CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000733-150

(Class Action)
SUPERIOR COURT

G. ARCHAMBAULT and **R. BRUZZESE**

Petitioners

-vs.-

ABBOTT LABORATORIES, LIMITED, legal person duly constituted, having its head office at 8401 Trans-Canada Highway, City of Montreal, Province of Quebec, H4S 1Z1

and

ABBOTT PRODUCTS INC., legal person duly constituted, having its head office at Valleywood Corporate Centre, 60 Columbia Way, Suite 102, City of Markham, Province of Ontario, L3R 0C9

and

ABBOTT PRODUCTS CANADA INC., legal person duly constituted, having its head office at Valleywood Corporate Centre, 60 Columbia Way, Suite 102, City of Markham, Province of Ontario, L3R 0C9

and

ABBVIE PRODUCTS LLC, legal person duly constituted, having its head office at 100 Abbott Park Road, City of Abbott Park, State of Illinois, 60064, U.S.A.

Respondents

MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION
&
TO ASCRIBE THE STATUS OF REPRESENTATIVE
(Art. 1002 C.C.P. and following)

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

I. GENERAL PRESENTATION

A) The Action

1. Petitioners wish to institute a class action on behalf of the following group, of which they are members, namely:

    - all persons residing in Canada who were prescribed and/or used ANDROGEL and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

    Alternately (or as a subclass)

    - all persons residing in Quebec who were prescribed and/or used ANDROGEL and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

2. "ANDROGEL" is a testosterone replacement therapy (TRT)[1] drug, which is a hormone treatment often prescribed to patients in order to counter the effects of absent or low testosterone or male hypogonadism[2];

3. Petitioners contend that the Respondents represented to the medical and healthcare community, to Health Canada and the United States Food and Drug Administration ("USFDA") and to the Class Members that ANDROGEL was a safe and effective treatment for its intended use. In addition, the Respondents concealed their knowledge of ANDROGEL's defects from the medical and healthcare community, Health Canada and the USFDA, and from Class Members;

[1] Testosterone replacement therapy is often referred to as Androgen replacement therapy (ART).
[2] Male hypogonadism is a medical term which describes a diminished functional activity of the male gonads (the testes) that may result in diminished sex hormone biosynthesis.

4. The Respondents packaged, promoted, marketed, distributed, labelled, and/or sold ANDROGEL as a safe and effective treatment despite a wealth of existing knowledge that the drug had dangerous side effects including, life-threatening cardiac events, strokes, thrombosis[3], death and other serious medical problems;

5. The Respondents, in combination with other pharmaceutical companies involved in the manufacture of testosterone therapies, have been engaging in disease-mongering[4] marketing campaigns, described more fully herein, to "alert" physicians and consumers about the under-diagnosis of low testosterone, its symptoms and the supposed grave health risks resulting from the lack of or under-treatment thereof. In reality, these supposed "symptoms" are more often than not caused by the natural aging process;

6. As a result of this disease-mongering, diagnoses of low testosterone have increased exponentially and this increase is believed to be directly related to the business practices of the Respondents and other similar pharmaceutical companies involved in the manufacture, distribution, marketing, and sale of testosterone replacement therapies;

7. The Respondents continue to design, manufacture, develop, prepare, process, inspect, test, package, promote, market, distribute, label, and/or sell ANDROGEL throughout Canada, including within the province of Quebec, with inadequate warnings as to its serious and adverse side effects including, life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems, which in turn causes physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences which are described in more detail below;

B) <u>The Respondents</u>

8. Respondent Abbott Laboratories Limited ("Abbott Ltd.") is a Canadian pharmaceutical corporation, with its head office in Saint-Laurent, Quebec. Abbott Ltd. is and was at all relevant times involved in the design, manufacture, development, preparation, processing, inspection, testing, packaging, promotion, marketing, distribution, labelling, and/or sale of pharmaceutical products including ANDROGEL. It does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises* and from a copy of the Government of Canada Canadian Company Capabilities Complete profile, produced herein *en liasse* as **Exhibit R-1**;

[3] Thrombosis is the formation or presence of a blood clot in a blood vessel, obstructing the flow of blood through the circulatory system.

[4] Disease mongering is a pejorative term for the practice of widening the diagnostic boundaries of illnesses and aggressively promoting their public awareness in order to expand the markets for treatment.

9. Respondent Abbott Products Canada Inc.[5] ("Abbott Products Canada") is a Canadian pharmaceutical corporation with its head office in Mississauga, Ontario. Abbott Products Canada is and was at all relevant times involved in the design, manufacture, development, preparation, processing, inspection, testing, packaging, promotion, marketing, distribution, labelling, and/or sale of pharmaceutical products including ANDROGEL;

10. Respondent Abbott Products Inc.[6] ("Abbott Canada") is a Canadian pharmaceutical corporation with its head office in Mississauga, Ontario. Abbott Canada is and was at all relevant times involved in the design, manufacture, development, preparation, processing, inspection, testing, packaging, promotion, marketing, distribution, labelling, and/or sale of pharmaceutical products including ANDROGEL. On May 14, 2002, Abbott Canada (as it was then known) obtained approval from Health Canada for the sale of ANDROGEL in Canada, the whole as appears more fully from a copy of the Press Release entitled "Androgel™ Approved in Canada - First Gel Testosterone Replacement Therapy Now Available" dated May 14, 2002 and from a copy of the DocGuide article entitled "Androgel(TM) Approved In Canada" dated May 14, 2002, produced herein *en liasse* as **Exhibit R-2**;

