C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

500-06-000758-157

S U P E R I O R C O U R T
(Class Action)

PIERRE VACHON, residing and domiciled at 14 Sauriol, in the city of Repentigny, Province of Quebec, J6A 4V7, Canada;

Petitioner

-vs-

GLAXOSMITHKLINE INC., a legal person, having its principal place of business at 7333 Mississauga Rd, Mississauga, ON L5N 6L4, Canada;

-and-

GLAXOSMITHKLINE PLC, a legal person, having its principal place of business at 980 Great West Road, Brentford, England, TW8 9GS, United Kingdom;

Respondents

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

IN SUPPORT OF HIS MOTION FOR PERMISSION TO INSTITUTE A CLASS ACTION AND OBTAIN THE STATUS OF A REPRESENTATIVE, PETITIONER RESPECTFULLY SUBMITS AS FOLLOWS:

GENERAL PRESENTATION

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

> "Any person in Quebec, including their estates, executors, personal representatives, their dependants and family members, who were prescribed and ingested Avodart and suffered from high-grade prostate cancer, breast cancer, or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility".

(hereinafter, referred to as the "**Group Member(s)**", the "**Group**", the "**Class**", the "**Member(s)**");

2. The Respondent GlaxoSmithKline plc, a corporation incorporated pursuant to the laws of the United Kingdom, is the parent company of GlaxoSmithKline Inc. as well as dozens of other foreign subsidiaries bearing the GlaxoSmithKline brand;

3. The Respondent GlaxoSmithKline Inc., a private company incorporated pursuant to the laws of Ontario, is a wholly-owned subsidiary of GlaxoSmithKline plc;

4. Respondents GlaxoSmithKline plc and GlaxoSmithKline Inc. are hereinafter collectively referred to as "**GSK**", unless specified otherwise, and include any subsidiaries, affiliates, predecessors or related companies;

5. GSK at all material times carried on business as a partnership, joint venture or other common enterprise inextricably interwoven with each other, making each Respondent vicariously liable for the acts and omissions of the others;

6. GSK research, develop, design, test, manufacture, label, package, supply, market, sell, advertise, and distribute various pharmaceutical products worldwide, including dutasteride, under the brand name "Avodart" in Canada;

7. Avodart was approved for sale in Canada by Health Canada on or around November 14th, 2003;

8. GSK marketed Avodart for the treatment of prostate problems including benign prostatic hyperplasia ("**BPH**");

9. BPH is a common condition thought to be caused by a combination of genetic factors, and a hormone called 5a-dihydrotestosterone ("**DHT**"). Dutasteride and finasteride are categorized as a 5-alpha reductase inhibitors ("**5-ARI**");

10. 5-ARIs are synthetic compounds that inhibit the conversion of testosterone to DHT. and thus lowers DHT levels which leads to a reduction in prostatic volume, thereby treating an underlying cause of BPH; dutasteride inhibits two of the three isoforms of 5-alpha reductase, I and II, whereas finasteride only inhibits type II;

11. 5-ARIs can cause a number of serious side effects, including but not limited to:

    a) temporary and permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile impotence, and infertility;

    b) breast cancer;

    c) high-grade prostate cancer;

12. From when they introduced Avodart into the Canadian market, GSK knew or ought to have known that Avodart can cause, contribute to, or increase the risk of high-grade prostate cancer; breast cancer; or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility, based on:

    a) medical and scientific journals, studies, and trials;
    b) post-marketing adverse drug reaction reports;
    c) scientific knowledge of a biologically plausible mechanism associated with the group of drugs to which Avodart belonged;
    d) scientific knowledge of side effects associated with the group of drugs to which Avodart belonged; and
    e) other evidence to be presented at trial.

13. However, the Respondents failed to disclose in the product monograph a clear, complete, and current warning in all appropriate sections that:

    1) Avodart can cause, contribute to, or increase the risk of high-grade prostate cancer; breast cancer; or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility; and

    2) scientific analysis of post-marketing adverse events reports in patients who used Avodart, or similar drugs which lower DHT in a similar manner to Avodart, was conducted and revealed that Avodart can cause the previously described serious side effects.

