C A N A D A

PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

N°: 500-06-000648-135

SUPERIOR COURT
(Class Action Division)

CAMILO BARATTO

Plaintiff

v.

MERCK INC.

MERCK FROSST CANADA & CO

Defendants

APPLICATION TO OBTAIN THE MEDICAL RECORDS, AND TO ALLOW THE MEDICAL AND PRE-TRIAL EXAMINATIONS OF SELECTED CLASS MEMBERS

By the Defendants — November 20, 2020

(Art. 587 C.C.P.)

TO THE HONOURABLE CHRISTINE BAUDOUIN, J.S.C., SITTING AS CASE MANAGEMENT JUDGE HEREIN, THE DEFENDANTS SUBMIT THE FOLLOWING:

I. INTRODUCTION

1. By a decision dated July 26, 2018 herein, the Court of Appeal reversed a judgment of the Honourable Claude Dallaire, J.C.S., and authorised the Plaintiff ("**Baratto**"[1]) to institute a class action against the Defendants (collectively, "**Merck**") on behalf of the following class, as modified by Baratto's counsel during the argument before the Court of Appeal [our translation]:

> [TRANSLATION]
>
> All persons residing in Quebec who were prescribed Propecia and/or Proscar for the treatment of common

[1] In accordance with legal usage and for the sake of brevity, the plaintiff will be referred to as "Baratto" herein, no disrespect being intended in that regard.

> baldness before November 18, 2011 and who developed at least one of the following conditions, which persisted following discontinuance of use:
>
> - Sexual dysfunction;
> - Decreased libido;
> - Erectile dysfunction;
> - Ejaculatory disorders;
> - Decreased volume of ejaculate;
> - Shrinking of the genitals;
> - Gynecomastia;
> - Testicular pain;
> - Anhedonia and difficulty reaching orgasm; or
> - Depression.

as appears from the judgment of the Honourable Claude Dallaire, J.C.S., communicated herewith as **Exhibit R-1** and from the decision of the Court of Appeal communicated herewith as **Exhibit R-2**.

2. The class is therefore limited to persons, in fact men, who meet all of the following conditions:

a) they reside in Quebec; and

b) they were prescribed Propecia and/or Proscar, that is, not a generic version of finasteride manufactured by a third party; and

c) they received this prescription for the treatment of common baldness (alopecia), that is, not for the treatment of benign prostatic hyperplasia (“BPH”), a condition that typically affects older men who would be prescribed Proscar containing five times the amount of finasteride compared with Propecia tablets, which are prescribed to typically younger men suffering from alopecia (5 mg per day *v.* 1 mg per day); and

d) they received this prescription before November 18, 2011, a date chosen because of a modification in the Propecia/Proscar product monograph as of that date. Thus, any man who got a prescription of Propecia or Proscar for the treatment of alopecia after that date is excluded from the class, and

no claim may be brought for any such prescription obtained after that date; and

e) they developed at least one of the allegedly related sexual or psychological conditions described above which persisted following discontinuance of use, and therefore only includes men (i) who developed one or more of the sexual or psychological conditions described above while using Propecia or Proscar; and (ii) who interrupted the treatment; and (iii) whose said conditions, which started while they were using the medication, persisted following the date on which they stopped using it, for a minimum period of time that has yet to be determined (Baratto having never supplied a definition of what "persistence" should mean in that context).

3. The Court of Appeal identified the main factual and legal issues to be addressed collectively as follows [our translation]:

> **IDENTIFIES** as follows the main factual and legal issues to be addressed collectively:
>
> a) Are the following health risks associated or caused by the use of Propecia or Proscar:
>
> - Sexual dysfunction;
> - Decreased libido;
> - Erectile dysfunction;
> - Ejaculatory disorders;
> - Decreased ejaculate volume;
> - Shrinking of the genitals;
> - Gynecomastia;
> - Testicular pain;
> - Anhedonia and difficulty reaching orgasm, or;
> - Depression.
>
> b) If so, can these risks persist after cessation of use?
>
> c) Have the respondents adequately and sufficiently informed the class members of these risks and of the risk that they will persist after cessation of use?

d) Did the respondents know or should they have known the risks associated with the use of Propecia and Proscar?

e) Did the Respondents breach their obligations to conduct adequate clinical trials before and after the sale of Propecia and Proscar?

f) Did the Respondents commit a fault engaging their civil liability?

as appears from the decision of the Court of Appeal, Exhibit R-2.

4. The Court of appeal identifies the conclusions sought in the class action as follows [our translation]:

> **IDENTIFIES** the conclusions sought in the class action as follows:
>
> a) **ALLOW** the class action for the Plaintiff and each class member;
>
> b) **ORDER** Merck, solidarily, to pay to the Plaintiff an amount of at least $100,000, which can be adjusted, in compensation for the physical, psychological and moral damages suffered, as well as for past and future care costs, with interest at the legal rate plus the additional indemnity since the assignation;
>
> c) **ORDER** Merck, solidarily, to pay to each of the other class members an amount to be determined in compensation for the physical, psychological and moral damages suffered, as well as for the loss of income and the costs of past and future care, the whole with interest at the legal rate plus the additional indemnity since the assignation;
>
> d) **ORDER** Merck, solidarily, to pay to each of the class members an amount of $10,000, which can be adjusted, as punitive damages, the whole with interest at the legal rate plus the additional indemnity since the assignation;

e) **ORDER** the collective recovery of the class members' claims for non-pecuniary damages if the evidence allows same;

f) **ORDER** the collective recovery of class members' claims for punitive damages;

g) **ORDER** the collective recovery of class members' claims for pecuniary damages if the evidence allows same and, alternatively, **ORDER** the individual recovery of the class members' claims for pecuniary damages;

h) **WITH COSTS**, including the cost of notice and all experts' reports;

5. Although Baratto makes serious allegations against Merck, and although he initiated his proceedings seven years ago, that is, on April 8, 2013, over the course of these proceedings he has never filed any expert report supporting his claim that Proscar and Propecia could cause the persistent sexual or psychological adverse events described above, and explaining the basis upon which this claim would rest.

6. On July 17, 2019, Baratto filed the Originating Application herein, as appears from the Court record.

7. Merck is well founded in fact and in law to request that Baratto, a selection of ten class members (the "**Selected Members**"), and any other class member who Baratto intends to call as a witness at the common issues trial, be ordered to communicate to Merck their relevant medical, counselling and pharmaceutical records, and that Merck be allowed to subject Baratto and the said class members to medical and pre-trial examinations, the whole as more fully described in the conclusions to this application.

II. MERCK'S APPLICATION TO RECEIVE THE MEDICAL, COUNSELING AND PSYCHOLOGICAL RECORDS OF SELECTED CLASS MEMBERS, AND TO SUBJECT SAME TO MEDICAL AND PRE-TRIAL EXAMINATIONS

8. The allegedly "persistent" sexual and psychological symptoms raised by Baratto herein are prevalent among men and constitute highly individualized and multifaceted phenomena. A host of physical, psychological and social factors must be analyzed in each case to determine what may have caused or contributed to such symptoms, as described more fully below.