11. Respondent AbbVie Products LLC[7] ("AbbVie") is an American pharmaceutical corporation with its head office in Abbott Park, Illinois. AbbVie is a wholly-owned subsidiary of non-party AbbVie, Inc., the whole as appears more fully from a copy of an extract from AbbVie, Inc.'s Form 10-K filed with the United States Securities and Exchange Commission, produced herein as **Exhibit R-3**;

12. On or about January 1, 2013, AbbVie's parent company, non-party, AbbVie, Inc., separated from its parent company, non-party Abbott Laboratories, which had previously announced that it would be separating into two (2) companies, one in medical products and the other in research-based pharmaceuticals. This separation involved AbbVie, Inc. taking ownership of several medical products, including ANDROGEL, the whole as appears more fully from a copy of the Canada Newswire Press Release entitled "Abbott to Separate into Two Leading Companies in Diversified Medical Products and Research-Based Pharmaceuticals" dated October 19, 2011, from a copy of the Abbott Deutschland Press Release entitled "Abbott to Separate into Two Leading Companies in Diversified Medical Products and Research-Based Pharmaceuticals" dated October 19, 2011, from a copy of the Abbott Press Release entitled "Abbott Selects AbbVie as New Name for Future Research-

[5] Prior to February 19, 2010, Abbott Products Canada Inc. was known as Solvay Pharma Canada Inc.
[6] Prior to February 19, 2010, Abbott Products Inc. was known as Solvay Pharma Inc. which was an amalgamation of Solvay Pharma Inc. and Solvay Pharma Clinic Inc. (January 8, 2001).
[7] Prior to November 2012, Abbvie Products LLC was known as Abbott Products LLC, which was formerly known as Abbott Products, Inc., and previously known as Solvay Pharmaceuticals, Inc.

Based Pharmaceutical Company" dated March 21, 2012, from a copy of the Abbott Press Release entitled "Abbott Completes separation of Research-Based Pharmaceuticals Business" dated January 2, 2013, from a copy of Abbott Laboratories Form 10-K for the fiscal year ended December 31, 2013, and from a copy of AbbVie, Inc.'s Annual Report for 2013, produced herein *en liasse* as **Exhibit R-4**;

13. AbbVie is and was at all relevant times involved in the design, manufacture, development, preparation, processing, inspection, testing, packaging, promotion, marketing, distribution, labelling, and/or sale of pharmaceutical products including ANDROGEL;

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

15. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other. Unless the context indicates otherwise, all Respondents will be referred to as "Abbott" for the purposes hereof;

C) <u>The Situation</u>

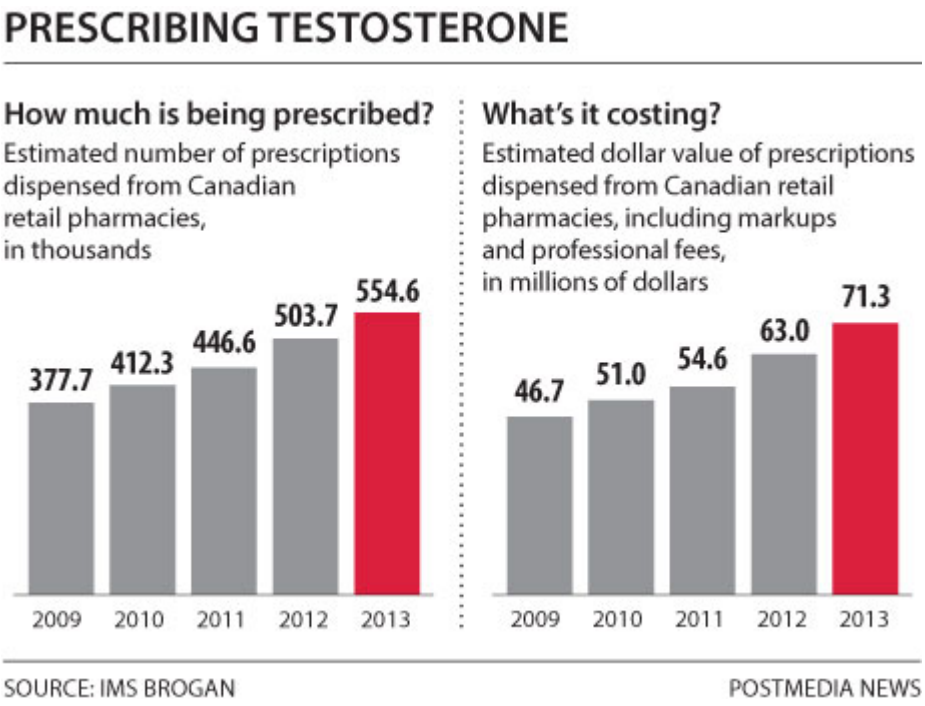
I. <u>Testosterone-Replacement Therapy (TRT)</u>

16. Testosterone is a steroid hormone from the androgen group and is found in humans and other vertebrates. In humans and in other mammals, testosterone is secreted primarily by the testicles of males and, to a lesser extent, the ovaries of females;

17. Testosterone-replacement products have been available in the Canadian and U.S. markets since the mid-1950s and ANDROGEL has not and does not currently carry warnings with respect to the serious cardiovascular risks, the whole as appears more fully from a copies of the Product Monograph for ANDROGEL revised as at January 28, 2015 and from copies of the Compendium of Pharmaceuticals and Specialities from the years 2011, 2010, 2009, 2008, 2005, 2004, and 2003, produced herein respectively as **Exhibit R-5** and *en liasse* as **Exhibit R-6**;

18. Prescriptions for testosterone replacement products in Canada and elsewhere have been on the rise. They are was most commonly prescribed to men between the ages of 40 and 59 and the elderly population (65 years old and over) is the second most prescribed age group;

