THE HIGH COURT
JUDICIAL REVIEW

[2022] IEHC 621

[2021 No. 316 JR]

BETWEEN:

ANDRIUS BOGUSAS

APPLICANT

-AND-

MINISTER FOR HEALTH, REVENUE COMMISSIONERS, MINISTER FOR FINANCE, IRELAND, AND THE ATTORNEY GENERAL

RESPONDENTS

JUDGMENT of The Hon. Mr. Justice Alexander Owens delivered on the 26th day of October 2022.

1. The applicant claims that European Union law relating to free movement of goods entitles him to import into the State and market to the public hemp oil preparations containing the psychoactive agent tetrahydrocannabinol (THC). He claims that Irish law is out of line with laws of other EU Member States where hemp oil containing THC can be marketed for use other than in approved products administered under medical supervision.

2. He seeks an order compelling the Minister for Health (the Minister) to conduct a review of whether and to what extent THC should be permitted in hemp oil. He wants the Minister to carry out a risk assessment and change the law to set a threshold tolerance for THC in hemp oil in line with that assessment.

3. The applicant also seeks an order setting aside seizure and forfeiture under the Customs Act 2015 of a package, invoiced as containing 215 vials of hemp oil. This liquid included THC. He wants Customs to return the vials to him. He asserts that Irish law authorising seizure and forfeiture of hemp oil containing up to 0.2% THC should be disapplied because it is contrary to EU law.

4. If the applicant is correct in his argument, this means that European law entitles him to an advantage in the market over competitors who have taken care to market to the public hemp oil preparations which are free of THC, as required Irish law, European law, and international law.

5. The hemp oil comes from Slovenia. The applicant asserts that hemp oil products containing up to 0.2% THC may be produced and marketed to the public there. He points to para.77 of the judgment of the European Court (Fourth Chamber) of 19 November 2020, Case C-663/18,(Marketing of Cannabidiol (CBD)) "Kanavape" which refers to a statement by the European Commission that "…the CBD at issue in the main proceedings…" may lawfully be "…produced and marketed…" in the Czech Republic.

6. Ireland and the other Member States of the EU are parties to the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 protocol amending the Single Convention on Narcotic Drugs 1961 (the Single Convention) and to the Convention on Psychotropic Substances of 1971 (the 1971 Convention) (the Conventions). Irish law

relating to permitted use of THC conforms with the requirements of the 1971 Convention.

7. THC is the main psychoactive ingredient in Cannabis. It is listed in Schedule I to the 1971 Convention under the "other non-proprietary or trial name" . It follows that Article 7 of the 1971 Convention applies to THC. This requires that parties to the 1971 Convention must prohibit all use of THC except for scientific and very limited medical purposes. Any permitted activities must be strictly regulated. EU law accepts the rules laid down by the Conventions as generally binding.

8. Any laws or practices which permit unrestricted public access to preparations containing THC are, prima facie, contraventions of obligations under Article 7 of the 1971 Convention. Ireland and other Member States are precluded from taking measures which permit unrestricted marketing of preparations containing THC to the public.

9. The judgment in Case C-663/18 (Marketing of Cannabidiol (CBD)) "Kanavape" does not decide that the Minister is precluded from preventing uncontrolled marketing to the public of preparations containing THC.

10. Irish courts must disapply national law where this law is not in accordance with the law of the European Union. In general, Article 34 of the Treaty of Functioning of the European Union (TFEU) requires that products marketed in any Member State may not be subject to more restrictive marketing rules in any other Member State. The normal presumption is in favour of requiring conformity with the control regime in the Member State which applies less restrictive rules.

11. Article 7 of the 1971 Convention obliges all contracting parties to forbid unrestricted public access to preparations containing THC.

12. Unilateral action or inaction by a Member State which permits marketing to the public of preparations containing THC does not result in this activity becoming lawful in other Member States. There is no basis on which EU rules relating to free movement of goods can be applied in a manner which undermines the rule of international law in this way.

