offlor No. T-2030-13 Recu/Rec FEDERAL COURT 2014 1 IAN 3 SERVICE OF A TRUE COPY BETWEEN: HEREOF ADMITTED 3.12V. THIS. DAY OF NEIL ALLARD **TANYA BEEMISH** 28 .14 **DAVID HEBERT SHAWN DAVEY** Solicitor for $A \cdot G \in C$ PLAINTIFFS AND:

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

DEFENDANTS

AFFIDAVIT OF DAVID W. PATE

I, DAVID W. PATE, Ph.D., M.Sc., of 280 – 1857 West 4th Avenue, Vancouver, British Columbia, MAKE OATH AND SAY AS FOLLOWS, THAT:

1. I am currently the Director, Canadian Advanced Studies Institute Ltd. in Vancouver, British Columbia and now produced and marked as Exhibit "A" to this my affidavit is a copy of my Curriculum Vitae which sets out that I graduated in 1974 with a Bachelor of Arts degree in science, with a major in Biology and a minor in Chemistry from Webster University in St. Louis, Missouri in 1974 and then a Masters of Science degree in Biology, from the University of Missouri – St. Louis at St. Louis, Missouri in 1979. I have also obtained a Doctor of Philosophy degree in Pharmaceutical Chemistry from the University of Kuopio, Finland in 1999. My CV also sets out my other education and training as well as professional appointments, research grants and memberships and scientific societies as well as my research interests and other academic and professional activities past and present. A significant amount of my research and experience has been in relation to the medicinal use of cannabis (marihuana).

2. Now produced and marked as Exhibit "B" to this my affidavit is a list of my publications as of July 15th, 2011 showing the various topics I have researched and studied and again indicating significant research in relation to cannabis (marihuana).

3. I appeared and was qualified as an expert in botany and pharmacology in the Supreme Court of British Columba in the case of *R. v. Owen Edward SMITH (2012 BCSC 544)* before the Honourable Mr. Justice Johnson in which the court ruled on April 13th, 2012 that on the evidence there had been a violation of liberty and security rights of the medical marihuana users protected by s.7 of the *Canadian Charter of Rights and Freedoms* and remedied the breach by deleting the word "dried" wherever it appeared in the *Marihuana Medical Access Regulations*. As a consequence the definition of "dried marihuana" became superfluous and was also deleted from those Regulations, leaving in place the balance of the Regulations but removing what the Court described as an artificial restriction on the lawful use of marihuana to its dried form. Now produced and marked as Exhibit "C" to this my affidavit are the Reasons for Judgment in *R. v. Smith* and I refer in particular to paragraphs 125-129 and 131.

4. I am informed by counsel for Mr. Smith, Mr. Kirk Tousaw, and verily believe it to be true, that the Federal Crown (Government of Canada) appealed that decision and that the matter was heard before the British Columbia Court of Appeal on December 6th, 2013 and judgment has been reserved.

5. Now produced and marked as Exhibit "D" to this my affidavit is a copy of the Expert Report that I prepared and that was filed in the *Smith (supra)* proceedings in the Supreme Court of British Columbia. That report sets out my background, history and experience and the focus of my work and expertise in relation to the cannabis plant and I hereby depose to the same information contained therein as my evidence in this affidavit and verily believe the contents of that report to be true.

2

6. I am informed by counsel for Mr. Smith, Mr. Kirk Tousaw, that my evidence as an expert was accepted by the BC Supreme Court and in particular by Mr. Justice Johnson and that in coming to his decision he accepted my evidence as follows as set out at paragraph [45] of his reasons for judgement:

- The active compounds of the cannabis plant are manufactured in cells at the reservoir base of, and stored in, structures called glandular trichomes.
- These glandular trichomes contain resin, and it is in the resin where the plant secretes THC and CBD.
- From the perspective of either a medicinal or recreational marihuana user, it is the contents of the glandular trichomes that are important.
- There is no known medical utility to the plant matter that is left behind after the glandular trichomes, or their contents, are separated from the host cannabis plant, or in the glandular trichomes themselves after the resin is extracted from them.
- There are different mechanisms for getting the therapeutic components, whether THC or CBD into the body, and Dr. Pate [the defence expert] described each.
- One can ingest the compound orally: if one were taking THC for gastrointestinal conditions such as Crohn's disease or Irritable Bowel Syndrome this would arguably deliver the therapeutic benefit more directly to the site of pathology.
- Oral ingestion also has the benefit of prolonging the effects of the drug in the system, with the corresponding detriment of taking longer to build a therapeutic level of the drug than would occur with smoking, for example
- Because of the slow build-up of the drug in the body, dosages are more difficult to manage, as it takes some time to determine when the optimum therapeutic level has been reached.
- Because orally ingested THC or CBD stays in the system longer, it would be better for someone with a chronic condition of pain or glaucoma, where some level of therapeutic dosage would remain while the patient slept.
- Smoking achieves a far quicker benefit, as the drug enters the body through the lungs and is dispersed rapidly.
- The level of THC in the body also declines much more quickly with smoke than with orally ingested THC.

- Smoking would be a better way to take a therapeutic dose in case of a sharp increase in pain or discomfort.
- Smoking also has harmful side effects associated with inhaling smoke which although less deleterious than tobacco smoke, may pose risks to the health nonetheless.
- A fourth application or ingestion method would be to spray a solution containing the active compound under the tongue, called trans-mucosal. Its advantages include faster assimilation of the drug, like smoking, without the risks associated with smoking.
- The cannabis marihuana plant and its active compounds are unlikely to cause physical harm in themselves, unlike other drug compounds where taking too much can lead to death.

7. I understand that the Government of Canada in the Marihuana for Medical Purposes Regulations (*MMPR*), and by amendments to the Narcotic Control Regulations (*NCR*) is limiting possession and distribution of cannabis (marihuana) to its "dried form" and therefore again precluding the use of this substance in less harmful and more effective ways through the use of it in forms other than "dried" such as in its natural form as a green plant or extracts such as oils and tinctures and concentrates.

8. I swear this Affidavit in support of an Application for an Order under s.24(1) of the *Canadian Charter of Rights and Freedoms* as the appropriate and just interim remedy, in the nature of:

I. An interim constitutional exemption from ss.4,5 and 7 of the Controlled Drugs and Substances Act for all persons medically approved under the Narcotic Control Regulations C.R.C., c.1041 (NCR), the MMAR or the MMPR, including those patients who have a caregiver 'person responsible' for them designated to produce for them, including an exemption for that caregiver 'person responsible' designated producer, pending trial of the merits of the action or such further Order of the court as may be necessary;

or, alternatively

II. an interlocutory exemption/injunction preserving the provisions of the *MMAR* relating to personal production, possession, production location and storage, by a patient or designated caregiver 'person responsible for the patient' and

related ancillary provisions, and if necessary, limiting the applicability of certain provisions of the *MMPR* to such patients or designated caregivers that are inconsistent with their s. 7 constitutional right under the *Charter* pending the decision of this Court on the merits of this action.

or alternatively, and together with

III. an interim/interlocutory order in the nature of *mandamus* to compel the Defendant to process all applications, renewals and modifications to any licences pursuant to the *MMAR* in accordance with all of its provisions (other than those challenged as unconstitutional herein), notwithstanding ss.230, 233-234, 237-238, 240-243 of the *MMPR* relating to applications under the *MMAR* after September 30th, 2013 as reflected in the amended *MMAR* sections 41-48.

and such further and other relief as the court deems appropriate and just in all of the circumstances.

Alameda SWORN BEFORE ME at the Gity of San) Francisco, the State of California, USA, this 16th day of January, 2014 A Commissioner for Taking Affidavits in) and for the State of California, USA

1/1/. Pate

DAVID W. PATE

State of California, County of Alameda Subscribed and sworn to (or affirmed) before me on

200 2013 Jan this (6⁴⁴ day of _

by David Pate proved to me on the basis of satisfactory evidence

to be the person(s) who appeared before me.

Notary Public - Pust



PAGES 6 THROUGH 8 HAVE BEEN REMOVED FOR PRIVACY REASONS.

October 15, 2013



This is Exhibit the afficavit of swom before me e 16th this Nota A commissioner for taking Affidevita for-Difish-Columbia

LIST OF PUBLICATIONS

I. ORIGINAL PUBLICATIONS:

1a. Primary Research

avid W Pat.

1. Juntunen, Juha, Juhani Huuskonen, Krista Laine, Ricku Niemi, Hannu Taipale, Tapio Nevalainen, David W. Pate, and Tomi Järvinen. Anandamide prodrugs 1. Water-soluble phosphate esters of arachidonylethanolamide and *R*methanandamide. *European Journal of Pharmaceutical Sciences* 19: 37-43 (2003).

2. Laine, Krista, Kristiina Järvinen, David W. Pate, Arto Urtti and Tomi Järvinen. Effect of the enzyme inhibitor, phenylmethylsulfonyl fluoride, on the IOP profiles of topical anandamides. *Investigative Ophthalmology and Visual Science* 43 (2): 393-397 (2002).

3. Laine, Krista, Tomi Järvinen, Juha Savinainen, Jarmo T. Laitinen, David W. Pate and Kristilna Järvinen. Effects of topical anandamide uptake inhibitors, AM404 and olvanil, on intraocular pressure in normotensive rabbits. *Pharmaceutical Research* 18 (4): 494-499 (2001).

4. Jarho, Pekka, David W. Pate, Rudolf Brenneisen and Tomi Järvinen. Hydroxypropyl-*beta*-cyclodextrin and its combination with hydroxylpropylmethylcellulose increases aqueous solubility of *delta*⁹-tetrahydrocannabinol. *Life Sciences* 63 (26): PL381-384, 1998.

5. Pate, David W., Kristiina Järvinen, Arto Urtti, Vaidyanath Mahadevan, Tomi Järvinen. Effect of the CB1 receptor antagonist, SR 141716A, on cannabinoid-induced ocular hypotension in normotensive rabbits. *Life Sciences* 63 (24): 2181-2188 (1998).

6. Pate, David W., Kristiina Järvinen, Arto Urtti, Vaidyanath Mahadevan, Tomi Järvinen. Effects of topical *alpha*-substituted anandamides on intraocular pressure in normotensive rabbits. *Pharmaceutical Research* 14: 1738-1743 (1997).

7. Callaway, J.C., T. Tennilä and D.W. Pate. Occurrence of "omega-3" stearidonic acid (*cis*-6,9,12,15-octadecatetraenoic acid) in hemp (*Cannabis sativa* L.) seed. *Journal of the International Hemp Association* 3 (2): 61-63 (1996).

8. Jarho, Pekka, Arto Urtti, David W. Pate, Pekka Suhonen and Tomi Järvinen. Increase in aqueous solubility, stability and *in vitro* corneal permiability of anandamide by hydroxypropyl-*beta*-cyclodextrin. *International Journal of Pharmaceutics* 137: 209-216 (1996).

9. Pate, David W., Kristiina Järvinen, Arto Urtti, Pekka Jarho, Mette Fich, Vaidyanath Mahadevan and Tomi Järvinen. Effects of topical anandamides on intraocular pressure in normotensive rabbits. *Life Sciences* 58 (21): 1849-1860 (1996). 10. Jarho, Pekka, Arto Urtti, Kristiina Järvinen, David W. Pate and Tomi Järvinen. Hydroxypropyl-*beta*-cyclodextrin increases aqueous solubility and stability of anandamide. *Life Sciences* 58 (10): PL181-185 (1996).

