CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

No.:

500-06-001262-233

SUPERIOR COURT
(Class Actions)

ANDREW KRASKA, having their elected domicile at [redacted]

Applicant

v.

JOHNSON & JOHNSON INC., legal person having its head office at 88 McNabb Street, Markham, Ontario, L3R 5L2, Canada

and

PROCTER & GAMBLE INC., legal person having its head office at 4711 ST Younge, Toronto, Ontario, M5W 1C5, Canada

and

GLAXOSMITHKLINE CONSUMER HEALTH CARE SRL, legal person having its head office at 2600-595 Burrard Street, Vancouver, BC, V7X 1L3, Canada

and

RB HEALTH (CANADA) INC. legal person having its head office at 2300-550, Burrard Street, Box 30, Vancouver, BC, V6C 2B5, Canada

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND APPOINT APPLICANT AS CLASS REPRESENTATIVE
(Art. 571 C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL YOUR APPLICANT STATES AS FOLLOWS:

A. OVERVIEW

1. Consumers in Quebec have been misled about the performance and efficiency of orally administered over-the-counter cold and cough medicine containing the ingredient

phenylephrine ("**Cold Medicine**"), represented to act as a decongestant and alleviate nasal congestion, fever, sneezing, sinus pressure, runny nose and cough (collectively "**Cold/Cough Symptoms**").

2. Unbeknownst to the consumer, the Defendants' have falsely represented to Quebec consumers that these products will provide them relief of their Cold/Cough Symptoms, notably that when administered at recommended dosages, as this ingredient is t completely ineffective. These Cold Medicine products impacted by the false and misleading statements about their efficacy are listed in **Schedule A** to this claim.

3. As a result of false representations about the efficacy of the Cold Medicine, the Applicant has lost money and time spent purchasing and using these products for nasal congestion relief without receiving full or any value in return. Applicant seeks authorization of a class action against the Defendants on behalf of the following group:

> All persons in Quebec who purchased, between January 1, 2007 and date this case is authorized as a class action, any Cough Medicine listed in Schedule A to the Application for Authorization.

The "**Class**" and "**Class Members**" and the "**Class Period**"

B. DEFENDANTS AND THEIR ACTIVITIES

4. At all material times, the Defendant Johnson & Johnson ("**J&J**") under the division of McNeil Consumer Healthcare ("McNeil") manufactured and distributed in Quebec medication under the brand names of Tylenol and Benylin, as appears on the copies of the J&J Drug Product Pages retrieved from Health Canada website **Exhibit P-1**, and the corporate history information of J&J retrieved from CIDREQ as **Exhibit P-2**.

5. At all material times, the Defendant Procter & Gamble Inc. ("**P&G**") manufactured and distributed in Quebec medication under the brand name of Vicks, as appears on the copy of P&G Drug Product Pages retrieved from the Health Canada website **Exhibit P-3**, and the corporate history information of P&G retrieved from CIDREQ as **Exhibit P-4.**

6. At all material times, the Defendant Glaxosmithkline Consumer Health Care sri ("**Glaxo**"), manufactured and distributed in Quebec Cough Medicine under the brand name of NeoCitran, as appears on the copy of Glaxo Drug Product Pages retrieved from the Health Canada website **Exhibit P-5**, and the corporate history information of Glaxo retrieved from CIDREQ as **Exhibit P-6.**

7. At all material times, the Defendant RB Health (Canada) Inc. ("**RB**") manufactured and distributed Cough Medicine in Quebec under the brand name of Mucinex, as appears on the copy of RB Drug Product Pages retrieved from the Health Canada website **Exhibit P-7**, and the corporate history information of RB retrieved from CIDREQ as **Exhibit P-8.**

C. THE INEFFECTIVENESS OF THE COLD MEDICINE

8. Nasal congestion is a persistent and bothersome cold symptom which can either appear acutely or chronically in the daily lives of people of all ages. The ingredient phenylephrine,

which is found in many popular decongestant products, was first introduced into the market after being approved by the US Food and Drug Administration ("**FDA**") in 1976, see the copy of the 1976 Monograph, at PDF pages 110-111 or page 38399-38400 included in support of this claim as **Exhibit P-9.**

9. In 1982, the US Advisory Review Panel on OTC Oral Cavity Drug Products reviewed the safety and effectiveness data on two oral nasal decongestant ingredients, including phenylephrine hydrochloride and classified it as a nasal decongestant in Category III "available data are insufficient to classify as safe and effective, and further testing is required, as seen on the copy of the 1994 Monograph, at PDF pages 6 and 7 which is included as **Exhibit P-10**.