9. Baratto's case is a prime example of the highly individualized nature of his alleged symptoms. He had pre-existing physical and psychological conditions associated with these symptoms; there were environmental stressors and confounding factors in his life contemporaneously to his consumption of finasteride; and he consumed other medications that could contribute to his reported symptoms both during and after his consumption of finasteride, as described more fully below.

10. Baratto himself does not even claim to have experienced several of the persistent adverse reactions allegedly caused by finasteride, which were only included in the class definition during the hearing on appeal, namely: decreased volume of ejaculate, shrinking of the genitals, gynecomastia, and anhedonia. Thus, evidence provided by other class members is necessary with respect to these alleged symptoms.

11. The Originating Application includes exhibits composed of purportedly scientific articles, commentaries, literature reviews and meta-analyses that discuss finasteride but do not establish nor purport to establish that finasteride can cause or even contribute to the appearance of the persistent symptoms alleged by Baratto, for the reasons discussed below.

12. Contrary to these materials, Merck's evaluation of finasteride's safety was based on randomized, placebo-controlled and double-blind clinical studies with large

sample sizes, which show that adverse events reported during the use of finasteride by a small percentage of participants resolved upon discontinuation of therapy.

13. Baratto's counsel have confirmed that they wish to produce certain class members as witnesses at the hearing, without Merck having had an opportunity to review their medical records beforehand, to subject them to medical examinations, and to examine them on discovery. This would be unfair to Merck and in violation of the fundamental principles of procedure.

14. It is appropriate and necessary for this Court to order ten class members (the "**Selected Members**"), as well as any other class member or members that Baratto wishes to call as witnesses at the hearing, to communicate their relevant medical, counselling and pharmaceutical records, to undergo a medical examination by experts selected by Merck, and to be subject to a pre-trial examination regarding issues relevant to their alleged persistent adverse reactions for the following reasons.

15. First, as a matter of fairness, the Court should not just hear the circumstances of the class members whom the Plaintiff's counsel selects for the trial, but should hear about some who will be selected in an open manner under the supervision of this Court. This would give the Court better insight into the highly variable facts and circumstances the class members present.

16. Second, as the Plaintiff cannot point to any clinical trial data to support his claims, virtually his entire case that finasteride can cause persistent sexual dysfunction is based on voluntarily reported, unverified adverse experience reports that can be made by anyone. As described more fully below in Section VI, these adverse experience reports are subject to many limitations. Evidence from the Selected Members would provide the Court with insight based on real life examples into how unreliable the adverse experience reports can be, and specifically would provide important illustrations of the principle that the mere fact that an adverse experience is reported after use of a medication does not mean that the medication caused the adverse experience. Adverse experience reports are made by people like the

Selected Members and the Defendants submit that the evidence will show that there are numerous reasons other than finasteride that will explain the conditions that the Selected Members are alleging.

17. Third, the Defendants submit that the evidence will show that there are numerous reasons other than finasteride that will explain the conditions that the Selected Members are alleging would provide real life illustrations to support the expert testimony concerning the many causes and highly individualized nature of sexual dysfunction.

18. Fourth, evidence from the Selected Members would assist the Court in answering the common questions about general causation in the event the Court (contrary to the Defendants' position based on the reliable scientific evidence) determines that it cannot exclude some hypothetical possibility that finasteride could cause one or more of the alleged persistent effects in some hypothetical class member. The evidence from the Selected Members would support the Defendants' alternative argument that the Court should answer the questions by stating that the Court could never conclude on the balance of probabilities (even assuming a hypothetical general effect) that finasteride caused any individual class member's individual injuries due to the highly subjective, individualized nature of the conditions the class members assert and the many possible alternative causes of those conditions.

19. Fifth, evidence from the Selected Members would inform the Court's consideration of the shape of any remedies phase, which the Defendants submit (and which the Plaintiff's counsel admitted at the November case conference), would require full trials on specific causation (whether finasteride, as opposed to other alternative causes, caused the specific class member's alleged injuries) as well as many other issues including, as just some examples: what information the individual class member requested and received upon being prescribed finasteride; whether the class member followed the instructions provided by the Defendants and/or the

class member's doctor in taking the medicine; whether the class member had "persistent" adverse conditions; and the fact and amount of damages.

20. In this regard, the Court of Appeal noted that the judge on the merits will need to implement appropriate "measures" and "modalities" at any recovery stage in order to account for differences that could exist between class members (at paragraph 72 of the decision). With respect, the Defendants reiterate that any such recovery process would be exceedingly complex given the variety and the highly individualized nature of the persistent sexual and psychological symptoms alleged herein. It is thus necessary for this Court to be presented with concrete examples of these individual differences in order to determine if such "measures" and "modalities" can be put in place and, in the affirmative, which "measures" and "modalities" should be put in place in that regard.

21. Sixth, evidence from the Selected Members would demonstrate that no form of collective relief is possible because the individualized nature of each class member's claim would require a full trial on each of their individualized circumstances.

22. Merck proposes that the Selected Members be determined by mutual agreement of the parties or, if such an agreement cannot be reached, by this Court.

23. In the event that a Selected Member or a proposed witness refuses to participate in the above-mentioned measures, Merck requests that this Court bar such person from providing testimony herein.

24. Several men who have registered on the website of Baratto's counsel have confirmed that they are willing to testify in the context of these proceedings.

III. PREVALENCE AND MULTIFACETED NATURE OF ERECTILE DYSFUNCTION

25. An affidavit by Dr. Lynn Stothers, Professor in the Department of Urological Sciences at the University of British Columbia with cross appointments in the School of Public Health and in the Department of Obstetrics and Gynecology at the said university, and a licensed physician in British Columbia, was filed by consent at

the authorization stage herein, as appears from the said affidavit dated December 18, 2015, communicated herewith as **Exhibit R-3**.

26. Dr. Stothers addressed several issues that are relevant to the class action and to this application, including issues related to sexual dysfunction in men generally and to erectile dysfunction ("**ED**") in particular, and to the psychological symptoms alleged herein.

A. Prevalence of ED

27. ED is a man's consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual activity. A three-month minimum duration of symptoms is accepted for establishment of the diagnosis.

28. As confirmed by Dr. Stothers, the prevalence of ED among males less than 40 years of age is reported in the range of 10 %. This means that whether or not a man who used Proscar or Propecia also experienced ED (in whatever sequence) is no indication one way or the other respecting an association with the use of the medication, much less that it would be caused by the medication, because a significant percentage of men, including men who used Proscar or Propecia, will experience ED in any event.

29. In fact, Baratto's claim that the symptoms he alleges would persist notwithstanding the cessation of treatment (while hair loss resumes after the treatment is interrupted) leads to the <u>contrary</u> inference that these symptoms <u>are not</u> related, much less caused, by the medication, since according to Baratto these symptoms occur whether or not class members are still using the medication.

