to communicate important facts that would duly inform the decisions of a consumer.

75. The consumers of the Class could not provide a clear and enlightened consent to the conclusion of the contract (their purchase), which was not validly formed.

76. As a result, the following claims may equally be levied against the Defendants under the following provisions of the C.C.Q.:

a. A reduction of their obligations under Art. 1407 C.C.Q., with the benefit of the presumption of "un dol" as stated in Art. 253 C.P.A.;

b. Compensatory damages for the outright violations of their obligations of good faith;

77. All, it goes without saying, in complete contradiction of Defendant J&J's "corporate credo."

Estimate of the Value of the Claim

78. It is, at this stage, given the vast market for Defendants' Tylenol Products, difficult to evaluate the exact value of the claim. However, as regards the Québec Subclass Petitioner estimates the value of the claim at $ 10 million, *sauf à parfaire*, based on the following facts:

a. The total sales in Canada for Tylenol Products containing APAP, in 2013, was approximately $148 million.

b. Based on this number, the total sales for Tylenol Products in Quebec during the last three years would be approximately $107 million.

c. Based on this number, the total sales for Tylenol Products in the Rest of Canada during the last three years would be approximately $337 million.

d. Presuming that Defendants generate around the same net profit margin on the Tylenol Products sold in Quebec as with their global operations, being 22%, Defendants would have earned a net profit of over $23 million during this period in Quebec.

79. In addition, the Petitioner seeks an award of punitive damages in the amount of $100 per consumer, in accordance with section 272 of the *Consumer Protection Act*. This is, among others, reflective of:

e. The gravity of the Defendants' fault, including the unconscionable nature of their decision to deliberately prioritize their bottom line by actively and recklessly concealing material information to the consuming public, and the major health dangers it poses to the Class (including death and liver damage) and broader society's faith in the pharmaceutical market, as well as;

f. The Defendants' patrimonial situation; and

g. The antisocial conduct on the part the Defendants, legal persons established for a private interest, who were obviously greedy to make profits.

80. Based upon the same facts, the total value of the claim as regards the ROC Subclass is estimated to be $30 million

<u>The criteria for the authorization of a class proceeding are met</u>

81. Petitioner respectfully submits that all of the criteria of section 575 C.C.P. are met here.

82. First, the questions of law for all of the members of the class - i.e. whether the Defendants breached their duties to inform and of good faith as to material matters of risk - are all identical.

83. Moreover, there are no significant individual questions to be dealt with in the present case. No individual corporal claims are at issue.

84. Second, it is respectfully submitted that the facts alleged justify the conclusions sought for the reasons given above.

85. Third, the composition of the class makes it impossible or impractical to use any procedural vehicle other than the class proceeding.

86. Indeed, Petitioner estimates that the class includes thousands of consumers, the identity of whom is unknown.

87. Finally, the Petitioner is in a proper position to adequately represent the class members, as she has reviewed the relevant information and conducted an investigation into the practices and behaviour of the Defendants, hired competent counsel, and diligently pursued the present claim.

Questions to be decided collectively

88. In light of the above, the Petitioner respectfully submits that this Honourable Court should authorize the proposed class actions and identify the following questions to be dealt with collectively:

a. Whether the Material Omissions indeed constitute information that is material to the members of the class' consumer knowledge;

b. Whether Defendants have a duty to inform the members of the Québec Subclass as to the Material Omissions under the provisions of the *Consumer Protection Act* and whether they breached said duty;

c. Whether Defendants have a duty to inform the members of the class as to the Material Omissions under the provisions of the *Competition Act* and whether they breached said duty;

d. Whether Defendants breached their duties of good faith until the *Civil Code of Quebec* vis-à-vis the members of the Québec Subclass in the consumer market;

e. If any of b. to d. are answered in the affirmative, whether Defendants are entitled to compensatory damages by reason of the violations; And if so, in what amount?;

f. Whether the class members are entitled to punitive damages by reason of the violation by the Defendants of the *Consumer Protection Act*,; And if so, in what amount?;

g. Whether collective recovery of compensatory and punitive damages is appropriate.

Collective recovery

89. Petitioner respectfully submits that the total amount of the claims can be determined with sufficient precision such that collective recovery should be ordered.

Individual claim of the Petitioner

90. Petitioner is a member of the proposed class having consumed Tylenol Products for decades without any knowledge of the above.