10. In February 2007, a Citizen's Petition was submitted to the US Food and Drug Administration requesting that there be an amendment to the dosage of oral phenylephrine listed in the Final Monograph on oral decongestants citing that phenylephrine is unlikely to relieve nasal stuffiness at the maximum FDA approved dose of 10 mg, see **Exhibit P-11** for a copy of the 2007 Citizen's Petition.

11. In March 2007, a systematic review and meta-analysis led by Randy C Hatton et al. ("2007 Hatton Study"), was released reporting that the oral phenylephrine of 10mg did not significantly affect nasal airway resistance compared to placebo in unpublished studies involving 138 patients, as appears on the copy of the 2007 Hatton Study included in support of this claim as **Exhibit P-12**.

12. While two studies published in June and August 2007 (respectively the "2007 Glaxo Study" and the "2007 Wyeth Study"), found the opposite conclusion that the studies support the effectiveness of a single oral dose of phenylephrine 10 mg as a decongestant in adults with acute nasal congestion associated with the common cold, it ought to be noted that these studies were conducted by the pharmaceutical companies themselves, see **Exhibits P-13** for a copy of the 2007 Glaxo Study and **Exhibit P-14** for a copy of the 2007 Wyeth Study.

13. In December 2007, the FDA convened a *Nonprescription Drugs Advisory Committee* ("NDAC") meeting to evaluate the safety and effectiveness of orally administered phenylephrine as nasal decongestants, as appears on the minutes of the hearing dated December 14, 2007, retrieved from the FDA website and filed in support of this application as **Exhibit P-15.**

14. Notably, as seen on page 5 of **Exhibit P-15**, the NDAC concluded that additional studies were needed to support the effectiveness of phenylephrine in a 10mg immediate release formulate when dosed every 4 hours for treatment of nasal congestion and the committee made the following notes:

> *It was noted by the committee that the standard to support "effectiveness" was not clearly defined. The committee noted that individual studies show some benefit of the 10 mg strength, but the results are not consistent across studies for NAR and are even murkier for symptom measures. The committee agreed that symptoms are the essential primary endpoint. While one half the studies were positive and one half negative, in none of the studies was the placebo superior to PEH, adding support to the effectiveness of PEH. The committee felt that efficacy may not be generalizable to a wide population based on small studies. The committee noted*

that the available evidence consists primarily of studies conducted 40 years ago and included fewer than 200 people across all the studies.

15. In July 2015, an article by Meltzer et al. ("2015 Meltzer Study") further confirming the inefficacy of phenylephrine for the treatment of nasal congestion was published online detailing findings that phenylephrine hydrochloride doses of up to 40mg every 4 hours are not significantly better than placebo in reducing subjective nasal congestion scores, as appears on a copy of the 2015 Meltzer Study proffered in support of this Application as **Exhibit P-16**.

16. In November 2015, another Citizen's Petition was submitted requesting that oral phenylephrine be removed from the Final Monograph for over-the-counter nasal decongestant products and provided the results of four reported studies after 2007 that found that phenylephrine was no more effective than placebo in decreasing nasal congestion and increasing the dose fourfold provided no additional benefit, as seen on pages 2-6 of the copy of the Hatton Hendeles 2015 Citizen's Petition included in support of this claim as **Exhibit P-17.**

17. In October 2020, the Joint Task Force Rhinitis Practice Parameter of the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology indicated that doses of phenylephrine up to 40 mg a day are ineffective, as seen on page 746 of the copy of the October 2020 Rhinitis Practice Parameter Update included in support of this claim as **Exhibit P-18.**

18. In 2022, a paper by Hatton and Hendeles published in the journal *Annals of Pharmacotherapy* questioned why oral phenylephrine remained on the market despite compelling evidence of its ineffectiveness as a decongestant, as seen on the copy of this article proffered in support of this Application as **Exhibit P-19**.