B. Physical and Psychosocial Issues that Cause or Contribute to ED

30. As confirmed by Dr. Stothers, several physical and psychosocial issues cause and contribute to ED. A key point related to the pathophysiology of ED is that ED is a symptom of many underlying causes and diseases.

31. Various physical factors can interfere with the mechanism of erection in men. Each has an associated odds ratio, which is a measure of association between exposure to a certain factor and the risk that the condition will develop in the future.

32. The most common physical risk factors that indicate that a patient currently does or will in the future experience ED and their respective odds ratio are as follows: antidepressant use (9.1); use of antihypertensive drugs (4.0); diabetes (2.9); obstructive lower urinary tract symptoms (2.2); smoking (1.6); high blood pressure (1.6); prostate enlargement (1.6); body mass index greater than 30 kg/m^2 (1.5); and cardiovascular disease (1.1).

33. Authors have also noted that the use of corticosteroids (such as prednisone, used by Baratto, as further discussed below) can cause ED. Other factors such as elevated cholesterol and physical inactivity can also contribute to ED. Up to 25% of patients may be taking a drug that has been associated with ED during the period of use (such as Baratto who used an antidepressant, as further discussed below).

34. There are also many psychological factors and interpersonal relationship issues that can contribute to ED. They include relationships with past and present partners; relationship distress; family life; financial distress; work-related stress; feelings of guilt or shame; past sexual trauma; depression; and other mental illnesses. Contextual factors such as religion, culture and societal norms can also contribute to ED.

C. Diagnosing ED and Assessing Potential Causes

35. As confirmed by Dr. Stothers, the evaluation of ED and understanding of its underlying cause or causes in a patient requires a thorough history and physical examination of the patient. The physical examination is necessary as it may reveal possible etiologies, or causes, for ED. It is evaluated on an individual basis and this precludes diagnosis on a common basis, as too many factors come into play, both as potential causes and in the diagnosis of the condition.

36. The history related to ED involves the reporting by the patient, or the partner, or the patient and partner together, of difficulty attaining or maintaining an erection sufficient to permit sexual intercourse. Components of the history required include the sexual and psychosocial history and anatomic features, including penile curvature with erection and morning erections. The sexual history includes the duration for which symptoms have been present, the conditions in which they were observed, and any exacerbating or facilitating circumstances (partner specific/situation circumstances, performance anxiety).

37. In addition to the age of the patient, an important component of the history also includes a history of medical comorbidities and risk factors for ED, in particular the vascular, neurologic and endocrine systems need to be reviewed. These comorbidities a medical history of diabetes, high blood pressure, cardiovascular disease, neurologic disease (spinal cord injury, traumatic or non-traumatic, traumatic brain injury), and surgical history including any related to the cardiovascular system, neurologic system, pelvic area, genitalia or prior cancer therapy.

38. Symptom scores, which are questionnaires patients self-complete, are commonly employed as part of an individual patient's case history. They may be used over time to document features of the ED and response to therapy. There are a number of these which have been validated for use in ED, and a commonly employed one is the *International Index of Erectile Function*, which is used to classify ED from "not present" through "severe."

39. Physical exam includes height, weight (calculation of body mass index), blood pressure, presence of secondary sexual characteristics, and neurologic and genital exam including palpation for penile plaques.

40. Following history and physical examination, a list of potential etiologies is derived in a given individual. In the absence of organic risk factors, a primary psychogenic ED causation may be suspected. ED may be classified as organic (neurologic or cardiovascular condition present in the patient), psychogenic or mixed etiology. In

the latter the physician may determine that there are both organic and psychogenic contributors in a given patient.

41. Further tests are ordered in an effort to differentiate the organic and psychological components. However, despite a thorough evaluation, the clinician may not be able to conclusively determine the etiology or may recognize contributions of more than one etiology in an individual.

42. Laboratory testing in patients with ED is used to rule in or out certain conditions on an individual basis. Recommended tests in the setting of ED often include blood examination of fasting glucose, chemistry, lipid profile and testosterone. Thyroid levels are ordered if there is clinical suspicion of thyroid disease.

43. Specialized tests for organic ED are available and are typically employed during specialist evaluation of ED. These are used to examine the vascular system in an effort to demonstrate an organic problem with the arteries or veins. Tests such as nocturnal penile tumescence measure tumescence and rigidity of the penis and have been used to help differentiate organic causes from psychogenic causes through objectively evaluation using non-invasive means.

44. It is reported by the American Urological Association's guidelines on ED that psychological overlay is common in ED. Hence, assessment by a psychologist or psychiatrist to evaluate psychologic contributions to ED should be sought as well. Features that are reported to be more commonly associated with psychogenic ED include situational symptoms, sudden onset of symptoms, and the presence of morning erections.

45. Psychological evaluation is helpful to examine for psychological and partner/social situations that can contribute to a greater or lesser extent in an individual case of ED. The interview includes exploring details of sexual partner relationships, traumatic life events, cultural and religious concerns. Professionals in psychology and psychiatry typically perform these evaluations.

46. In light of the foregoing, Dr. Stothers confirms that the diagnosis and assessment of ED can only be done on an individual basis, as a thorough evaluation is required to establish contributing factors in individuals and as specialized tests need to be performed on individual patients.

IV. SUPPORT MATERIALS PROVIDED BY BARATTO, CLINICAL STUDIES PERFORMED BY MERCK, AND OTHER SCIENTIFIC LITERATURE

47. Dr. Stothers reviewed the 16 purportedly “scientific” articles submitted by Baratto in support of his allegations at the authorization stage, 13 of which he also files as exhibits in support of his Statement of Claim.

48. For the reasons more fully explained in her affidavit, Dr. Stothers concludes that most raise significant concerns as to the methodology followed, such that their findings are not reliable, and that causation for persistent ED, anxiety and depression following exposure to and subsequent discontinuation of finasteride administration is not established by these reports:

a) five do not constitute scientific studies since they are only opinions of the authors, letters or editorials or are study abstracts and do not provide sufficient information to assess the study, and thus cannot be used and are not meant to be used to establish causation;

b) three are review articles of selected literature with the same lead author and are not comprehensive systematic reviews. General review articles contain literature selected by the authors, whereas systematic reviews require a comprehensive review of the literature through a structured process which clearly relates how articles were selected and either included or excluded in the analysis. Only systematic reviews are relied upon to ensure all reliable evidence from the medical literature related to the clinical question is captured leading to objective assessment of the current stage of knowledge;

c) two are studies with severe methodological limitations such that their findings are not reliable. In these studies, participants were recruited through