11. Pate, David W., Kristiina Järvinen, Arto Urtti, Pekka Jarho and Tomi Järvinen. Ophthalmic arachidonylethanolamide decreases intraocular pressure in normotensive rabbits. *Current Eye Research* 14 (9): 791-797 (1995).

12. Laster, B.H., S.B. Kahl, D.W. Pate, E.A. Popenoe and R.G. Fairchild. Biological efficacy of boronated low density lipoproteins (LDL) for neutron capture therapy (NCT) as measured in cell culture. *Cancer Research* 51: 4588-4593 (1991).

13. Cashman, John R., John Proudfoot, David W. Pate and Thomas Högberg. Stereoselective *N*-oxygenation of zimeldine and homozimeldine by the flavincontaining mono-oxygenase. *Drug Metabolism and Disposition* 16 (4): 616-622 (1988).

14. Pate, David W. and John E. Averett. The flavonoids of *Datura*. *Biochemical Systematics and Ecology* 14 (6): 647-649 (1986).

15. Pate, David W. Possible role of ultraviolet radiation in evolution of *Cannabis* chemotypes. *Economic Botany* 37 (4): 396-405 (1983).

1b. Critical Reviews

16 Järvinen, Tomi, David W. Pate and Krista Laine. Cannabinoids in the treatment of glaucoma. *Pharmacology & Therapeutics* 95: 203-220 (2002).

17. Deferne, Jean-Luc and David W. Pate. Hemp seed oil: A source of valuable essential fatty acids. *Journal of the International Hemp Association* 3 (1): 1, 4-7 (1996).

18. Pate, David W. Guide to the scientific literature on potential medical uses of *Cannabis* and the cannabinoids. *Journal of the International Hemp Association* 2 (2): 74-76 (1995).

19. Pate, David W. Chemical ecology of *Cannabis. Journal of the International Hemp Association* 1 (2): 29, 32-37 (1994).

20. Clarke, Robert C. and David W. Pate. Medical marijuana. *Journal of the International Hemp Association* 1 (1): 9-12 (1994).

I. ORIGINAL PUBLICATIONS: 2. Patents and patent publications

1. Whittle, Brian; Geoffrey Guy, David Downs and David Pate. Processes and apparatus for extraction of active substances and enriched extracts from natural products. International Patent Cooperation Treaty Document WO 02/89945 (November 14, 2002); Australian Patent 2002255150 (January 22, 2009); Canadian Patent 2446195 (July 22, 2008); China Patent 1,524,007 (March 28, 2007); European Patent (Pending); Israel Patent 158709 (February 1, 2008); New Zealand Patent 529,360 (December 8, 2005); U.S. Patent 7,622,140 (November 24, 2009); Great Britain Patent 2,376,464 (September 9, 2004); Great Britain Patent (divisional) 2,400,319 (March 31, 2005); Great Britain Patent (divisional) 2,400,320 (March 31, 2005).

2. Pate, David W. Enhanced isolation chambers for ascending-stream extractive vaporizer. U.S. Patent 6,481,437 (November 19, 2002).

3. Järvinen, Tomi; Kristiina Järvinen, Arto Urtti and David W. Pate. Method for the preparation of a pharmaceutical composition. International Patent Cooperation Treaty Document WO 00/38671 (July 6, 2000); Finnish Patent 109087 (May 31, 2002).

4. Pate, David W. Vaporizer for inhalation and method for extraction of active ingredients from a crude natural product or other matrix. International Patent Cooperation Treaty Document WO 99/11311 (March 11, 1999); Rep. S. Africa Patent 09/7845 (June 30, 1999); U.S. Patent 6,250,301 (June 26, 2001); New Zealand Patent 502,419 (October 9, 2001); Australian Patent 735,700 (October 25, 2001); Indian Patent 187,132 (September 6, 2002); European Patent 1,007,124 (October 17, 2007); Canadian Patent 2,297,057 (April 4, 2009).

5. Pate, David W.; Tomi Järvinen, Kristiina Järvinen and Arto Urtti. Anandamide analogue compositions and method of treating intraocular pressure using same. International Patent Cooperation Treaty Document WO 96/01558 (January 25, 1996); U.S. Patent 5,977,180 (November 2, 1999); Canadian Patent 2,192,965 (December 4, 2007).

6. Pate, David W.; Tomi Järvinen, Kristiina Järvinen and Arto Urtti. Anandamides useful for the treatment of intraocular hypertension, ophthalmic compositions containing the same and methods of use of the same. U.S. Patent 5,631,297 (May 20, 1997).

I. ORIGINAL PUBLICATIONS: 3a. M.Sc. Thesis

The phytochemical ecology of *Cannabis*. University of Missouri-St. Louis. April, 1979.

3b. Ph.D. Dissertation

Anandamide structure-activity relationships and mechanisms of action on intraocular pressure in the normotensive rabbit model. Kuopio University Publications A. Pharmaceutical Sciences 37, 1999.

I. ORIGINAL PUBLICATIONS: 4. Proceedings Publications

1. Pate, David W. Development of *Cannabis*-based therapeutics. <u>Prospects for</u> <u>Cannabinoid Drug Development</u>, February 23-24, 1998. "Medical Use of Marijuana: Assessment of the Science Base" Workshop Series. Institute of Medicine, National Academy of Sciences, Washington, D.C., *Journal of the International Hemp Association* 5 (1): 36-39 (1998). 2. Pate, David W. Anandamides: Alternative cannabinoids for glaucoma? In: <u>Biorohstoff Hanf (Bioresource Hemp), Proceedings of the Symposium</u>, February 27-March 2, 1997, Frankfurt am Main, Germany, nova-Institute, Büro Hürth, Cologne, p. 684.

3. Pate, David W. Hemp seed: A valuable potential food crop. *In ibid.*, p. 484.

4. Jarho, P., A. Urtti, D.W. Pate, P. Suhonen and T. Järvinen. The effects of HP-*beta*-CD on aqueous solubility, stability and *in vitro* corneal penetration of anandamide. In <u>Proceedings of the Eighth International Symposium on Cyclodextrons</u>, Szejtli, J. and L. Szente, Eds., p. 395-398, Kluwer Academic Publishers, The Netherlands, 1996.

5. Pate, David W., Some national policies and practices on *Cannabis*. <u>Hamppu</u> <u>Kulttuurikasvina-Hankasalmen hamppuseminaari (Proceedings from the Hankasalmi</u> <u>Hemp Seminar</u>), J.C. Callaway and A. Hemmilä, Eds., Hankasalmen kunnan monistamo (Hankasalmi County Press), September 9, 1995, Hankasalmi, Finland.

6. Pate, David W., Products and potentials: *Cannabis* hemp in Finland. *In ibid.*

7. Pate, David W. *Cannabis*: The chemistry of its ecology and evolution. In: <u>Biorohstoff Hanf (Bioresource Hemp), Proceedings of the Symposium</u>, March 2-3, 1995, Frankfurt am Main, Germany, 2nd Edition, nova-Institute, Büro Hürth, Cologne, pps. 164-169.

8. Kahl, Stephen B., David W. Pate, Brenda H. Laster, Edward A. Popenoe and Ralph G. Fairchild. *In vitro* biological efficacy of boronated low density lipoproteins for NCT. *In* <u>Progress in Neutron Capture Therapy for Cancer</u>, Barry J. Allen, Douglas E. Moore and Baiba V. Harrington, Eds., pp. 365-68, Plenum Press, NY, 1992.

II. BOOK CHAPTERS

1. Callaway, J.C. and David W. Pate. Hemp Seed Oil. Chapter 6 in <u>Gourmet</u> <u>Oils and Health-Promoting Specialty Oils</u>, A. Kamal-Eldin and R. Moreau, Eds., pp. 185-213, American Oil Chemists Society Press, Champaign, IL, 2009.

2. Pate, David W. Taxonomy of the Cannabinoids. Part I, Chapter 2 in <u>Cannabis</u> and <u>Cannabinoids</u>: <u>Pharmacology</u>, <u>Toxicology</u> and <u>Therapeutic</u> <u>Potential</u>, F. Grotenhermen and E. Russo, Eds., pp. 15-26, Haworth Press, Binghamton, NY, 2002. (German version: *Cannabis* und Cannabinoide: Pharmakologie, Toxikologie und therapeutisches Potenzial, F. Grotenhermen, Hrsg., Verlag Hans Huber, Bern, Schweis, 2001.)

3. Pate, David W. Glaucoma. Part II, Chapter 19 in *ibid*, pp. 215-224.

4. Pate, David W. Anandamides: Potential Glaucoma Medicine? Part VI, Chapter 34 in *ibid*, pp. 371-380.

5. Pate, David W. The Phytochemistry of *Cannabis*: Its Ecological and Evolutionary Implications. Chapter 2 *in* <u>Advances in Hemp Research</u>, P. Ranalli, Ed., pp. 21-42, Haworth Press, Binghamton, NY, 1999.

6. Pate, David W. Hemp Seed: A Valuable Food Source. Chapter 11 in *ibid.* pp. 243-255.

7. Clarke, Robert C. and David W. Pate. The Economic and Environmental Value of *Cannabis*. Chapter 17 *in <u>Cannabis</u> in <u>Medical Practice</u> M.L. Mathre, Ed., pp. 192-211, McFarland and Company, Jefferson, NC, 1997.*

8. Clarke, Robert C. and David W. Pate. Medical Marijuana. Section 4 in <u>Hemp</u> <u>Today</u>, E. Rosenthal, Ed., pp. 303-309, Quick American Archives, Oakland, CA, 1994.

9. Kahl, Stephen B., David W. Pate, and Larry A. Wainschel. Low density reconstitutions with alkyl and aryl carboranes. *In* <u>Advances in Neutron Capture</u> <u>Therapy</u>, A.H. Soloway et al., Eds., pp. 399-402, Plenum Press, NY, 1993.

III. BOOK REVIEWS

1. Pate, D.W., <u>Health Defence</u>, by Paul Clayton. (Reviewed at the author's request.) *http://www.amazon.co.uk/exec/obidos/tg/stores/detail/-/books/0905553632/customer-reviews/qid=1009227965/sr=1-1/ref=sr_sp_re/202-8882573-2530250* (April 27, 2001).

2. Pate, D.W., <u>Nutritional and Medicinal Guide to Hemp Seed</u>, by Kenneth Jones. *Journal of the International Hemp Association* 3 (1): 43-44 (1996).

3. Pate, D.W., <u>Industrial Hemp</u>, by John Roulac and Staff. *Journal of the International Hemp Association* 2 (1): 42 (1995).

IV. PRESENTATION ABSTRACTS

1. Pate, David W. Anandamides and glaucoma: An update. The Second National Clinical Conference on *Cannabis* Therapeutics: Analgesia and Other Indications. May 3-4, 2002, Portland, Oregon, USA. (http://www.youtube.com/watch?v=aBCDZ-czKuM)

2. Tomi Järvinen, Juha Juntunen, Juhani Huuskonen, Tapio Nevalainen, David W. Pate and Krista Laine. Water-soluble anandamide prodrugs. International Cannabinoid Research Society Meeting, June 28-30, 2001, Madrid, Spain, Symposium Program and Abstracts.

