CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-001023-197

(Class Action)
SUPERIOR COURT

M. ROYER

Petitioner

-vs.-

SANOFI CONSUMER HEALTH INC., legal person duly constituted, having its head office at 2905 Place Louis-R.-Renaud, City of Laval, Province of Quebec, H7V 0A3

and

GLAXOSMITHKLINE INC., legal person duly constituted, having its head office at 245 Boulevard Armand-Frappier, City of Laval, Province of Quebec, H7V 4A7

and

SANDOZ CANADA INCORPORATED, legal person duly constituted, having its head office at 110 rue De Lauzon, City of Boucherville, Province of Quebec, J4B 1E6

and

PHARMASCIENCE INC., legal person duly constituted, having its head office at 6111, avenue Royalmount, Suite 100, City of Montreal, Province of Québec, H4P 2T4

and

APOTEX INC., legal person duly constituted, having its principal establishment at 2970 avenue André, City of Dorval, Province of Quebec, H9P 2P2

and

PRO DOC LTÉE, legal person duly constituted, having its head office at 2925 boul. Industriel, City of Laval, Province of Québec, H7L 3W9

and

SANIS HEALTH INC., legal person duly constituted, having its principal establishment at 1250 rue Guy, 11th Floor, City of Montreal, Province of Quebec, H3H 2T4

and

SIVEM PHARMACEUTICALS ULC, legal person duly constituted, having its elected domicile at 4705 rue Dobrin, City of Montreal, Province of Quebec, H4R 2P7

Respondents

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

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

I. GENERAL PRESENTATION

A) The Action

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

    - All persons residing in Canada who purchased and/or ingested the drug, RANITIDINE (sold under the brand name ZANTAC® as well as under various generic names) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternatively (or as a subclass)

- All persons residing in Quebec who purchased and/or ingested the drug, RANITIDINE (sold under the brand name ZANTAC® as well as under various generic names) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

2. "ZANTAC" is the brand name version of the generic drug ranitidine, which is used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease;

3. Unless the context indicates otherwise, the word "ZANTAC" as used herein will be understood to mean both the brand name drug Zantac as well as the generic drugs containing ranitidine;

4. The Respondents developed, designed, manufactured, tested, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold ZANTAC as safe and/or effective despite a wealth of existing knowledge that consumption of the drugs exposed users to unsafe levels of the carcinogen *N*-Nitrosodimethylamine (NDMA);

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

6. In short, the Respondents' liability rests on (i) inadequate warning that the consumption of ranitidine exposed humans to unsafe levels of NDMA, (ii) failure to notify of the full scope of risks known to be associated with and caused by ZANTAC, and (iii) safety misrepresentations;

7. Respondents continue to market, label, package, promote, advertise, import, distribute, and/or sell ZANTAC throughout Canada, including within the province of Quebec, with inadequate warnings as to the associated exposure to unsafe levels of the carcinogen, NDMA;

B) <u>The Respondents</u>

8. Respondent Sanofi Consumer Health Inc. ("Sanofi") is a Canadian pharmaceutical corporation, with its head office in Laval, Quebec. Sanofi is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of

ZANTAC as an over-the-counter medicine. Its ZANTAC products are sold in the formats of 75 MG and 150 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* **Exhibit R-1**;

9. Respondent Sanofi is the current owner of the following trade-marks:

   (a) "ZANTAC 75" (TMA535314), which was filed on August 3, 1998,

   (b) "ZANTAC 150" (TMA778793), which was filed on August 8, 2006,

   (c) "ZANTAC PILL AND SWIRL DESIGN" (TMA725162), which was filed on October 2, 2008,

   The whole as appears more fully from copies of said trade-marks from the CIPO database, produced herein *en liasse* as **Exhibit R-2**;

10. Respondent GlaxoSmithKline Inc. ("GlaxoSmithKline"), is a Canadian pharmaceutical corporation, with its head office in Mississauga, Ontario. Glaxo has previously been involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of ZANTAC as a prescription medicine. Its ZANTAC products were sold in the formats of 15 MG, 25 MG, 150 MG, 300 MG, and 400 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* **Exhibit R-3**;

