## FORM 171C Rule 171

## REPLY

No. T-2030-13

FEDERAL COURT

BETWEEN:

NEIL ALLARD TANYA BEEMISH DAVID HEBERT SHAWN DAVEY

**PLAINTIFFS** 

AND:

## HER MAJESTY THE QUEEN IN RIGHT OF CANADA

**DEFENDANTS** 

## REPLY

- 1. The Plaintiffs admit the allegations contained in paragraphs 4-19, 20 (first sentence and second sentence to the words "authorized in the future") 21-29, 32-33, 35, 37-39, 45 (first sentence), 47 (first sentence), 51, 52, 62, 64-70, 72-73, 80, 84, 86, 95.
- 2. The Plaintiffs deny the allegations contained in paragraphs 40-43, 46, 53-61, 63 (first sentence), 74.
- 3. The Plaintiffs have no knowledge of the allegations contained in paragraphs 20 (the last portion of the second sentence after the word "future"), 44, 45 (second sentence), 47 (second sentence) and puts the Defendants to the strict proof of the details in that regard, 48-50.
- 4. In reply to the latter part of paragraph 20, the Plaintiffs say that whatever the impacts are of any Declarations made by the Court with respect to the constitutionality of the impugned legislation on current and future licenced producers, first responders (police, fire, ambulance) neighbours of residential properties where marihuana is presently grown for medical purposes, as well as the public at large, will be different types of impact in that it will not necessarily

impact their constitutional rights and any potential impacts on them are remedial by reasonable regulation to render such impacts to be minimal or non existent. The Plaintiffs put the Defendants to the strict proof of such impacts on such groups enumerated between 1999 and 2014.

- 5. While the Plaintiffs admit paragraphs 24-30, the Plaintiffs say that Canada's international obligations are subject to Canada's Constitution and in particular the provisions of the Canadian Charter of Rights and Freedoms and that the legislation referred to, including in particular the Food and Drugs Act (FDA), while also extending to the regulation of food and natural health care products, the focus of such regulations is in relation to the sale of such products to the public and not the production of such products for personal consumption that not for distribution to anyone else in Canada by way of sale or otherwise.
- 6. In reply to paragraph 31, the Plaintiffs say that the complete life cycle of the marihuana plant varies depending upon a large number of variables including whether or it is produced from seed or clones, indoors or outdoors or partly indoors and partly outdoors, with or without fertilizer and subject to various other factors and variables.
- 7. In reply to paragraph 34, the Plaintiffs understand that Sativex ® is whole plant based whereas Cesamet ® is synthetic and understands that they are prescribed for certain specific ailments at substantial cost.
- 8. In reply to paragraph 36, the Plaintiffs, while admitting the first sentence, and accepting the first part of the second sentence, reply that the safety and efficacy standards that apply to other drugs for therapeutic use may not have been met but that it is known and documented by the Defendants that Cannabis and its cannabinoids have no lethal dose ratio and are relatively non-toxic to healthy, developed cells and organs and are not central nervous system depressants so they will not cause respiratory failure such as ethanol and/or opiate based drugs. There have been an estimated 120 controlled clinical trials in the USA assessing the therapeutic efficacy of Cannabis and cannabinoids in some 6,500 subjects, a cohort of subjects substantially greater than would typically participate in clinical trials for more conventional therapeutics that are usually approved on the basis of a single clinical trial.
- 9. In reply to paragraphs 40-52, the Plaintiffs say that the Defendants were required by the courts to provide a constitutionally viable exemption from the CDSA to provide reasonable access to Cannabis to medically approved patients. The Plaintiffs say that the Defendants are responsible for the formula in the Regulations that did not limit the size of plants but nevertheless also required destruction of any excess to stay within prescribed storage limits. The Plaintiffs further say that the Defendants failed to attend upon and rectify complaints during the course of the MMAR program to ameliorate any negative impacts that developed and it failed in its responsibility under the regulations to inspect licenced premises to ensure public health, safety and security for producers and

their neighbours and others alike and that all of the problems identified, the specific details and numbers of which are unknown to the Plaintiffs and are within the possession and control of the Defendants, are remedial by reasonable regulation including modification to existing regulations to eliminate any of the impacts described without the need to abolish the ability to personally produce or have a caregiver produce for one in a healthy, safe and secure manner with no risk to any members of the public, including first responders and others identified.