Internet advertisement on the website “Propeciahelp.com”, an advocacy web forum dedicated to “spreading awareness about undocumented, unresolved Finasteride Side Effects which can persist despite discontinuing the medication, for an unknown percentage of men worldwide”. This method of selection raises major concerns of selection bias, as the men selected claimed to be “victims” of alleged Propecia side effects. There is no way to confirm that the subjects were exposed to finasteride, nor the dose each would have consumed. Telephone or Skype methods of interviewing subjects were reported in one and physical examination is not included in the evaluation; thus comorbities obtained through the physical examination such as blood pressure, measured height and weight and genital diagnosis would not be measured by the investigator;

d) one is a prospective cohort study with no control group, which is a significant limitation acknowledged by the authors. The lack of a control group limits the ability to exclude other causes or contributing factor to ED;

e) two are very small basic science studies, with no confirmation that the subjects were exposed to finasteride:

   i) in one, subjects were recruited through Propeciahelp.com (a selection method that raises major concerns of selection bias, as discussed above), and the control group was men with phimosis (a condition present in Baratto). In a case control, cases (men who have a condition or disease) are compared to controls (men who do not have the condition or disease but who are otherwise similar); due to the control group used, this study does not support a finding in this case;

   ii) in the other, where a small number of men provided cerebral spinal fluid, subjects were recruited from the “Italian Network of Finasteride Side Effects” and include two of the same subjects from the prior

study of foreskin. The limited population size, lack of confirmed exposure to the drug and selection methods limit generalizability of the conclusions of these studies;

f) one is based on a population of men who took finasteride for the treatment of BPH, not hair loss, in an older population. The study was not designed to measure the increase in ED among those exposed to finasteride compared to a placebo group. Comparison was made between those taking finasteride to others treated with tamsulosin, a drug which has a different mechanism of action to finasteride in the treatment of BPH;

g) neither of the two remaining studies concludes that there is a causal link between finasteride and persistent ED or depression:

   i) one is a database study using data from the US FDA Adverse Events Reporting Database (that is, pharmacovigilance data): it discusses the source and limitations of this publicly available data and the authors draw no conclusion respecting finasteride as a cause of persistent ED, anxiety or depression;

   ii) the other is a meta-analysis conducted for the purpose of examining the quality of adverse events reporting in other studies. The authors indicate that “permanent sexual adverse events have yet to be established in higher quality studies, such as randomized controlled trials” and draw no conclusion respecting finasteride as a cause of persistent ED, anxiety or depression.

49. These materials contain no randomized controlled trials with blinding nor any adequately blinded prospective controlled studies in men with hair loss and documented exposure to finasteride. Individually or collectively, they do not meet the criteria required to establish that finasteride would cause persistent ED, anxiety or depression and do not establish such a causal relationship.

50. Dr. Stothers also reviewed the Propecia and Proscar clinical trials, that is, double-blind, placebo-controlled Phase III pivotal studies submitted by Merck to Health Canada. For the reasons explained in her affidavit, she concludes that Merck vigorously monitored all side effects of concern during the clinical trial phase.

51. Merck specifically monitored the presence of potential sexual side effects by having study participants complete Sexual Function Questionnaires included as part of the Case Report Forms. The Case Report Forms were administered by nurses who were blinded (that is, they did not know whether a patient was on treatment or placebo), so there is not ability of the nurses to bias the test results.

52. In Dr. Stothers' opinion, the Case Report Forms utilized by Merck were a reliable and scientific method of studying side effects, which minimized side effect reporting bias. The Study Protocols and Case Report Forms demonstrate that Merck was actively seeking to report the existence of all side effects and the persistence of any side effects during the clinical trial phase.

53. The randomized double-blind, placebo-controlled trials undertaken by Merck are regarded as the gold standard of clinical research. In Dr. Stothers' opinion, the Phase III studies undertaken by Merck were well-designed, high powered (having a large number of participants) and long term in duration.

54. The medical evidence provided by these studies is of the highest quality and the most scientifically valid evidence, and they do not support Baratto's claim that sexual side effects persist after discontinuation of treatment.

55. Finally, Dr. Stothers conducted her own independent review of the scientific literature on the Cochrane database, which reports systematic review articles using the principles of evidence-based medicine, and using the Oxford levels of evidence to identify scientific literature showing a potential association between finasteride and anxiety or depression, finasteride and ED, and finasteride and symptoms forming part of the general category of "sexual dysfunction".

56. Her review did not reveal any evidence from scientific articles that would suggest a causal relation between the use of finasteride and persistent ED, anxiety or depression founded on the applicable scientific principles.

57. Dr. Stothers concludes that the scientific literature submitted by Baratto, the clinical trials conducted by Merck, and her own independent review of the available scientific research have not shown any evidence supporting general causation of persistent ED, anxiety or depression by finasteride following discontinuation of treatment.

V. METHODOLOGY TO DETERMINE GENERAL CAUSATION IN A COMMON ISSUES TRIAL

58. Dr. Stothers was also asked to assess whether, in light of the scientific literature she reviewed, there is a methodology that could be used to determine general causation in the context of a common issues trial. She notes that ED and its complex nature of comorbidities makes generalizability to the population at large very difficult. Standard reference textbooks in urology indicate that:

> It is importantly recognized that medications may affect other components of the male sexual response cycle including sexual desire, arousal, and orgasm, which secondarily hampers erectile function. Of additional importance, the assignment of causation of ED for any particular medication is conditional, requiring that an increased prevalence exists in the target population compared with the placebo group after stratification for known risk factors or compared with another drug with an equivalent therapeutic effect, and further, a credible physiologic mechanism should be established experimentally.
>
> (*Campbell-Walsh Urology,* 10th Edition, Wein, Kavoussi, Novick, Partin, Peters, Saunders Elsevier Publisher, Copyright 2012).

59. The available scientific evidence including well-controlled clinical trials does not support a conclusion that finasteride is capable of causing persistent ED, depression or anxiety. This is confirmed by two of the studies submitted by Baratto in which the authors state that additional placebo-controlled randomized studies would need to be conducted to support a claim of general causation of finasteride to persistent ED, anxiety or depression. The study criteria would need to incorporate the principles such as suggested in reference textbooks on the matter: prospective, randomized, include a placebo, and include stratification and design principles related to risk of erectile dysfunction, anxiety and/or depression.

60. As stated above, Baratto has not provided any studies meeting these criteria, and Dr. Stothers' own review of the existing literature has not revealed any such evidence supporting causation of finasteride to persistent ED, anxiety or depression. In this context, Dr. Stothers is of the opinion that the existing scientific literature does not allow for a determination of general causation of persistent ED, anxiety or depression by finasteride following discontinuation of treatment.

VI. PHARMACOVIGILANCE DATA ALLEGED BY BARATTO

61. The originating application also points to post-marketing adverse event reports respecting the alleged persistent adverse reactions raised by Baratto.

62. These post-marketing reports are anecdotal, can be made by anybody, are not validated by Health Canada, and do not allow for any conclusions to be drawn regarding whether a drug caused the reported adverse event, as appears from paragraphs 87 to 100 of the affidavit of Ms. Anne Tomalin, regulatory expert in that field, filed by consent at the authorization stage, communicated herewith as **Exhibit R-4**.