11. ZANTAC has been marketed in Canada since as early as December 31, 1982 by either GlaxoSmithKline or Sanof;

12. Respondent Sandoz Canada Incorporated ("Sandoz") is a Canadian pharmaceutical corporation, with its head office in Boucherville, Quebec. Sandoz is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of RANITIDINE as both an over-the-counter and a prescription medicine. It has been marketing RANITIDINE in Canada since as early as May 15, 2001. Its RANITIDINE products are sold in the formats of 50 MG, 150 MG, and 300 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the Registraire des enterprises **Exhibit R-4**;

13. Respondent Pharmascience Inc. ("Pharmascience") is a Canadian pharmaceutical corporation, with its head office in Montreal, Quebec. Pharmascience is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of RANITIDINE as both an over-the-counter and a

prescription medicine. It has been marketing RANITIDINE in Canada since as early as April 25, 2000. Its RANITIDINE products are sold in the formats of 75 MG, 150 MG, and 300 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* **Exhibit R-5**;

14. Respondent Apotax Inc. ("Apotex") is a Canadian pharmaceutical corporation, with its head office in Toronto, Ontario. Apotex is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of RANITIDINE as both an over-the-counter and a prescription medicine. It has been marketing RANITIDINE in Canada since as early as December 31, 1987. Its RANITIDINE products are sold in the formats of 75 MG, 150 MG, and 300 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises*, produced herein as **Exhibit R-6**;

15. Respondent Pro Doc Ltée. ("Pro Doc") is a Canadian pharmaceutical corporation, with its head office in Laval, Quebec. Pro Doc is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of RANITIDINE as a prescription medicine. It has been marketing RANITIDINE in Canada since as early as December 31, 1988. Its RANITIDINE products are sold in the formats of 150 MG and 300 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* **Exhibit R-7**;

16. Respondent Sanis Health Inc. ("Sanis") is a Canadian pharmaceutical corporation, with its head office in Fredericton, New Brunswick. Sanis is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of RANITIDINE as a prescription medicine. It has been marketing RANITIDINE in Canada since as early as July 26, 2010. Its RANITIDINE products are sold in the formats of 150 MG and 300 MG. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* **Exhibit R-8**;

17. Respondent Sivem Pharmaceuticals ULC ("Sivem") is a Canadian pharmaceutical corporation, with its head office in Vancouver, British Columbia. Sivem is involved in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of RANITIDINE as a prescription medicine. It has been marketing RANITIDINE in Canada since as early as June 11, 2012. Its RANITIDINE products are sold in the formats of 150 MG and 300 MG. It does business throughout Canada, including within the province of Quebec, the whole as

appears more fully from a copy of an extract from the *Registraire des enterprises* **Exhibit R-9**;

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

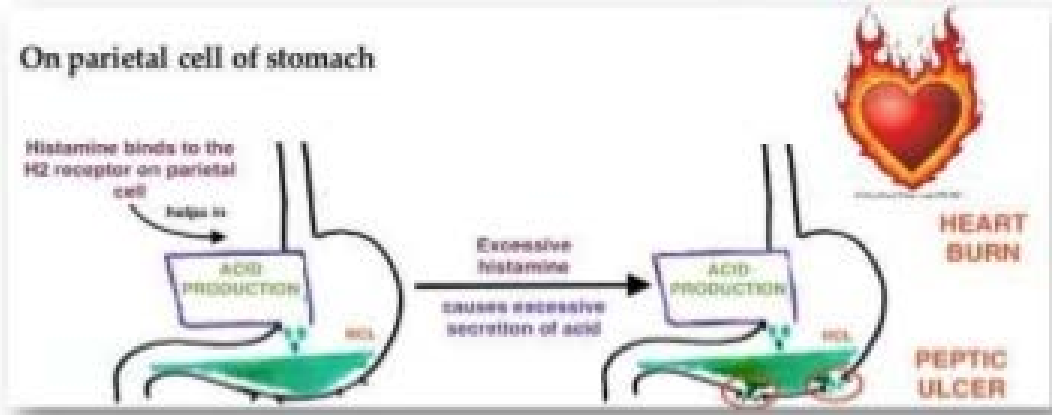
19. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other;

C) The Situation

I. What is Ranitidine?

20. Ranitidine belongs to a group of medicines called Histamine 2 (H_2) Blockers, also known as Histamine 2 Receptor Antagonists (H_2RAs). This group of drugs helps relieve heartburn symptoms by reducing the amount of acid your stomach produces in response to histamine, the whole as appears more fully from a copy of an extract from Respondent Sanofi's website at www.zantac.ca, produced herein as **Exhibit R-10**;