- In reply to paragraphs 53-61, the Plaintiffs say they have no knowledge of the 10. specific abuses or incidents of 'misuse' alleged relative to the total number of program participants and locations and put the Defendants to the strict proof thereof in relation to each alleged negative consequence. The Plaintiffs accept that there have been a number of misuses/abuses by a minority of permit holders and say that they have arisen in part due to the failure on the part of the Defendants to remedy complaints and conduct inspections and to ensure reasonable regulation of all to prevent abuses and protect legitimate patients that are in full compliance with the law. The Defendants designed the program and its Regulations and have the power and ability to modify those Regulations in order to ensure that the law is complied with and still provides a viable exemption instead of abolishing the personal production and designated caregiver provisions without any attempt at remediation short of prohibition, resulting in obvious negative consequences to at least those patients who are acknowledged to be unable to afford the increased prices.
- 11. In further answer to paragraphs 53-61, the Plaintiffs say that ironically the over supply apparently produced by misuser/abusers of the program (as well as a result of legalization developments internationally and in the USA, including extensive medical legalization) has resulted in a substantial glut on the illicit market resulting in many of the illicit operations going out of business, a reduction in the cost of marihuana per gram in the illicit market and a substantially reduced interest on the part of organized criminals and others in thefts due to the reduced value of the product and the inability to dispose of it at a reasonable price.
- 12. In reply to paragraph 63, the Plaintiffs say that the MMPR will not improve access for medically approved patients who will not be able to afford the new increased Licenced Producer prices nor those who could not afford illicit market prices and learned to produce in a safe and secure manner in their dwellings at less cost than estimated by Licenced Producers and will deprive them of their choice over the nature and quality of their medicine that they have developed, some of them over the last 14 years of the MMAR Program. The Food and Drugs Act applies to those who produce and sell food and drugs and natural health care products to the public to protect the public but not those who produce such items as food or grow medicinal plants for themselves only and not for distribution.
- 13. In reply to paragraph 71, the Plaintiffs say that the repeal of the MMAR will result in the violation of the s.7 constitutional rights of some medically approved

patients who, due to their inability to afford Licenced Producer prices or otherwise, will be forced to choose between their liberty and health. The Plaintiffs welcome the Defendants withdrawal from the production of drugs and its return to the role of a regulator so as to ensure they will have more time and resources to ensure the proper enforcement of the regulations for the benefit of the great majority of law abiding patients who have not contributed to nor participated in any of the unintended consequences alleged.

- 14. In reply to paragraphs 74-78, the Plaintiffs say that the steps taken by the Defendants to provide for reasonable access to a legal continuous stable and adequate supply have not been reasonable and the models used to estimate demand and supply do not reflect the reality of the Canadian demand by patients in accordance with the MMAR provisions based on prior years of operation of the program, including the amounts approved by their physicians overall, including the grams per day approved over time in individual cases and have made no provision for a viable reasonable continuous supply for such approved patients like the Plaintiffs and others like them who cannot afford estimated Licenced Producer prices or their special programs and choose to maintain control over the quality and production of their own medicine at a lesser cost than licenced producers, over many years.
- 15. In reply to paragraph 76 the Plaintiffs point out that the quantity of overstock referred to comes from Prairie Plant Systems which originated as the government research supply and as a result of litigation resulted in the Defendants making this supply available to patients, but it was found to be ineffective and of undesirable quality by a substantial majority of the approved patients, as documented by the Defendants, and it is unreasonable for the Defendants to rely upon such inadequate, and ineffective supply when they know it to be considered as an inferior quality product by the substantial majority of the MMAR patients.
- 16. In reply to paragraphs 77 and 78, the Plaintiffs put the Defendants to the strict proof of the amount available ready to be sold by Licenced Producers by March 31<sup>st</sup>, 2014, the detailed price ranges and particular details of the discounts offered for low income individuals confirming that they do not go below \$3.00 a gram.
- 17. In reply to paragraph 79, the Plaintiffs say while the *MMPR*'s intent may be achieved for some medically approved patients and may reduce some negative impacts that arose as a result of the Defendant's failure to properly regulate and inspect under the *MMAR*, the *MMPR* will not improve the situation for the Plaintiffs and others similarly situated who will not be able to afford the Licenced Producer prices, have developed a process where they can produce their own good quality medicine effectively at a cost that they can afford, and who are able to do so without any negative impacts on any others and who are willing to be subject to additional reasonable regulations to facilitate continuation of their personal production or by a designated caregiver.