13. It follows that if a Member State allows use of a "Schedule I" psychoactive substance, such as THC, in a manner which is not permitted under Article 7 of the 1971 Convention, this national rule or concession cannot engage Article 34 of the TFEU. Any activity so permitted remains within the principle that unauthorised trade in narcotic or psychotropic drugs does not come within Article 34. These activities are treated as 'res extra commercium.'

14. "Schedule I" narcotic and psychoactive drugs which are not distributed through channels which are strictly controlled by the competent authorities to be used for medical and scientific purposes are, because of their very nature, subject to a prohibition on offering to the public for sale in all Member States.

15. Even if Article 34 of the TFEU was considered as capable of applying to unrestricted marketing of hemp oil containing THC to the public, the applicant's claim could not succeed. This is because Article 36 of the TFEU permits Member States to impose restrictions on marketing of goods as precautionary measures for protection of public health. The evidence demonstrates that Irish controls on unrestricted marketing of hemp oil containing any THC to the public are justified on health grounds.

16. The applicant has not placed any evidence before this Court which shows that current restrictions on unrestricted public access to preparations containing THC may not be fully warranted. Without some evidence on this, his claim that these restrictions are in excess of what is allowed by Article 36 of the TFEU cannot be maintained.

17. It follows that this application must be dismissed. The challenge to this seizure and forfeiture was made after expiry of the time limit permitted by O.84, r.21(1) of the Rules of Superior Courts. The applicant has not met the requirements of O.84, r.21(3). The evidence does not establish that there is good and sufficient reason for extending the time to challenge the legality of this seizure and forfeiture or that the circumstances which resulted in his failure to make the application for leave within the period specified in O.84, r.21(1) were outside his control or could not reasonably have been anticipated. This challenge is also dismissed for this reason.

18. This package seized by Customs was shipped from Slovenia. The invoice exhibited by the applicant described the content of the vials as "PH Drops 10ml 10% 1000mg / HMP oil." The invoice was not directed to the address to which the goods were consigned. The package was seized as contraband by officers of Customs in exercise of statutory powers on 21 October 2020 because the contents tested positive for THC. THC in this form may not lawfully be imported into the State by the applicant. It is subject to the general prohibition on import, production and supply of controlled drugs contained in Regulation 5 of the Misuse of Drugs Regulations 2017 (S.I. No. 173/2017). This package was not seized as contraband on grounds that it contained cannabidiol.

19. Correspondence from the applicant's solicitor prior to issue of these proceedings asserted that the hemp oil seized "…may contain traces of THC, which are lawfully permitted within parameters specified under, inter alia EU regulation 1307/2013."

20. The applicant states the hemp oil which he seeks to market is produced from hemp with a THC content not exceeding 0.2%. This is the same percentage figure as that laid down by the EU as a parameter for THC in hemp cultivated as an agricultural crop using EU approved seed varieties. He adopts this as a standard potentially applicable to THC in hemp oil. He asserts that hemp oil products which include THC within this tolerance may be "lawfully permitted."

21. There is no direct evidence of the level of THC in the vials within the package seized by Customs. That package was consigned to a convenience address in Malahide. The vials were unlabelled and were not accompanied by any statement setting out the composition of their contents.

22. The applicant had previously been caught by the Irish authorities with hemp oil which was confiscated. Both the exporter and the importer knew that the contents of the package were contraband in Ireland. The package was not accompanied by anything which tied the applicant to ownership.

23. This illustrates difficulties which Customs and Gardaí face when dealing with unregulated products containing THC or any other controlled drug. These items come into the State unmarked and without accreditation. The hemp oil could originate anywhere in the world and might contain any amount of THC or other psychoactive substances only permitted in regulated medicinal products.