19. Also in 2022, the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology submitted a Statement of Support to the FDA in support of for the 2015 Citizen's Petition. requesting the removal of oral phenylephrine hydrochloride from over-the-counter nasal decongestant products), as appears in the copy of this Statement of Support as **Exhibit P-20**.

20. On September 12, 2023, the FDA released a Briefing Document on the efficacy of oral phenylephrine as a nasal decongestant prepared for the panel members of the Advisory Committee which states at page 33:

> *As a result of our evaluation, we believe that the new efficacy data far outweigh the data provided to the Agency as part of the original Panel review. These results suggest that: 1) oral PE at monographed dosages is not effective as a decongestant (i.e., in the face of the new data, the original data are likely not sufficient to support a GRASE determination), 2) oral doses up to 40 mg would also not be effective, 3) finding an effective oral dose that is also safe is not feasible (meaning that doses higher than 40 mg would need to be explored but would also not be safe to study due to effects on blood pressure), and 4) an appropriate dosing interval for oral PE has not been established (meaning that, based on the PK data, an every-4-hour dosing interval is likely too long). Therefore, in addition to lack of efficacy, there may be no path to evaluating higher doses of oral PE as a nasal decongestant.*

As seen on the copy of the September 11-12, 2023 Briefing Document filed in support of this claim as **Exhibit P-21**.

D. THE DEFENDANTS' FALSE REPRESENTATIONS AND LIABILITY

21. At all material times, each of the Defendants made representations to the proposed Class Members that their respective Cold Medicine products were effective for the treatment and relief of nasal congestion and set these representations out in the dosage indicated on the labelling of each of their Cold Medicine products.

22. However, the Cold Medicine is not effective for the relief of nasal congestion, as was concluded by the US FDA on September 12, 2023, see **Exhibit P-21**.

23. The Defendant J&J represent that their Cold Medicine product Benylin Extra Strength Cold & Sinus will "clear your head". J&Js advertising will lead a consumer to understand that their product is an effective decongestant:

> *Trust the effective and fast relief of BENYLIN EXTRA STRENGTH Cold & Sinus DAY/NIGHT Tablets. This portable and convenient solution will relieve your worst symptoms during the day and help you rest at night.*

As appears on **Exhibit P-22**, a copy of J&J product representation.

24. The representations go on to describe the product will relieve symptoms including nasal congestion and indicates in the dosage that the active ingredient of 5mg of phenylephrine is a decongestant, all as appears on **Exhibit P-22** J&J product representation.

25. The Defendant J&J represent that their Cold Medicine products Tylenol Extra Strength Cold Daytime and Tylenol Extra Strength Cold Nighttime each have 5mg of the active ingredient phenylephrine hydrochloride whose purpose is to act as a decongestant, as appears from the screenshot of the ingredients filed in support of this claim as **Exhibit P-23**.

26. The Defendants P&G hold out to consumers that performance is one of the three main factors that goes into choosing their product ingredients and note that "*every ingredient has a role in delivering the performance you expect from our products. We seek to use the best ingredients for our products for you can use them with confidence,*" as appears on **Exhibit P-24** representations about ingredients performance.

27. Further, P&G represent to consumers that their Cough Medicine product Vicks DayQuil Cold & Flu Multi-Symptom Relief Non-Drowsy Liquid has a medicinal ingredient of 10 mg of phenylephrine hydrochloride which acts as a nasal decongestant and relieves nasal congestion, among other effects, as appears on **Exhibit P-25**, Vicks Dayquil product representation.

28. The Defendants Glaxo represented that their NeoCitran Extra Strength Cold & Sinus Night, their most popular formula of NeoCitran, is destined for use to relieve cold and flu symptoms that include sinus and nasal congestion and indicate that phenylephrine of a 10mg dosage

acts as a nasal decongestant, see **Exhibit P-26,** Glaxo NeoCitran Extra Strength Night product representation.