21. In more technical terms, H_2 blockers are a class of medications that block the action of histamine at the histamine H_2 receptors of the parietal cells in the stomach – this decreases the production of stomach hydrochloric acid, which relieves heartburn, ulcers (duodenal and gastric), and certain conditions, such as Zollinger-Ellison disease, in which the stomach produces too much acid. In over-the-counter (OTC) strengths, these medicines are used to relieve and/or prevent heartburn, acid indigestion, and sour stomach. H2-blockers may also be used for other conditions as determined by a physician, the whole as appears more fully from a copy of an extract from the Mayo Clinic website at www.mayoclinic.org and from a copy of an extract from the Drugs.com website at www.drugs.com, produced herein *en liasse* as **Exhibit R-11**;



22. There are several H_2 blockers on the market. In Canada, there are four brand names on the market; (i) ranitidine (ZANTAC), (ii) cimetidine, (iii) famotidine (Pepcid), and (iv) nizatidine; there are also generic forms available, the whole as appears more fully from a copy of an extract from the International Foundation for Gastrointestinal Disorders' website at www.aboutgerd.org, produced herein as **Exhibit R-12**;

23. According to Respondent Sanofi (Exhibit R-10), Ranitidine's mechanism of action is as follows:

    - Your stomach produces excess acid – This acid is produced in response to histamine released in the stomach. Histamine interacts with the cells in your stomach, known as the parietal cells, stimulating the production of acid.

    - Your esophagus is irritated – You feel heartburn when acid from your stomach escapes your stomach and irritates your esophagus.

    - The H2 Blockers take effect – H2 Blockers such as ZANTAC® interrupt the process by which histamine interacts with the cells in your stomach that produce acid.

    - There is less acidity – Reducing the production of acid, in turn, decreases the amount of acid that can be regurgitated during reflux, bringing acid production control for up to 12 hours.

24. ZANTAC is available in 3 forms, (i) ZANTAC 75 Regular Strength, (ii) ZANTAC 150 Maximum Strength, and (iii) ZANTAC 150 Cool Mint Maximum Strength. The key difference between the three is the amount of ranitidine they contain, ZANTAC 75 contains 75mg of ranitidine and ZANTAC 150 contains 150mg of ranitidine, the whole as appears more fully from copies of extracts from Respondent Sanofi's website at www.zantac.ca, produced herein *en liasse* as **Exhibit R-13**;

25. Ranitidine was discovered in 1976 and approved for sale in Canada in 1981. In 1982, Respondent GlaxoSmithKline began selling ZANTAC in Canada, the whole as appears more fully from a copy of the "Factum of the Respondent on Appeal/ Appellant on Cross-Appeal (Redacted)" in *Her Majesty the Queen* v. *GlaxoSmithKline Inc.*, Court File No. 33874 and from a copy of the SCC decision in *Canada* v. *GlaxoSmithKline Inc.*, [2012] 3 SCR 3, 2012 SCC 52, produced herein *en liasse* as **Exhibit R-14**;

26. Since then, ZANTAC has become the best-selling drug in history as a result of a shrewd, multifaceted marketing strategy that has enabled the product to dominate the acid marketplace, the whole as appears more fully from a copy of the Journal of Healthcare Marketing article entitled "How Zantac Became the Best-Selling Drug in History" dated winter 1996, produced herein as **Exhibit R-15**;

27. ZANTAC is one of the most popular tablet brands of acid inhibitors in the world and in Canada. However, ZANTAC's popularity and enormous sales were only made possible because of a deception perpetrated by the drug's manufacturers on consumers who have purchased Zantac since it hit the market in 1983;

II. <u>*N*-Nitrosodimethylamine (NDMA)</u>

28. The Respondents never disclosed to consumers that the drug has a critical defect: When ingested, Zantac produces in the human body high quantities of NDMA, a chemical that the World Health Organization has described as "clearly carcinogenic", the whole as appears more fully from a copy of the World Health Organization's Concise International Assessment Document for *N*-Nitrosodimethylamine, produced herein as **Exhibit R-16**;

29. The primary sources of human exposure to NDMA are tobacco smoke, chewing tobacco, diet (cured meats [particularly bacon], beer, fish, cheese, and other food items), toiletry and cosmetic products (for example, shampoos and cleansers), interior air of cars, and various other household goods, such as detergents and pesticides. In addition, NDMA can form in the stomach during digestion of alkylamine containing foods. Alkylamines are naturally occurring compounds which are found in some drugs and in a variety of foods, the whole as appears more fully from a copy of the Agency for Toxic Substances and Disease Registry's public health statement regarding NDMA dated December 1989, produced herein as **Exhibit R-17**;