3. Krista Laine, Tomi Järvinen, Juha Savinainen, Jarmo T. Laitinen, David W. Pate and Krista Laine. Anandamide uptake inhibitors, AM404 and Olvanil, decrease intraocular pressure in normotensive rabbits. International Cannabinoid Research Society Meeting, June 28-30, 2001, Madrid, Spain, Symposium Program and Abstracts.

4. Juntunen, Juha; Huuskonen, Juhani; Laine, Krista; Niemi, Riku; Taipale, Hannu; Pate, David W. and Järvinen, Tomi. Water-soluble phosphate ester prodrugs of arachidonylethanolamide and *R*-methanandamide. European Federation for Pharmaceutical Sciences World Conference on Drug Absorption and Drug Delivery. June 18-20, 2001, Copenhagen, Denmark, Symposium Program and Abstracts, pps. 101-102.

5. Laine, K., Järvinen, K., Pate, D.W., Urtti, A., Järvinen, T. Effects of phenylmethyl sulfonyl fluoride on the intraocular pressure profile of anandamide. Arch Pharm 333: S1,7 (2001).

6. Kristiina Järvinen, Krista Laine, David W. Pate, Arto Urtti and Tomi Järvinen. The effect of topical anandamide on intraocular pressure, with and without a topical transport inhibitor. Proceedings of the XIV International Congress of Eye Research. October 15-20, 2000, Santa Fe, New Mexico, USA, p. S.77.

7. Pate, David W. Exo/Endo cannabinoids as potential glaucoma medicines. Bioresource Hemp Symposium, September 13-16, 2000, Wolfsberg, Germany.

8. Laine, Krista, Kristiina Järvinen, David W. Pate, Arto Urtti and Tomi Järvinen. Effects of phenylmethylsulfonyl fluoride, and its administration with SR141716A, on anandamide-induced intraocular pressure profile in normotensive rabbits. International Cannabinoid Research Society Meeting, June 22-24, 2000, Hunt Valley, MD, USA, Symposium Program and Abstracts, p. 121.

9. Pate, David W. *Cannabis* and human cannabinoids: Their potentials as medicines. The First National Clinical Conference on *Cannabis* Therapeutics, Medical Marijuana: Science-Based Clinical Applications. April 6-8, 2000, University of Iowa, Iowa City, Iowa, USA.

10. Pate, David W., Pekka Jarho, Rudolf Brenneisen and Tomi Järvinen. Cyclodextrins improve aqueous solubility and stability of cannabinoids. International Cannabinoid Research Society Meeting, June 18-20, 1999, Acapulco, Mexico. Symposium Program and Abstracts, p. 78.

11. Pate, David W. Development of *Cannabis*-based therapeutics. Pharmaciae Sacrum Symposium, *Cannabis*: het groene medicijn? De medicinale toepassingen van *Cannabis*, Dec. 9-11, 1998. University of Gronigen, The Netherlands, Abstracts booklet, pp. 31-32.

12. Pate, David W., Kristiina Järvinen, Arto Urtti, Vaidyanath Mahadevan and Tomi Järvinen. Effect of CB₁ receptor antagonist on cannabinoid-induced ocular hypotension in rabbits. International Cannabinoid Research Society Meeting, July 23-25, 1998, La Grand Motte, France. Symposium Program and Abstracts, p. 74.

13. Pate, David W. Anandamides: Alternative cannabinoide in der glaukombehandlung. *In Cannabis* und Cannabinoide als Medizin pps. 42-43, November 22, 1997. Arbeitsgemeinschaft *Cannabis* als Medicine, Cologne, Germany.

14. Pate, David W., Kristiina Järvinen, Pekka Jarho, Arto Urtti and Tomi Järvinen. Topical application of ophthalmic *alpha*-substituted anandamides decreases intraocular pressure in normotensive rabbits. International Cannabis Research Society Meeting, June 14-16, 1996, West Dennis, Massachusetts. Symposium Program and Abstracts, p. 6.

15. Jarho, P., D.W. Pate, P. Suhonen, A. Urtti and T. Järvinen. The Effects of HP-*beta*-CD on aqueous solubility, stability and *in vitro* corneal penetration of anandamide. The 8th International Cyclodextrin Symposium, March 30-April 2, 1996, Budapest, Hungary. Symposium Program and Abstracts, Section 3, p.14.

16. Pate, David W., Kristiina Järvinen, Arto Urtti and Tomi Järvinen. Topical application of ophthalmic anandamides decreases intraocular pressure in normotensive rabbits. International Cannabis Research Society Meeting, June 8-10, 1995, Scottsdale, Arizona. Symposium Program and Abstracts, p. 54.

17. Jarho, P., A. Urtti, D. Pate and T. Järvinen. Hydroxypropyl-*beta*-cyclodextrin increases *in vitro* corneal penetration of arachidonylethanolamide. XXXVIII. Nordic Meeting of Pharmacology & XIII Helsinki University Course in Drug Research, May 18-20, 1995. Pharmacology and Toxicology (Abstracts) 76 (S-II): 51.

18. Urtti, A., D. Pate, K. Järvinen, P. Jarho, T. Järvinen. Ophthalmic arachidonylethanolamide decreases intraocular pressure in rabbits. Association for Research in Vision and Ophthalmology Annual Meeting, May 14-19, 1995, Fort Lauderdale, Florida. Investigative Ophthalmology & Visual Science, Proceedings Abstracts 36 (4): S720.

19. Pate, David W. *Cannabis*: The chemistry of its ecology and evolution. Second International Congress for the Study of Modified States of Consciousness. October 3-7, 1994, Lerida, Spain.

20. Kahl, S.B., D.W. Pate, B.H. Laster, E.A. Popenoe and R.G. Fairchild. *In vitro* biological efficacy of boronated low density lipoproteins (LDLs) for neutron capture therapy. Fourth International Symposium on Neutron Capture Therapy for Cancer, December 3-7, 1990, Sydney, Australia.

21. Cashman, John R., John Proudfoot, David W. Pate and Thomas Högberg. Unusual rearrangements in the oxidative metabolism of tertiary amines. Pacific Conference on Chemistry and Spectroscopy, October 26-28, 1988, San Francisco, California.

V. POPULAR MEDIA

1. "Hemp and Flax: The Smoothie". *Journal of Industrial Hemp* 13(1): 93-95 (2008).

2. Profiled as expert witness in "Bud, Inc." by Ian Mulgrew, Random House Canada, Toronto, 2005.

3. Interviewed by Lisa Nainggolan in "Marijuana-a missed market opportunity?" *Scrip (World Pharmaceutical News)*, pps. 22-26. December, 1997.

4. Interview of Dr. Yukihiro Shoyama. Journal of the International Hemp Association 4 (2): 95-96 (1997).

5. Interview of Dr. Rudolf Brenneisen. *Journal of the International Hemp Association* 4 (1): 22-25 (1997).

6. Appearance on the "Whatever Happened to Hemp" episode produced by Kate Howell for the "Omnibus" current-affairs series of BBC Radio, London, England. Presented by David Lodge on May 3-8, 1997.

7. Interview of Dr. Mahmoud A. ElSohly. *Journal of the International Hemp Association* 3 (1): 43-44 (1996).

8. Appearance on the "Hemp: Raw Material of the Future" program. Produced and presented by Helen Barrington for Radio Nederlands, Amsterdam, The Netherlands, February 28, 1996.

9. Appearance on the "Medical Marijuana" episode of the "Norder Licht" (Northern Lights) science series. Produced and presented by Jan Diederen for VPRO Television, Amsterdam, The Netherlands, October 2, 1995.

10. Interview of Dr. Raphael Mechoulam. *Journal of the International Hemp* Association 1(1): 9-12 (1994).

Citation: R. v. Smith, 2012 BCSC 544 Date: 20120413 Docket: 149345-2 **Registry: Victoria** ÷., This is Entret me attic.vit o Ale Regina sworn issicre mes en bth this. \${7 € ٧. for taking Alfidavita Commissioner **Owen Edward Smith** ate

IN THE SUPREME COURT OF BRITISH COLUMBIA

Before: The Honourable Mr. Justice Johnston

OLIN E. RUST Сомм. # 2040563 Ø OTARY PUBLIC - CALIFORNIA ALAMEDA COUNTY MY COMM. EXP. SEP. 7, 2017

Reasons for Judgment

On Voir Dire

Counsel for the Public Prosecution Service of Canada: P.A. Eccles and K. Guest

Counsel for the Accused:

Place and Date of Trial:

K.I. Tousaw

2012 BCSC 544 (CanLII)

Victoria, B.C. January 16-20, 23-26, 2012; February 1, 6-8, 27-29, 2012; March 1, 2012

> Victoria, B.C. April 13, 2012

Place and Date of Judgment:

[1] This is a challenge to the medical marihuana regime developed in response to court decisions starting with *R. v. Parker* (2000), 49 O.R. (3d) 481, 146 C.C.C. (3d) 193 (C.A.).

[2] The accused Owen Smith is charged that on December 3, 2009, he possessed one of the forms of tetrahydrocannabinol ("THC") prohibited by the *Controlled Drugs and Substances Act*, S.C. 1996, c. 19 ("*Act*"), for the purpose of trafficking, and that on the same day he possessed cannabis (marihuana).

[3] For the purposes of a *voir dire*, the accused admits that, as he was separating THC from cannabis marihuana, baking it into cookies, putting THC-infused oil into capsules, and making a variety of other products that contained THC, so that his employer could sell them, he had in his possession THC for the purposes of distribution. He also admits to possession of dried marihuana.

[4] On this *voir dire*, the accused says that the government's responses to court rulings since *Parker* have not only been inadequate, but have been close to contemptuous of orders and directions of the court, and the appropriate remedy for this would be a judicial stay of proceedings.

[5] He argues as well that the *Act* and the *Marihuana Medical Access Regulations*, SOR/2001/227 ("*MMAR*"), as amended from time to time up to his arrest, cannot constitutionally prohibit his rendering of dried cannabis plant material into oils and other substances infused with the active ingredients of the cannabis plant, particularly THC, for medical purposes. To the extent that the *Act*'s provisions and the *MMAR*'s provisions attempt to do so, the accused says that they infringe on his right to life, liberty and security of the person under the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11, s. 7 ("*Charter*"), as well as those rights of others. He seeks a declaration from Part VII of the *Constitution Act*, 1982, c. 11, s. 52(1), that, to the extent that the provisions are inconsistent with the *Charter*, s. 7, in limiting lawful possession of marihuana for medical purposes to possession in the form of dried cannabis, those provisions are of no force or effect.

[6] In context, the accused was employed at what seems to be a form of compassion club, to render marihuana plants in such a way as to separate the active ingredients from the plant itself, and to infuse those active ingredients into a variety of edible and other products for sale through the club.

[7] These issues were canvassed on a *voir dire* heard before a jury was empanelled for the trial.

