C A N A D A

PROVINCE OF QUÉBEC

DISTRICT OF MONTREAL

Nº 500-06-000648-135

S U P E R I O R C O U R T

(Class Action)

CAMILO BARATTO

Plaintiff

v.

MERCK CANADA INC.

MERCK FROSST CANADA & CIE

Defendants

AMENDED SUMMARY DISCLOSURE OF GROUNDS OF DEFENCE

(Art. 170 C.C.P.)

IN ACCORDANCE WITH THE CASE PROTOCOL, THE DEFENDANTS RESPECTFULLY SUBMIT THE FOLLOWING AS THEIR SUMMARY GROUNDS OF DEFENCE HEREIN (…):

A. Proscar and Propecia

1. Merck Canada Inc. ("**Merck Canada**") is headquartered in Kirkland, Quebec and is one of Canada's leading research-based pharmaceutical companies, employing approximately 775 people across Canada. Merck Canada is authorized by Health Canada to market, and until April 21, 2021 marketed, the medications PROSCAR® and PROPECIA® for approved indications in Canada. Merck Frosst Canada & Cie, headquartered in Nova Scotia, is neither the manufacturer nor the market authorization holder for Proscar or Propecia.

1.1 As of April 21, 2021, Organon Canada Inc. became the new market authorization holder for Proscar and Propecia in Canada.

2. Proscar (5 mg finasteride film-coated tablets) is a prescription medication that is indicated and was approved by Health Canada for the treatment of benign prostatic

hyperplasia ("**BPH**") in typically older men with an enlarged prostate, to cause regression of the enlarged prostate and improve urinary flow and related symptoms. As stated in the Proscar Product Monograph, "[p]atients with an enlarged prostate are the appropriate candidates for therapy with PROSCAR®." The Product Monograph adds that "[t]he recommended dosage of PROSCAR® is one 5 mg tablet daily with or without food", and that BPH "occurs in the majority of men over the age of 50 and its prevalence increases with age".

3. Propecia (finasteride 1 mg film-coated tablets) is a prescription medication that is indicated and was approved by Health Canada 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, which may affect men as early as in their 20s. As stated in the Propecia Product Monograph, clinical studies for Propecia "were conducted in men between 18 to 41 years of age" and "[t]he recommended dosage is one 1 mg tablet daily".

B. Health Canada's Exacting Review, Approval and Pharmacovigilance Process

1) Notice of Compliance

4. The process for bringing new pharmaceutical drugs to market in Canada is rigorous, exacting and strictly regulated. Manufacturers of pharmaceutical drugs cannot sell products in Canada without the approval of Health Canada, which it issues in the form of a Notice of Compliance ("**NOC**"). In order to obtain an NOC, the manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the *Food and Drugs Act*, R.S.C., 1985, c. F-27 and the *Food and Drug Regulations*, C.R.C., c. 870.

5. Submissions are approved or rejected based on three basic premises: the product can be made consistently and the product quality can be assured; the efficacy of the drug is acceptable based on randomized, controlled clinical trials; and the safety profile of the drug is acceptable based on the risk/benefit assessment. The most basic decision in determining whether to approve a drug or not is making the risk/benefit assessment. All drugs have benefits and all drugs have risks. Health Canada will not issue an NOC unless it is satisfied that all of the required information has been provided and that the New Drug meets the required safety and efficacy standards.

6. Health Canada's filing requirements for New Drugs are extensive, both in terms of the type and volume of material involved. These requirements are mandatory and the manufacturer will not be able to market a drug unless it has strictly complied with them. In the case of a New Drug, a manufacturer seeking approval to market the drug in Canada must file a New Drug Submission ("**NDS**") with Health Canada. The NDS contains voluminous clinical and nonclinical information, such as *in vitro* and animal testing data available for the drug, establishing the safety and efficacy of the New Drug, as well as the chemistry and manufacturing information and the proposed Product Monograph.

7. For each indication that a company is submitting for approval, two positive pivotal Phase III trials have to be submitted, which are the most important from a regulatory point of view. These are well conducted, well designed, and controlled (either placebo or active), randomized, double-blind studies conducted in large populations. The randomization and the blinding ensure that bias is minimized.

8. Health Canada's review process is rigorous and exacting. Health Canada considers the manufacturer's data in the context of the total knowledge it has from all sources in its review of the safety and efficacy of the New Drug.