29. The Defendant Glaxo made a similar representation about their other product NeoCitran Extra Strength Total Cold Night, by also indicating it is used for nasal and sinus congestion and that phenylephrine is an active ingredient for nasal decongestant, see **Exhibit P-27,** Glaxo NeoCitran Total Night product representation.

30. The Defendant RB represented to consumers that their Cold Medicine MUCINEX Multi-Action Cold & Sinus Caplets "helps relieve your cold and flu symptoms in 1 simple solution", "temporarily relieves symptoms of nasal and chest congestion due to common cold" and lists phenylephrine hydrochloride in a 5mg dosage as a nasal decongestant, as appears on **Exhibit P-28**, RB Health Mucinex product representation.

31. Throughout the Class Period, each of the Defendants consistently made inaccurate representations, including by omission, regarding the efficacy of orally administered phenylephrine as a nasal decongestant. The Defendants made their respective false or misleading representations knowingly or recklessly throughout the Class Period.

E. THE APPLICANT'S PERSONAL CLAIM AGAINST THE DEFENDANTS

32. The Applicant, Andrew Kraska, was subjected to the Defendant J&J's misleading and deceitful marketing practices. , During the winter months of years 2020-2022, tthe Applicant routinely purchased the Cold Medicines Tylenol Extra Strength Cold and Sinus Daytime and Tylenol Extra Strength Cold and Sinus Nighttime, listed at items No. 9 and No. 10 of Schedule A.

33. As a physical person who acquired this Cold Medicine product for their own personal use, the Applicant is a consumer under section 1e) of the *Consumer Protection Act.*

34. When purchasing and using the above listed Cold Medicines, the Applicant saw on the product label of the Cold Medicine product that the dosage of phenylephrine was 5mg, and that this active ingredient, as a decongestant, would alleviate his symptoms of nasal congestion.

35. The Tylenol Extra Strength Cold and Sinus Daytime and Tylenol Extra Strength Cold and Sinus Nighttime products are Cold Medicines manufactured by the Defendant J&J and each contain 5mg of phenylephrine hydrochloride per tablet, as seen on the screenshot of the ingredients listed on this product, **Exhibit P-23.**

36. The Applicant purchased this product under the pretense that he was obtaining a medicinal product containing an active ingredient that would provide decongestion.

37. Had the Applicant known that the Cold Medicine product was ineffective to treat the symptoms of nasal congestion, he would not have purchased these Cold Medicine products.

38. As a result, Defendant J&J has made a false and misleading representation in breach of section 52 of the *Competition Act* and/or in breach of articles 219, 221(g), 228 of the *Consumer Protection Act,* and their conduct is considered a prohibited business practice under article 215 of the *Consumer Protection Act.*

39. The Applicant hereby claims to be returned the amount of monies he paid for the purchase of this Cold Medicine product (including moral punitive damages), subject to adjustment by the Court.

F. FACTS GIVING RISE TO CLAIMS HELD BY CLASS MEMBERS

40. The facts that give rise to the personal claim of the Applicant are the same as each personal claim belonging to members of the Class as against the Defendants.

41. Each Class Member purchased a Cough Medicine product manufactured or distributed by the Defendants, as set out in **Schedule A**, about which the Defendants made false and misleading representations, knowingly and/or recklessly, regarding the efficacy of the active ingredient, phenylephrine, notably that doses of 5 to 10 mg every four hours would provide decongestion.

42. Each Class Member was exposed to these representations because they saw any or all of the following:

    a. The representations made on the labelling on the side of the physical bottles of the products;

    b. The representations that were displayed on the Canadian websites of each of these Defendants listing the dose and ingredients in each of these products

43. As such, each Class Member is also justified in claiming damages, including punitive damages, as these are a direct result of the Defendants' conduct.

44. Class Members, as credulous and inexperienced consumers with rights under the *Consumer Protection Act,* were each subjected to the Defendants' ignorance, carelessness, or serious negligence with respect to the obligations they owe to customers.

45. Each Class Member has a common interest in liability, the determination of which could be assessed collectively in a single trial as liability in this case focuses on the conduct of the Defendants without consideration for any circumstances of individual class members.