Legal Background

[8] Schedule II of the *Act* lists "cannabis, its preparations, derivatives and similar synthetic preparations," including those listed in nine sub-paragraphs. Possession of any of the listed substances is a hybrid offence under s. 4 of the *Act*, punishable by up to five years if proceedings are by indictment, and to a fine of up to \$1,000 and/or imprisonment for up to six months for a first offence, and a fine up to \$2,000 and/or to one year in jail for a subsequent offence if proceedings are summary. Possession of any of the substances listed in Schedule II for the purpose of trafficking is an offence under s. 5, with punishment up to imprisonment.

[9] In July 2000, the Ontario Court of Appeal released its decision in *Parker*. Mr. Parker had been investigated and charged twice: the first time he was charged with cultivation under the *Narcotic Control Act*, R.S.C. 1985, c. N-1, and the second time with possession under the *Act*, the former having been replaced by the latter between the two charges. The Court ruled that the former prohibition against cultivation of marihuana set out in the *Narcotic Control Act* was unconstitutional as it infringed the rights under the *Charter* of an accused who had shown a need for marihuana to control his epilepsy. The Court declared the possession offence --- which the new *Controlled Drugs and Substances Act*, s. 4, continued --- was invalid as it applied to marihuana, and the Court suspended the effect of its declaration for one year. It granted an exemption from the marihuana prohibitions in s. 4 to the respondent Mr. Parker during the period of suspension in order to permit him to possess marihuana for his medical needs.

[10] *Parker* arose from facts which established that Mr. Parker had epilepsy, that he required marihuana because marihuana, taken with drugs prescribed by his doctors, helped to control seizures which, if not controlled, could at minimum harm his health and at worst, end his life.

[11] In its reasons, the Court of Appeal agreed with the trial judge that marihuana had medicinal value, at least as to the THC component, and perhaps as to other components.

[12] At the end of the period of suspension, the Government of Canada promulgated the *MMAR*. In its first iteration, the *MMAR* established a regulatory scheme by which someone could apply for an Authorization To Possess marihuana. An applicant needed support of one physician if the need were based on a terminal illness, one specialist if it were based on a listed condition and associated with a terminal condition, and two specialists if the need were based on another medical condition.

[13] The first *MMAR* made no provision for access to marihuana by those who were granted an Authorization To Possess.

[14] There were further challenges, both to the *Act*, when it replaced the *Narcotic Control Act* in 1996, and to the *MMAR*. The successful challenges prompted amendments to the *MMAR*, including provisions that permitted holders of an Authorization To Possess to obtain authorizations that would permit them to produce the marihuana they were authorized to possess. As well, third parties could obtain authorizations to supply marihuana to those with an Authorization To Possess.

[15] Although this is an admittedly rough summary, it is fair to say that after the first major change brought about by *Parker*, subsequent changes in the law have been incremental.

[16] The developments since *Parker* have led the accused here to assert that government response to various court declarations has been inadequate or, worse, obstructive. Some of those developments have led counsel for the Crown to suggest that some court decisions have strayed into the legislative or policy sphere, traditionally and constitutionally the area where Parliament is supreme.

Facts

[17] Commendably, counsel agreed on admissions for the purpose of this *voir dire* only. These include:

- On December 3, 2009, Cst. Peter Gill of the Victoria Police Department attended to an apartment building at #205 — 865 View Street, Victoria, British Columbia, in response to a complaint from the manager of that building that he (the manager) had received complaints of a strong offensive "skunky" odour coming from Apartment 204 ("the apartment") and wafting throughout the building.
- 2. Constables Gill and Sark arrived at the apartment building at about 3:00 p.m. and attended to the door to the apartment. Constable Gill could hear loud music coming from the apartment, as well as smell baking. Constable Gill knocked on the door to the apartment, announced himself, and then entered into a brief discussion with Mr. Smith, who initially declined to open the door to the apartment. After a further brief conversation Mr. Smith opened the door to the apartment. Mr. Smith was alone in the apartment.
- 3. Constable Gill produced his police identification to Mr. Smith and stepped into the apartment, a small bachelor suite of approximately 400 square feet, with a small bathroom as the only room with a door in the suite. Constable Gill immediately noted a strong odour of baking within the suite, which was quite warm, and that it appeared as if the suite was being used solely as a bakery. There was nothing in the

suite indicative of anyone actually residing in it — no couch, no bed, no television, no clothing nor personal articles.

- 4. Directly beside Mr. Smith, just inside the doorway to the apartment, in plain view, was a small table with a plastic baggy containing approximately one gram of what Cst. Gill believed to be marihuana, along with another gram of the same substance beside the baggy along with scissors that appeared to have marihuana residue on them.
- 5. Constable Gill arrested Mr. Smith for possession of the marihuana he had seen in plain view, then called for assistance to deal with the balance of the various items in the apartment.
- 6. A search warrant for the apartment was obtained and executed later that day, into the early morning hours of the next. The police seized from the apartment the forty-eight items set out on the four page Exhibit Flow Chart. It is admitted that this Exhibit Flow Chart accurately sets out the description of the exhibit seized, where it was located, who located it, and continuity of it after seizure. The Exhibit Flow Chart is admitted for the truth of its contents. There is no issue as to the continuity of any exhibits. Continuity is admitted, as is the nature of all substances.
- The police videotaped their entry of the apartment under the search warrant, and videotaped the apartment itself as it was originally found. This videotape is admitted.
- 8. The quantities of marihuana derivatives that were seized from the apartment were possessed for the purposes of trafficking.
- For the purpose of the *voir dire* only, Mr. Smith admits all elements of Counts One and Two.

[18] The accused is employed by Leon Edward (Ted) Smith, to whom he is not related, to process dried marihuana into a number of different products, including cookies, oil-filled capsules, and other edible and non-edible products.

[19] The accused works full-time for Mr. Ted Smith, and earns somewhere between \$10 and \$13 per hour.

[20] Mr. Ted Smith operates an enterprise called the Cannabis Buyers Club of Canada ("Club").

[21] Although there is a society involved somehow, it appears that the Club is a sole proprietorship wholly owned by Mr. Ted Smith.

[22] The Club admits to membership those who can satisfy Mr. Ted Smith, or those he delegates to screen applicants for membership, that they suffer from a permanent physical disability or disease.

[23] The applicant must produce satisfactory evidence of such a condition, which could be in the form of a document from a physician, a cancer test result, a laboratory test result, or, in some cases, evidence of a prescription for medications recognized by Mr. Ted Smith as being ordinarily prescribed for permanent physical disability or disease.

[24] This distinguishes Mr. Ted Smith's Club from Compassion Clubs with which he is familiar. He understands that Compassion Clubs require a form or certificate signed by a doctor before they will admit someone to membership, and turn away applicants who cannot obtain a doctor's signature.

[25] Mr. Ted Smith's Club is available to those who can persuade him of their need, but who cannot obtain written support for medical marihuana use from a doctor.

[26] An applicant who cannot provide sufficient documentary evidence of permanent physical disability or disease is turned away.

[27] Mr. Ted Smith will not accept as sufficient for membership evidence emanating from naturopathic physicians, chiropractors, or doctors of Chinese medicine.

[28] Mr. Ted Smith will not accept an applicant who has a mental health disorder.

[29] Mr. Ted Smith estimated that the Club has between 3,700 to 4,000 members, and perhaps 5% to 10% of those hold a valid Authorization To Possess dried marihuana issued by Health Canada under the *MMAR*.

[30] Club rules are relatively simple, and include a proscription against reselling or giving away products purchased from the Club, and a warning about operating heavy equipment or driving after consuming Club products.

[31] Mr. Ted Smith says he has taken away 500 to 600 memberships over the years because members have resold or given away cannabis products obtained from the Club.

[32] Mr. Ted Smith buys marihuana in pound quantities, and pays employees, like the accused Mr. Smith, to render between 5% and 10% of the dried marihuana into other forms like cookies, oils, capsules and ointments. The bulk of the dried marihuana is packaged and sold through the store openly operated by the Club in downtown Victoria.

[33] The Club operates its store under a non-profit society formed by Mr. Ted Smith, and while the society maintains minimal records, neither the Club nor the store keeps records.

[34] Mr. Ted Smith estimates that the store generates revenue of about \$6,000 to \$6,500 per day. He estimates that between 5% and 10% of that volume represents edible and other products, not dried marihuana, and says this proportion is closer to the 5% lower end. Mr. Ted Smith aims for a profit margin of between 20% and 25%.

[35] Neither the store nor the Club collects or remits HST, nor does the business pay income taxes.

Scientific and Regulatory Evidence

Expert Evidence

[36] The accused relied on the evidence of Dr. David Pate, who was qualified as an expert in botany and pharmacology.

[37] The Crown called Dr. Hanan Abramovici, who was qualified as an expert in pharmacology and neuroscience, and Mr. Eric Ormsby, a manager at Health Canada. All three swore affidavits instead of producing written reports or opinions, in an apparent fusion of the documents referred to in s. 657.3 of the *Criminal Code*, R.S.C. 1985, c. C-46. There were no objections to this procedure.

[38] Dr. Pate and Dr. Abramovici, while well-meaning and honest, strayed from objective opinion into advocacy, and each appeared at times argumentative when testifying.

[39] Dr. Abramovici's criticism of Dr. Pate for making assertions with little scientific support is well taken, although lack of science surrounding cannabis marihuana can be partly explained by governmental and public attitudes toward the plant and its products.

[40] Dr. Abramovici lapsed into some of the same reliance on anecdotal evidence for which he criticized Dr. Pate: for example, at the end of para. 23 of his affidavit, he speculates that the number of people injured in accidents arising from solvent-based extractions is probably underestimated as some reported delaying medical treatment because of fear of prosecution.

[41] Dr. Pate seemed a bit too willing to accept some benefits of cannabis products as possible, based on his common sense or extrapolation from other evidence.

[42] Dr. Abramovici swore to an affidavit that contained, in its final four paragraphs, an argument in the form of conclusions that was inserted by his supervisor, Dr. Desjardins. Although Dr. Abramovici swore that he agreed with the

contents of these paragraphs, his supervisor's input was not readily apparent, and her willingness to interfere in his opinions is troubling.

[43] The way in which Dr. Pate gave some of his evidence suggested that he was both amused and frustrated by government attitudes toward cannabis marihuana and its components, given its pervasiveness in both the underground economy and its growing acceptance as medicine. This has lessened the weight I put on Dr. Pate's evidence.

[44] The way in which Dr. Abramovici gave some of his evidence suggested that he was only too aware that Health Canada was his employer. While I accept his assurance that his opinions were his, and not dictated to him by his employer, the interference by Dr. Desjardins, coupled with the tone of Dr. Abramovici's affidavit and his oral evidence, have lessened the weight I put on his evidence.

Dr. Pate's Evidence

[45] From Dr. Pate's evidence I accept:

- The active compounds of the cannabis plant are manufactured in cells at the base of, and stored in, structures called glandular trichomes.
- The main active compounds are primarily tetrahydrocannabinol ("THC") and cannabidiol ("CBD").
- Generally speaking, the concentration of glandular trichomes increases as one moves higher up the cannabis plant, with fewer glandular trichomes near the root, and many near the top.
- Viewed microscopically, the glandular trichomes appear to be stalk rising from the plant surface with a globular top. Dr. Pate accurately analogized this structure to a golf ball on a tee.
- These glandular trichomes contain resin, and it is in the resin where the plant secretes THC and CBD.