30. The dangers of NDMA have been publicly known for over 40 years. NDMA itself belongs to a family of chemicals called N-nitrosamines, which Health Canada classifies as a "probable human carcinogen", the whole as appears more fully from a copy of The New York Times' article entitled "Personal Health" dated October 3, 1979 and from a copy of the Health Canada Press Release entitled

"Health Canada assessing NDMA in ranitidine" dated September 13, 2019, produced herein *en liasse* as **Exhibit R-18**;

31. In December 1989, the Agency for Toxic Substances and Disease Registry published the following (Exhibit R-17):

> "NDMA is very harmful to the liver of animals and humans. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding. Animals that ate food, drank water, or breathed air containing high levels of NDMA over a period of days or several weeks also developed serious, noncancerous, liver disease. When rats, mice, hamsters, and other animals ate food, drank water, or breathed air containing lower levels of NDMA for periods more than several weeks, liver cancer and lung cancer as well as non-cancerous liver damage occurred. The high level short-term and low level long-term exposures that caused noncancerous liver damage and/or cancer in animals also usually resulted in internal bleeding and death.
>
> Although there are no reports of NDMA causing cancer in humans, it is reasonable to expect that exposure to NDMA by eating, drinking, or breathing could cause cancer in humans.";

32. Recent scientific testing conducted by Valisure LLC and ValisureRX LLC (collectively "Valisure") "has detected extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products," including Zantac, the whole as appears more fully from a copy of the Valisure Citizen Petition to the U.S. Food and Drug Administration dated September 9, 2019 and from a copy of The Wall Street Journal article entitled "FDA Finds Probable Carcinogen in Some Versions of Zantac" dated September 13, 2019, produced herein *en liasse* as **Exhibit R-19**;

33. The tests conducted by Valisure show that "ranitidine can react with itself in standard analysis conditions…at high efficiency to produce NDMA at dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen" (Exhibit R-19);

34. Valisure's testing – which employs the U.S. FDA's own gas chromatography/ mass spectrometry ("GC/MS") protocol – detected 2,511,469 ng of NDMA per 150 mg tablet of Zantac, which is 26,000 times greater than the amount that can be safely ingested daily (Exhibit R-19);

35. The U.S. National Institutes of Health provided the following: "The typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for 4 to 8 weeks, and maintenance doses of 150 mg once daily." Moreover, chronic use of the drug is common "for

therapy of heartburn and indigestion", the whole as appears more fully from a copy of the U.S. National Institutes of Health website at livertox.nih.gov, produced herein as **Exhibit R-20**;

36. Thus, a typical consumer who is taking Zantac over the course of eight weeks to treat peptic ulcer disease is exposed to more than 280,000,000 ng (or 0.28 grams) of NDMA. A consumer who takes a 150 mg maintenance dose of Zantac once daily is exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year. Again, the U.S. FDA's permissible intake limit of NDMA is 96 ng per day, which translates to just 0.000034 grams per year;

37. Zantac is used not only by adults, but is also given to children and teenagers to treat gastroesophageal reflux, among other things;

38. In addition, when ZANTAC was tested "in conditions simulating the human stomach," the quantity of NDMA detected was as high as 304,500 ng per tablet – 3,171 times more than the amount that can be safely ingested daily (Exhibit R-19);

39. Recent peer-reviewed scientific literature has demonstrated the existence of dangerous levels of NDMA in the urine of those who have taken ranitidine, the whole as appears more fully from a copy of the Oxford article entitled "Oral intake of ranitidine increases urinary excretion of *N*-nitrosodimethylamine" dated March 18, 2016, produced herein as **Exhibit R-21**;

40. The Respondents knew or should have known that ranitidine exposes users to unsafe levels of the carcinogen NDMA. During the time periods that the Respondents manufactured and distributed the drug (outlined above), numerous scientific studies were published showing, among other things, that ranitidine forms NDMA when placed in drinking water and that a person who consumes ranitidine has a 400-fold increase of NDMA (Exhibit R-21), such as:

    (a) Massimiliano Sgroi, et al., N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review of formation and removal, 191 CHEMOSPHERE 685 (Oct. 15, 2017), produced herein as **Exhibit R-22**;