14. Numerous studies warn that men have experienced sexual dysfunction as a persistent side-effect while using, and even after discontinuing, use of Avodart;

15. For instance, in 2011, in an article published in the Journal of Sexual Medicine, "Adverse Side Effects of 5a-Reductase Inhibitors Therapy: Persistent Diminished Libido and Erectile Dysfunction and Depression in a Subset of Patients", communicated herewith as **exhibit P-1,** the authors reviewed the subject and concluded that:

> "5-ARIs therapy, while improving urinary symptoms in patients with BPH and may prevent hair loss, produce significant adverse effects in some individuals including loss of libido, ED (erectile dysfunction), ejaculatory dysfunction, and potential depression. *They are serious enough to preclude them from pursuing such therapy."* (our emphasis)

16. In a 2014 article of the Korean Journal of Urology, "The Dark Side of 5a-Reductase Inhibitors' Therapy: Sexual Dysfunction, High Gleason Grade Prostate Cancer and Depression", communicated herewith as **exhibit P-2,** the authors reviewed evidence from major clinical trials in the 2000s. They concluded that "(...) the data from a number of clinical studies (...) clearly show that in some patients, treatment with 5a-RIs diminished libido, erectile, and ejaculatory function";

17. On January 21, 2013, GSK updated its product monograph (communicated herewith as **exhibit P-3)** to mention that Avodart can cause, contribute to, or increase the risk of sexual dysfunction that may persist after the cessation of treatment with Avodart;

18. In July 2003, the results of a large-scale clinical trial (the Prostate Cancer Prevention Trial, "**PCPT**") were published in the New England Journal of Medecine, in an article entitled "The Influence of Finasteride on the Development of Prostate Cancer", communicated herewith as **exhibit P-4**. In this article, the authors linked finasteride (a drug of the same group as dutasteride) to an increased risk of high-grade prostate cancer;

19. High-grade prostate cancer is a very aggressive type of cancer that grows and spreads quickly (see for instance Peter A Humphrey's article published in the Journal of Modern Pathology in 2004, entitled "Gleason Grading and Prognostic Factors in Carcinoma of the Prostate", communicated herewith as **exhibit P-5);**

20. In April 2010, the results of a large-scale clinical trial involving dutasteride (the REDUCE trial) were published also in the New England Journal of Medicine, under the title "Effect of Dutasteride on the Risk of Prostate Cancer", communicated herewith as **exhibit P-6.** In this article, the authors linked dutasteride with an increased risk of high-grade prostate cancer;

21. The purpose of the two clinical trials was to provide evidence in support of a new use for finasteride and dutasteride: to prevent prostate cancer;

22. In fact, GSK had been for many years pursuing global approval for the use of Avodart to reduce the risk of prostate cancer;

23. Notwithstanding the results of the above mentioned trials, and of an important body of scientific commentary on those studies, GSK did not include a clear warning of the risk of high-grade prostate cancer on their product;

24. In December 2010, an FDA advisory panel (in the U.S.) reacted to the PCPT and REDUCE trials by refusing proposals by Defendant and Merck & Co. to allow 5-ARIs to

be used to reduce the risk of prostate cancer;

25. In March 2011, GSK stated that they will no longer pursue global approval (marketing authorization) for the use of Avodart to reduce the risk of prostate cancer;

26. On March 12, 2012, Health Canada issued an alert to health professionals and the public that finasteride and dutasteride may be associated with "an increased risk of developing a serious form of prostate cancer known as high-grade prostate cancer", the whole as it appears more fully in the text of this alert, communicated herewith as **exhibit P-7;**

27. Notwithstanding GSK's numerous updates to their product monographs over the years, and what they knew or ought to have known about Avodart and its potential side effects and health risks, GSK negligently continued to market Avodart without clear, complete, and current warnings that Avodart can cause, contribute to, or increase the risk of high-grade prostate cancer; breast cancer; or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

28. The Petitioner, Pierre Vachon, is a resident of Repentigny, Quebec;

29. In the Fall of 2007, the Petitioner visited Dr. Daniel Pharand because he was having difficulties urinating. He was 67 years old;

30. Dr. Pharand diagnosed the Petitioner with Benign Prostatic Hyperplasia and in December 2007 prescribed Petitioner finasteride at a dose of 5mg per day.

31. From December 2007 Petitioner began taking finasteride;

32. In December 2011, Petitioner stopped taking finasteride and was prescribed dutasteride (Avodart), at a dose of 0.5mg per day, by Dr. Pharand, and later by Dr. Adams;

33. After regular Prostate-Specific Antigen (PSA) blood tests showed a continual and dramatic rise in his PSA level, the Petitioner had biopsies of his prostate in August 2011 and May 2012; both biopsies yielded negative results for cancer;

34. In July 2012, a new biopsy revealed that the Petitioner had localized prostate cancer;

35. At the time, Petitioner had been taking 5-ARI drugs without interruption for more than four and a half years, the whole as it appears more fully in the Petitioner's pharmaceutical records, communicated herewith as **exhibit P-8**;

36. Petitioner had no family history of prostate cancer;

37. In October 2012 Petitioner was informed by Dr. Pharand for the first time of his prostate cancer;

38. Petitioner was offered all treatment options, both curative and surgical;

39. In February 2013, Petitioner visited Dr. Kevin C. Zorn, a uro-oncologist, who, recommended surgical removal of the affected prostate in view of the risk associated with the Petitioner's condition;