- The highest concentration of glandular trichomes is found on or near the outer surface of unfertilized female flowers.
- From the perspective of either a medicinal or recreational marihuana user, it is the contents of the glandular trichomes that are important.
- There are various methods for separating the glandular trichomes from the plant itself: one can agitate dried flowers from the marihuana plant over a fine mesh or screen, causing the glandular trichomes to fall off and pass through the mesh, leaving the host plant material behind; one can immerse the plant material in cold water, then strain the water through a fine mesh to capture the glandular trichomes.
- Both these methods remove the glandular trichomes intact, with the resin still contained inside.
- If the results of these methods of extraction are compressed, it is often referred to as "hash" if the dry sieve method is used, or "bubble hash" if it is wet sieved. If it is not compressed, but left in dry powdered form, it is often referred to – erroneously according to Dr. Pate – as "kif" or "pollen."
- Other methods extract the resin from the glandular trichomes: one might rub the flowers in their hands, then scrape the resin off the hand; one could soak either the trichome-bearing plant, or just separated trichomes themselves, in fat such as butter or food-grade oil, as the contents of glandular trichomes are fat soluble. The same applies to alcohol, as the glandular trichome contents are also alcohol soluble.
- The results of fat-based extraction methods are often referred to as "cannabis cooking oil" or "cannabis butter."
- Other methods involve using petrochemical solvents such as petroleum ether to take up the resin from the glandular trichome, then evaporating off

the solvent. The results of the solvent-based extraction method is often called "hash oil."

- These methods result in separation of THC, CBD, and other potentially active ingredients called terpenes from the plant matter.
- There is no known medical utility to the plant matter that is left behind after the glandular trichomes, or their contents, are separated from the host cannabis plant, or in the glandular trichomes themselves after the resin is extracted from them.
- A caveat on that statement is the possibility that there may be some cannabinoid inside a leaf, not as readily accessible or as easily rendered as the glandular trichomes on the leaf surface.
- If the glandular trichomes containing the active compounds are not separated from the cannabis plant, a user can access the active compounds by smoking dried plant material with the glandular trichomes still attached.
- Release of the active compounds does not require heat as high as that produced by smoking, and an alternative way of inhaling the active compounds is through a vaporizer, which releases the active compounds at a lower temperature than smoking. Vaporizers cost approximately \$500.00.
- The medical benefits from THC include anti-inflammatory and antispasmodic effects, increasing appetite in those whose appetites are suppressed by medical treatments such as are administered to AIDS patients, and alleviation of nausea in those taking chemotherapy for cancers.

- The well-known non-medical effect of THC is its psychoactive effects, an unwanted side effect from a medical point of view, a primary benefit from a recreational user's point of view.
- CBD has some anti-inflammatory benefits, including some analgesic effects.
- There may be some potential anti-psychotic benefit from CBD in high doses, but that has not yet been fully studied.
- The glandular head of the trichome also is known to contain terpenes.
- Terpenes are compounds commonly associated with aromas, for example pine or mint.
- CBD also has some potential to inhibit the metabolism of THC by the liver, thus reducing the body's ability to intercept and eliminate the medical benefit of THC.
- There are different mechanisms for getting the therapeutic components, whether THC or CBD into the body, and Dr. Pate described each.
- One can ingest the compound orally: if one were taking THC for gastrointestinal conditions such as Crohn's disease or Irritable Bowel Syndrome this would arguably deliver the therapeutic benefit more directly to the site of pathology.
- Oral ingestion also has the benefit of prolonging the effects of the drug in the system, with the corresponding detriment of taking longer to build a therapeutic level of the drug than would occur with smoking, for example.
- Because of the slow build-up of the drug in the body, dosages are more difficult to manage, as it takes some time to determine when the optimum therapeutic level has been reached.

- Because orally ingested THC or CBD stays in the system longer, it would be better for someone with a chronic condition of pain or glaucoma, where some level of therapeutic dosage would remain while the patient slept.
- Smoking achieves a far quicker benefit, as the drug enters the body through the lungs and is dispersed rapidly.
- The level of THC in the body also declines much more quickly with smoked marihuana than with orally ingested THC.
- Smoking would be a better way to take a therapeutic dose in case of a sharp increase in pain or discomfort.
- Smoking also has harmful side effects associated with inhaling smoke which, although less deleterious than tobacco smoke, pose risks to health nonetheless.
- A fourth application or ingestion method would be to spray a solution containing the active compound under the tongue, called trans-mucosal. Its advantages include faster assimilation of the drug, like smoking, without the risks associated with smoking.
- There are some cannabis, or similar, products that have gone through the clinical trial process and become available.
- One is Sativex, an extract of the cannabis marihuana plant that contains THC and CBD in equal proportions, taken as an oral spray.
- Another is Marinol, a synthetic THC in a sesame oil capsule.
- Another is Navalone, similar to Marinol.
- There remains a risk that a cannabis compound mixed with another drug, like an opioid or alcohol, can have worse results than either drug alone, and as well, the risk that the psychoactive effects of THC can adversely

affect judgment, perception and reaction in those operating automobiles or dangerous machinery.

- Some research is being conducted on cannabis products, but a few clinical trials are needed to bring cannabis products to market.
- However one takes the active compounds in cannabis marihuana, it is unlikely that one will suffer any long lasting harm from an overdose.
- There is some potential for terpenes to have a role in the efficacy of cannabinoids, but this also needs much more research.
- The cannabis marihuana plant and its active compounds are unlikely to cause physical harm in themselves, unlike other drug compounds where taking too much can lead to death.
- It is not possible to tell by looking what the contents of a cookie might be, or what concentration of THC a capsule of oil might contain.

Dr. Abramovici's Evidence

[46] In spite of Dr. Abramovici's doubts about the reliability of evidence of its medical benefits, I infer that the efficacy of marihuana and its therapeutic components in the treatment or management of some medical conditions has been established by custom and usage, but that the precise basis for the efficacy or success is masked to some extent by the belief set or faith with which many medical users have approached their use, and has been made more difficult to achieve or to measure by the historical proscriptions against marihuana use.

[47] Dr. Abramovici pointed out problems that might arise from the lack of quality control or standards being applied or enforced in the underground or illegal marihuana market.

[48] Dr. Abramovici was responsible for updating the Health Canada publication Information for Health Care Professionals, which deals with cannabis marihuana. The front page of this document bears a sub-heading "Marihuana (marijuana, cannabis) dried plant for administration by ingestion or other means Psychoactive agent."

[49] The bottom of the front page bears this warning: "Marihuana (marijuana, cannabis) is not an approved therapeutic substance in Canada and no marihuana product has been issued a notice of compliance by Health Canada authorizing sale in Canada".

[50] The document itself is a compilation of peer-reviewed literature and published materials assembled by Dr. Abramovici.

[51] In the portion of the document that deals with the chemistry of cannabis marihuana, it states at s. 1.2: "Marihuana smoke contains many of the same carcinogenic chemicals found in tobacco smoke." The section goes on to compare in a general way the relative potential harms from smoking marihuana as opposed to tobacco, without arriving at a conclusion.

[52] Later, in s. 8.1, the document reaffirms the carcinogenic aspects of smoked marihuana, but says that the epidemiological link between marihuana use and cancer is inconclusive.

[53] At s. 8.2, the document reads:

Mucosal biopsy specimens taken from chronic marihuana smoker who reported only smoking marihuana showed a number of histopathic changes including basal cell hyperplasia, stratification, goblet cell hyperplasia, cell disorganization, inflammation, basement membrane thickening, and squamous cell metaplasia.

...

Heavy chronic cannabis smokers presented with symptoms of bronchitis, including wheezing, production of phlegm and chronic cough and long-term cannabis smoking may be a risk factor for chronic obstructive pulmonary disease.

[54] The first section was not translated during the *voir dire*; Dr. Abramovici did say it described negative findings in the lungs of chronic marihuana smokers, and

2012 BCSC 544 (CanLII)

those negative findings could be minimized by not smoking or reducing smoking. The second section makes clear some of the harmful effects of heavy chronic cannabis smoking.

Mr. Ormsby's Evidence

[55] Mr. Ormsby provided testimony by affidavit.

[56] He described the process by which a drug can become approved for marketing in Canada under the *Food and Drugs Act*, R.S.C. 1985, c. F-27, and the *Food and Drug Regulations*, C.R.C., c. 870.

[57] The rigors of the current regulatory regime can be explained in part as a response to the experience with Thalidomide in the mid-1960's. There, a drug used to treat nausea in pregnant women caused severe and lasting side effects in their infant children.

[58] Drugs derived from or based on plants are taken through the *Food and Drugs Act* processes under the *Natural Health Products Regulations*, SOR/2003-196. Cannabis products are excluded from this process by the combined operation of the definition of "natural health product," their inclusion in Schedule II of the *Controlled Drugs and Substances Act*, and their consequent exclusion through Schedule 2 of the *Natural Health Products Regulations*.

[59] Marihuana produced under contract to Her Majesty the Queen in Right of Canada or under a designated-person production licence as defined in the *MMAR* is exempt from the application of the *Food and Drugs Act* and the *Food and Drug Regulations* by the *Marihuana Exemption (Food and Drugs Act) Regulations*, SOR/2003-261.

[60] If the ingredients of a substance offered as a medicine are not fully identified, or if the quantities of any ingredients that have been identified are not known, there are risks that include over-dosing and under-dosing, complications arising from

combining the effects of cannabis marihuana with prescribed or other drugs, and risks of contamination or adulteration in the unregulated production process.

[61] There is an obvious difference between those who produce their products in an industry that is tightly regulated, such as the pharmaceutical drug industry, and unregulated producers such as the Club: with the former, there will be standards of production and inspection that ensures consistency of content, predictability of results of use, and greater assurance that contaminants will be eliminated or prevented in the manufacturing process; by contrast, in a bakery such as operated by the Club and staffed by the accused, the cannabis marihuana plants used can only be subjected to visual inspection for contaminants, the processes for rendering active compounds out of the cannabis plant are unsophisticated and unregulated, and the active compounds contained in the foods, oils, and topical products are not capable of precise measurement.

[62] Anecdotal reports of the efficacy of cannabis products in the treatment or management of various diseases and conditions should be approached with some caution: there is the possibility that someone will report experiencing results they have been led to expect, or for which they hoped, from taking a substance -- the so-called placebo effect.

[63] Whether a substance actually achieves the desired result can best be determined through double-blind clinical trials, and that is an expensive and time-consuming process.

[64] Topical administration of the drug, by applying it directly to the site of skin infections, or to inflamed joints, is controversial. The controversy arises in part because, according to the Health Canada document *Information for Health Care Professionals*, prepared by Dr. Abramovici, THC is hydrophobic, meaning that it does not go through water well, and water is a large component of human skin. Dr. Pate and Dr. Abramovici disagreed about the effectiveness of applying cannabis products to the skin.

[65] It is a fair summary to say that the steps required to obtain approvals necessary to market a new drug, or to make new claims for an existing drug, can be very lengthy and expensive.

[66] It is also a fair inference from Mr. Ormsby's evidence that the approval processes are designed with a manufacturing process in mind, where there will be a manufacturing site or sites, where quality can be controlled, and which will be amenable to inspection, supervision and control by regulatory authorities.