19. As of 2013, more than 550,000 prescriptions for testosterone-containing drugs were filled in Canada, which was up from only 378,000 in 2009 (see figure below). This has been partially attributed to the heavy marketing campaigns directed to aging baby boomers[8] to delay normal biological body changes that come with aging, the whole as appears more fully from a copy of the Canada.com article entitled "Testosterone use growing amid new safety concerns" dated March 7, 2014, produced herein as **Exhibit R-7**;



20. In Canada, there are twelve (12) testosterone-containing products that are currently marketed for use as testosterone replacement therapy: ANDRIOL, ANDRODERM, ANDROGEL, AXIRON, DELATESTRYL, DEPO-TESTOSTERONE, TESTIM and their equivalent generics. These products were approved for use by Health Canada in adult males who are experiencing medical conditions because their body cannot produce enough testosterone;

21. After receiving 35 reports of cardiovascular problems involving testosterone therapy products, Health Canada reported that there is a possible correlation with cardiovascular risk; i.e. there is a risk of adverse cardiovascular events associated with ANDROGEL, the whole as appears more fully from a copy of the Health Canada Summary Safety Review dated July 15, 2014, produced herein as **Exhibit R-8**;

II. <u>What is AndroGel?</u>

[8] Baby boomers are people born during the demographic Post–World War II baby boom between the years 1946 and 1964.

22. ANDROGEL belongs to a group of medicines called Testosterone Replacement Therapy (TRT). It is a clear, colourless, topical gel that is applied to the shoulders, upper arms, and/or abdomen once per day for absorption into the skin and slow release into the bloodstream;

23. On May 14, 2002, Respondent Abbott Canada obtained approval for ANDROGEL from Health Canada in the 1% strength for the "treatment for male testosterone insufficiency (low testosterone or andropause)" in the 2.5 and 5 gram packets and in 2004 the 1.25 gram metered dose pump was approved (Exhibit R-2);

24. Since its introduction, ANDROGEL has become the leading testosterone product in Canada. In 2010, it captured 73% of the Canadian market share, generating approximately $27 million in retail sale from pharmacies, the whole as appears more fully from a copy of the Canadian Medical Association Journal (CMAJ) article entitled "Brouhaha erupts over testosterone-testing advertising campaign" dated November 8, 2011, produced herein as **Exhibit R-9**;

25. On February 29, 2000, ANDROGEL was approval for use in the United States by the United States Food and Drug Administration for use as a testosterone replacement therapy in men with low testosterone, the whole as appears more fully from a copy of The Body article entitled "AndroGel Offers New Option for Testosterone Replacement" dated March 31, 2000, produced herein as **Exhibit R-10**;

26. On June 24, 2008, the Patented Medicine Prices Review Board[9] accepted a Voluntary Compliance Undertaking (VCU) from Respondent Abbott Canada (which at the time was Solvay Pharma Inc.) to reduce the price of the AndroGel 2.5g/pouch to the 2008 maximum non-excessive (MNE) price of $2.1263 and to offset cumulative excess revenues received from May 2002 to December 31, 2007 by making a payment of $3,327,180.61 to the Government of Canada. Solvay Pharma also reimbursed excess revenues obtained in 2008, the whole as appears more fully from a copy of the Voluntary Compliance Undertaking of Solvay Pharma Inc. to the Patented Medicine Prices Review Board dated June 24, 2008 and from a copy of the Canadian Generic Pharmaceutical Association (CGPA) News Release entitled "The Real Story Behind R&D Spending by Brand-Name Drug Companies in Canada" dated 2009, produced herein *en liasse* as **Exhibit R-11**;

27. On January 30, 2009, the Federal Court dismissed Abbott Canada's application for judicial review of the Minister of Health's refusal to list ANDROGEL on the patent register, the whole as appears more fully from a copy of the judgment in *Solvay Pharma Inc. v. Canada (Attorney General)*, 2009 FC 102, [2010] 1 F.C.R. 391, produced herein as **Exhibit R-12**;

28. Contrary to the representations made to the medical community, and ultimately to the patients themselves, ANDROGEL is associated with an increased risk of suffering a myocardial infarction, stroke, thrombolytic event and/or death;

29. ANDROGEL has also been linked to several other severe and life changing medical disorders in users including, but not limited to, enlarged prostates and increased serum prostate-specific antigen levels;

30. Secondary exposure to ANDROGEL can cause side effects in others. In 2009, the USFDA issued a black box warning for ANDROGEL prescriptions, and in 2010 the Canadian monograph was similarly revised, advising patients of reported virilization[10] in children who were secondarily exposed to the gel (Exhibits R-5 and R-6);

31. Since 2010, the product monograph (Exhibit R-5), has contained the following warning; however prior to then, there was no mention whatsoever about virilization:

Serious Warnings and Precautions
SECONDARY EXPOSURE TO TESTOSTERONE

[9] The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body that protects consumers and contributes to health care by ensuring that the manufacturers' prices of patented medicines are not excessive.

[10] Virilization is a condition in which a female develops male sex characteristics, or a newborn boy has increased male characteristics at birth.