91. Not only did Petitioner consume Tylenol Products, but she also occasionally gave some to her two children (born in 1998 and 2000) when they were young, having no knowledge of the potentially dangerous effects of APAP on them.

92. It is only in 2017 that Petitioner learned of the above.

93. Had she been properly informed, Petitioner's use of Tylenol products would certainly have been different and less frequent. She would also have looked for alternatives.

94. Petitioner also certainly would never have given her children any Tylenol Products.

95. She is therefore entitled to compensatory damages from the Defendants in the form of the reimbursement of part of the cost she incurred in purchasing Tylenol Products. Such amount is estimated at $400.

96. She is also entitled to claim $100 in punitive damages as a result of the intentional breach by the Defendants of their obligations under the *Consumer Protection Act*.

Appropriate district in which to proceed

97. The Petitioner respectfully submits that the district of Montreal is the most appropriate district for the present case to be heard as both Defendants have their registered office therein and a substantial number of proposed class members also reside therein.

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

FOR THESE REASONS, MAY IT PLEASE THE COURT TO:

A. **AUTHORIZE** the petitioner to pursue the present proceeding on behalf of the proposed class in the judicial district of Montreal;

B. **CERTIFY** the Class comprising two subclasses as proposed below:

> All of the physical persons residing in Quebec who bought any of the Tylenol Products, listed below, manufactured and/or sold and/or marketed by Johnson & Johnson Inc. (Canada) and McNeil Consumer Healthcare (Canada) containing acetaminophen alone or in combination with other medications (the "Québec Subclass")
>
> All of the physical persons residing in the rest of Canada who bought any of the Tylenol Products, listed below, manufactured and/or sold and/or marketed by Johnson & Johnson Inc. (Canada) and McNeil Consumer Healthcare (Canada) containing acetaminophen alone or in combination with other medications (the "ROC Subclass")
>
> "Tylenol Products"
>
> Adults:

1) TYLENOL Rapid Release Gels
2) TYLENOL Extra Strength
3) TYLENOL Liquid Gels
4) TYLENOL Regular Strength
5) TYLENOL Ultra Relief
6) TYLENOL Muscle Aches & Body Pain
7) TYLENOL Back Pain
8) TYLENOL Arthritis Pain
9) TYLENOL NUIT Extra Fort
10) TYLENOL Body Pain Night
11) TYLENOL Complete Cold, Cough & Flu
12) TYLENOL Complete Cold, Cough & Flu Plus Mucus Relief Liquid Gels
13) TYLENOL Complete Cold, Cough & Flu Plus Mucus Relief Syrup
14) TYLENOL Complete Cold, Cough & Flu Plus Mucus Relief Nighttime Syrup
15) TYLENOL Cold
16) TYLENOL Cough
17) TYLENOL Flu
18) TYLENOL Cold & Sinus
19) TYLENOL Sinus

Infants and Children:

20) Infants' TYLENOL Drops
21) Infants' TYLENOL Fever & Sore Throat Pain
22) Children's TYLENOL Liquid
23) Children's TYLENOL Chewables
24) TYLENOL Fièvre et mal de gorge, pour enfants
25) Junior Strength Children's TYLENOL FASTMELTS
26) Children's TYLENOL Cold & Stuffy Nose
27) Children's TYLENOL Cold
28) Children's TYLENOL Cold & Cough Nighttime
29) Children's TYLENOL Cold & Cough
30) Children's TYLENOL Complete Cold Cough & Fever
31) Children's TYLENOL Complete Cold Cough & Fever Nighttime

C. **IDENTIFY** as follows the collective questions:

a. Whether the Material Omissions indeed constitute information that is material to the members of the class' consumer knowledge;

b. Whether Defendants have a duty to inform the members of the class as to the Material Omissions under the provisions of the *Consumer Protection Act* and whether they breached said duty;

c. Whether Defendants have a duty to inform the members of the class as to the Material Omissions under the provisions of the *Competition Act* and whether they breached said duty;

d. Whether Defendants breached their duties of good faith under the *Civil Code of Quebec* vis-à-vis the members of the class in the consumer market;

e. If any of b. to d. are answered in the affirmative, whether Defendants are entitled to compensatory damages by reason of the violations; And if so, in what amount?;

f. Whether the class members are entitled to punitive damages by reason of the violation by the Defendants of the *Consumer Protection Act, Competition Act,* and/or the *Civil Code of Quebec*; And if so, in what amount?;

g. Whether collective recovery of compensatory and punitive damages is appropriate.