- 18. In reply to paragraph 81, the Plaintiffs say that the intent of the MMPR will not be met except to a limited extent and that the MMPR will continue to impede access to those who will not be able to afford the estimated Licenced Producer prices and who have invested in a safe and secure set up and production facility that has enabled them to produce their quality medicine at a reasonable cost below even all special programs offered by Licenced Producers.
- 19. In reply to paragraph 82, the Plaintiffs say that the *MMPR* makes no provision for those medically approved patients who will not be able to afford the initial increases referred to over the period of unestimated time indicated. The Plaintiffs say that Licenced Producers will never be able to produce cannabis at a cost equivalent to their ability to produce their own medicine in there already safe and securely constructed facilities that they have developed to be effective over time. Consequently, the Plaintiffs say that they will be denied reasonable access to their medicine due to the failure on the part of the Defendants to provide or allow for a viable exemption for them to continue at least during this alleged time that remains undefined and for the foreseeable future.
- 20. In reply to paragraph 83, the Plaintiffs say that there are sufficient strains available in the market currently and that Licenced Producers will not be able to custom produce for each patient supplying them with a particular strain due to the enormous number of different strains and enormous number of different patients and the Plaintiffs are content with the current strains that they have been working with and that have proved to be effective for them without the need to resort to others and to recommence the process they had been involved in over many years of finding effective strains that work for them.
- 21. In reply to paragraph 85, the Plaintiffs say that this maximum possession limit is unreasonable and unduly restrictive and no similar limits are imposed upon others who possess prescribed drugs or natural health care products under the Controlled Drugs and Substances Act or Food and Drug Act or Narcotic Control Regulations and the limits proposed will make travel away from one's premises or producer for any length of time or distance to be problematic depending upon the patient's dosage per day and how long and how far away the patient will be from the source of supply. This will be particularly complicated in the case of patients using means other than the smoking (that has a negative impact upon their health, as documented by the Defendants) of "dried marihuana" or other products. The Plaintiffs further say that the substantial majority of patients are law abiding citizens who have no interest in the diversion of any of their medicine to the illicit market which they see as diminishing in any event as a result of oversupply and an apparent trend towards legalization. As in the past, the Plaintiffs will take appropriate security measures in relation to their premises and persons to ensure that they are not the victims of crime.
- 22. In reply to paragraphs 87-88, the Plaintiffs put the Defendants to the strict proof with respect to the details alleged beyond anecdotal evidence and say that the problems identified are subject to reasonable regulation and remediation and fail

to take into account the substantial majority of law abiding medical patients, like the Plaintiffs who have not experienced any public health or safety concerns as a result of producing in their dwelling places and who have reasonable sized production facilities in private dwellings that have been constructed professionally and subjected to inspection to ensure no public health and safety concerns and are in full compliance with the *MMAR*.

- 23. In reply to paragraph 88 the Plaintiffs put the Defendants to the strict proof of the matters alleged therein and say that they have not experienced any such problems in their outdoor production, take adequate security steps to ensure no diversion, have never had a complaint of cross contamination from others nearby, including the industrial hemp growers and say that once again there are remedial measures that can be taken short of prohibition of personal production by patient or caregiver to address any concerns.
- 24. In reply to paragraphs 89-94 the Plaintiffs say that the complete answer is contained in the decision of the Supreme Court of British Columbia in *R. v. Smith* 2012 BCSC 544 that specifically dealt with the limitation or restriction to dried marihuana only finding that this restriction did little or nothing to enhance the State interest, including the State interest in preventing diversion of the drug, or controlling false and misleading claims of medical benefit. The court found the restriction to be arbitrary and that its engagement of the rights to liberty and security of the person did not accord with principles of fundamental justice. The Defendants have simply reenacted in the *MMPR* the provision that was struck down by the courts in the *MMAR*, in British Columbia, and therefore will prejudice and set back the acquired rights of patients under that decision.
- 25. In further reply to paragraphs 89-94, the Plaintiffs say that the creation of any such products is for their personal consumption and not for sale to the public, and accepts that it is their responsibility to do so in a safe and secure manner that does not put themselves or any members of the public at risk and puts the Defendants to the proof of any specific problems that have arisen in relation to such products in British Columbia since the decision in *Smith* on April 13<sup>th</sup>, 2012.
- 26. In reply to paragraphs 95- 97 generally and paragraphs 98 through 102 (dealing with the elimination of personal production), and paragraphs 103 through 107 (dealing with limits on production locations), the Plaintiffs say it is not a matter of "avoiding the cost of purchasing commercially available equivalents" of their medicine, but that they simply cannot afford those costs due to their limited income and wish to control the nature and quality of their medicine and its cost, which includes production in their dwelling house to avoid the cost of producing elsewhere, and with the ability to move the plants outdoors from time to time, or even temporarily, to reduce electrical costs, instead of being compelled to rely on others. The Plaintiffs say that, like Terrence Parker, their cultivation of cannabis (marihuana), in their dwelling place, is incidental to their need to possess it for its therapeutic medical use, as approved by their physicians, for the treatment of their diagnosed illnesses. Like Terrence Parker this allows them to control the