24. The applicant has exhibited a copy of a page entitled "Test Certificate No.: 2017-20." This was issued to his Slovenian supplier. It is dated 17 July 2017. It provides an analysis of THC, CBD and other Cannabis related contents in what are described as "CBD Drops 5%" and discloses the THC content of the cannabinoid profile as "1,4 mg/g". This document includes a photographic representation of a small bottle with a dropper in the lid. The bottled is labelled "CBD Drops."

25. The applicant also exhibits a letter from the HSE dated 18 March 2020 and an analysis report relating to a sample analysed on 31 October 2019 by Public Analyst Laboratory in Dublin. The report provides a risk assessment of a product described as "CBD 5% Extract Organic" submitted to the laboratory for testing. I am prepared to assume that this sample was sourced from the same supplier. The documents disclose that it originated in Slovenia. The declared value was 5%, 500 mg in a 10ml pack size with a manufacturer's recommended dose of 3 drops daily. The accredited analysis provided readings of the following levels of controlled drugs within the sample: "Delta-9-tetrahydrocannabinol 420 mg/kg; delta-8-tetrahydrocannabinol 43 mg/kg and cannabinol 53.5 mg/kg."

26. The HSE evaluation of the results of the analysis states as follows: "This product contains 0.387mg/ml of the psychotropic substance THC. The maximum recommended dosage of 6 drops per day would deliver 0.077mg of THC. As the EFSA (European Food Safety Authority) acute reference dose (0.001 mg/kg body weight) is dependent on a person's weight, the FSAI (Food Safety Authority of Ireland) has adopted an upper limit of 0.1mg THC/day (EFSA acute reference dose for a 100kg person) which includes a significant proportion of the Irish population. The intake of THC in a day (0.077 mg) from this product at the maximum stated dosage would not exceed the EFSA acute reference dose for a 100kg person (0.1mg)."

27. This demonstrates that the hemp oil which the applicant seeks to import into Ireland is harmful because it contains a quantity of THC which makes it capable of being abused. This is not an accidental trivial contamination of the food chain by minute traces of a harmful substance.

28. The applicant states that the hemp oil is extracted from paste derived from the leaves and flowers of the cannabis plant. These leaves and flowers are also the source of THC

and other proscribed psychoactive agents. There is therefore a significant risk that hemp oil will be contaminated by psychoactive agents.

29. In 2020 the Food Safety Authority of Ireland (FSAI) reported on the result of a survey dealing with "Regulatory Issues with Hemp-based Food and Food Supplements on the Irish Market". This report has been put in evidence by the Minister. The purpose of the survey was to "…determine the regulatory compliance of food and food supplements, predominantly in liquid form that claim to contain CBD in Ireland." In other words, the survey was mainly concerned with hemp oil containing cannabidiol.

30. Analytical data from the product batches tested by the Public Analyst Laboratory in Dublin showed as follows: "84% (32/38) of products tested were found to contain the psychotropic substance THC. If consumed at the maximum stated dosage, 37% (14/38) of products tested could deliver levels of Δ9-THC (Delta-9-tetrahydrocannabinol) that would significantly exceed the EFSA acute reference dose…."

31. Part 7.1 of the World Health Organisation (WHO), Expert Committee on Drug Dependence: forty-first Report, WHO Technical Report Series, No. 1018 (the Committee) states that adverse effects of cannabis are similar to those produced by THC alone. The report sets out the effects of cannabis. What holds good for cannabis must also hold good for THC which is the cause of the adverse effects. Following consumption, these effects include dizziness and impairment of motor control and cognitive function. The risks reported for children include respiratory depression, tachycardia, and temporary coma. Cannabis can cause physical dependence in habitual users. In other words, it is addictive. Those who are addicted suffer withdrawal symptoms upon abstinence. Chronic use affects the developing brain of young people. Long term use results in increased risk of mental health disorders such as anxiety, depression, and psychotic illness.