9. Health Canada reviewers are well qualified and comprehensive in their review of an NDS. Reviewers within Health Canada are physicians, pharmacologists or other scientists with doctorate level academic training in such areas as neurological biometrics. There are no reviewers in Health Canada's Therapeutic Products Directorate with less than a Ph.D. in terms of academic credentials.

10. Safety is a particular area of focus and concern for Health Canada. In instances where the drug has been approved in other countries, Health Canada will review the postmarketing adverse reaction reports from these countries as part of its review of the NDS. Health Canada's practice is to ask to see the updated list of postmarketing adverse reactions before it will approve the NDS and will ensure that the Product Monograph adequately addresses these adverse reactions. If there are any concerns about the safety of the drug, Health Canada will make a decision that is conservative and not let the product move through to approval.

2) Product Monograph

11. Health Canada must also approve the Product Monograph before it can be finalized and an NOC issued. A Product Monograph is the document that describes, among other things, the indications for which the drug has been approved, the cautions that are associated with the drug, the adverse reactions that may be seen and the dosage that has been approved.

12. Like the rest of the NDS, the Product Monograph is subject to its own review by scientific experts with clinical and/or medical expertise. The manufacturer is required to submit a draft of the proposed Product Monograph in its NDS. During the review of an NDS, the Product Monograph is reviewed sentence by sentence and word by word to ensure that the very best information is provided to Healthcare Professionals when the document is approved.

13. When the Product Monograph has been reviewed, the manufacturer is contacted and the changes required to the Product Monograph are outlined. Frequently meetings or teleconferences are set up to discuss the changes required to ensure that there is a clear reflection of the data in the NDS.

14. As a drug is used widely, it is normal to learn more about it, and as new information is gathered, changes are frequently made to the Product Monograph. It is expected that all drug products will have changes brought to the Product Monograph after they are approved and put on the market, as more information is learned about the product under real-world use. This is a normal part of the process of the life-cycle of a pharmaceutical product.

3) Pharmacovigilance

15. After an NOC is issued, Health Canada continues to monitor safety and efficacy data about approved drugs in what is known as the pharmacovigilance process. Ongoing information is obtained through Health Canada's own independent research as well as from submissions from manufacturers.

16. Data on postmarketing adverse events must be collected and submitted to Health Canada by the manufacturer. An adverse event is an untoward experience that has a temporal association with the use of a drug, that is, it occurs while or shortly

after the drug is taken. There is no implication that the drug caused the adverse event.

17. All of the postmarketing information is reviewed at Health Canada by Drug Safety Specialists with backgrounds in pharmacy, epidemiology and medicine. These specialists enter the data into a database and continually review the information for signals of a problem occurring with a drug.

18. Post-marketing reports of adverse events can be very difficult to interpret. They can be given by anybody with or without any kind of medical training; they are not validated by Health Canada in any way; the information provided may be marginal; the language used may be ambiguous; there is no denominator allowing the determination of an incidence rate; and there is no information regarding the number of patients who used the drug or the duration of use.

19. Thus, post-marketing reports of adverse events are ***not*** equivalent to a result from a properly conducted clinical trial or scientific study and do ***not*** mean and are not intended to mean that the drug has caused the reported adverse events. Health Canada's role is to consider and evaluate adverse event reports 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.

C. Approval of Proscar and Propecia

20. Prior to the approval of Proscar and Propecia, rigorous pre-clinical and clinical studies were performed to establish their safety and efficacy profiles, and the results of these studies were submitted to Health Canada as part of the NDS.

21. The clinical trials program for Proscar and Propecia for the purpose of their approval in Canada not only complied with the *Food and Drug Regulations*, but included randomized, double-blind, placebo-controlled trials that are regarded as the gold standard of clinical research. All potential side effects, and specifically potential sexual side effects, were vigorously monitored during the clinical trial phase.

22. The Proscar and Propecia clinical trials included over 8,000 men, with some patients followed for up to 7 years. They demonstrated the safety, efficacy and positive benefit-risk profile of both medicines.

23. Health Canada approved the sale of Proscar in Canada by issuing an NOC in October 1992, including the Product Monograph. At that time, Proscar was approved for the treatment of symptomatic BPH. Health Canada later approved further indications for Proscar, none of which include the treatment of male pattern hair loss.

24. Health Canada approved the sale of Propecia in Canada as well as its Product Monograph by issuing an NOC in June 1998. Health Canada approved one indication for Propecia, that is, the treatment of male pattern hair loss in men with mild to moderate scalp hair loss of the vertex and anterior mid-scalp.