40. In February 2013, Petitioner stopped taking Avodart;

41. In May 2013, Mr. Vachon underwent surgical removal of his prostate;

42. In September 2013, Petitioner met with Dr. Zorn to follow-up with his condition and his PSA level had improved;

43. In 2014, Petitioner's PSA level began to climb again and cancer was detected once again in January 2015;

44. Between February and March 2015, Petitioner had 30 sessions of radiotherapy to treat the area surrounding his former prostate;

45. Had the Petitioner been made aware of the increased risk of prostate cancer before he began taking the 5 ARIs, he would not have taken these medications;

46. The damages suffered by the Petitioner are a direct and proximate result of the Respondents' conduct;

47. As a consequence of the foregoing, the Petitioner is justified in claiming damages;

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

48. Consumers reasonably relied and rely upon the Respondents to ensure that Avodart is safe for human consumption and that all potential health risks are properly warned, such as an increased risk of high-grade prostate cancer, breast cancer, and permanent forms of sexual dysfunction, including but not limited to, reduced sex drive, erectile dysfunction, and infertility;

49. The negligence and misrepresentations of the Respondents were a direct and proximate cause of the injuries and damages suffered by Group Members;

50. As a result of the Respondents' faults described herein, Group Members have suffered and claim damages for the following :

a) compensatory damages as may be proved in this Honourable Court for:

(i) personal injury or death;
(ii) economic loss;

(iii) pain and suffering;
(iv) loss of income and earning capacity;
(v) loss of amenities and enjoyment of life;
(vi) loss of guidance, care and companionship;
(vii) costs of future care and related expenses;

b) exemplary and punitive damages;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

The composition of the group makes the application of Article 59 or 67 C.C.P. impractical or impossible for the reasons detailed below:

51. The number of potential Group Members is so numerous that joinder of all Members is impracticable. While the exact number of Group Members is unknown to Petitioner at the present time and can only be ascertained from sales and distribution records maintained by the Respondents and their agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Quebec;

52. Based on the number of potential Group Members, it is impossible for the Petitioner to identify all potential Group Members and obtain a mandate from each of them;

53. 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 Group Members themselves could afford such individual litigation, the Court system could not as it would be overloaded;

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

The questions of fact and law which are identical, similar, or related with respect to each of the Group Members:

55. The recourses of the Group Members raise identical, similar or related questions of fact or law, namely:

a. Does the ingestion of Avodart cause, contribute, or materially increase the risk of: high-grade prostate cancer; breast cancer; or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility?

b. Were the Respondents negligent in designing, developing, testing, distributing, marketing, or selling Avodart?

c. Were the Respondents negligent in the designing, developing, and testing of Avodart by failing to have adequately tested, researched, and monitored Avodart, and

failing to discover that Avodart can cause, contribute to, or materially increase the risk of high-grade prostate cancer, breast cancer, or sexual dysfunction?

d. Did Respondents adequately inform the medical community and consumers of the risks associated with the ingestion of Avodart?

e. Are Respondents liable to pay compensatory damages to the Group Members, and if so, in what amount?

f. Are Respondents liable to pay moral damages to the Group Members, and if so, in what amount?

g. Are Respondents liable to pay punitive or exemplary damages to the Group Members, and if so, in what amount?

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

56. The action that the Petitioner wishes to institute for the benefit of the members of the Group is an action in damages for product liability;

57. The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings are:

GRANT Petitioner's action against the Defendants;

CONDEMN Respondents to pay an amount in compensatory damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in moral damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

ORDER the treatment of individual claims of each member of the group in accordance with Articles 1037 to 1040 C.C.P.;

THE WHOLE with interest and additional indemnity as provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members;

58. Petitioner suggests that this class action be exercised before the Superior Court in the District of Montreal for the following reasons:

(a) The Respondents sell Avodart in the District of Montreal;

(b) Many Group Members are domiciled in the District of Montreal;

(c) The Respondents have a business establishment in the District of Montreal;

(d) The Petitioner's legal counsel is domiciled in the District of Montreal;

59. The Petitioner, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the Members of the Group, since Petitioner:

(a) took Avodart and was diagnosed with prostate cancer;

(b) understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;

(c) is available to dedicate the time necessary for the present action before the Courts of Quebec and to collaborate with Group attorneys in this regard;

(d) is ready and available to manage and direct the present action in the interest of the Group Members that the Petitioner wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Group;

(e) does not have interests that are antagonistic to those of other members of the Group;

(f) has given the mandate to the undersigned attorneys to obtain all relevant information to the present action and intends to keep informed of all developments;

(g) is, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Members of the Group and to keep them informed;

60. 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;

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

"Any person in Quebec, including their estates, executors, personal representatives, their dependants and family members, who were prescribed and ingested Avodart and suffered with high-grade prostate cancer, breast cancer, or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility."