46. None of the Class Members could have reasonably understood until the FDA's Briefing Document of September 11-12, 2023 was widely disseminated in the media, as appears on this Canadian CBC News Article dated September 12, 2023, included in this claim as **Exhibit P-29**.

47. Under the principles set out in article 2904 CCQ regarding the impossibility to act, none of the Class Members had the necessary information to act for themselves until such news was widely and publicly disseminated. As a result, the prescription period is postponed until September 12, 2023 when this information was circulated as such on Canadian news outlets. The doctrines of postponement, discoverability, fraudulent concealment, and CCQ articles 2880 & 2904 all apply to postpone the running of any prescription period.

G. IDENTICAL, SIMILAR OR RELATED QUESTIONS OF FACT OR LAW

48. The conclusions sought by each class member are the same and raise identical, similar or related questions of fact and law, namely:

    a. Does the ingredient phenylephrine contain medical properties that treat symptoms of nasal decongestion effectively, or at all?

    b. During the Class Period, did the Defendants, or any of them, make representations to Class Members that the ingredient phenylephrine contains medical properties that effectively treat nasal congestion? If yes, for which Cold Medicines in Schedule A and during what time periods?

    c. Were any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period false or misleading representations within the meaning of the *Consumer Protection Act* or the *Competition Act*? If yes, for which Cold Medicines in Schedule A and during what time periods?

    d. If phenylephrine is not effective for treating symptoms of nasal decongestion, or minimally effective, is that a latent defect under the *Consumer Protection Act* or the *Civil Code of Quebec*?

    e. Do any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period constitute a civil fault under section 1457 CCQ? If so, did the civil fault cause injury to Class Members?

    f. What is the value of any damages, and can the damages, or any portion of them, be aggregated?

    g. Are the Defendants liable to pay punitive damages to the Class Members? If so, in what amount?

H. COMPOSITION OF CLASS MAKES RULES OF MANDATE IMPRACTICAL

49. The composition of the Class makes it difficult and/or impractical to apply the rules of mandates to take part in judicial proceedings on behalf of others for consolidation of proceedings pursuant to articles 59 or 67 C.C.P.

50. The historical and current sales data set out in the September 2023 Briefing Document of the FDA estimates there were between approximately 184 and 242 million bottles/packaging sold for over-the-counter cough/cold/allergy oral products containing phenylephrine from U.S. retail stores to consumers between 2018 and 2022, as appears from page 70, Figure 26 of **Exhibit P-21** filed in support of this claim.

51. The size of the class is unknown to the Applicant but estimated to be above one million. Based on the data in Exhibit P-21, assuming that the all-Canada population is 10% of the American population, and that the population of Quebec is 23% of the all-Canada population, leads to an estimate that there were between 4,232,000 - 5,566,000 bottles/packages sold of over-

the-counter cough/cold/allergy oral products containing phenylephrine in Quebec between 2018-2022.

52. The Applicant is ignorant of the identities of most of the Class Members sought to be included in this action.

53. In the circumstances, it would be impracticable and impossible for the Applicant to obtain a mandate from each Class Member or to join them all into a single action.

54. Moreover, the modest amount that each Class Member is likely entitled to claim against the Defendants makes it likely that the majority of these Class Members would hesitate to file their own individual action against the Defendants, never mind the fact that the costs associated with launching an individual claim to pursue one's right before the courts would be largely more significant than the amount each member can hope to obtain as a result of such individual actions.

55. In the circumstances, the class action procedure is the only appropriate procedure for the proposed class members to access justice and pursue their respective claims against the Defendants effectively and efficiently.

I. PROPOSED CLASS REPRESENTATIVE

56. The Applicant seeks to be appointed the status of representative Applicant for the following reasons.

57. As a class member himself, the Applicant has a personal interest in seeking the conclusions sought.

58. The Applicant has the time, energy, will and determination to assume and perform the duties incumbent upon him that are required to carry out the proposed class action.

59. The Applicant acts in good faith with the only goal in accessing justice and the relief sought for themselves and for the other class members.

60. The Applicant does not have any circumstances that would put them in conflict with the other members of the class.

J. NATURE OF THE CLASS ACTION AND CONCLUSIONS SOUGHT

61. The nature of the action the Applicant intends to bring on behalf of the class members is an action in compensatory and punitive damages.