    (b) Yong Dong Liu, et al., Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination: A Computational Study, 48 ENVTL. SCI. & TECHNOLOGY 8653 (June 26, 2014), produced herein as **Exhibit R-23**;

    (c) Julien Le Roux, et al., Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation, 45 WATER RESEARCH 3164 (Mar. 26, 2011), produced herein as **Exhibit R-24**;

(d) Ruqiao Shen & Susan A. Andrews, Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection, 45 WATER RESEARCH 944 (Oct. 13, 2010), produced herein as **Exhibit R-25**;

(e) Giovanni Brambilla & Antonietta Martelli, Update on genotoxicity and carcinogenicity testing of 472 marketed pharmaceuticals, 681 MUTATION RESEARCH 209 (Sept. 19, 2008), produced herein as **Exhibit R-26**;

(f) Giovanni Brambilla & Antonietta Martelli, Genotoxic and carcinogenic risk to humans of drug–nitrite interaction products, 635 MUTATION RESEARCH 17 (Dec. 6, 2006), produced herein as **Exhibit R-27**;

41. On September 13, 2019, Health Canada issued a press release (Exhibit R-18) to inform Canadians of the presence of NDMA in some ranitidine drugs;

42. On September 17 and again on September 25, 2019, Health Canada released press releases requesting that companies stop distributing ranitidine drugs in Canada while it assesses NDMA, the whole as appears more fully from a copy of the Health Canada press release entitled "Health Canada requests that companies stop distributing ranitidine drugs in Canada while it assesses NDMA; additional products being recalled" dated September 25, 2019, to which the September 17, 2019 press release is appended, produced herein as **Exhibit R-28**;

43. Despite the weight of scientific evidence showing that ranitidine exposed users to unsafe levels of the carcinogen NDMA, none of the Respondents disclosed this risk to consumers, healthcare professionals and the public. Had Defendants disclosed that consumption of ZANTAC and its generic versions containing ranitidine results in unsafe levels of NDMA in the human body, no person, let alone a reasonable person, would have purchased and consumed ZANTAC or the generic equivalent containing ranitidine;

44. Copies of the various product monographs are produced herein *en liasse* as **Exhibit R-29**;

III. The Respondents' Liability

45. The Respondents have either not adequately studied ZANTAC or have failed to make public the results of any studies or investigations that they might have conducted;

46. Despite evidence that ingestion of ZANTAC produces in the human body high quantities of NDMA, the Respondents have either failed to investigate or conduct any studies on the safety of ZANTAC and/or failed to make public the results of any studies or investigations that they might have conducted;

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

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

49. The Respondents were negligent in the development, design, manufacture, testing, marketing, labelling, packaging, promotion, advertising, distribution, and/or sale of ZANTAC in one or more of the following respects:

    a. They knew or should have known that consumption of ZANTAC containing ranitidine results in unsafe levels of NDMA in the human body;

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

    c. They failed to conduct appropriate testing to determine whether and to what extent the ingestion and/or use of ZANTAC poses serious risks, including the production of unsafe levels of NDMA;

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

    e. They failed to adequately test ZANTAC in a manner that would fully disclose the production in the human body high quantities of NDMA;

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

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

    h. They failed to advise that the ingestion and/or use of ZANTAC produces in the human body high quantities of NDMA;

    i. They failed to advise the medical and scientific communities of the exposure users to unsafe levels of the carcinogen NDMA;

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

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

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

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

n. They failed to warn Class Members and their physicians that the risks associated ZANTAC would exceed the risks of other available acid reducing drugs;

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

p. They failed to accurately and promptly disclose to Health Canada information relating to the exposure to NDMA associated with ZANTAC and to modify ZANTAC' product monographs and product labelling accordingly in a timely manner;

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

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

50. The Respondents concealed and failed to disclose their knowledge that consumption ZANTAC exposed users to unsafe levels of the carcinogen NDMA as well as their knowledge that they had failed to fully test or study the drug;

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

51. Over the course of decades, the Petitioner has purchased and ingested ZANTAC as well as ranitidine on a daily basis;

52. At no time was the Petitioner made aware that when ingested, ZANTAC (ranitidine) produces in the human body high quantities of NDMA;