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

(a) Does the ingestion of Avodart cause, contribute, or materially increase the risk of: high-grade prostate cancer; breast cancer; or permanent forms of sexual dysfunction, including but not limited to reduced sex drive, erectile dysfunction, and infertility?

(b) Were the Respondents negligent in designing, developing, testing, distributing, marketing, or selling Avodart?

(c) Were the Respondents negligent in the designing, developing, and testing of Avodart by failing to have adequately tested, researched, and monitored Avodart, and failing to discover that Avodart can cause, contribute to, or materially increase the risk of high-grade prostate cancer, breast cancer, or sexual dysfunction?

(d) Did Respondents adequately inform the medical community and consumers of the risks associated with the ingestion of Avodart?

(e) Are Respondents liable to pay compensatory damages to the Group Members, and if so, in what amount?

(f) Are Respondents liable to pay moral damages to the Group Members, and if so, in what amount?

(g) Are Respondents liable to pay punitive or exemplary damages to the Group Members, and if so, in what amount?

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

GRANT Petitioner's action against the Defendants;

CONDEMN Respondents to pay an amount in compensatory damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in moral damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to every Group Member, amount to be determined by the Court, plus interest as well the additional indemnity;

ORDER the treatment of individual claims of each member of the group in accordance

with Articles 1037 to 1040 C.C.P.;

THE WHOLE with interest and additional indemnity as provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members;

DECLARE that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

FIX the delay of exclusion at 60 days from the date of the publication of the notice to the Members;

ORDER the publication of a notice to the Members of the Group in accordance with Article 1006 C.C.P.;

THE WHOLE with costs to follow.

MONTREAL, September 10 2015

Merchant Law Group LLP

MERCHANT LAW GROUP LLP

Attorneys for the Petitioner

NOTICE OF PRESENTATION

TO: **GLAXOSMITHKLINE INC**
7333 Mississauga Rd
Mississauga, ON L5N 6L4

-and-

GLAXOSMITHKLINE PLC
980 Great West Road
Brentford, England, TW8 9GS
United Kingdom

TAKE NOTICE that the Petitioner has filed this MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE THE STATUS OF REPRESENTATIVE in the office of the Superior Court of the Judicial District of Montréal.

The Motion will be presented before one of the Honourable Judges of the Superior Court of Québec, District of Montréal, on **October 14, 2015** at **9:00 AM**, in room **2.16** of the Courthouse of Montréal situated at 1 Notre Dame East, Montréal, Québec. On that date, the Court may exercise such powers as are necessary to ensure the orderly progress of the proceeding or the Court may hear the case.

Montréal, September 10, 2015

Merchant Law Group LLP

Merchant Law Group LLP
Attorneys for the Petitioner

In support of its motion, the Petitioner discloses the following exhibits:

Exhibit P-1: Copy of Traish A.M., Hassani J., Guay A.T. et al. "Adverse Side Effects of 5a-Reductase Inhibitors Therapy: Persistent Diminished Libido and Erectile Dysfunction and Depression in a Subset of Patients", J Sex Med 201; 8: 872-884;

Exhibit P-2: Copy of Traish A.M., Mulgaonkar A, Giordano N. "The Dark Side of 5a-Reductase Inhibitors' Therapy: Sexual Dysfunction, High Gleason Grade Prostate Cancer and Depression", Korean J Urology 2014; 55:367-379;

Exhibit P-3: Copy of Avodart Product Monograph, January 21, 2013;

Exhibit P-4: Copy of Thompson I.M., Goodman P.J., Tangen C.M. et al. "The Influence of Finasteride on the Development of Prostate Cancer", N Engl J Med 2003; 349:215-224;

Exhibit P-5: Copy of Humphrey, P. A. "Gleason Grading and Prognostic Factors in Carcinoma of the Prostate", J Modern Pathology, 2004; 17(3):292-306;

Exhibit P-6: Copy of Andriole G.L., Bostwick D.G., Brawley O.W. et al. "Effect of Dutasteride on the Risk of Prostate Cancer", N Engl J Med 2010; 362:1192-1202;

Exhibit P-7: "Finasteride (Proscar, Propecia) and dutasteride (Avodart, Jalyn) may increase the risk of high-grade prostate cancer", Health Canada Alert, March 19, 2012;

Exhibit P-8: Pierre Vachon's history of drug prescriptions, from January 2007 to December 2012.

DO GOVERN YOURSELF ACCORDINGLY,

Montréal, September 10, 2015

Merchant Law Group LLP

Merchant Law Group LLP
Attorneys for the Petitioner