32. Users of hemp oil or any other substance as a narcotic are not concerned with the maximum recommended daily dose. It would be naïve to think that potential consumers, including children, would not seek out this product for misuse as a psychotropic drug if it were freely available. Its potential as a source of psychotropic substances will also be exploited by criminals.

33. The Committee formulated a proposal to the Commission on Narcotic Drugs of the WHO (the CND) that Schedule 1 to the Single Convention be amended by including a footnote stating that "Preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9-tetrahydrocannabinol are not under international control". The Committee considered that this recommendation was "…in keeping with the recommendation of the fortieth ECDD that preparations considered pure cannabidiol not be controlled. The Committee recognised that trace elements of Δ9-THC may be found in medical preparations, such as the concentration of 0.15% in Epidiolex…"

34. The Committee appears to have decided on the threshold of 0.2% THC because it might be difficult for some states to chemically analyse Δ9-THC to an accuracy of 0.15%.

35. There is a world of difference between an approved medicine such as "Epidiolex," which is administered under medical supervision, and a preparation which may be consumed in any quantity at will or may possibly be abused by further processing.

36. The Horizontal Working Party on Drugs (HDG) of the Council of the EU rejected the viability of this course as unworkable and not supported by science. The HDG is an expert body within the EU which prepares drugs strategies, co-ordinates with Member States and outside bodies and works in co-operation with other EU agencies concerned with addiction and enforcement.

37. In line with this advice, the agreed position of the EU and the Member States on this proposal was that it should be rejected. Council Decision (EU) 2021/3 of 23 November 2020 on the position to be taken on behalf of the European Union, at the reconvened sixty-third session of the Commission on Narcotic Drugs, on the scheduling of Cannabis and Cannabis-related substances under the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971 OJ L 4, 7.1. 2021, (the Council Decision) mandated Member States to vote against it at the CND. This proposal was overwhelmingly rejected at a vote of the CND on 2 December 2020.

38. The reason for the EU position was explained in para.(26) of the recitals to the Council Decision: "(26) However that recommendation would lower the current control for those preparations. Moreover, the establishment of that limit of 0.2 percent of delta-9-tetrahydrocannabinol is not sufficiently supported by scientific evidence, the wording of that recommendation does not exclude possible divergent interpretations concerning the way of calculating that limit of 0.2 percent delta-9-tetrahydrocannabinol, and the technical implementation of that recommendation will be difficult for reasons of technical and administrative capacity. The differentiated treatment of cannabidiol compared to other cannabinoids is not in line with the existing structure of the Schedule of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. The recommendation, as it has been drafted does not offer the necessary legal certainty."

39. While no case can be made treating pure cannabidiol (CBD) derived from hemp as proscribed because it is not a narcotic or psychoactive agent, the position is different where a preparation containing CBD also contains THC. Lack of scientific support for setting 0.2% as a safe upper limit for THC in CBD preparations was a central feature of the reasoning of the HDG which led to rejection by the Member States of the suggested change to the Single Convention. The other reasons were technical and administrative difficulties in operating a regime of control based on a tolerance level for THC. Hungary voted to reject the suggested change for different reasons.

40. The Minister has explained that the possibility of permitting on some basis use of CBD oil which includes a THC content of 0.2% or lower has been considered and will continue to be considered by the Department of Health. This is in line with current EU policy which is explained in para. (28) of the recitals to the Council Decision: "(28) However

the Union would welcome further consultation with all relevant stakeholders on a recommendation on the appropriate level of international control for Cannabis preparations with a low delta-9-tetrahydrocannabinol content, while ensuring the protection of public health and welfare, taking into consideration the existing structure of the international drug control system for Cannabis as well as the technical and administrative capacity that is needed for implementation of such a recommendation."

41. The Irish legal framework relating to importation, cultivation, processing and use of cannabis plants and substances derived from cannabis is set out in the Misuse of Drugs Act 1977 (the 1977 Act) and regulations made by the Minister under that Act.