25. At all material times, Merck Canada exercised reasonable care in making its applications for approval and its other filings with Health Canada with respect to Proscar and Propecia.

D. Postmarketing Monitoring of Safety and Efficacy Data for Proscar and Propecia

26. Once Proscar and Propecia respectively became available for sale in Canada, Merck Canada continuously and diligently monitored their safety and efficacy and updated their respective Product Monographs on a timely basis.

27. Pharmaceutical manufacturers cannot unilaterally change or supplement information regarding safety or efficacy contained in the Product Monograph, including the Consumer Information part or “package insert”, without approval from Health Canada. Each revision to the Proscar and Propecia Product Monographs was approved by Health Canada after an extensive review process.

28. To the extent that Merck Canada received or became aware of reports of postmarketing serious adverse events, which are made regardless of causality, in connection with the use of Proscar or Propecia, it reported the events to Health Canada as required by the *Food and Drug Regulations*, and met and exceeded all its regulatory requirements and related legal obligations in this regard.

E. Prescribing Proscar or Propecia

29. Propecia and Proscar are regulated prescription pharmaceutical drugs and were only available to the Plaintiff and class members through learned intermediaries, by prescription through a physician and filled by a pharmacy. Propecia and Proscar

are prescribed to patients based on a physician's independent medical judgment and are intended to be used by a patient only as directed by a physician.

30. The physicians attending each of the individual class members exercised independent judgement with respect to prescribing Propecia and/or Proscar to each of them. Furthermore, these physicians exercised independent judgment with respect to the information they provided to each of the individual class members in that regard.

31. Risks are inherent in the use of any prescription pharmaceutical drug. The Defendants discharged their obligation to adequately inform the Plaintiff and class members of such risks by warning treating physicians, dispensing pharmacists and/or the hospitals or medical centres in which care was provided through the Product Monograph.

32. At all material times, Merck Canada provided adequate and sufficient information and warnings regarding the risks of Propecia and Proscar to physicians in Quebec who, in exercising their independent medical judgment, chose to prescribe Propecia and Proscar to individual class members, including the Plaintiff.

F. The Alleged Adverse Events

33. The Plaintiff alleges that class members developed at least one of sexual dysfunction, decreased libido, erectile dysfunction, ejaculatory disorders, decreased ejaculate volume, shrinking of the genitals, gynecomastia, testicular pain, anhedonia, difficulty reaching orgasm and/or depression that persisted after the discontinuation of treatment (the "**Alleged Adverse Events**").

34. The class is limited to men: (i) who reside in Quebec; and (ii) who were prescribed Propecia and/or Proscar, that is, not a generic version of finasteride manufactured by a third party; and (iii) who received this prescription for the treatment of male pattern hair loss, that is, not for the treatment of BPH, a condition that typically affects older men who would be prescribed Proscar containing five times the amount of finasteride compared with Propecia tablets; and (iv) who received this prescription before November 18, 2011, on which date the Propecia and Proscar product monographs were modified; and (v) who developed at least one of the (…) above-described conditions while using Propecia or Proscar; and (vi) who interrupted the treatment; and (vii) whose (…) said condition or 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, the Plaintiff having never supplied a definition of what "persistence" should mean in that context.

35. The Defendants vehemently deny that Propecia or Proscar were defective in any way and that they cause the Alleged Adverse Events. At all material times, Propecia and Proscar were fit, safe, and effective for their intended uses as reflected in the Product Monograph, and were approved by Health Canada in the context of the thorough, exacting and continuous process described above.

36. As of today, even though this matter has been ongoing for almost ten years, the Plaintiff has never submitted any explanation whatsoever as to how Propecia or Proscar purportedly cause any of the Alleged Adverse Events. As more fully described below, in May 2021 the Plaintiff communicated an expert report to the Defendants. The Plaintiff's own expert does not support the Plaintiff's claim that finasteride 1 or 1.25 mg used daily for male pattern hair loss can cause sexual, psychological and physical adverse events that would persist notwithstanding the discontinuation of treatment, nor can he identify any biological basis for such a claim.

37. A key feature of the Plaintiff's allegations, the literature he filed and the postmarketing reports of adverse events to which he refers is that they are based on anecdotal cases, that is, uncontrolled observations of a limited number of individuals. Such cases may be compelling to the human psyche, as people are more moved by stories than statistics, but they do not establish in any way that Propecia or Proscar cause any of the Alleged Adverse Events. At best anecdotes generate questions, not answers.