63. This is clearly stated in the Proscar and Propecia Product Monographs, which have been approved by Health Canada:

> The following additional adverse reactions have been reported in post-marketing experience with PROSCAR® and/or finasteride at lower doses. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

as appears from the Proscar product monograph dated April 27, 2007 (the version that was current when Baratto consumed broken pieces of Proscar in October 2008), communicated herewith as **Exhibit R-5**, at pages 3, 10 and 20.

64. Moreover, post-marketing ADR data can be very difficult to interpret, for a number of reasons.

65. First, the Information about the ADR may be marginal. All that is required for an event to qualify as an adverse reaction is : (a) an identifiable reporter, which can be anybody, (b) an identifiable patient, (c) a suspect product (according to the reporter), and (d) an adverse reaction. These reports are not validated by Health Canada in any way. Even if there is no knowledge of what the patient was being treated for, how long he had taken the drug, whether he had taken any other drugs that might have caused the reaction, or what the dose was, the incident is considered an Adverse Reaction and should be reported as such.

66. Second, the language used to report the ADR may be ambiguous, as these reports can emanate from anybody and with different terms being used. Consider the terms, “feel lightheaded”, “feel dizzy”, “feel faint” or “hypotension”. Also consider that this information may be recorded in English or French or Portuguese, and needs to be translated across languages.

67. Third, there is no denominator that would allow the determination of an incidence rate. While the raw number of adverse reactions reported is known, the postmarketing ADR data does not include any information regarding the number of patients who used the drug or the duration of use. Although a database may have, say, 27

cases of a particular event, it is very difficult if not impossible to calculate the incidence of this event based on these reports because the number of patients who have taken the drug, in what dosages, and for which duration is unknown.

68. It is not possible to draw conclusions respecting causation for adverse events based on anecdotal postmarketing reports. Health Canada's role is to consider and evaluate ADR data in the context of other information it has about a given drug and to determine whether a measure should be adopted, for instance a change to the Product Monograph.

69. As confirmed by Ms. Tomalin, the fact is that all relevant Proscar and Propecia data submitted by Merck were reviewed by Health Canada, and each review involved a review of the Product Monographs containing Prescribing Information for healthcare professionals and Consumer Information, which were subsequently approved.

70. It is also a fact that clinical trials in approximately 8,000 men with either Proscar or Propecia, including 5-year data, more fully discussed by Dr. Stothers, showed no evidence of erectile dysfunction, decreased libido, ejaculation disorder, decreased volume of ejaculate, anxiety and/or depression continuing after treatment was stopped.

71. There have only been some *ad hoc* reports of some of these conditions occurring after the product was approved and put on the market, that is, in the pharmacovigilance data, however these reports are extremely difficult to interpret and do not establish causality for the reasons discussed above.

72. In order to determine whether a given drug has indeed caused an adverse reaction that is the object of an *ad hoc* postmarketing report, proper studies would need to be carried out, for instance controlled clinical trials.

73. As confirmed by Ms. Tomalin, Health Canada reviewed the Product Monographs for Proscar and Propecia multiple times over the years and each time approved the Product Monographs after an extensive review process.

74. No safety advisory relating to the conditions listed above has ever been posted by Health Canada, nor have these conditions been addressed in the Canadian ADR Newsletter.

75. This indicates that Health Canada was satisfied with the disclosure given at all relevant times, on the basis of the information available at the time.

VII. A CASE IN POINT: BARATTO'S CLAIM OF PERSISTENT SYMPTOMS ALLEGEDLY CAUSED BY HIS CONSUMPTION OF BROKEN PIECES OF PROSCAR FOR A ONE MONTH PERIOD BACK IN OCTOBER 2008

76. Baratto's case is a prime example of the highly individualized nature of his alleged symptoms.

77. He had pre-existing physical and psychological conditions associated with his alleged symptoms; there were environmental stressors and confounding factors in his life contemporaneously to his consumption of finasteride; and he consumed other medications which could contribute to his reported symptoms during and subsequent to his consumption of finasteride, as described more fully below.

A. Baratto's Situation

78. Baratto is a 39 year old man who, by his own account, for many years would have suffered from a variety of serious sexual and psychological issues: decreased libido, ED, troubles ejaculating, pain in the testicles, anxiety, and depression, which allegedly would persist to this day.

79. Although his medical and counselling records show a long history of medical, sexual and psychological factors that may help shed light on his condition, an Internet search has convinced Baratto that these alleged ailments are all due to the fact that, back in October 2008, when he was 28 years old, in order to help prevent his hair loss, he consumed the equivalent of 6½ tablets or 0.03 g (32 mg) of Proscar.

80. That quantity, 32.5 mg, represents Baratto's total consumption of Proscar over the course of his lifetime. To put this in context, men who are prescribed Proscar for

the treatment of BPH will consume 5 mg of the medication every day for a period of several years, often for the remainder of their life. These men consume more Proscar in one week than Mr. Baratto consumed in his entire life.

81. Proscar is not indicated for the treatment of male pattern hair loss. It is a prescription medication indicated and approved by Health Canada for the treatment of BPH in typically older men with an enlarged prostate. The Proscar product monograph includes the following statements:

> Patients with an enlarged prostate are the appropriate candidates for therapy with PROSCAR® […],
>
> Benign prostatic hyperplasia (BPH) occurs in the majority of men over the age of 50 and its prevalence increases with age […],
>
> The recommended dosage of PROSCAR® is one 5 mg tablet daily with or without food […],

as appears from the Proscar product monograph dated April 27, 2007, exhibit R-5, at pages 3, 10 and 20.

82. The prescription medicine that was approved and is indicated for the treatment of alopecia, which may affect men as early as in their 20s, such as Baratto, is Propecia. The Propecia product monograph includes the following statements:

> […] [Propecia is] indicated for the treatment of male pattern hair loss (androgenetic alopecia) in [men] who have mild to moderate scalp hair loss of the vertex and anterior mid-scalp.
>
> Clinical studies were conducted in men between 18 to 41 years of age" […] [not in elderly men (over the age of 65)],
>
> The recommended dosage is one 1 mg tablet daily […],

as appears from the Propecia product monograph dated June 24, 2006 (the version that was current when Baratto consumed broken pieces of Proscar in October 2008) communicated herewith as **Exhibit R-6**, at pages 3 and 8.

83. Although the active ingredient in Proscar and Propecia, finasteride, is the same, they are different medicines, they come in different doses, they are approved by Health Canada and indicated for different conditions, the appropriate candidates for their use are different, and they have different product monographs.

84. Baratto tampered with the Proscar tablets by breaking through the protective coating and splitting them in four pieces, presumably to approximate the dosage of Propecia tablets, thereby effectively remanufacturing the medication. Merck did not test, seek to register, label, or supply the tablets remanufactured and ingested by Baratto, and Health Canada did not authorize Proscar for the treatment of alopecia, nor Baratto's remanufacture of Proscar into an unapproved medicine comprising four presumably unequal pieces of approximately 1.25 mg each from which the film coating had been removed. Baratto, in fact, took neither Proscar nor Propecia.