53. Had the Respondents properly disclosed this fact, Petitioner would not have purchased and ingested ZANTAC;

54. Petitioner is aware that several lawsuits were filed in the United States due to the defects associated with ZANTAC and due to the Respondents' conduct related thereto, as appears more fully from a copy of the U.S. Complaints, produced herein *en liasse* as **Exhibit R-30**;

55. As a result of the Respondents' conduct, the Petitioner suffered damages including, but not limited to physical and mental/emotional injuries, including pain, suffering, anxiety (the very problem he was trying to resolve), fear, loss of quality and enjoyment of life, damage to or loss of reputation, extensive financial losses (including the loss of sentimental family jewelry pieces), loss of income, expenses relating to his treatment in the rehab centres, and the apportioned cost of ZANTAC;

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

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

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

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

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

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

    a. Physical and psychological injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, increased risk of stomach and bladder cancer;

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

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

d. Punitive damages;

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

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

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

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

62. All of these damages to the Class Members are a direct and proximate result of the use of ZANTAC and the Respondents' conduct, negligence and reckless failure to adequately disclose necessary information and the risks associated with the drug;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

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

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

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

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

66. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having

contradictory judgments on questions of fact and law that are similar or related to all members of the Class;

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

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

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

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

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

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

    a) Does the ingestion of ZANTAC expose users to unsafe levels of NDMA?

    b) Did the Respondents fail to adequately test ZANTAC both before and/or after placing it on the market?

    c) Did the Respondents adequately and sufficiently advise/ warn the Class Members, Health Canada, and/or their physicians about the production of NDMA in the human body from the ingestion of ZANTAC?

    d) Did the Respondents know or should they have known about the risks associated with the use of ZANTAC?

    e) In the affirmative to any of the above questions, did the Respondents' conduct engage their solidary liability toward the members of the Class?

    f) Are the Defendants liable to pay compensatory damages to the Class Members?

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

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

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

73. The action that the Petitioner wishes to institute on behalf of the members of the Class is an action in damages, injunctive relief, and declaratory judgment;

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

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

DECLARE that the Defendants failed to provide adequate warnings that ranitidine exposed users to unsafe levels of the carcinogen NDMA;

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

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

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

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

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

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

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

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

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

A) The Petitioner requests that he be attributed the status of representative of the Class

75. Petitioner is a member of the Class;

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

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

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

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

80. Petitioner has given instructions to his attorneys to put information about this class action on its website and to collect the coordinates of those Class Members that wish to be kept informed and participate in any resolution of the present matter, the whole as will be shown at the hearing;

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

82. Petitioner understands the nature of the action;

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

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

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

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

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

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

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

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present application;

AUTHORIZE the bringing of a class action in the form of an application to institute proceedings in damages, injunctive relief, and declaratory relief;

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

- All persons residing in Canada who purchased and/or ingested the drug, RANITIDINE (sold under the brand name ZANTAC® as well as under various generic names) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternatively (or as a subclass)

- All persons residing in Quebec who purchased and/or ingested the drug, RANITIDINE (sold under the brand name ZANTAC® as well as under various generic names) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

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

a) Does the ingestion of ZANTAC cause, exacerbate or contribute to an Does the ingestion of ZANTAC expose users to unsafe levels of NDMA?

b) Did the Respondents fail to adequately test ZANTAC both before and/or after placing it on the market?

c) Did the Respondents adequately and sufficiently advise/ warn the Class Members, Health Canada, and/or their physicians about the production of NDMA in the human body from the ingestion of ZANTAC?

d) Did the Respondents know or should they have known about the risks associated with the use of ZANTAC?

e) In the affirmative to any of the above questions, did the Respondents' conduct engage their solidary liability toward the members of the Class?

f) Are the Defendants liable to pay compensatory damages to the Class Members?

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

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

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

DECLARE that the Defendants failed to provide adequate warnings that ranitidine exposed users to unsafe levels of the carcinogen NDMA;

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

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

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

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

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

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

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

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

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

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

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Class Members, date upon which the members of the Class that have not exercised their means of exclusion will be bound by any judgment to be rendered herein;

ORDER the publication of a notice to the members of the group in accordance with article 579 C.C.P. within sixty (60) days from the judgment to be rendered herein in The Globe and Mail, the National Post, La Presse, and the Montreal Gazette;

ORDER that said notice be available on the Respondents' websites, Facebook page(s), and twitter accounts with a link stating "Notice to RANITIDINE (ZANTAC) prescribers and users";

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

THE WHOLE with costs, including all publication fees.

Montreal, October 2, 2019

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