38. The Alleged Adverse Events are prevalent in the general population irrespective of the consumption of Proscar or Propecia. (…) Male sexual dysfunction, including ejaculatory issues, loss of libido, and erectile dysfunction ("**ED**"), has an extremely high prevalence rate and an elevated incidence rate across all ages. The most frequent component of male sexual dysfunction, ED, has a reported prevalence of over 50% among men 40 to 70 years of age and of 15% to 35% in men less than 40. The incidence rates are generally believed to be about 1% to 2% per year in men over age 40, meaning that a man without ED at age 40 would have a 10 to 20% chance of developing it by age 50.

39. Moreover, there are multiple risk factors, confounding factors and comorbidities for the Alleged Adverse Events in any given individual. For instance, ED is a symptom of many underlying causes and diseases as both physical and psychosocial issues cause and contribute to its appearance.

40. As a result, the diagnosis and assessment of the Alleged Adverse Events can only be done on an individual basis and by way of a thorough evaluation of each patient in order to establish their contributing factors.

41. For instance, the diagnosis and assessment of ED requires a thorough history and physical examination of the patient, the administration of specialized questionnaires, and laboratory tests including specialized tests for organic factors that can materially contribute to ED. Moreover, given that many psychological factors and interpersonal relationship issues can contribute to ED, including relationship distress, family life, financial distress, work-related stress, feelings of guilt or shame, past sexual trauma, and depression, assessment by a psychologist or psychiatrist is also appropriate.

42. Following such examination and tests, ED may be classified as organic, psychogenic or of mixed etiology or, despite a thorough evaluation, the clinician may not be able to conclusively determine the condition's etiology.

G. The Plaintiff

43. The Plaintiff is a 42 year old man who, by his own account, for many years has suffered from a variety of serious sexual and psychological issues: decreased libido, ED, "troubles" ejaculating, pain in the testicles, anxiety, and depression, which would persist to this day.

44. The Plaintiff claims that, starting on October 5, 2008, he used Proscar to treat male pattern hair loss by breaking Proscar tablets in four pieces.

45. Although the active ingredient in Proscar and Propecia is the same, that is, finasteride, they are different medications, they come in different doses, they are approved by Health Canada and indicated for different conditions, the contents of their respective Product Monographs are different, and the appropriate candidates for their use are different. Proscar is not indicated and has not been approved for the treatment of male pattern hair loss.

46. The Plaintiff 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, in effect, remanufacturing the medication. Merck Canada did not test, seek to register, label, or supply, the tablets remanufactured by and ingested by the Plaintiff. The Plaintiff, in fact, took neither Proscar nor Propecia.

47. The Plaintiff alleged in two separate paragraphs of his Application for Authorization that starting on October 5, 2008 he used broken pieces of Proscar for a period of about one year, until November 2009. This was false: after a review of the Plaintiff's medical and pharmaceutical records, Merck Canada's attorneys discovered he had used broken pieces of Proscar for barely one month. With respect, the Plaintiff could not in good faith recall using Proscar for a period of one year when in reality he used it for barely one month, especially when he claims it had such drastic consequences on his health.

48. Since the Plaintiff broke the Proscar tablets in four pieces and now claims he took one broken piece a day, six days a week for a period of one month, he only ever consumed a maximum of 6½ Proscar tablets or 32.5 mg (1.25 mg per day over 26 days) of the medication in his entire life, back in October 2008. In fact, as pointed out by the authorization judge, even this reduced figure is probably inflated, the actual figure being most likely three Proscar tablets or 15 mg of the medication according to a questionnaire the Plaintiff completed years before he filed his Application for Authorization. To put this in perspective, men with BPH who use Proscar for its intended purpose will consume one 5 mg tablet every day for a period of multiple years.

49. The Plaintiff claimed that, before using Proscar in October 2008, he had never suffered from conditions similar to those he is alleging Proscar caused in this case. This is false. His medical records document several conditions for which he consulted long before he ever began using Proscar, including several associated with ED and psychological distress.

50. The Plaintiff did not disclose that, on the same date he started using Proscar, he also started using another drug, Prednisone, a glucocorticoid. (…) Glucocorticoids have been shown to have a direct effect on producing significant rates of reduced libido and ED. While it appears that the Plaintiff's exposure to Prednisone was

limited in time, and thus unlikely to have caused long-term persistent deficiency, the same can be said of the low dose of finasteride he used and his very limited exposure to the medication.