B. Alleged *vs.* Actual Use of Proscar by Baratto

85. On April 8, 2013, Baratto filed an Application for the Authorisation to Launch a Class Action and to be Appointed Representative (the "**Application**"), communicated herewith as **Exhibit R-7**. The Application sought the authorization to institute a class action against Merck on behalf of the following (overbroad) class:

> [TRANSLATION] All persons residing in Quebec who were prescribed and who consumed Propecia and/or Proscar medication for the treatment of common baldness.

86. Baratto alleged, in two separate paragraphs of his Application (paragraphs 3.2 and 3.9), that starting on October 5, 2008 he used broken pieces of Proscar for a period of one year, until November 2009. This was false: after a review of Baratto's medical and pharmaceutical records, Merck's attorneys discovered he had used broken pieces of Proscar for barely one month.

87. Given that Baratto tampered with the medication and broke the Proscar tablets in four pieces, and now claims he took one broken piece a day, six days a week, by

his own account he only ever consumed the equivalent of a maximum of 6½ Proscar tablets, or 0.03 g (1.25 mg/day x 26 days ≈ 32.5 mg or 0.03 g), back in October 2008.

88. Even this reduced figure is probably inflated, the actual figure being most likely three Proscar tablets, or 15 mg, according to a formal questionnaire Baratto completed years before he filed his motion, as appears from the said questionnaire communicated herewith as **Exhibit R-8**.

89. Thus Baratto's claim is that this very limited consumption of Proscar would have caused him to suffer several self reported and undiagnosed conditions, namely, decreased libido, ED, troubles ejaculating, pain in the testicles, anxiety, and depression, which would persist to this day, many years after the medication has been eliminated from his body.

C. Pre-exposure Symptoms, Simultaneous Exposure to Finasteride and Prednisone and Other Confounders and Comorbidities

90. In his Application Baratto claimed that, before using Proscar in October 2008, he had never suffered from similar conditions (at paragraph 3.6). This was also false. Dr. Stothers reviewed the medical, counselling and pharmaceutical records provided by Baratto. The records provided by Baratto begin in January 2004, such that it cannot be determined at this stage whether any self-report of ED or mood symptoms was present before.

91. That said, Baratto's supplied medical, counselling and pharmaceutical records document several pre-exposure symptoms, simultaneous exposure to finasteride and another drug (prednisone), and other confounders and comorbidities for which he consulted health professionals before, during and after he used Proscar, including several associated with ED and psychological distress.

1) Pre-exposure Symptoms

92. Phimosis was first documented by Dr. Katsounakis, Baratto's family doctor, on January 29, 2004, and thus before Baratto's exposure to finasteride in October 2008. Phimosis is a narrowing of the opening of the foreskin of the penis, so that it cannot be retracted or is difficult to retract and can be a cause of pain or result in balanitis, an infection of the glans penis. Dr. Katsounakis' notes also include at least two notes regarding balanitis, in March 2005 and September 2007. Phimosis and balanitis can be associated with ED.

93. Starting in June 2004 and throughout Baratto's medical records, there are numerous entries related to the diagnosis of psoriasis, an immune-mediated disorder of the skin. The prevalence of depression in psoriasis patients is increased and has been reported to be greater than 10 %, along with increased frequency of anxiety. A recent study has observed a significant increase in depression and anxiety in patients with psoriasis.

94. Dr. Katsounakis' notes from September 13, 2007 include the following: "alopecia → Proscar 1.25 x 6/7, φ". This indicates that Baratto, who was complaining of male pattern hair loss, would be prescribed 1.25 mg of Proscar per day (which Dr. Stothers understands to mean a 5 mg Proscar pill broken in four pieces), 6 days per week. This is followed by the Greek symbol for the letter *phi* ("φ") which is used in medical records to depict psychological concerns, or a possible referral to a psychologist, indicating that Baratto may have suffered significant distress before his exposure to finasteride.

95. Prior to exposure to finasteride, Baratto had been complaining of various health problems and had sought consultation for many different conditions, some of which relate to genito-urinary system. Conditions from visits include: vitiligo (a chronic skin condition characterized by portions of the skin losing their pigment, which occurs when skin pigment cells die or are unable to function); psoriasis, discussed above; migraines; phimosis, discussed above; balanitis, discussed above; three distinct requests for sexually transmitted diseases screening, including one related

to partner vulvar concerns and yeast infection; follow up further to the separation from his partner with diagnosis of ureaplasma, a bacterial infection; pubic rash and several pustules, that is, blisters or pimples on the skin containing pus; molluscum contagiosum, a viral infection which can affect adults who are sexually active or immunocompromised, in the pubic area; throat concerns; a nasal polyp (a polypoidal mass arising mainly from the mucous membranes of the nose and paranasal sinuses); hair loss; and muscular cramps.

2) Simultaneous Exposure to Finasteride and Prednisone

96. As confirmed by Dr. Stothers, an important confounding factor in this case is that on the same date that Baratto started taking finasteride, on October 5, 2008, he also started taking prednisone. Prednisone is a synthetic glucocorticoid, a type of corticosteroid. Glucocorticoids and testosterone share metabolic pathways. As a result, the consumption of prednisone could complicate a patient's metabolism of testosterone.

97. Prednisone is listed as a cause of ED in humans in the *Australian Prescriber*, an independent publication produced in Australia, which is a source of pharmaceutical information independent of pharmaceutical companies. While there is no general consensus on the issue, this is consistent with the findings of a study examining the effects of corticosteroids on male sexual function.

98. Corticosteroids like prednisone can also be associated with psychiatric side effects such as mood changes, as indicated in the *Compendium of Pharmaceuticals and Specialists* (the "**CPS**"), the standard Canadian reference text for pharmaceutical drug monographs approved by Health Canada.

99. The fact that Baratto began using finasteride and prednisone at the same time is a confounding factor or consideration respecting the symptoms alleged by Baratto and according to Dr. Stothers, it certainly cannot be said that taking prednisone did not cause or contribute to Baratto's self-reported ED.

3) Other Confounders and Comorbidities

100. Baratto's medical, counselling and pharmaceutical records also document several confounders and comorbidities (the simultaneous presence of two diseases or conditions in a patient).

101. As noted above, one comorbidity in this case is the physical examination finding of phimosis, which was documented in the medical record starting in 2004. Phimosis can be associated with ED through symptoms that the patient can experience such as pain with retraction of the penile foreskin or inability to retract the foreskin, which can contribute to painful intercourse, tearing, and trauma to the foreskin. A scientific study using a well-designed methodology has also found an increase in depression among patients with phimosis;

102. Also as noted above, psoriasis, a skin condition caused by an autoimmune disorder, was reported to be present in Baratto throughout the years. Psoriasis is a confounding condition related to an association with psychological conditions including depression. A recent, well designed study showed a three-fold increase in the incidence of depression in patients with psoriasis, compared to a control group of patients who do not suffer from identified skin conditions;

103. Furthermore, the nocebo effect, an adverse, nonspecific side effect occurring in conjunction with a medication but not directly resulting from the pharmacologic action of the medication, is also a potential confounder in this case. In lay terms, it is the opposite of a "placebo effect". Men who are told that they may suffer sexual side effects from taking a medicine are more likely to report such side effects than men taking the same medicine who are not told about that side effect. A clinical study found that men taking finasteride at the 5 mg dose for BPH had an increased frequency of sexual side effects after discussion of sexual side effects and access to the drug information sheet compared to no discussion.