- Virilization has been reported in children who were secondarily exposed to testosterone gel, including ANDROGEL.
- Children should avoid contact with unwashed or unclothed application sites in men using ANDROGEL.
- Healthcare providers should advise patients to strictly adhere to recommended instructions for use;

32. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with ANDROGEL, including fetal abnormalities, the whole as appears more fully from a copy of the AbbVie Safety Data Sheet issued September 18, 2014 in both English and French, produced herein *en liasse* as **Exhibit R-13**;

III. Medical Literature and Scientific Studies Behind the Drug

33. There have been numerous studies that demonstrate that testosterone replacement therapy in men increases the risk of cardiovascular and thrombolytic events;

34. On July 8, 2010, a trial entitled "The Testosterone in Older Men with Mobility Limitations" (TOM) was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events. The application of testosterone gel was associated with an increased risk of cardiovascular adverse events; however, the small size of the trial (209 men) and the unique population in that there was a high prevalence of hypertension, diabetes, hyperlipidemia, and obesity among the participants prevented broader inference from being made about the safety of testosterone therapy, the whole as appears more fully from a copy of the New England Journal of Medicine study entitled "Adverse Events Associated with Testosterone Administration" dated July 8, 2010, produced herein as **Exhibit R-14**;

35. In April 2013, the results of a meta-analysis of 27 previous smaller randomized trials, including the TOM Trial (Exhibit R-14), comparing testosterone with placebo indicated that the effects of testosterone on cardiovascular-related events varied with the source of funding of the trials – the thirteen (13) drug industry-funded trials failed to show any increase in cardiovascular events in the testosterone subjects, while the fourteen (14) non-industry-funded trials showed a significant 2.06-fold increased risk with testosterone. Regardless of funding, however, the analysis found there was an overall increased risk of cardiovascular-related events associated with testosterone replacement therapy, the whole as appears more fully from a copy of the BMC Medicine journal research article entitled "Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled trials" dated April 18, 2013 and from a

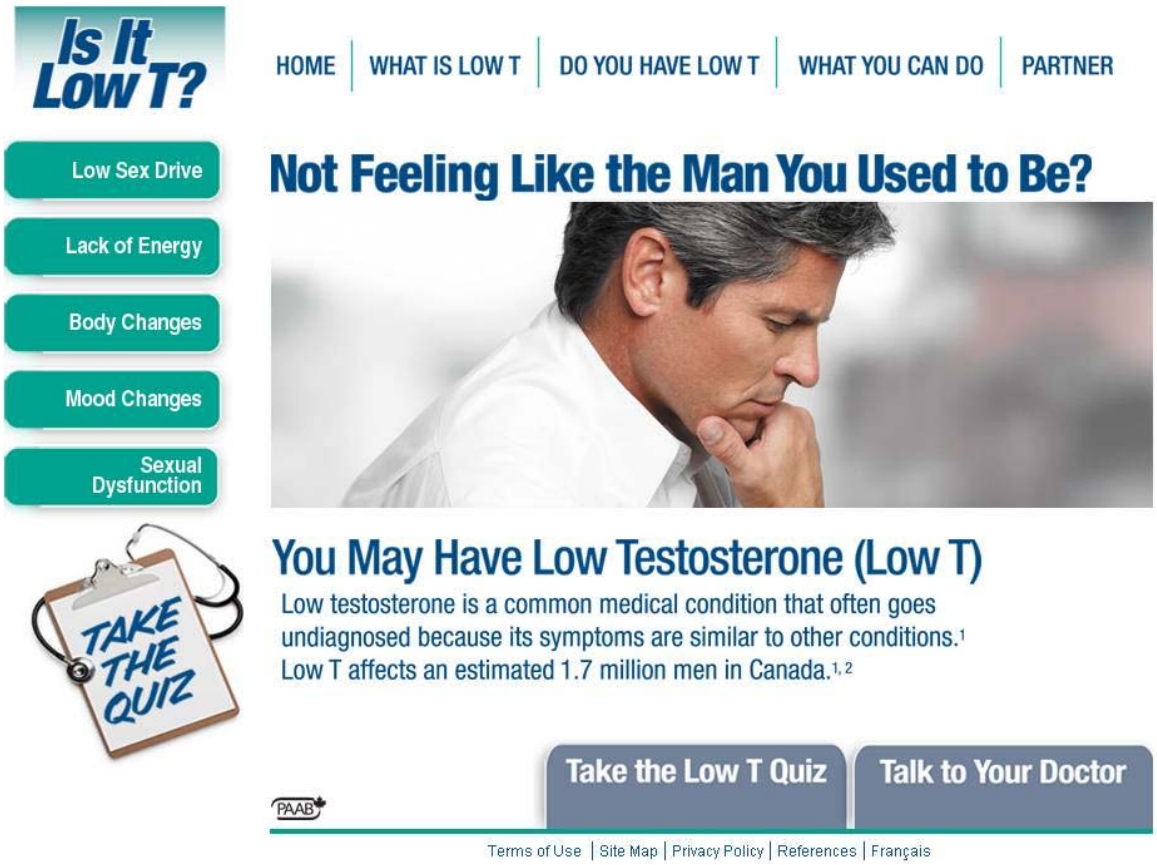
copy of the BMJ article entitled “Increased heart attacks in men using testosterone: the UK importantly lags far behind the US in prescribing testosterone” dated February 27, 2014, produced herein *en liasse* as **Exhibit R-15**;

36. In November of 2013, the Journal of the American Medical Association (JAMA) study was released entitled “Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels” which indicated that testosterone therapy raised the risk of death, heart attack and stroke by approximately thirty percent (30%), the whole as appears more fully from a copy of the Journal of the American Medical Association article entitled “Association of Testosterone Therapy With Mortality, Myocardial Infarction, and Stroke in Men With Low Testosterone Levels” dated November 6, 2013, produced herein as **Exhibit R-16**;

37. On January 29, 2014, a study was released in PLOS ONE entitled “Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men” which indicated that testosterone use doubled the risk of heart attacks in all men over sixty-five (65) years of age and men younger than sixty-five (65) years of age, with a previous diagnosis of heart disease, the whole as appears more fully from a copy of the PLOS ONE article entitled “Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men” dated January 19, 2014, produced herein as **Exhibit R-17**;