51. He also did not disclose that he had just started his professional career and that his long-time girlfriend had left him for another man after a two-month post-graduation trip in Southeast Asia. The Plaintiff himself described these important and extremely stressful life events to his psychiatrist as the context in which his problems appeared.

51.1 The Plaintiff also misled the Court at the authorization stage by claiming that he began experiencing certain of his alleged symptoms while using broken pieces of Proscar in October 2008, and that these would have "persisted" notwithstanding the discontinuation of treatment.

51.2 During his medical and pre-trial examinations held respectively on July 11 and 14, 2022, the Plaintiff revealed that, in fact, he incurred none of these conditions while using broken pieces of Proscar in October 2008, but, instead, would have started incurring new symptoms of ED for the first time several weeks after discontinuing treatment, when he began getting intimate with his new girlfriend at the time. Other symptoms allegedly would have appeared later.

51.3 The Defendants respectfully submit that the Plaintiff is not a member of the authorized class, that this class action was authorized under false pretenses, and that it cannot be pursued by the Plaintiff.

52. The Plaintiff's medical records disclose several confounding factors and comorbidities, including that he started using the antidepressant CELEXA® (citalopram) in July 2011. Citalopram is part of the group of drugs known as selective serotonin re-uptake inhibitors, or SSRIs. Citalopram can cause emotional side effects and mood changes. In more than 1% of patients, SSRIs can cause sexual dysfunction including anorgasmia (in which a person cannot achieve orgasm despite adequate stimulation), decreased libido, delayed ejaculation, and urinary frequency.

53. It is consistent with the Plaintiff's medical records that his self-reported ED symptoms, which we now know are alleged to have appeared for the first time only several weeks after he had already ceased using broken pieces of Proscar in October 2008, resolved and later developed from treatment with Citalopram. This is

an important confounding factor in this case given the claim respecting the alleged "persistent" nature of the symptoms after discontinuation of treatment, while the Plaintiff was, in fact, using Citalopram starting in July 2011.

54. Any one or a combination of these confounding factors could be the cause of the Plaintiff's self-reported alleged ED, anxiety and depression symptoms, and could explain their alleged persistence, rather than the Plaintiff's limited use of a small quantity of broken pieces of Proscar for one month in October 2008.

55. The Plaintiff's medical records disclose another fundamental flaw in his personal claim: his ED symptoms are only self-reported with no objective validation. This is a critical consideration because it is very difficult to diagnose and quantify ED based solely on a patient's self-report of ED symptoms. Proper diagnosis and quantification of ED requires measurement over time in order to determine the course of symptoms.

56. Another key concern is that the particular components of the self-reported ED in its initial presentation are only minimally or vaguely described in the medical records. They mention only "had ED" and "decreased libido". As for symptoms of "persistent" ED, the medical records indicate inconsistencies in the degree and/or presence of ED over time.

57. Moreover, in his Application for Authorization and examinations, the Plaintiff claims that, about four months after (…) using broken pieces of Proscar in October 2008, that is, in or about February 2009, he started looking for a cause and a solution to his problems and (…) was directed by his then girlfriend to the website called "www.propeciahelp.com", where he says he learned that several men who alleged they consumed Propecia and Proscar also reported having developed undesirable side effects similar if not identical to his, such as persistent sexual dysfunction and depression.

58. This website is an anti-finasteride advocacy web forum dedicated to the proposition that finasteride causes mental, physical and sexual side effects which continue despite quitting the medication. Of course, materials of this kind found on the Internet have no probative value as thousands upon thousands of websites can be found to support practically any claim at all, including that vaccines cause autism,

that magnets can relieve symptoms of arthritis, or that shark cartilage cures cancer. That said, unsurprisingly, this website convinced the Plaintiff that his self-reported subjective symptoms were due to his use of Proscar.

59. This indicates that the Plaintiff and other class members may have experienced the nocebo effect (the opposite of the placebo effect), that is, an adverse effect occurring in conjunction with a medication that does not result from its pharmacologic action but rather from the patient's belief that the intervention will cause harm. The Plaintiff and other class members visited the website "www.propeciahelp.com" when looking for a cause and a solution to their problems. By reading on the Internet about other men who claimed to have used finasteride and to be suffering from persistent ED, anxiety and depression as a result, they set an expectation that their concerns were caused by finasteride and would be persistent. All the elements for a nocebo effect were in place. In fact, a nocebo effect for sexual side effects has been documented in the scientific literature respecting finasteride as will be more fully demonstrated at the hearing.