62. The facts alleged the exhibits preferred in support justify the conclusions sought, which the Applicant wishes to introduce by way of an originating application, that read as follows:

a. **GRANT** the Representative Plaintiff's action against the Defendants on behalf of all the Class Members.

b. **CONDEMN** the Defendant to pay, solidarily, the Representative Plaintiff and the Class Members damages, including punitive damages in an amount to be determined by the Court.

c. **DECLARE** that an award of aggregate damages should be made.

d. **ORDER** the collective recovery of all damages to Class Members.

e. **CONDEMN** the Defendants, solidarily, to pay interest and additional indemnity on the above sums as provided for by law in accordance with article 1619 CCQ from the date of service of the *Application for Authorization to Institute a Class Action.*

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

g. **THE WHOLE WITH** costs, including all expert fees, notice fees, and expenses of the administrator, if any.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present application;

AUTHORIZE the bringing of a class action in the form of an originating application in damages;

APPOINT the Applicant, Mr. Andrew Kraska, the status of Representative Applicant of the persons included in the Class herein described as follows:

> All persons in Quebec who purchased, between January 1, 2007 and date this case is authorized as a class action, any Cough Medicine listed in Schedule A to the Application for Authorization.

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

a. Does the ingredient phenylephrine contain medical properties that treat symptoms of nasal decongestion effectively, or at all?

b. During the Class Period, did the Defendants, or any of them, make representations to Class Members that the ingredient phenylephrine contains medical properties that effectively treat nasal congestion? If yes, for which Cold Medicines in Schedule A and during what time periods?

c. Were any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period false or misleading representations within the meaning of the *Consumer Protection Act* or the *Competition Act?* If yes, for which Cold Medicines in Schedule A and during what time periods?

d. If phenylephrine is not effective for treating symptoms of nasal decongestion, or minimally effective, is that a latent defect under the *Consumer Protection Act* or the *Civil Code of Quebec*?

e. Do any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period constitute a civil fault under section 1457 CCQ? If so, did the civil fault cause injury to Class Members?

f. What is the value of any damages, and can the damages, or any portion of them, be aggregated?

g. Are the Defendants liable to pay punitive damages to the Class Members? If so, in what amount?

IDENTIFY as follows the conclusions sought by the class action in relation thereof:

a. **GRANT** the Representative Plaintiff's action against the Defendants on behalf of all the Class Members.

b. **CONDEMN** the Defendant to pay, solidarily, the Representative Plaintiff and the Class Members damages, including punitive damages in an amount to be determined by the Court.

c. **DECLARE** that an award of aggregate damages should be made.

d. **ORDER** the collective recovery of all damages to Class Members.

e. **CONDEMN** the Defendants, solidarily, to pay interest and additional indemnity on the above sums as provided for by law in accordance with article 1619 CCQ from the date of service of the *Application for Authorization to Institute a Class Action.*

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

g. **THE WHOLE WITH** costs, including all expert fees, notice fees, and expenses of the administrator, if any.

DECLARE that any member who has not requested his exclusion from the class be bound by any judgment to be rendered on the class action, in accordance with law;

FIX the delay for exclusion from the Class at 60 days from the date of notice to the Class and after the expiry of such delay the members of the class who have not requested exclusion be bound by any such judgment;

ORDER the publication of a notice to the members of the Class according to the terms to be determined by the Court;

REFER the record to the Chief Justice so that he may fix the district in which the class action is to be brought and the judge before whom it will be heard and In the event that the class action is

to be brought in another district, that the clerk of this Court be ordered, upon receiving the decision of the Chief Justice, to transmit the present record to the clerk of the district designated.

THE WHOLE with legal costs, including the cost of all notices.