IV. <u>The Respondents’ Disease-Mongering Marketing Campaigns</u>

38. Pharmaceutical companies involved in the manufacture of testosterone therapies, including Abbott, have been engaging in disease-mongering marketing campaigns, including, but not limited to, Abbott Canada campaigns such as: “Has He Lost That Loving Feeling” (in or about the summer of 2011), along with mail-outs to doctors and the creation of a website about low testosterone levels: www.lowt.ca, to alert physicians and consumers about the under-diagnosis of “low-T”, its symptoms and the supposed grave health risks resulting from lack-of or under-treatment (see screenshot below), the whole as appears more fully from a copy of an extract from the Respondents’ website at www.lowt.ca and from the Facts for Spouses/Partners available thereon, produced herein *en liasse* as **Exhibit R-18**;



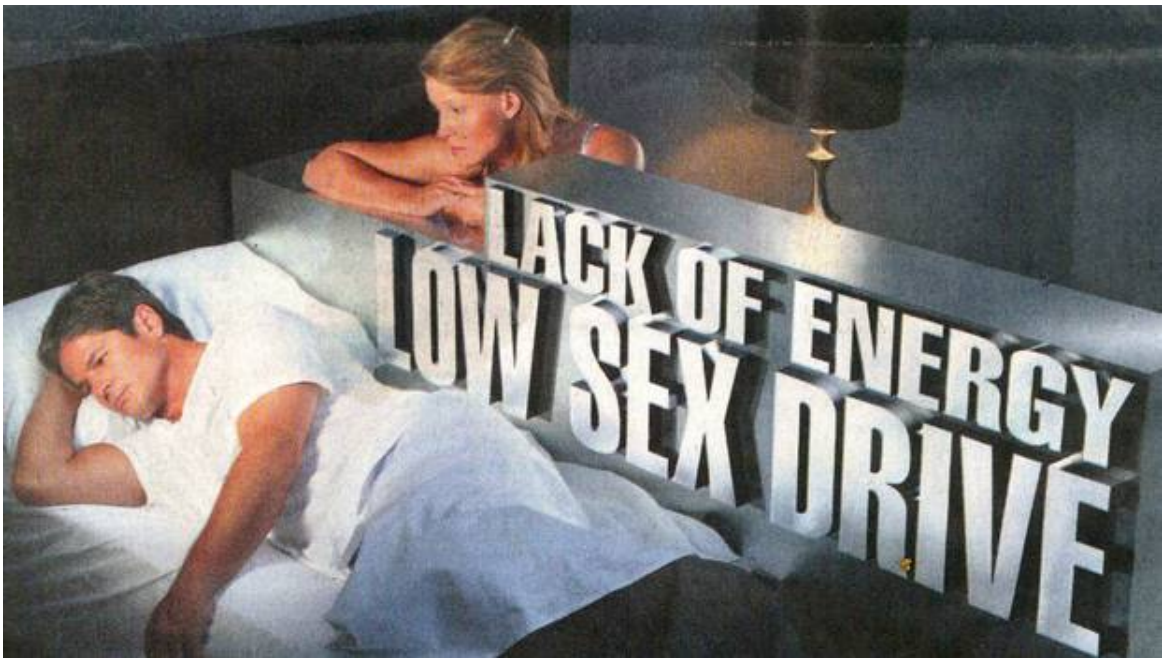
39. The Respondents' marketing strategies have been to aggressively market and sell ANDROGEL by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that the Respondents knew or ought to have known would result from use of its product;

40. The Respondents successfully marketed ANDROGEL by undertaking a "disease awareness" campaign, creating a consumer perception that low testosterone is prevalent among men and the symptoms previously associated with other physical and mental conditions, such as aging, stress, obesity, depression and lethargy, were actually attributable to a new disease, branded as low testosterone, the whole as appears more fully from a copy of The Globe and Mail article entitled "Testosterone campaign by drug company raises concerns" dated September 21, 2011, from a copy of The Globe and Mail article entitled "Sorry, guys, testosterone may not help your aging body" dated June 16, 2010, and from a copy of the Consumer Reports article entitled "Should I be tested for 'Low-T?'" dated June 3, 2013, produced herein *en liasse* as **Exhibit R-19**;

41. Testosterone manufacturers, such as the Respondents, spent $14.3 million in 2011 and $107.3 million in 2012 on marketing campaigns aimed at convincing the public of the supposed benefits of testosterone therapy, the whole as

appears more fully from a copy of the Consumer Reports article entitled “Do you need to be treated for low testosterone? Drugmakers spent more than $100 million advertising the drugs last year, but our experts aren't buying it” dated July 2013, produced herein as **Exhibit R-20**;

42. Depicted below are two (2) advertisements in the Respondents’ advertising campaign that suggest that low testosterone is far more common than it really is and which medical experts have complained about:



43. The Respondents' advertising program sought to create the image and belief by consumers and their physicians that the use of ANDROGEL was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though the Respondents knew or ought to have known this to be false;

44. In truth, low testosterone is far less common than the Respondents marketed and the symptoms of this supposedly commonplace disease are more likely attributed to normal aging and/or prevalent problems outlined herein (stress, obesity, depression and lethargy). The real symptoms of low testosterone include loss of body hair or muscle mass, testicular shrinkage and other clear symptoms of the disease;

45. According to the "Is it Low-T?" quiz on Abbott Canada's website, symptoms of "low-T"[11] include being "sad or grumpy", "experiencing deterioration in the ability to play sports", and "falling asleep after dinner". Most physicians agree that these symptoms can be caused by numerous other factors, the most prominent of which is the natural aging process, the whole as appears more fully from a copy of an extract from the Respondents' website at www.lowt.ca, produced herein as **Exhibit R-21**;

46. The Respondents purposefully downplayed, understated and ignored the health hazards and risks associated with using ANDROGEL. The Respondents deceived potential users by manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects;

[11] Low-T is low testosterone.