60. This applies squarely to the 71 men recruited for the "study" alleged in paragraphs 3.18 and 4.14 of the Originating Application (Exhibit P-7B), in which the Plaintiff participated, since these men were recruited precisely because they had registered on this website. Not only is this self-selected identification method deeply biased, it also raises grave concerns about the nocebo effect. This website was set up to convince users that Proscar and Propecia cause sexual and psychological side effects that persist after cessation of treatment. It is therefore not surprising that it produced its desired outcome.

61. Moreover, at least some of the studies alleged by the Plaintiff herein recruited participants from so-called "victims' websites" such as "www.propeciahelp.com", were funded by anti-finasteride organizations, and otherwise suffered from various additional methodological flaws. In at least one case, the Plaintiff was recruited to participate in a genetic research investigation respecting the so-called "post-finasteride syndrome" conducted in Italy by "the Administrator of http://www.PropeciaClassAction.com" using the email name "Propecia Class Action Lawsuit" and the email address "propeciaclassaction@gmail.com", as will be more fully established at the hearing.

H. Prescription

62. The claims of the Plaintiff and other class members are prescribed.

63. As stated above, in his Application for Authorization and examinations the Plaintiff claims that, about four months after (…) using broken pieces of Proscar in October 2008, that is, in or about February 2009, he started looking for a cause and a solution to his problems and (…) was directed by his then girlfriend to the website called "www.propeciahelp.com". He claims he then learned that several men who consumed Propecia and Proscar also reported having developed undesirable side effects similar if not identical to his, such as persistent sexual dysfunction and depression.

64. Thus, by the Plaintiff's own allegations and admissions, at least as early as February 2009, all the elements of his right of action had arisen: he had used Proscar for a period of one month; he had stopped using it; his prejudice had appeared, that is, his alleged "persistent" sexual and psychological symptoms; and his understanding was that these symptoms were caused by his use of Proscar. The Plaintiff filed his Application for Authorization on April 8, 2013, such that his claim is clearly prescribed.

I. Other Grounds of Defence

65. At this time, the Application does not describe the alleged claims, theory of the case and the underlying scientific bases with sufficient particularity to enable the Defendants to determine all of their rights or to assert all of their grounds of defence. (…)

65.1 On May 17, 2021, the Plaintiff communicated an expert report by Dr. Jean-Hugues Brossard, endocrinologist. The Plaintiff's own expert does not support the Plaintiff's claim that finasteride 1 or 1.25 mg used daily for male pattern hair loss can cause sexual, psychological and physical adverse events that would persist notwithstanding the discontinuation of treatment, nor can he identify any biological basis for such a claim. On the basis of the Plaintiff's own expert report, the Plaintiff's claim must fail.

65.2 On November 16 and December 1st, 2022, the Defendants communicated the expert reports of Dr. Gerald Brock, urologist, Dr. Pierre Blier, psychiatrist, and Dr.

George Well, epidemiologist and biostatistician. These distinguished experts all conclude that the available scientific data does not support the claim that finasteride 1 or 1.25 mg used daily for male pattern hair loss is associated with or can cause sexual, psychological and physical adverse events that persist after the discontinuation of treatment, and that, in fact, the available scientific data leads to the opposite conclusion.

65.3 These are also the formal conclusions independently issued by the American Urological Association ("**AUA**") in August 2021, as well as by the United States Food and Drug Administration ("**FDA**") in June 2022, after their respective reviews of the relevant scientific literature, in the following publications:

a. AUA — Lerner LB, McVary, KT, Barry MJ et al.: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806, a copy of which is communicated herewith as **Exhibit D-1**; and

b. FDA — Cavazzoni P. (M.D., Director, Center for Drug Evaluation and Research, FDA). FDA Final Response to Citizen Petition, Docket No. FDA-2017-P-5787, June 8, 2022, a copy of which is communicated herewith as **Exhibit D-2**.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

TO GRANT the Defendants' Amended Summary Disclosure of Grounds of Defence;

TO DISMISS the Plaintiff's Amended Statement of Claim;

THE WHOLE, with costs against the Plaintiff, including the Defendants' expert fees and costs herein.

Montreal, January 31, 2023

Blake, Cassels & Graydon L.L.P.

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EXHIBIT D-1 and EXHIBIT D-2

ORIGINAL

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