104. Thus, another comorbidity factor in this case is that Baratto visited the *Propecia-help.com* advocacy website shortly after he stopped using Proscar, that is, about

February or March 2009. This raises an important issue to the effect that, in reading about other people on the Internet who claimed to have used finasteride and to be suffering from persistent ED, anxiety and depression as a result, Baratto may have set an expectation that his concerns related to sexuality were caused by finasteride and would be persistent. In fact, in the application for authorization, Baratto explains that this is the effect that this website had on him.

105. The medical records also show that Baratto started using the antidepressant CELEXA® (citalopram), in July 2011. The CPS product monograph of citalopram indicates mood changes may be a side effect, and in the citalopram patient insert that it can cause emotional side effects as well as ejaculatory dysfunction.

106. Citalopram is part of the group of drugs known as selective serotonin re-uptake inhibitors ("**SSRIs**"). The CPS insert for SSRIs indicates that in over 1% of patients, SSRIs can cause sexual dysfunction including anorgasmia (inability to achieve orgasm despite adequate stimulation), decreased libido, delayed ejaculation, and issues with urinary frequency. Moreover, citalopram has been suggested to be a cause of persistent sexual dysfunction, and one of the studies filed by Baratto indicate that antidepressants can affect testosterone levels.

107. Thus, it would be consistent with the relevant scientific literature that Baratto's self-reported ED resolved after discontinuation of treatment with finasteride, and developed or then became persistent from treatment with citalopram. This is an important confounding factor in this case given the claim respecting the alleged persistent nature of the symptoms.

108. As explained by Dr. Stothers, any one of the foregoing confounding factors, or a combination of them, could be the cause of Baratto's self-reported ED, anxiety and depression symptoms and could explain their alleged persistence, rather than Baratto's use of finasteride for one month in October 2008.

109. She adds that there is no medical or scientific method that could be put in place to try to untangle, after the fact, which factor, if any, could have been involved in these reported symptoms.

D. No Objective Quantification of Baratto's ED Symptoms

110. As confirmed by Dr. Stothers, one fundamental issue with Baratto's medical records is that they contain no objective evaluation or validation of his ED symptoms: they do not document the nature of the ED other than by self-report.

111. It is very difficult to diagnose and quantify ED based solely on a patient's self-report of ED symptoms. ED is a topic many patients find difficult to discuss directly with a physician. Moreover, proper diagnosis and quantification requires measurement over time in order to determine the course of symptoms. Usually, when a patient complains of ED, the treating physician will perform a complete history and physical examination and will quantify the ED symptoms by using validated measurement scales, as more fully described above.

112. The only objective measure of genito-urinary function found in Baratto's medical records is an uroflow study, that is, a study that measures physiologic parameters of urination. This is done as a screening test when patients present with lower urinary tract symptoms to examine for pathology such as obstruction. This test was performed by Dr. Steinberg, a urologist, on June 12, 2012, and showed normal results.

113. Another key concern is that the particular components of ED in its initial presentation are minimally or vaguely described in Baratto's medical records. The records only mention "had ED" and "decreased libido". It is impossible to know whether the initial presentation was about only decreased libido or whether it also included other symptoms of sexual concern.

114. As for symptoms of "persistent" ED, the medical record indicates inconsistencies in the degree and/or presence of ED over time.

115. For example, exposure to (broken pieces of) Proscar was for a one-month period only in October of 2008, but following this there is reference to likely psychological ED on December 3, 2008; inconsistencies on the presence or absence of morning erections (occasional morning erections are mentioned in 2009), and in 2011 the records indicate an absence of morning erections); and the record mentions in 2009 that CIALIS, a PDE5 inhibitor, was used to treat ED and that it "worked well", but that Baratto was still complaining of symptoms of reduced libido. Yet, in 2012 the urologist plans a trial of CIALIS. It is not clear why the urologist notes seem to indicate that a trial of CIALIS had not started when prior notes indicated that it worked well.

116. There are no notes documenting what happened when oral therapy to treat ED was stopped: this would speak to the permanence of the symptoms, as an increase in ED symptoms would be expected when therapy to treat it is stopped.

117. This is important since, in September 2010, the medical record indicates that Baratto had intercourse but do not reveal whether he was still under oral therapy to treat ED at that time. If he was not, one would have to assume that the ED had resolved, or that in Baratto there is a natural history of ED where it goes away and returns later.

118. Dr. Stothers concludes that Baratto's medical records do not include any validation or quantification of his self-reported ED symptoms, nor any determination as to the cause of these symptoms.

119. Considering his various symptoms observed prior to exposure to finasteride, the simultaneous exposure to prednisone, and the various confounders and comorbidities documented in his medical records, it cannot be concluded that Baratto's self-reported persistent ED symptoms would have been caused by his exposure to 1.25 mg finasteride a day, six days a week, for a period of one month in 2008.

120. Furthermore, as discussed above, the scientific literature does not support a claim that finasteride is capable of causing persistent ED as a general matter, much less that it caused Baratto's self-reported ED.

VIII. JUDGMENT BY THE HONOURABLE CLAUDE DALLAIRE, J.C.S.

121. On December 21, 2016, the Honourable Claude Dallaire, J.S.C., dismissed Baratto's Application, as appears from her judgment (Exhibit R-1).

122. Among other things, the findings and conclusions by Madam Justice Dallaire include the following:

a) although Baratto alleged that he had consumed Proscar for one year, he had in fact consumed broken pieces of Proscar for barely a month, for a maximum consumption of six or seven tablets of Proscar over the course of his lifetime (paragraphs 36-37 and 164-171 of her judgment);

b) Baratto is self-diagnosed: his medical records contain no diagnosis of the sexual health problems he alleges. None of his physicians and therapists were able to objectively assess his symptoms (paragraphs 52 and 163 of her judgment);

c) although Baratto alleges he had never experienced ED and depression prior to consuming broken pieces of Proscar, his medical records show that he experienced psychological issues associated with his loss of hair and suffered from phimosis before using the medication (paragraphs 176 and 178-179 of her judgment);

d) when Baratto started taking Proscar he was starting a new job and had just recently separated from his girlfriend (paragraph 177 of her judgment);

e) Baratto had used other medications over the relevant years, including prednisone, a glucocorticoid which could have contributed to his symptoms,

which he started using at the same time he started using Proscar, and citalopram, an antidepressant that can cause ED, which he used for many years thereafter (paragraphs 53-54 and 199-200 of her judgment);

f) as confirmed by Dr. Stothers, ED is a symptom of many underlying causes and diseases, with nine common medical causes and eight psychological factors likely to intervene in making such a diagnosis, such that each class member's case would need to be subject to an extensive analysis in order to determine whether they suffered from the alleged adverse events, and it is likely that the information contained in the medical and psychological records of each class member would raise numerous questions on their respective causes of action (paragraphs 121 and 124 of her judgment);

g) Baratto's evidence of fault and causation is precarious at best (paragraph 149 of her judgment);

h) Baratto's allegations to the effect that Merck would not have conducted sufficient studies before marketing its products, and that it marketed products knowing them to be unsafe, are pure hypotheses that are not only unsupported but, in fact, contradicted by the evidence (paragraphs 183-186 of her judgment);

i) the literature filed by Baratto does not support any connection between finasteride and the allegedly persistent adverse effects he describes (paragraphs 209-213 of her judgment).