Montréal, September 14, 2023

Slater Vecchio

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SCHEDULE A – List of Cold Medicine Products Containing Phenylephrine

No.	Defendant	Product	DPN	Dosage
1	JOHNSON & JOHNSON INC.	BENYLIN EXTRA STRENGTH COLD & SINUS DAY	02273462	5mg
2	JOHNSON & JOHNSON INC.	BENYLIN EXTRA STRENGTH COLD & SINUS NIGHT	02306409	5mg
3	PROCTER & GAMBLE INC.	DAYQUIL COLD & FLU	02300842	10mg
4	PROCTER & GAMBLE INC.	DAYQUIL COMPLETE	02503638	10mg
5	PROCTER & GAMBLE INC.	DAYQUIL COMPLETE + VICKS VAPOCOOL	02481936	5mg
6	PROCTER & GAMBLE INC.	DAYQUIL COMPLETE + VICKS VAPOCOOL COLD & FLU LIQUID	02482428	10mg
7	PROCTER & GAMBLE INC.	DAYQUIL COUGH DM + CONGESTION	02503247	10mg
8	PROCTER & GAMBLE INC.	DAYQUIL SINUS LIQUICAPS	02273829	5mg
9	JOHNSON & JOHNSON INC.	EXTRA STRENGTH TYLENOL COLD DAYTIME	02276186	5mg
10	JOHNSON & JOHNSON INC.	EXTRA STRENGTH TYLENOL COLD NIGHTTIME	02276259	5mg
11	JOHNSON & JOHNSON INC.	EXTRA STRENGTH TYLENOL FLU DAYTIME	02275996	5mg
12	JOHNSON & JOHNSON INC.	EXTRA STRENGTH TYLENOL SINUS DAYTIME	02276003	5mg
13	JOHNSON & JOHNSON INC.	EXTRA STRENGTH TYLENOL SINUS NIGHTTIME	02276038	5mg
14	RB HEALTH (CANADA) INC.	MUCINEX MULTI-ACTION CONGESTION, COLD & COUGH	02433435	5mg
15	RB HEALTH (CANADA) INC.	MUCINEX MULTI-ACTION CONGESTION, COLD & FLU	02433451	5mg
16	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN COLD & SORE THROAT NIGHT	02246602	10mg
17	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN EXTRA STRENGTH COLD & CONGESTION	00843792	10mg

18	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN EXTRA STRENGTH COLD & SINUS NIGHT - APPLE CINNAMON	02456982	10mg
19	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN EXTRA STRENGTH COLD & SINUS NIGHT	02215403	10mg
20	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN EXTRA STRENGTH TOTAL COLD	02293994	10mg
21	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN EXTRA STRENGTH TOTAL COLD NIGHT	02409178	10mg
22	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	NEOCITRAN TOTAL COLD NIGHT	02413280	10mg
23	PROCTER & GAMBLE INC.	NYQUIL COMPLETE	02503549	10mg
24	PROCTER & GAMBLE INC.	NYQUIL COMPLETE + VICKS VAPOCOOL	02481928	5mg
25	PROCTER & GAMBLE INC.	NYQUIL COMPLETE + VICKS VAPOCOOL COLD & FLU LIQUID	02482401	10mg
26	PROCTER & GAMBLE INC.	NYQUIL COUGH DM + CONGESTION	02503611	5mg
27	PROCTER & GAMBLE INC.	NYQUIL KIDS	02520419	5mg
28	PROCTER & GAMBLE INC.	NYQUIL SINUS LIQUICAPS	02273810	5mg
29	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	ROBITUSSIN CHILDREN'S COLD	02394693	5mg
30	GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC	ROBITUSSIN CHILDREN'S COUGH & COLD BEDTIME	02394707	5mg
31	PROCTER & GAMBLE INC.	VICKS DAYQUIL COLD & FLU MULTI-SYMPTOM RELIEF LIQUICAPS	02272784	5mg
32	PROCTER & GAMBLE INC.	VICKS DAYQUIL COMPLETE COLD & FLU LIQUICAPS	02483378	5mg
33	PROCTER & GAMBLE INC.	VICKS DAYQUIL COMPLETE COLD & FLU LIQUID	02409534	10mg
34	PROCTER & GAMBLE INC.	VICKS DAYQUIL HOT REMEDY	02531518	10mg

35	PROCTER & GAMBLE INC.	VICKS NYQUIL COMPLETE COLD & FLU	02409542	10mg
36	PROCTER & GAMBLE INC.	VICKS NYQUIL COMPLETE COLD & FLU LIQUICAPS	02483351	5mg
37	PROCTER & GAMBLE INC.	VICKS NYQUIL HOT REMEDY	02531488	10mg

SUMMONS

(Articles 145 and following CCP)

Filing of a judicial application

Take notice that the Applicant has filed this Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff in the office of the Superior Court in the judicial district of Montreal.