quality of the product they use and to maximize its benefit and minimize the risks from a tainted or adulterated product, from the illicit market (or a licensed producer) and enables them, out of economic necessity, due to their being on disability pensions and/or of relatively limited economic means, and unable to afford illicit market or license producer prices, to obtain their medicine at reduced costs, without the need to rent additional premises, and enables them to spend what little income they have on necessities of life, food, shelter, transportation, and clothes, instead of licit or illicit street prices that are out of reach economically to them. Like Terrence Parker the Plaintiff's assert that they are entitled, as medically approved patients, to a constitutionally viable medical exemption to the prohibition against the possession and cultivation or production of cannabis (marihuana) for their medical health. The removal of this existing constitutional exemption under the MMAR will cause the plaintiffs, and approximately some 38,000 patients apparently similarly situated to have to, once again, choose between their liberty and their health and any reduction in the availability of their medicine for them will severely affect the security of their persons and is arbitrary, overbroad, and results in grossly disproportionate effects in violation of section 7 of the Canadian Charter of Rights and Freedoms.

- 27. In reply to paragraphs 108-113 (dealing with the limits on possession amounts), the Plaintiffs say that as part of their "viable constitutional exemption" they are entitled as medically approved patients to possess a sufficient quantity of their medicine as may be required depending upon the particular situation or circumstances at any particular time. An individual's illness and the amount of medicine that that individual requires is a fundamental personal decision between the patient and his physician that should not be interfered with by the government. Canada is a large country and while being able to possess up to 30 times the daily quantity of marihuana indicated by the health care practitioner under the MMAR appeared to be satisfactory to enable travel for up to a month away from one source of supply, the limit in the MMPR to 150 g at any time, will unreasonably restrict the viable constitutional exemption that some the Plaintiffs and others similarly situated are entitled to possess at any time by limiting their ability to travel away from their production facility and to have reasonable quantity of their medicine available to them wherever they may be, depending upon the grams per day approved by their physician. To interfere in this decision between the doctor and his patient is arbitrary, overbroad, will result in grossly disproportionate effects for some patients in violation of s.7 of the Charter.
- 28. In reply to paragraphs 114-119 (dealing with the prohibition on non-dried marihuana) the Plaintiffs, once again rely on the decision of the Supreme Court of British Columbia in R v. Smith, 2012 BCSC 544, which was heard by the Court of Appeal for British Columbia in December, 2013 and judgment is still reserved. The Plaintiffs say that the limitation or restriction or prohibition on the use of non-dried marihuana, approved by their physicians, does little or nothing to enhance the government's interest, including the government's interest in preventing diversion of the drug, or controlling false and misleading claims of medical

benefit. In accordance with Smith, the Plaintiffs say that this prohibition or restriction is arbitrary and engages their rights to liberty and the security of their person, and if removed from patients, including the Plaintiffs and others in British Columbia that are lawfully entitled to use non-dried marihuana as a result of the Smith decision, that decision by the Defendants, will cause them to have to choose between their liberty and their health if that restriction is re-imposed upon them and will remove the benefit they enjoy under that decision to the use of more effective medicine and to avoid the smoking of the medicine, which, as the Defendants have documented is harmful to their health. The Plaintiffs say that this prohibition is in violation of their rights under section 7 of the *Charter* and is arbitrary, overbroad and will result in grossly disproportionate effects.

In reply to paragraph 120 the Plaintiffs say that the onus is on the Defendants to 29. prescribe by law and demonstrably justify, in a free and democratic society, any reasonable limits on their s. 7 Charter rights. The Plaintiffs say that the objective of the MMPR's removal of personal production by patients of cannabis (marihuana) or by a designated caregiver, and the other limitations in the MMPR identified, and only to the extent applicable to personal producers or their designated caregivers, are not of sufficient importance to warrant the overriding of the Plaintiffs constitutional rights that are in issue. The Plaintiffs say that the objective is not "pressing and substantial" in all of the circumstances; that the means chosen is not reasonable and demonstrably justified; and while there might be a rational connection between the means chosen and the objective, the means chosen does not impair the right as little as possible in order to achieve the objective and, there is no proportionality between the objective and the effects of the legislation on the Charter protected interests of the Plaintiffs and others similarly situated, that it limits.

Dated: February 27, 2014

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