123. On July 26, 2018, the Court of Appeal allowed Baratto's appeal, as appears from the Decision of the Court of Appeal (Exhibit R-2).

124. However, the Court of Appeal did not question the validity of Madam Justice Dallaire's findings in any way. The Court simply concluded that she had surpassed her role as the authorization judge by weighing the evidence presented by the parties (paragraph 53 of the Court of Appeal decision).

125. The fact remains that Madam Justice Dallaire, who was seized of Baratto's application for authorization for a period of more than three years, found that the claim has no merit, and that each class member's case would need to be subject to an extensive analysis in order to determine whether they suffered from the alleged adverse events.

126. For all of these reasons, Merck respectfully submits that it is well founded in fact and in law to request that Baratto, the Selected Members and any class member who Baratto intends to call as a witness at the common issues trial, be ordered to communicate to Merck their relevant medical, counselling and pharmaceutical records, and that Merck be allowed to subject Baratto and the said class members to medical and pre-trial examinations, the whole as more fully described in the conclusions to this application.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

TO GRANT this application;

TO ORDER the Selected Members, within 90 days of the date on which they are advised of their selection and of this order, whichever occurs later, to communicate to the Defendants' counsel their complete medical, pharmaceutical and counselling records respecting their consultations, tests and test results, doctors' notes, diagnoses and prescribed treatments for male pattern hair loss (androgenetic alopecia), and for the conditions alleged in the Plaintiff's Originating Application, namely:

- sexual dysfunction,
- decreased libido,
- erectile dysfunction,
- ejaculatory disorders,
- decreased volume of ejaculate,
- shrinking of the genitals,
- gynecomastia,
- testicular pain,

- anhedonia and difficulty reaching orgasm, and
- depression,

including the persistence of these conditions following discontinuance of use of finasteride, for the period starting three years prior to their first use of Propecia or Proscar until the present day.

TO ORDER each of the Selected Members, within 60 days from the date on which the Defendants' counsel will have received all of the above-mentioned medical, psychological and pharmaceutical records of all the Selected Members, to undergo a medical examination by an expert selected by the Defendants;

TO AUTHORIZE the Defendants to examine each of the Selected Members before trial, within 90 days of the completion of the above-mentioned medical examinations;

TO ORDER, should the Plaintiff intend to examine class members other than himself as witnesses during the evidence stage of the common issues hearing, that he communicate the names and coordinates of the said class members within ten days from the date on which the Selected Members will have been identified, and **TO AUTHORIZE** the Defendants to conduct pre-trial examinations of each of the said class members subsequent to their communicating their relevant medical and psychological records and undergoing a medical examination, subject to the same modalities and within the same delays as described above for the Selected Members;

TO ORDER and **TO DECLARE** that any Selected Member, or other class member identified by the Plaintiff to be a witness at the common issues trial, who refuses to participate in the above-mentioned measures is deemed to have opted out of these proceedings as of the date of such refusal, for all legal intents and purposes whatsoever;

THE WHOLE with costs to follow.

RESPECTFULLY SUBMITTED,

Montreal, on this 20th day of November, 2020

Blake, Cassels & Graydon L.L.P.

BLAKE, CASSELS & GRAYDON LLP
Attorneys for the Defendants
M^tre^ Claude Marseille, Ad. E.
M^tre^ Ariane Bisaillon
1 Place Ville-Marie, Suite 3000
Montréal, Québec H3B 4N8
claude.marseille@blakes.com
Telephone: 514-982-5089
ariane.bisaillon@blakes.com
Telephone: 514-982-4137
Fax: 514-982-4099
Our reference: 00074966.000023

NOTICE OF PRESENTATION

TO: **M^tre^ Philippe H. Trudel**
M^tre^ Gabrielle Gagné
Trudel, Johnston & L'Espérance, S.E.N.C.
750, Côte de la Place d'Armes, bureau 90
Montréal, Québec H2Y 2X8

Attorneys for the Plaintiff

TAKE NOTICE that the present *Application to Obtain the Medical Records, and to Allow the Medical and Pre-Trial Examinations of Selected Class Members* will be presented for adjudication before the honourable Christine Baudouin, J.S.C. of the Superior Court of Québec, sitting in the Class Action Division for the District of Montreal, on **December 8, 2020**, at **2:00 PM**, in room to be determined, at the Montreal Courthouse located at 1, Notre-Dame Street East, Montréal, Québec, H2Y 1B6.

DO GOVERN YOURSELVES ACCORDINGLY.

Montréal, November 20, 2020

Blake, Cassels & Graydon L.L.P.

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BLAKE, CASSELS & GRAYDON LLP
Attorneys for the Defendants
M^tre^ Claude Marseille
M^tre^ Ariane Bisaillon
1 Place Ville-Marie, Suite 3000
Montréal, Québec H3B 4N8
claude.marseille@blakes.com
Telephone: 514-982-5089
Fax: 514-982-4099
ariane.bisaillon@blakes.com
Telephone: 514-982-4137
Our reference: 00074966.000023

Nº: 500-06-000648-135

SUPERIOR COURT
(Class Actions Division)
DISTRICT OF MONTRÉAL

CAMILO BARATTO

Plaintiff

v.

MERCK CANADA INC.

-and-

MERCK FROSST CANADA & CIE

Defendants

APPLICATION TO OBTAIN THE MEDICAL RECORDS, AND TO ALLOW THE MEDICAL AND PRE-TRIAL EXAMINATIONS OF SELECTED CLASS MEMBERS

BY THE DEFENDANTS — NOVEMBER 20, 2020

(ART. 587 C.C.P.)

ORIGINAL

Mtre Claude Marseille, Ad. E. **BB-8098**
Mtre Ariane Bisaillon
BLAKE, CASSELS & GRAYDON LLP
Barristers & Solicitors
1 Place Ville Marie, Suite 3000
Montréal, Québec H3B 4N8
Telephone Mtre Marseille: 514-982-5089
Telephone Mtre Bisaillon: 514-982-4137
Fax: 514 982-4099
Email: claude.marseille@blakes.com
ariane.bisaillon@blakes.com
Our File: 74966-23