D. **IDENTIFY** as follows the conclusions sought:

a. **GRANT** the class action of the Petitioner;

b. **CONDEMN** the Defendants solidarily to pay the amount of $40 million in compensatory damages to the class as defined above, *sauf à parfaire*, the whole bearing interest at the legal rate and the additional indemnity from the date of filing of the present proceedings;

c. **CONDEMN** the Defendants jointly to pay the amount of $100 per class member in punitive damages to the class as defined abovethe whole bearing interest at the legal rate and the additional indemnity from the date of filing of the present proceedings;

d. **ORDER** the collective recovery of these amounts;

e. **DECLARE** that Defendants are in breach of the provisions of the *Consumer Protection Act*, the *Competition Act*, and the *Civil Code of Quebec;*

f. **ORDER** that Defendants' conform to and respect the provisions of the *Consumer Protection Act*, the *Competition Act*, the *Civil Code of Quebec*;

g. **THE WHOLE** with costs, including expert and notice costs.

h. **DECLARE** that barring exclusion, the members of the class will be bound by any judgment to intervene in the class action in the manner provided by law;

i. **SET AT** 30 days the time period for a class member to ask to be excluded, at the expiry of which all of the members of the class who will not have sought exclusion will be bound by any judgment to intervene herein;

j. **ORDER** the publication of a notice to members of the class in a wording and by means appropriate for the present proceedings;

k. **REFER** the file to the Associate Chief Justice for determination of the district in which the present class proceeding will be heard and for the designation of the judge who will hear same;

l. **THE WHOLE** with costs.

MONTREAL, the 23rd day of October 2018

Renno Vathilakis inc.

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SUMMONS

(Articles 145 and following *C.C.P.*)

Filing of a judicial application

TAKE NOTICE that the Petitioner has filed this Motion for Authorization to institute a Class Action in the office of the Superior Court of Quebec, in the judicial district of Montreal.

Defendant's answer

You must answer the motion in writing, personally or through a lawyer, at the Montreal Courthouse situated at 1, Notre-Dame Street East, 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.

Failure to answer

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.

Content of answer

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.

Change of judicial district

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.

Transfer of application to Small Claims Division

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.

Calling to a case management conference

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.

Exhibits supporting the application

In support of the Application to institute proceedings, the plaintiff intends to use the following exhibits:

EXHIBIT P-1: Products page of the website, Tylenol.ca/products;

EXHIBIT P-2: Johnson & Johnson Annual Financials (marketwatch.com) ;

EXHIBIT P-3: Extract of the Defendant's company web site;

EXHIBIT P-4: Copy of a 2013 ProPublica report entitled "Use Only as Directed";

EXHIBIT P-5: Copy of a 2015 Toronto Star piece entitled "The Dark Side of Acetaminophen";

EXHIBIT P-6: Copy of the communiqué;

EXHIBIT P-7: Copy of La Presse report from September 15, 2016;

EXHIBIT P-8: Copy of a picture of the Tylenol Extra Strength caplets box.

EXHIBIT P-9: Copy of a picture of the Tylenol Products sold in the USA box.

These exhibits are available on request.

Notice of presentation of an application

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.

MONTREAL, the 23rd day of October 2018

Renno Vathilakis inc.

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Nº 500-06

SUPERIOR COURT
DISTRICT OF QUEBEC
PROVINCE OF MONTREAL

KATHLEEN GAUTHIER, a physical person domiciled and residing at 170, Sorbin Janson, in the City of Mont-Hilaire, judicial district of Ste-Hyacinthe, province of Québec J3H 4E5;

Petitioner

v.

JOHNSON & JOHNSON INC. (CANADA), a legal person established under the *Canadian Business Corporations Act*, and having its registered office at 85 rue Saint Paul O., in the city and judicial district of Montreal, province of Quebec, H2Y 3V4;

and

McNEIL CONSUMER HEALTHCARE GROUP, an operating division of Johnson & Johnson, a legal person established under the *Canadian Business Corporations Act*, and having its registered office at 85 rue Saint Paul O., in the city and judicial district of Montreal, province of Quebec, H2Y 3V4;

Defendants

MOTION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION

ORIGINAL

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