42. The scheme of the Act and regulations allows the Minister to designate "controlled drugs" and to impose restrictions and controls on possession, cultivation, production, import and export of those drugs. Amongst the main purposes of the Act as set out in the long title are "…to prevent the misuse of certain dangerous or otherwise harmful drugs, to enable the Minister for Health to make for that purpose certain regulations in relation to such drugs…"

43. Section 15(1) of the 1977 Act provides that, "Any person who has in his possession, whether lawfully or not, a controlled drug for the purpose of selling it or otherwise supplying it to another in contravention of regulations under section 5 of this Act, shall be guilty of an offence." The maximum penalty for infringement is imprisonment for life.

44. Section 1(1) of the 1977 Act defines "cannabis" and "cannabis resin": "…cannabis (except in cannabis resin) means any plant of the genus Cannabis or any part of any such plant (by whatever name designated) but includes neither cannabis resin nor any of the following products after separation from the rest of any such plant, namely- (a) mature stalk of any such plant, (b) fibre produced from such mature stalk, or (c) seed of any such plant…;" "…cannabis resin means the separated resin, whether crude or purified, obtained from any plant of the genus Cannabis…"

45. The cannabis plant has not traditionally been cultivated for production of hemp in Ireland. As a general rule, its seeds may not be germinated as this activity will generate a plant. S.17(1) of the 1977 Act, as amended, provides that: "A person shall not cultivate….any plant of genus Cannabis ….except under and in accordance with a licence issued in that behalf under section 14(1)."

46. The definitions of "cannabis" and "cannabis resin" in the 1977 Act are formulated to ensure that the cannabis plant and potentially harmful derivative drugs may not be cultivated, developed, or used in the State, except to the extent permitted by strict regulation, and that existing safe uses of harmless parts of the plant continue to be permitted. The stalks and fibres and seeds can be imported and used for purposes such ropes and mats and for food.

47. Hemp is similar to flax. The principal historic reasons for cultivation of hemp are to make hemp ropes and fabrics from its fibres, to use its seeds as food and to use its leaves and flowers as a source of psychoactive drugs such as THC.

48. Cannabidiol can be extracted from the leaves of the plant using carbon dioxide or ethanol. It can also be generated synthetically. Cannabidiol is the main component of hemp oil. Cannabidiol is not separately listed as a controlled drug. Cannabidiol which has been extracted from cannabis resin or from the plant as a whole and imported into the State could possibly come within the statutory definitions of "cannabis" and "cannabis resin." in the 1977 Act.

49. Cannabidiol has no narcotic or psychoactive effects and there is no reason why it should be restricted. The question put to the European Court by the referring tribunal in Case C-663/18 (Marketing of Cannabidiol (CBD)) "Kanavape" was answered in the light of evidence which established these matters. The court concluded that cannabidiol did not come within the definitions of cannabis or cannabis resin in the Single Convention and that it was not a psychotropic substance.

50. That judgment has removed any doubt that the definitions of "cannabis" and "cannabis resin" in the 1977 Act should be treated as excluding cannabidiol extracted from cannabis or cannabis resin. This has implications for import, manufacture, and sale in Ireland of products containing cannabidiol.

51. Cannabidiol may be imported into Ireland and marketed without contravening any prohibition under the 1977 Act. It is used in a number of products. The main product is hemp oil. In recent years hemp oil has been produced for use as a health supplement. There is some evidence that cannabidiol has potential health benefits. Trade in products containing CBD is now big business.

52. Cannabis, cannabis resin, cannabinol and cannabinol derivatives are all specified as controlled drugs in the Schedule to the 1977 Act. Regulations made under s.5 of the 1977 Act prohibit importation and sale of these drugs, except as specified medical preparations under licence. "Cannabinol derivatives" are defined as meaning: "…the following substances, except where contained in cannabis or cannabis resin, namely, tetrahydro derivatives of cannabinol and 3-alkyl homologues of cannabinol or its tetrahydro derivatives…" So, THC is a controlled drug. Preparations containing THC contain controlled drugs.