[67] The evidence of Dr. Abramovici and Mr. Ormsby sets out various bases for concern on the part of the regulators if a substance with unknown ingredients, variable potency of its psychoactive component, poorly researched therapeutic benefits, and unknown provenance were to be widely available and touted as a medical treatment. It is convenient to classify these concerns as ones of quality control.

Crown and Defence Positions

[68] The Crown also argued that some of the claims made by the Club recipe book support the argument in favour of sustaining the current regulatory scheme. It is convenient to label these as misleading advertising questions.

[69] The recipe book makes claims such as:

Cannabis can be used to replace almost any type of allopathic medicine, from diuretics to anti-depressants – ear oil; throat sprays and salves that reduce tumors;

<u>Gayle's Super Treats</u> are medicinal biscuits for dogs. Veterinarians have watched tumors disappear, arthritis reverse, and heard chronic cough go away;

To heal broken bones, keep a Cannapatch in place for 10 days to 3 weeks (changing every couple of days);

Tumors of all types (including breast and fibroids) have been reduced with the use of cannabis.

[70] Crown, in argument, likened these claims to a sales pitch for snake oil. Crown enlisted these implausible claims to show the risks posed by any loosening of the

current restrictions on lawful possession of cannabis, and thus to support Crown's argument in aid of continuing strict control on medical marihuana.

[71] In oral argument, counsel for the Crown maintained that the public needs protection from claims such as those suggesting that a marihuana poultice could heal a broken bone. Yet that argument pays too little attention to the apparent fact that government has elected to keep marihuana beyond the reach of its various agencies set up to protect the public from false or overblown claims, such as through the *Natural Health Products Regulation,* for example, or perhaps the *Canada Consumer Product Safety Act,* S.C. 2010, c. 21.

[72] The Crown argued strenuously that the risk of diversion of derivative substances such as THC-infused oils was unacceptably high when compared to their unproven benefits, and, as well, great care had to be taken when contemplating a declaration that might appear to open the way for the dangerous processes of solvent-based extraction.

[73] The current licensing scheme, which restricts authorized medical users to dried marihuana, or that limits the number of plants a licensed producer may grow, allows police or regulators to easily ascertain whether a medical possessor or producer is exceeding the limits of their respective authorizations, thus limiting the chances that some of the product ostensibly might be diverted into the illegal distribution network.

The Issue

[74] This *voir dire* does not turn on whether the requirement that a doctor approve of medical marihuana use ("physician as gatekeeper") offends the *Charter*.

[75] Nor is it necessary for the purposes of this *voir dire* to decide whether there is a threshold level of medical need that must be established to invoke the protection of the *Charter*. Two of the four witnesses, Ms. Quin and Ms. Herman, who testified as members of the Club who obtain products other than dried marihuana, have been issued Authorizations To Possess by Health Canada, and a third, Ms. Arthurs, applied months ago with the support of her doctor, and is waiting the Authorization To Possess that will probably be issued to her. The fourth, Ms. Large, has been refused by her previous doctor, who retired, and by her present doctor.

[76] Instead, what is at issue here is the requirement imposed by Health Canada through s. 2 of the *MMAR* that those to whom an Authorization To Possess has been issued can lawfully possess their marihuana in dried form only.

[77] If and when Ms. Quin, Ms. Herman, or Ms. Arthurs render the dried marihuana in their lawful possession into another form, such as by infusing it into cooking oil or by separating the glandular trichomes from the dried plant material and mixing those trichomes into tea, they would be subject to prosecution because they would have lost the protection that an Authorization To Possess applies to dried marihuana. Likewise, Mr. Smith is liable to conviction for the offence of possessing THC for the purposes of trafficking if he changes dried marihuana by rendering it into oil, butter, salves, etc., for someone with an Authorization To Possess, whether commercially or gratuitously.

The Law

[78] It is illegal in Canada to possess, produce, or distribute marihuana.

[79] That is a policy choice made by the Government of Canada in exercise of a constitutional right.

[80] *R. v. Malmo-Levine*, [2003] 3 S.C.R. 571, has confirmed that the prohibition against recreational use of marihuana is constitutionally sound.

[81] I find on the evidence before me that marihuana has some medicinal benefits. That finding is not really necessary: Health Canada has acknowledged this by issuing Authorizations To Possess to Ms. Quin and Ms. Herman, and the opening comments by the Ontario Court of Appeal in *Parker* should put the matter beyond question in any event. [82] *Parker* involved a charge each of cultivation and possession of marihuana. The accused put evidence before the trial judge that his epilepsy was lifethreatening, that marihuana improved his health, and that the statutory scheme of the time put a blanket prohibition on cultivation and possession of marihuana that made him liable to prosecution and imprisonment. The Ontario Court of Appeal agreed that a blanket prohibition against possession that exposes someone to criminal prosecution for using marihuana as a medical treatment is constitutionally invalid (paras. 152-153).

[83] A regulatory scheme that would permit someone to possess marihuana for medical purposes but forces a medical user to obtain their marihuana from an illegal source (street or other level trafficker), or which prohibits compensation for an authorized producer is constitutionally invalid (*Hitzig v. Canada* (2003), 171 C.C.C. (3d) 18).

[84] A regulatory scheme that arbitrarily restricts the number of authorized users for whom a producer can produce marihuana is constitutionally invalid (*R. v. Beren and Swallow*, 2009 BCSC 429; *Sfetkopoulos v. Canada (Attorney General*), 2008 FC 33, affirmed 2008 FCA 328; leave to appeal denied, [2008] S.C.C.A. No. 531).

[85] A regulatory scheme that requires physician approval of marihuana for medical use is constitutionally valid (*Beren*).

[86] A regulatory scheme that requires a physician to approve the use of marihuana for it to become authorized is constitutionally invalid, if physicians as a group refuse to participate in the approval process (*R. v. Mernagh*, 2011 ONSC 2121).

[87] In more general terms, s. 7 of the *Charter* requires two stages of analysis. The first level of inquiry is whether one of the protected interests – life, liberty or security of the person – is engaged, or sufficiently put at risk, by the state action in question (*Ref. re Motor Vehicle Act (British Columbia), s. 94(2)*, [1985] S.C.R. 486). If the applicant passes the first stage, the second level of inquiry asks whether the state's engagement of the protected right nonetheless complies with the principles of fundamental justice. If it does not comply, then the state action infringes the s. 7 right.

[88] The Crown concedes the first level of the s. 7 inquiry: the *MMAR* as currently drafted engages the liberty interests of at least the witnesses Quin and Herman, and will engage Ms. Arthurs' when she receives her Authorization To Possess. As well, these women's liberty interests are affected by the fact that their right to choose how to take medication they are authorized to possess is a decision of fundamental personal importance such as described in *Parker*, para. 92. Finally, the accused's risk of punishment up to imprisonment also takes the inquiry under s. 7 to the second stage on his behalf. Mr. Smith's liberty interests are engaged when he distributes to those who possess an Authorization. See Dickson C.J.C. in *Morgentaler*, cited in turn by the Ontario Court of Appeal in *Parker* at para. 79:

As an aside, I should note that the appellants have standing to challenge an unconstitutional law if they are liable to conviction for an offence under that law even though the unconstitutional effects are not directed at the appellants per se: *R. v. Big M Drug Mart Ltd.*, at p. 313.

[89] Although strictly speaking it is not necessary to go further in view of the liberty interests engaged, I find that the security of the person interests of the witnesses Quin, Herman, and Arthurs (again, assuming she will receive her Authorization To Possess in due course) are also engaged by the *MMAR*. The requirement that limits the form in which they are legally entitled to possess their medicine to dried marihuana is, to paraphrase the obiter language of *Parker* at para. 111, an interposition of the threat of criminal prosecution between them and the form of medication found effective to treat the symptoms of their very serious illnesses.

Principles of Fundamental Justice

[90] Although Crown concedes this initial stage of the s. 7 analysis, Crown contests the second stage, and says that these engagements comply with the principles of fundamental justice and therefore are not infringements.

[91] In Canadian Foundation for Children, Youth and the Law v. Canada (Attorney General), 2004 SCC 4, the Supreme Court of Canada summarized the criteria required of a "principle of fundamental justice" at para. 8 as:

... it must be a legal principle.

... there must be sufficient consensus that the alleged principle is "vital or fundamental to our societal notion of justice."

... the alleged principle must be capable of being identified with precision and applied to situations in a manner that yields predictable results.

[92] These are broadly stated criteria reflecting general principles.

[93] Four years earlier, the Ontario Court of Appeal applied much the same reasoning in *Parker*, at para. 112, but went on to focus on a principle of fundamental justice identified in *Rodriguez v. British Columbia (Attorney General)* (1993), 3 S.C.R. 519 at p. 594:

Where the deprivation of a right in question does little or nothing to enhance the state's interest (whatever it may be), it seems to me that a breach of fundamental justice will be made out, as the individual's rights will have been deprived for no valid purpose.

[94] The court in *Parker* continued at para. 117:

[117] To summarize, a brief review of the case law where the criminal law intersects with medical treatment discloses at least these principles of fundamental justice:

- (i) The principles of fundamental justice are breached where the deprivation of the right in question does little or nothing to enhance the state's interest.
- (ii) A blanket prohibition will be considered arbitrary or unfair and thus in breach of the principles of fundamental justice if it is unrelated to the state's interest in enacting the prohibition, and if it lacks a foundation in the legal tradition and societal beliefs that are said to be represented by the prohibition.
- (iii) The absence of a clear legal standard may contribute to a violation of fundamental justice.
- (iv) If a statutory defence contains so many potential barriers to its own operation that the defence it creates will in many circumstances be practically unavailable to persons who would prima facie qualify for the defence, it will be found to violate the principles of fundamental justice.

(v) An administrative structure made up of unnecessary rules, which result in an additional risk to the health of the person, is manifestly unfair and does not conform to the principles of fundamental justice.

[95] Crown and defence focused much of their argument on the balance between the state interest and the impairment of the s. 7 right. At the core of the dispute is the identification of different legitimate state interests.

[96] Crown argued that one legitimate interest of the state served by the *MMAR*, as the regulations are currently framed, is to prevent or to control the risk of diversion of medical marihuana from lawful to unlawful streams. The requirement that medical marihuana remain in its dried form is a primary mechanism by which diversion is made difficult, since in its dried form marihuana is more readily quantified by police or regulators, and thus it can easily be determined whether any particular quantity seen exceeds the quantity permitted by an authorization, whether to possess or to produce.

[97] The defence responds that the legitimate state interest is harm avoidance, and that interest is not served by prohibiting derivatives of marihuana.

[98] The Crown's argument contemplates the possibility that someone to whom Health Canada has issued an Authorization To Possess will abuse the privilege represented by the authorization in order to engage in illegal activities. The Crown argues that such a person may more easily mask their illegal activities if they can render dried marihuana into other forms less easily measured or quantified by unaided observation.

[99] While it seems logical that it is easier to judge by looking whether a quantity of dried marihuana is within limits set out in an authorization than it would be if the active ingredient had been infused into oil or butter, some direct evidence on the point would have been helpful. If it is beyond the ability of the scientific staff of Health Canada to ascertain that a given quantity of dried marihuana, if rendered down so as to separate its glandular trichomes, would, if infused into oil or butter, yield a measurable quantity, in whatever unit of measurement one might select, I would have expected to hear some better evidence of that, and I did not.