47. As part of their marketing of ANDROGEL, the Respondents employed a "pull marketing" technique[12] whereby direct-to-consumer advertising campaigns were disseminated that were designed to influence patients, including the Petitioner, to make inquiries to their prescribing physician about ANDROGEL and/or request prescriptions for ANDROGEL, the whole as appears more fully from a copy of an extract from the Respondents' website at www.androgel.com, produced herein as **Exhibit R-22**;

48. In the course of their direct-to-consumer advertisements, the Respondents encouraged Class Members to have an "open, honest conversation with your doctor" and "at your appointment you should discuss your symptoms and ask if you should have your testosterone (T) levels evaluated" (Exhibit R-21), while failing to adequately disclose to patients the serious side effects including life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems;

49. For example, on the Respondents' website under the Respondents fail to mention these serious side effects and instead only list out the following:

> AndroGel 1.62% can cause serious side effects, including:
>
> - If you already have enlargement of your prostate gland, your signs and symptoms can get worse while using AndroGel 1.62% (including changes in urination)
> - Possible increased risk of prostate cancer
> - In large doses, AndroGel 1.62% may lower your sperm count
> - Swelling of your ankles, feet, or body, with or without heart failure. This may cause serious problems for people who have heart, kidney, or liver disease
> - Enlarged or painful breasts
> - Having problems breathing while you sleep (sleep apnea)
> - Blood clots in your legs or lungs. Signs and symptoms of a blood clot in your leg can include leg pain, swelling,

[12] A "pull marketing" technique primarily targets patients by urging them to "pull" or request certain drugs from their physicians whereas a "push marketing" technique primarily targets physicians by urging them to "push" certain drugs onto their patients.

> or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
>
> The most common side effects of AndroGel 1.62% include increased prostate specific antigen (a test used to screen for prostate cancer), mood swings, hypertension, increased red blood cell count, and skin irritation where AndroGel 1.62% is applied.

The whole as appears more fully from a copy of an extract from the Frequently Asked Questions portion of the Respondents' website at www.androgel.com, produced herein as **Exhibit R-23**;

50. It is this manner that sales of ANDROGEL have been steadily rising despite the number of serious and life-threatening side effects related to the medication. In fact, the Respondents are actually looking to expand their market size to include its use for male adolescents, the whole as appears more fully from a copy of the PR Newswire article entitled "Solvay Pharmaceuticals, Inc. Announces Submission of Supplemental New Drug Application for AndroGel(R) in Male Adolescents" dated June, 2014, produced herein as **Exhibit R-24**;

V. Regulatory Response

51. On January 31, 2014, the USFDA announced that it would be launching an investigation into testosterone therapies, such as ANDROGEL, the after two well-run studies were published (Exhibits R-16 and R-17) which concluded that middle-aged and older men prescribed these products were at an increased risk of suffering from strokes, heart attacks and death, the whole as appears more fully from a copy of the USFDA Safety Announcement "FDA Drug Safety Communication: FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products" dated January 31, 2014, produced herein as **Exhibit R-25**;

52. Health Canada is also re-evaluating the safety of testosterone-containing products and working with manufacturers to update the Canadian product labels regarding the risk (Exhibit R-7), the whole as appears more fully from a copy of the Health Canada Information Update dated July 15, 2014, produced herein as **Exhibit R-26**;

53. On June 19, 2014, the USFDA announced that it will be requiring all manufacturers of testosterone replacement therapy products to include a general warning in the drug labeling about the risk of venous thromboembolism (blood clots in the veins), the whole as appears more fully from a copy of the USFDA Announcement entitled "FDA adding general warning to testosterone products about potential for venous blood clots" dated June 19, 2014, produced herein as **Exhibit R-27**;

54. On March 3, 2015, the USFDA announced that the benefits and safety of the use of testosterone replacement therapy to relieve symptoms in men who have low testosterone due to aging alone has not been established and that it will be requiring manufacturers to change their labelling to clarify their approved uses, the whole as appears more fully from a copy of the Safety Announcement entitled "FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use" dated March 3, 2015, produced herein as **Exhibit R-28**;

55. No similar update has been made to the Canadian label;

56. Despite the publicity surrounding the reports of various studies and regulatory investigations, the Respondents continue to market and distribute ANDROGEL as being safe and effective.

57. Despite various warning changes, the Respondents' marketing of ANDROGEL continues to fail to warn consumers, healthcare professionals and the public of the serious and significant risk of life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems;

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

58. Although ANDROGEL is packaged, promoted, marketed, distributed, labelled and/or sold as a safe and effective prescription drug, it has the serious side effect of the increased risk for life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems;

59. A reasonably prudent drug designer, manufacturer, developer, preparer, processer, inspector, tester, packager, promotor, marketer, distributer, labeller, and/or seller in the Respondents' position would have adequately warned both doctors and patients of the risks associated with the use of ANDROGEL;

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

61. The Respondents were negligent in the design, manufacture, development, testing, preparation, processing, inspection, testing, packaging, promotion, marketing, packaging, distribution, labelling and/or sale of ANDROGEL in one or more of the following respects:

a. They knew of should have known that ANDROGEL increased the risk of the adverse side effects of myocardial infarction, stroke, thrombolytic events and death;

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

c. They failed to conduct appropriate testing to determine whether and to what extent the use of ANDROGEL poses serious health risks;

d. They failed to adequately test the product prior to placing it on the market;

e. They failed to adequately test ANDROGEL in a manner that would fully disclose the side effects of myocardial infarction, stroke, thrombolytic events and death;