53. These definitions are clear. They are designed to facilitate enforcement. The substances prescribed as "controlled drugs" include some material not covered by the definition of cannabis in the Single Convention, such as cannabis leaves which are capable of being used for marijuana cigarettes and residues of leaves and flowering tops from which cannabis resin has been extracted. Article 28(3) of the Single Convention obliges the parties to "…adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant." The leaves, which are a source of psychoactive substances, are misused to make cannabis resin and for smoking.

54. Hemp is grown as a cash crop in some Member States of the European Union. This activity has always been legal. The provisions of Article 34 of the TFEU apply to this activity and also to use of hemp to make ropes and fibres and use of hemp seeds as food. It may also be cultivated and used as a source of THC for purposes within strict limits allowed by the Conventions. It may be cultivated for use of the leaves and flowers to produce cannabidiol as a bye-product.

55. Areas of land used for agricultural production of hemp are "eligible hectares" under Regulation (EU) No 1307/2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 "if the varieties used have a tetrahydrocannabinol content not exceeding 0.2%": see Article 32(6) of Regulation (EU) No 1307 of 2013. The purpose of the limitation of the tetrahydrocannabinol content in plant varieties in Article 32(6) is to try to ensure that EU payments do not operate as subsidy for agricultural production of hemp for psychoactive drugs.

56. This provision is supplemented by Article 35(3) which provides that, "In order to preserve public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 70 laying down rules making the granting of payments conditional upon the use of certified seeds of certain hemp varieties and the procedure for the determination of hemp varieties and the verification of their tetrahydrocannabinol content referred to in Article 32(6)."

57. Article 189(1) of Regulation (EU) 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing the common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 OJ L 347,20.12.2013, supplements this protective regime by prohibiting importation into the EU of hemp unless it is: " (a) raw true hemp falling within CN code 5302 10 00 meeting the conditions laid down in Article 32(6) and in Article 35(3) of Regulation (EU) No 1307/2013; (b) seeds of varieties of hemp falling within CN code ex 1207 99 20 for sowing accompanied by proof that the tetrahydrocannabinol level of the variety concerned does not exceed that fixed in accordance with Article 32(6) and in Article 35(3) of Regulation (EU) No 1307/2013; (c) hemp seeds other than for sowing, falling within CN code 1207 99 91 and imported only by importers authorised by the Member State in order to ensure that such seeds are not intended for sowing."

58. Hemp within heading 57.1 of the "Brussels Nomenclature" referred to in Annex 1 of the TFEU is an "agricultural product" to which Articles 38 to 44 of the TFEU dealing with the common agricultural policy apply. This nomenclature relates to fibres and is identical to that used in the description of flax. This does not refer to leaves, flowers, or seeds. It refers to "true hemp (Cannabis sativa), raw or processed, but not spun; tow and waste of true hemp (including pulled or garnetted rags or ropes)."

59. These Regulations only deal with control of psychoactive agents contained in hemp in the context of support schemes under the common agricultural policy and to ensure a common organised market within the EU. They protect this market from imported product by ensuring that imports of raw hemp and hemp seeds for use in industrial processing or agriculture comply with EU standards.

60. The 0.2% threshold has no necessary correlation with THC content of preparations derived from processing of parts of the plant which yield psychoactive agents. This threshold is not a measure of safety of non-medicinal use of THC.

61. Section 13(1)(a) of the 1977 Act gives the Minister, acting in the public interest, power to designate a controlled drug as one to which that subsection applies so that its manufacture, production, preparation, sale, supply, distribution, and possession is unlawful except for purposes of research or other special purposes specified in an order under that section of the Act. Where such a designation is made in respect of any controlled drug, the specified permitted activity may be made subject to licencing, permits, or authorisations under s.14 of the 1977 Act, to which conditions may be attached.