[100] This is quite apart from the fact that one who has an Authorization To Possess marihuana, who chooses to render the dried marihuana, infuse it into butter, and bake it into cookies, is amenable to control through the restrictions on the amount of dried marihuana he or she can obtain.

[101] The defence argues that it is arbitrary to expose someone who has a valid Authorization To Possess to criminal sanction if they prefer to take the medicine orally rather than by smoking it.

[102] The Crown says that the *Charter* does not protect a right to tasty cookies: someone who prefers to take their marihuana orally can eat it or bake the dried marihuana into cookies, in spite of some evidence that in its dried form, marihuana is not particularly palatable.

[103] The Crown's argument trivializes this aspect of the arbitrariness issue: the question is not whether constitutional protection is sought for tasty cookies, it is whether a prohibition against someone granted a permit to lawfully possess a medicinal substance that would be illegal but for the permit should not be restricted in how they choose to take the medicine unless the restriction serves a state interest that has more weight than the individual's choice on how to take their medicine.

[104] The defence argues that the restriction to dried marihuana compels people to smoke to get the medical benefit from the drug, and that smoking the drug is more unhealthy than eating it or applying it topically.

[105] The Crown says that no additional risk has been shown on the evidence.

[106] It seems to me that the recital of the risk of smoking the drug set out in the Health Canada *Information for Health Care Professionals* is sufficient to show that there is some additional risk from smoking, over and above any risk arising from taking the drug orally.

[107] As well, this Crown argument does not deal with one of the products produced by the accused, namely capsules filled with oil that has been infused with THC and whatever else is rendered from the dried plant material by the accused. The police investigation of the "bakery" turned up several bottles of oil labeled "Ryanol," one of which was near some empty capsules and a tray apparently designed to facilitate filling empty capsules. There is no dispute that one of the products produced by the accused and offered for sale by the Club was Ryanol capsules, filled with edible oil infused with THC, and easily swallowed. The production by the accused of the Ryanol capsules takes the issue beyond the "tasty cookie" level on which the Crown would like it decided.

[108] I have so far avoided dealing with the arguments based on inflated claims to the efficacy of some of the products offered for sale by the Club.

[109] This *voir dire* has been complicated by a sense that the accused is in many ways a surrogate for Mr. Ted Smith and the Club. Many of the Crown arguments concerned what the Crown said were misleading claims of the medical efficacy of many of the products offered for sale made in Club literature.

[110] Inflated claims, false or misleading advertising and such matters can be dealt with in ways other than unnecessary criminalization of the way in which some people choose to take medicine to which they are entitled. One need only look at the recently-enacted *Canada Consumer Product Safety Act* to find an example.

[111] Some general considerations bear repeating.

[112] Courts should not decide issues of law, particularly constitutional issues, that are not necessary to the resolution of the matter before the court: see, for example, *Phillips v. Nova Scotia (Commission of Inquiry into the Westray Mine Tragedy)*, [1995] 2 S.C.R. 97, at paras. 5-11; *R. v. Banks*, 2007 ONCA 19, at para. 25.

[113] Bearing in mind the respective constitutional positions of parliament and the courts, these excerpts from *Schachter v. Canada*, [1992] 2 S.C.R. 679, at paras. 26 and 31 respectively, are apt:

Generally speaking, when only a part of a statute or provision violates the Constitution, it is common sense that only the offending portion should be declared to be of no force or effect, and the rest should be spared ...

... Therefore, the doctrine of severance requires that a court define carefully the extent of the inconsistency between the statute in question and the requirements of the Constitution, and then declare inoperative (a) the inconsistent portion, and (b) such part of the remainder of which it cannot be safely assumed that the legislature would have enacted it without the inconsistent portion.

Breach of the Principles of Fundamental Justice

[114] I conclude that the restriction to dried marihuana in the *MMAR* does little or nothing to enhance the state's interests, including the state interest in preventing diversion of a drug, or controlling false and misleading claims of medical benefit. I find that the restriction is arbitrary, and that its engagement of the rights to liberty and security does not accord with the principles of fundamental justice, and therefore infringes those rights.

Section 1: Reasonable and demonstrably justified in a free and democratic society

[115] The Crown has the burden of showing on a preponderance of probabilities that this dried marihuana limitation on the liberty and security rights protected by s. 7 is reasonable and demonstrably justified in a free and democratic society (R. v. Oakes, [1986] 1 S.C.R. 103).

[116] The Crown may do so by, first, showing that the legislative objective underlying the restriction is pressing and substantial, and, second, by showing that the means chosen are reasonable and demonstrably justified. The second stage in turn requires that the Crown show that the measure is rationally connected to the objective and thereby is fair and not arbitrary; that there is a reasonable degree of infringement on the right; and that the benefits and costs of the provisions are proportionate.

[117] I accept that one legislative objective of the restriction to dried marihuana is to limit the risk that the regime making marihuana available for medical purposes might

facilitate the trafficking of illegal drugs. I accept that the objective of limiting or decreasing the trafficking in a psychoactive substance is sufficiently important to warrant overriding a constitutionally protected right or freedom. I also accept that Parliament's interest in controlling the claims that might be made for medical efficacy of a particular product, as well as its interest in regulating the purity of substances sold as medicine, are pressing and substantial.

[118] Whether the Crown has shown that the means chosen by Parliament – the restriction of medical marihuana to its dried form – are reasonable and demonstrably justified, is weighed according to the analysis in *Oakes*, beginning with whether the means chosen by Parliament to achieve these objectives are fair and not arbitrary (para. 70).

[119] According to *Oakes*, a measure can be said to be fair and not arbitrary where it is shown that it has been carefully designed to achieve the objective sought -- in other words, where it is rationally connected to that objective.

[120] If the objective in question is to discourage diversion of medical marihuana into the illegal market, then Crown's argument that restriction to dried marihuana is fair and not arbitrary presumes that no laboratory analysis is needed to enable a police officer or other investigator to distinguish dried marihuana (which might not be in its whole leaf form) from any other dried plant which might also not be in its whole leaf form. If it is possible to distinguish chopped up, dried marihuana from other dried plant material such as might be found in most kitchen spice jars, it seems to me that there should have been evidence led on the point. I am not prepared to infer that it is necessary to restrict medical marihuana to its dried form in order to make enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws possible. I am not concerned with making enforcement of the drug laws easy if the cost of doing so puts the rights protected by s. 7 of the *Charter* at risk. In the absence of clear evidence that the restriction to dried marihuana is necessary, I conclude that this restriction is arbitrary.

[121] Furthermore, under the "rational connection" step of the s. 1 analysis, the Crown's argument, to the extent that it is based on risk of diversion, also loses much force in light of the Crown's concession that under the current regulatory scheme, someone with an Authorization to Possess might lawfully bake their dried plant material into a cookie batter or any other food, mix it into a salve, or otherwise deal with it in a similar fashion, so long as they used it as dried material.

[122] I conclude that there is little rational connection between the restriction to dried marihuana and the legitimate objective of preventing diversion of lawful medical marihuana into the illegal market.

[123] I conclude that the restriction to dried marihuana unnecessarily, and therefore to an unreasonable degree, impairs the security right to choose how to ingest the medicinal ingredients in the safest and most effective manner. Given these two findings under the second stage of the s. 1 analysis, I also find that it intrudes disproportionately on the constitutionally protected rights.

[124] Therefore, the dried marihuana restriction's infringement of s. 7 rights to liberty and security of the person is not saved by s. 1.

Remedy

[125] The question becomes what remedy is appropriate, given the considerations just outlined.

[126] The word "dried" appears 58 times in the *MMAR*. Many of its appearances are in formulae by which one calculates the maximum amount or number of marihuana or marihuana plants that may be possessed under the permits issued pursuant to the regulations.

[127] I have reviewed the regulations, including these formulae, and have concluded that it would do no greater violence than necessary to remedy the constitutional breach to delete the word "dried" wherever it appears in the *MMAR*, and I so direct.

[128] As a consequence, the definition of "dried marihuana" becomes superfluous and is also deleted.

[129] This leaves in place the requirement that one obtain and retain the authorizations provided under the *MMAR* in order to lawfully access marihuana for medical purposes, but removes the artificial restriction of that lawful use to marihuana in its dried form.

Judicial Stay

[130] Judicial discretion to grant a stay has been discussed in *R. v. Nixon*, 2011 SCC 34. Two approaches to a judicial stay can lead to the court's use of its discretion, under the *Charter*, s. 24(1), to grant an appropriate and just remedy in the circumstances. First, a *Charter* infringement not saved by a s. 1 analysis may lead the court to exercise its discretion under s. 24(1) to grant a judicial stay (or another remedy). Where the court finds a *Charter* violation, the court must still balance the violation with the remedy, and might not always find that a judicial stay serves societal interests (*R. v. O'Connor*, [1995] 4 S.C.R. 411, at para. 69). Second, abuse of process itself, while formerly a distinct common law doctrine, has merged with s. 7 (*O'Connor*) and, where found, could also lead to use of s. 24(1) to produce a judicial stay. Abuse of process can arise from unfairness of the accused's trial (*Nixon*, at para. 39) or from a residual category of acts "tending to undermine society's expectations of fairness in the administration of justice" (*Nixon*, at para. 41). Where in the latter form, as defence counsel alleges in this case:

A stay of proceedings will only be appropriate when: "(1) the prejudice caused by the abuse in question will be manifested, perpetuated or aggravated through the conduct of the trial, or by its outcome; and (2) no other remedy is reasonably capable of removing that prejudice" (*Nixon*, at para. 42).

[131] In this case, I have found there has been a violation of liberty and security rights of the medical marihuana users protected by s. 7, as well as Mr. Smith's liberty right. However, I find that society's interests in having the charges against Mr. Smith tried on their merits outweigh the violation of Mr. Smith's liberty right, at least sufficiently to deny him the judicial stay he seeks.

[132] Second, defence would have me find abuse of process in the government's response to court decisions since *Parker* that disregards some of those decisions entirely, or that responds in such a minimal fashion as to amount to a cavalier treatment of courts and their decisions on constitutional matters.

[133] I do not share the defence view of government's response to the various court decisions. This is an area where a substance that continues to be illegal, and constitutionally so (*Malmo-Levine*), must also, since *Parker*, be available to those with a demonstrated medical need. How to achieve a balanced solution is a question that must be left to legislators. The accused would have me ascribe bad faith or motive to Parliament's serial responses, through the *MMAR*, to the court decisions that prompted changes. In my view, a court should be slow to attribute such bad faith or motive to legislative response to court decisions.

[134] I do not find a lack of good faith or an abuse of the processes of the court in this case that would warrant consideration of a judicial stay of proceedings, and that application is denied.