Exhibits supporting the application

In support of the *Application for authorization to Institute a Class Action,* the Applicant relies on the following exhibits:

Exhibit P-1:	Copy of the J&J Drug Product Pages retrieved from Health Canada website
Exhibit P-2:	Copy of the corporate history information of J&J retrieved from CIDREQ
Exhibit P-3:	Copy of the P&G Drug Product Pages retrieved from the Health Canada website
Exhibit P-4:	Copy of the corporate history information of P&G retrieved from CIDREQ
Exhibit P-5:	Copy of the Glaxo Drug Product Pages retrieved from the Health Canada website
Exhibit P-6:	Copy of the corporate history information of Glaxo retrieved from CIDREQ
Exhibit P-7:	Copy of the RB Drug Product Pages retrieved from the Health Canada website
Exhibit P-8	Copy of the corporate history information of RB retrieved from CIDREQ
Exhibit P-9	Copy of the FDA 1976 Monograph
Exhibit P-10	Copy of the FDA 1994 Monograph
Exhibit P-11	Copy of the 2007 Citizen's Petition to the FDA
Exhibit P-12	Copy of the 2007 Hatton Study
Exhibit P-13	Copy of the 2007 Glaxo Study
Exhibit P-14	Copy of the 2007 Wyeth Study
Exhibit P-15	Copy of the NDAC meeting minutes of the hearing dated December 14, 2007, retrieved from the FDA website
Exhibit P-16	Copy of the 2015 Meltzer Study

Exhibit P-17	Copy of the Hatton Hendeles 2015 Citizen's Petition
Exhibit P-18	Copy of the October 2020 Rhinitis Practice Parameter Update
Exhibit P-19	Copy of the 2022 article by Hatton and Hendeles published in the journal *Annals of Pharmacotherapy*
Exhibit P-20	Copy of the 2022 American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology Statement of Support
Exhibit P-21	Copy of the September 11 and 12, 2023 FDA Briefing Document
Exhibit P-22	J&J Screenshot of Product Representation
Exhibit P-23	J&J Screenshot of Extra Strength Tylenol Product Representation
Exhibit P-24	P&G Representations about Ingredients Performance
Exhibit P-25	P&G Vicks DayQuil Product Representation
Exhibit P-26	Glaxo NeoCitran Extra Strength Night Product Representations
Exhibit P-27	Glaxo NeoCitran Total Night Product Representation
Exhibit P-28	RB Health Mucinex Product Representation
Exhibit P-29	Copy of CBC News Article dated September 12, 2023

The exhibits in support of the application are available upon request.

Defendants' answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1 Rue Notre-Dame Est, Montreal, Québec, H2Y 186, 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 Applicant's lawyer or, if the Applicant is not represented, to the Applicant.

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 case required by the Code, cooperate with the Applicant 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 files, 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.

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.

Montréal, September 14, 2023

Slater Vecchio

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NOTICE OF PRESENTATION

TO:

JOHNSON & JOHNSON INC., legal person having its head office at 88 McNabb Street, Markham, Ontario, L3R 5L2, Canada

PROCTER & GAMBLE INC., legal person having its head office at 4711 ST Younge, Toronto, Ontario, M5W 1C5, Canada

GLAXOSMITHKLINE CONSUMER HEALTH CARE SRI, legal person having its head office at 2600-595 Burrard Street, Vancouver, BC, V7X 1L3, Canada

RB HEALTH (CANADA) INC. legal person having its head office at 2300-550, Burrard Street, Box 30, Vancouver, BC, V6C 2B5, Canada

TAKE NOTICE that Applicant's *Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff* will be presented before the Superior Court at 1 Rue Notre-Dame E, Montréal, Quebec, H2Y 1B6, on the date set by the coordinator of the Class Action chamber.

GOVERN YOURSELF ACCORDINGLY.

Montréal, September 14, 2023

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