62. The cannabis plant may be used in the State under licence for growing hemp and for other permitted activities. The Minister has permitted these activities in exercise of powers given by s.13 of the 1977 Act in the Misuse of Drugs Act 1977 (Controlled Drugs) (Designation) Order 2022 (S.I. No. 211 of 2022) which lists cannabis as one of a number of drugs to which s.13(1) of that Act applies. The relevant parts of current regulations are identical to provisions previously contained in the revoked Misuse of Drugs (Designation) Orders 2017 (S.I 174 of 2017) and 2021 (S.I 122/2021).

63. These Regulations specify in Schedule 2 the authorised purposes as follows: "Purposes specified for the purposes of section 13(1)(a) of the Act- The following purposes, namely;- (a) research, forensic analysis or use as an essential intermediate or starting material in an industrial manufacturing process; (b) the growing of hemp from seed varieties specified, by the Commission of the European Communities as being eligible for the purposes of Article 1 of Regulation (EU) No. 1307/2013 of the European Parliament and of the Council of 17 December 2013; subject to such licencing provision under the Act and the Regulations made thereunder as are applicable."

64. Their purpose is to permit agricultural production in Ireland of EU approved hemp varieties under licence. Irish farmers should be in the same position as their European counterparts. It is likely that the Minister would impose conditions confining cultivation by licensees to production of hemp as a cash crop and regulating further use or disposal of elements of the plant which are a potential source of psychoactive substances to ensure that they are not misused. Article 28(1) of the Single Convention requires strict control of cultivation of the cannabis plant for the production of cannabis and cannabis resin. Article 28(2) specifies that the Single Convention "…shall not apply to cultivation exclusively for industrial purposes (fibre and seed) or horticultural purposes." "Horticultural purposes" as a reference to use for food.

65. The Minister has made regulations under the 1977 Act which provide other limited exceptions to the prohibition on import and possession of cannabis and cannabis related controlled drugs. Regulation 6 of the Misuse of Drugs Regulations 2017 (S.I. 173 of 2017) (the 2017 Regulations) allows importation, cultivation and supply of cannabis under licence.

66. These regulations allow healthcare professionals to hold and prescribe certain extracts of cannabis which have been given marketing authorisation as medicinal products as specified in para. 5 of Schedule 4 Part 1. They also allow for medical use of a preparation or product specified in Schedule 1 to the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (S.I. 262 of 2019) and permitted for use by those regulations, as amended.

67. Marketing and use of pharmaceutical preparations containing THC are prohibited unless they are medicinal products with a marketing authorisation granted by the Health Products Regulatory Authority or some other competent authority in the EU, UK, or the Swiss Confederation, or unless they come within a special regime which allows specified use of cannabis-based psychoactive agents.

68. Irish law criminalises possession of even minute quantities of controlled drugs for purpose of supply to another. This facilitates effective enforcement. It is a reasonable legislative approach which ensures maximum protection to the public from dangers associated with narcotic drugs. This also complies with the State's international obligations. It may be that many poisons and controlled drugs can be consumed in minute quantities without injury to human health. That fact is not, of itself, a sound basis for making it lawful to permit uncontrolled access to minute quantities of such materials.

69. Article 7(a) of the 1971 Convention provides as follows: "In respect of substances in Schedule 1, the parties shall: (a) Prohibit all use except for scientific and very limited medical purposes by duly authorised persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them; …"

70. The provisions of Article 7 of the 1971 Convention include further obligations of parties to that Convention "… to; …require that manufacture, trade, distribution and possession be under a special licence or prior authorisation; …prohibit export and import except when both exporter and importer are the competent authorities or agencies of the exporting and importing country or region , respectively, or other persons or enterprises which are specifically authorized by the competent authorities of their country or region for the purpose..."

71. "Preparation" is defined in Article 1(f) of the 1971 Convention as meaning: "(i) Any solution or mixture , in whatever physical state, containing one or more psychotropic substances, or (ii) One or more psychotropic substances in dosage form".