"R.T.C. Johnston, J." The Honourable Mr. Justice Johnston

File No.149345-2 Victoria Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

REGINA

OWEN EDWARD SMITH

the afficavit of swom belore ma et this 16th C

This is Ext

A Commissioner for taking Alfidavits for Billian Columbia

Pate

OLIN E. RUS COMM. # 2040563 NOTARY PUBLIC - CALIFORNIA 0 ALAMEDA COUNTY MY COMM. EXP. SEP. 7

EXPORT REPORT OF DR. DAVID PATE

Kirk Tousaw Barrister Law Office of Kirk Tousaw 142-757 West Hastings, Suite 211 Vancouver, British Columbia V6C1A1 Counsel for Accused

Peter Eccles Crown Counsel Public Prosecution Service of Canada BC Regional Office 900-840 Howe Street Vancouver, BC V6Z 2S0

- 1. My name is Dr. David W. Pate and I make this expert report on the basis of my own personal knowledge, study and experience.
- 2. I hold two advanced degrees; a Master of Science in Biology and a Doctor of Philosophy in Pharmaceutical Chemistry. My current professional emphasis is the study of cannabis products, including cannabinoids and other constituent components of the *Cannabis* plant, both from a botanical and pharmaceutical perspective.
- Attached to and made part of this report as Exhibit A is my curriculum vitae. Attached to and made part of this report as Exhibit B is a list of my publications.
- 4. The emphasis of my professional work is the medicinal aspects of phytocannabinoids (cannabinoids produced in the *Cannabis* plant) and endocannabinoids (cannabinoids endogenous to the human body).
- 5. Based on my professional expertise, knowledge and study, I am aware of the following facts and hold the following opinions.
- The Cannabis plant (producing the crude drug, marijuana) is a dieocius plant in the family Cannabacae.
- 7. The female *Cannabis* plant produces flowers, referred to in slang vernacular as "buds", which themselves are composed of varying parts.

These parts include the pistil, bracteole (i.e., perigonal bract), and subtending leaflet.

8. :

- 9. The primary therapeutically active compounds found in *Cannabis* are secreted by the plant in the glandular trichomes that are found in their highest population concentration on the bracteole abaxial (i.e., outer) surface of unfertilized female flowers. These glandular trichomes are often referred to as "resin glands". This is scientifically inaccurate as the glandular trichomes manufacture, contain and surround the resin itself.
- 10. The two primary therapeutically active compounds found in the resin are tetrahydrocannabinol (THC) and cannabidiol (CBD), plus associated minor cannabinoids and terpenes.
- 11. Within each category of compound there are several to many particular chemical species.
- 12. For example, there are at least dozens of terpenes and several cannabinoids found in the resin contained within the glandular trichomes of the *Cannabis* plant.
- 13. Cannabinoids are not found in any other plant species, although the human body produces fatty acid functional analogues (i.e., endocannabinoids) that also fit into cannabinoid receptors in the human body (e.g., brain). Terpenes are found broadly in the plant kingdom, including in mints, fruits, spices and flowers.

- 14. The medical effects of cannabinoids have been well documented and there is no reasonable dispute, in my opinion, that these compounds are therapeutically active in humans. Terpenes may very well augment these effects.
- 15. Cannabis has a number of phenotypes, commonly referred to as strains. Various strains are created by breeding different varieties of the plant with each other. Different strains are reputed to produce differing effects on the patient, depending on the individual and condition.
- 16. A reason for the differing effects, which include varying levels of efficacy for a variety of medical symptoms and conditions, is probably due to varying amounts and ratios of the therapeutically active compounds.
- 17. It has been suggested, and in my opinion it is correct, that the various compounds can produce synergistic effects and that any one compound, in isolation, may not provide the full spectrum of medical benefits sought by the patient.
- 18. This is because the effects, both positive and negative, of the primary active ingredients may be enhanced or mitigated by secondary compounds. In this regard I attach and incorporate into my opinion the following studies: "Cannabis and Cannabis Extracts: Greater Than the Sum of Their Parts?" McPartland, John

M., and Ethan B. Russo. Co-published simultaneously in Journal of Cannabis Therapeutics (The Haworth Integrative Healing Press, an imprint of The Haworth Press, Inc.) Vol. 1, No. 3/4, 2001, pp. 103-132; and: Cannabis Therapeutics in HIV/AIDS (ed: Ethan Russo), and "Taming THC: Potential Cannabis Synergy and Phtyocannabinoid-Terpenoid Entrourage Effects." Ethan B. Russo, British Journal of Pharmacology (2011) 163 pages 1344-1364.

- 19. The glandular trichomes containing these chemical compounds can be isolated from the female flowers, thus eliminating most of the plant matter in the final product.
- 20. There are a variety of methods for isolating the glandular trichomes, including the use of micro-pore screens upon which dried flowers are agitated, causing the glandular trichomes to fall off and pass through the screen; and immersion of the plant matter in cold water followed by straining the water through fine mesh to capture the glandular trichomes. These processes result in removal of the glandular trichomes from most other plant matter, but leave the resin housed within the glandular trichomes.
- 21. Alternatively, it is possible to directly extract the resin contained within the glandular trichomes by rubbing the flowers by hand then scraping the sticky resin from the hands; by soaking the whole plant matter (or isolated trichomes) in fat (typically food-grade oils

or butter) or alcohol and then straining out the plant debris (the glandular trichome contents are fat and/or alcohol soluble, but are not water soluble); and with the use of petrochemical solvents (e.g., petroleum ether) that are then evaporated. These are extraction processes that result in the separation of the active compounds, such as THC, CBD and terpenes, from the plant matter, including from the glandular trichomes.

- 22. The resin-containing glandular trichomes remaining after the processes referred to in paragraph 20 are often referred to as "hash" (dry sieved) or "bubblehash" (wet sieved) when found in lump or brick form due to compression, or often referred to (erroneously) as "kif" or "pollen" when found in uncompressed powder form. The material remaining after cannabis extraction into fats is often called "cannabis cooking oil" or "cannabis butter" and the extract produced by solvent extraction is often called "hash oil."
- 23. All of these processes are designed to capture the glandular trichomes and/or their contents (i.e., the therapeutically active resin), while removing most or all of the plant matter and the various by-products that remain in the plant matter following harvest.

- 24. The plant matter itself is not a desired therapeutic component, except as a vehicle for carrying the resin prior to, and during, the act of pyrolysis and smoke inhalation.
- 25. This is because plant matter can contain a variety of harmful or unwanted compounds, which may include heavy metals, fertilizer residue, pesticides, molds and insect remnants.
- 26. In addition, plant matter is composed of non-digestible cellulose which, while not harmful, may be contra-indicated for persons with gastro-intestinal conditions.
- 27. Moreover, this plant matter contains silicified non-glandular trichomes that are not digestible and have no therapeutic value, but which, due to their micro-abrasive potential, may be contraindicated for persons with gastro-intestinal sensitivities.
- 28. The glandular trichomes themselves are not a desired therapeutic component, except as a vehicle for carrying the resin prior to, and during, the act of extraction into fat, alcohol, solvents or fatty bodily fluids.
- 29. There are multiple ways to ingest the active compounds in cannabis. These include:
 - a. Inhalation: This is either a high-temperature process by which the plant matter, and/or the glandular trichomes themselves, are heated to the point of ignition and the smoke is inhaled

(using a cigarette/"joint" or a pipe) or a low-temperature process by which the plant matter is heated only to the point at which the active ingredients vaporize and become an airborne aerosol which is then inhaled (commonly referred to as "vaporization.") b. Oral ingestion: This is a process by which the active ingredients are ingested by eating or drinking. Typically, food products are prepared using cannabis-infused oil or butter. Essentially any food product that is made with fat and cannabis will be infused with cannabis resin extracted *in situ*. Common forms of these baked goods are cookies and brownies. In addition, cannabis capsules can be produced that contain an extract of the glandular trichomes which are swallowed in the same manner as over-the-counter remedies, prescription pharmaceuticals or natural health products.

- c. Topicals: Oil-based preparations into which the resin has been extracted are either applied directly to the skin or are dispersed from patches which are applied to the skin.
- d. Trans-mucosal: This method of ingestion is typically an alcohol extract of the resin that is sprayed under the tongue.
- 30. The modes of ingestion set out above carry with them different risks and benefits. Specifically, for purposes of this opinion, I focus

on the relative benefits of oral ingestion or topical administration vs. the method of inhalation.

- 31. A primary benefit of orally ingesting cannabis-based medicines arises for people suffering from gastro-intestinal conditions such as Crohn's Disease or Irritable Bowel Syndrome. For these individuals, oral ingestion allows for the application of therapeutic compounds directly to the site of pathogenicity. Good pharmaceutical practice dictates the use of a minimum effective drug amount and a treatment as close to the site of pathogenicity as possible. This provides the benefit of direct therapeutic action that can be more effective and require lesser dosages, thus ameliorating potential unwanted side effects.
- 32. Another benefit of oral ingestion is that it produces longer lasting therapeutic effects than inhalation. Inhalation tends to produces spikes in the systemic load of the active compounds which quickly fall to low levels, resulting in elevating patient blood levels with more of the active compounds than necessary while making the effect of these compounds more transient. Oral ingestion, by contrast, provides a plateau of longer and more stable systemic load of the therapeutic agents. This eliminates the need to repeatedly ingest the medicine at short intervals in order to achieve continuous therapeutic benefits. It also allows for the treatment to

continue during sleeping hours. This latter aspect is particularly of benefit to glaucoma patients.

- 33. Another benefit of oral ingestion is the elimination of any damage that may be caused by smoking the dried flowers, a practice discouraged within contemporary medicine. Oral ingestion also excludes possible damage that could be caused by the inhalation of unwanted substances found in or on the plant matter.
- 34. For certain chronic conditions, oral ingestion is often the more effective mode of ingestion for the reasons set out above.
- 35. For acute (and particularly crisis) conditions, inhalation may be preferred because of the rapid onset of symptom relief coupled with the transient nature of the condition itself.
- 36. By way of example, inhalation would be preferable to oral ingestion to treat the acute pain and other symptoms associated with migraine headaches.
- 37. For many of the same reasons that oral ingestion is preferable to inhalation, topical administration is preferable for certain conditions such as inflammatory skin conditions or some forms of chronic pain, particularly of the joints. The onset time of topical administration is quicker than oral administration, the drug is better targeted to the site of action, and a full systemic treatment to

obtain a localized therapeutic benefit is not administered. An added benefit is the elimination of psychoactive side-effects.

- 38. In addition to the foregoing, I hold the following opinions:
 - a. The Cannabis plant is harvested for the medicinal resin
 - compounds found inside the glandular trichomes of the plant.
 - b. There is no medical utility to the dried plant matter.
 - c. In essence, the plant is no more than a carrier for the glandular trichomes that are, themselves, a manufacturing site and reservoir for the resin that contains the cannabinoids and terpenes.
 - d. There are negative effects associated with ingesting whole
 Cannabis plant matter, either orally or by smoke inhalation,
 which can range from minor to serious.
 - e. Ingesting the resin by means of smoking would be less harmful to the patient than smoking the dried plant matter which bears the resin because: (a) less would need to be consumed to achieve the desired therapeutic effect and, (b) the pyrolysis products of unwanted bulk plant materials would not be inhaled.
 - f. Ingesting the resin compounds in the form of baked goods is, for some conditions, significantly more effective than other routes of administration.

g. Topical application of the compounds in the resin by way of salves or oils produces no psychoactive side effects while also being more effective for the appropriate conditions.

h. There exists no scientific basis, either botanical or

pharmaceutical, to differentiate between the whole dried plants and the glandular trichomes or contained resin in a manner that permits patient access to the whole dried plant, but not the glandular trichomes or contained resin harvested from that very same plant.