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

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 use of ANDROGEL could result in severe and disabling side effects, including, but not limited to, myocardial infarction, stroke, thrombolytic events and death;

i. They failed to advise the medical and scientific communities of the potential to increase the risk of myocardial infarction, stroke, thrombolytic events and death;

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

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

l. They failed to provide adequate updated and current information to class members and their physicians respecting the risks of ANDROGEL as such information became available;

m. They failed to provide prompt warnings of potential hazards of ANDROGEL in the products' monograph (Exhibit R-5) and in the products' labelling;

n. They failed to warn that Class Members and their physicians that the risks associated ANDROGEL would exceed the risks of other available anticoagulant medications;

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

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

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

r. They disregarded reports of myocardial infarction, stroke, thrombolytic events and death among patients;

s. They failed to accurately and promptly disclose to Health Canada information relating to myocardial infarction, stroke, thrombolytic events and death associated with ANDROGEL and to modify ANDROGEL product monograph and product labelling accordingly in a timely manner;

t. They failed to monitor and to initiate a timely review, evaluation and investigation of reports of myocardial infarction, stroke, thrombolytic events and death associated with ANDROGEL in Canada and around the world;

u. They failed to properly investigate cases of myocardial infarction, stroke, thrombolytic events and death caused by ANDROGEL; and

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

62. Despite the vast availability of knowledge indicating that ANDROGEL use is causally-related to myocardial infarction, stroke, thrombolytic events and death, the Respondents not only failed to provide adequate labelling to warn Class Members of the risks associated with the use of ANDROGEL, but

instead incongruously promoted and marketed ANDROGEL as a safe and effective drug, effectively appropriating the ability of doctors and patients to make informed decisions regarding their health;

63. The Respondents concealed and failed to completely disclose their knowledge that ANDROGEL was associated with or could cause myocardial infarction, stroke, thrombolytic events and death as well as their knowledge that they had failed to fully test or study said risk;

64. The Respondents ignored the association between the use of ANDROGEL and the risk of myocardial infarction, stroke, thrombolytic events and death;

65. The Respondents' failure to disclose information that they possessed regarding the failure to adequately test and study ANDROGEL for myocardial infarction, stroke, thrombolytic events and death risk further rendered any warnings for this medication inadequate;

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

66. On or about February 2, 2014, Petitioner Archambault was prescribed ANDROGEL 1% in the 5 gram packet by his family physician and he used it as directed;

67. On November 8, 2014, Petitioner Archambault suffered a heart attack and he was brought by ambulance to the Hôpital du Sacré-Coeur de Montréal located at 5400 Gouin Boulevard, in Montreal, Quebec;

68. Petitioner Archambault stopped taking ANDROGEL immediately upon suffering the heart attack; i.e. on November 8, 2014;

69. Petitioner Archambault remained in the hospital until January 15, 2015, at which point he was transferred to the Richardson Hospital for rehabilitation at 5425 Bessborough Avenue, in Montreal, Quebec where he remained until March 5, 2015 when he was released as an outpatient;

70. Petitioner Archambault agreed to initiate ANDROGEL treatment in an effort to treat his lack of energy and the Petitioners relied on claims made by the Respondents that ANDROGEL was safe and effective;

71. At no time were the Petitioners made aware of the risks associated with the use of ANDROGEL including the suffering of a cardiovascular event;

72. Had the Respondents properly disclosed the risks associated with ANDROGEL, Petitioner Archambault would have avoided the risk of suffering cardiac arrest by not using ANDROGEL at all;

73. The Petitioners have recently discovered, while researching online, that a class action proceeding was filed in Ontario due to the defects associated with ANDROGEL and due to the Respondents' conduct related thereto, the whole as appears more fully from a copy of the Ontario Statement of Claim, produced herein as **Exhibit R-29**;

74. As a result of the Respondents' conduct, Petitioner Archambault suffered damages including, but not limited to multiple organ dysfunction, memory loss, neurological damage, speech problems/impediment, loss of use of his left hand, irregular heartbeat, brain damage, difficulty moving, and lost income, including future income, in addition to pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increased risk of health problems, and the apportioned cost of the ANDROGEL;

75. Petitioner Bruzzese has lost the support, guidance, care, consortium, and companionship that she had come to rely upon from her husband in addition to lost income, including future income;

76. Petitioners' damages are a direct and proximate result of the use of the drug ANDROGEL, the Respondents' negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug ANDROGEL;

77. In consequence of the foregoing, Petitioners are justified in claiming damages;

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

78. Every member of the class has purchased and/or used the drug, ANDROGEL or is the successor, family member, assign, and/or dependant of a person who purchased and/or used ANDROGEL;

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

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

    a. Physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems;

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 ANDROGEL side effect services;

c. Loss of income and loss of future income;

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

e. Punitive damages;

81. 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 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;

82. All of these damages to the class members are a direct and proximate result of the use of ANDROGEL and 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 renders the application of articles 59 or 67 C.C.P. difficult or impractical

83. Petitioners are unaware of the specific number of persons who used and/or purchased ANDROGEL, which information is confidential, however, it is safe to estimate that it is in the tens of thousands;

84. Class Members are numerous and are scattered across the province;

85. 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.

Further, 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;

86. 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;

87. 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;

88. 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 questions of fact and law which are identical, similar, or related with respect to each of the class members with regard to the Respondents and that which the Petitioners wish to have adjudicated upon by this class action</u>

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

90. The damages sustained by the class members flow, in each instance, from a common nucleus of operative facts, namely, Respondent's misconduct;

91. The recourses of the members raise identical, similar or related questions of fact or law, namely:

a) Does ANDROGEL cause, exacerbate or contribute to an increased risk of life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems?

b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as designers, manufacturers, developers, preparers, processors, inspectors, testers, packagers, promotors, marketers, distributers, labellers and/or sellers of ANDROGEL?

c) Was ANDROGEL designed, manufactured, developed, prepared, processed, inspected, tested, packaged, promoted, marketed, distributed, labelled, and/or sold with defects that increase a patient's risk of life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems?

d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for ANDROGEL?

e) Did the Respondents fail to adequately and properly test ANDROGEL before and/or after placing it on the market?

f) Did the Respondents know or should have known about the risks associated with the use of ANDROGEL?

g) Did the Respondents knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use of ANDROGEL?

h) Did the Respondents knowingly, recklessly or negligently misrepresent to Class Members and/or their physicians the risks of harm from the use of ANDROGEL?

i) Did the Respondents knowingly fail to disclose and warn of ANDROGEL's defects?

j) Did the Respondents adequately and sufficiently warn Class Members and/or their physicians about the risks associated with the use of ANDROGEL?

k) Should ANDROGEL have been sold with more appropriate warnings?

l) Did the Respondents engage in false advertising when they represented, through advertisements, promotions and other representations, that ANDROGEL was safe or omitted to disclose material facts regarding ANDROGEL's safety?

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

n) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?

o) Are members of the class entitled to bodily, moral, and material damages?

p) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking ANDROGEL?

q) Are the members of the class entitled to recover as damages an amount equal to the purchase price of ANDROGEL or any part of the purchase price?

r) Are members of the class entitled to aggravated or punitive damages?

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

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

93. The action that the Petitioners wish to institute on behalf of the members of the Class is an action in damages, injunctive relief, and declaratory judgment;

94. The conclusions that the Petitioners wish to introduce by way of a motion to institute proceedings are:

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

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

ORDER the Defendants to modify the product monograph, the product labelling, and the marketing and promotional practices for ANDROGEL;

RESERVE the right of each of the members of the class to claim future damages related to the use of ANDROGEL;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioners 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 motion to authorize a class action;

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

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

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

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

A) <u>The Petitioners request that they be attributed the status of co-representatives of the Class</u>

95. Petitioners are members of the Class;

96. Petitioners are ready and available to manage and direct the present action in the interest of the members of the Class that they wish to represent and are 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 of Quebec and the *Fonds d'aide aux recours collectif*s, as the case may be, and to collaborate with their attorneys;

97. Petitioners have the capacity and interest to fairly and adequately protect and represent the interest of the members of the Class;

98. Petitioners have given the mandate to their attorneys to obtain all relevant information with respect to the present action and intend to keep informed of all developments;

99. Petitioners, with the assistance of their attorneys, are 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;

100. Petitioners have given instructions to their 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;

101. Petitioners are in good faith and have instituted this action for the sole goal of having their 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;

102. Petitioners understand the nature of the action;

103. Petitioners' interests are not antagonistic to those of other members of the Class;

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

104. A great number of the members of the class reside in the judicial district of Montreal and in the appeal district of Montreal;

105. Respondent Abbott Laboratories, Limited has its head office in the judicial district of Montreal;

106. The Petitioners' attorneys practice their profession in the judicial district of Montreal;

107. The present motion is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

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

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

- all persons residing in Canada who were prescribed and/or used ANDROGEL and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternately (or as a subclass)

- all persons residing in Quebec who were prescribed and/or used ANDROGEL and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

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

a) Does ANDROGEL cause, exacerbate or contribute to an increased risk of life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems?

b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as designers, manufacturers, developers, preparers, processors, inspectors, testers, packagers, promotors, marketers, distributers, labellers and/or sellers of ANDROGEL?

c) Was ANDROGEL designed, manufactured, developed, prepared, processed, inspected, tested, packaged, promoted, marketed, distributed, labelled, and/or sold with defects that increase a patient's risk of life-threatening cardiac events, strokes, thrombosis, death and other serious medical problems?

d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for ANDROGEL?

e) Did the Respondents fail to adequately and properly test ANDROGEL before and/or after placing it on the market?

f) Did the Respondents know or should have known about the risks associated with the use of ANDROGEL?

g) Did the Respondents knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use of ANDROGEL?

h) Did the Respondents knowingly, recklessly or negligently misrepresent to Class Members and/or their physicians the risks of harm from the use of ANDROGEL?

i) Did the Respondents knowingly fail to disclose and warn of ANDROGEL's defects?

j) Did the Respondents adequately and sufficiently warn Class Members and/or their physicians about the risks associated with the use of ANDROGEL?

k) Should ANDROGEL have been sold with more appropriate warnings?

l) Did the Respondents engage in false advertising when they represented, through advertisements, promotions and other representations, that ANDROGEL was safe or omitted to disclose material facts regarding ANDROGEL's safety?

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

n) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?

o) Are members of the class entitled to bodily, moral, and material damages?

p) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking ANDROGEL?

q) Are the members of the class entitled to recover as damages an amount equal to the purchase price of ANDROGEL or any part of the purchase price?

r) Are members of the class entitled to aggravated or punitive damages?

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

GRANT the class action of the Petitioners and each of the members of the class;

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

ORDER the Defendants to modify the product monograph, the product labelling, and the marketing and promotional practices for ANDROGEL;

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

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioners 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 motion 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 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 1006 C.C.P. within sixty (60) days from the judgment to be rendered herein in LA PRESSE, the MONTREAL GAZETTE and THE GLOBE AND MAIL;

ORDER that said notice be available on the Respondents' websites, Facebook page(s), and twitter accounts with a link stating "Notice to ANDROGEL 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 publications fees.

Montreal, March 9, 2015

(S) Andrea Grass

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