72. Article 3.1 and Article 3.2 of the 1971 Convention provide as follows: "1. Except as provided in the following paragraphs of this article, a preparation is subject to the same measures of control as the psychotropic substance which it contains, and, if it contains more than one substance, to the measures applicable to the most strictly controlled of those substances. 2. If a preparation containing a psychotropic substance other than a substance in Schedule I is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, the preparation may be exempted from certain of the measures of control provided in this Convention in accordance with paragraph 3."

73. Once processing activities are applied to cannabis leaves or resin, any "preparation" produced from these elements of the plant may include THC. At that stage "manufacture," is taking place. This is defined in Article 1(i) of the 1971 Convention as meaning "…all processes by which psychotropic substances may be obtained…" The controls specified in Article 7 of the 1971 Convention must be applied to THC within these preparations.

74. THC so obtained in any liquid is a tincture, extract, or preparation of cannabis within the nomenclature in the Single Convention. It is a Schedule 1 Substance in the 1971 Convention. As such, its special uses are tightly restricted.

75. It is irrelevant that a "Schedule I" substance may only be present in a preparation in a low amount or in a form which makes it difficult to extract and misuse. The views of advisory bodies on safe level of Schedule 1 substances such as THC within preparations are irrelevant, except in the context of permissible medical and scientific use.

76. Even if such views were relevant to making hemp oil containing THC generally available, current thinking does not support the case made by the applicant. The position advocated by the applicant that a tolerance level should be set for THC in hemp oil preparations is not supported by expert advice available to the Minister. The HDG and the CND have also rejected the viability of this course.

77. Council Framework Decision 2004/757/HA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drugs trafficking OJ L 223, 11.11.2004 (the Framework Decision) is binding on Member States.

78. Article 1 of the Framework Decision defines "drugs" as including any substances covered by the Single Convention (as amended by the 1972 Protocol) and the 1971 Convention. Article 2(1) is concerned with production and supply of "drugs" other than acts "…committed by…perpetrators exclusively for their own personal consumption as defined by national law…"

79. Article 2(1) of the Framework Decision provides as follows: "Each Member State shall take the necessary measures to ensure that the following intentional conduct when

committed without right is punishable: (a) the production, manufacture, extraction, preparation, offering, offering for sale, distribution, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transportation, importation or exportation of drugs; (b), the cultivation of opium poppy, coca bush or cannabis plant; (c) the possession or purchase of drugs with a view to conducting any of the activities listed in (a);…" It is clear from this wording that implementing legislation in Member states must follow a scheme of general prohibition of use of substances which are established narcotics or psychoactive drugs, except in accordance with licences and authorisations . A legal person may not engage in any of these activities "without right".

80. Member States must enact national rules which establish the circumstances in which legal persons within their territories may lawfully engage in any business activities listed in Article 2(1). These activities include marketing substances such as THC in preparations. What is not formally authorised remains unauthorised.

81. Member States may not abuse the objectives of the Framework Decision and the Conventions by permitting national relaxations of the prohibited activities relating to psychoactive substances which are not permitted by the Conventions.

82. While the EU is not a party to the Single Convention or the 1971 Convention, it is a party to the Convention against Illicit Traffic in Narcotic Substances of 1988. This is the third of the three major UN conventions on narcotic drugs and psychotropic substances. Its stated objects include reinforcing and supplementing the measures provided in the Single Convention and the 1971 Convention.

83. The Framework Decision and adherence by the EU to this convention show acceptance of obligations imposed by the Conventions. These EU legal rules and actions adopt the Conventions in such a way as to make their provisions part of the EU legal order. This includes the core requirement in Article 7 of the 1971 Convention prohibiting "all use" of Schedule I substances "…except for scientific and very limited medical purposes by duly authorised persons…" Each Member State is committed as part of this international legal order to a restrictive regime.

84. While it is undoubtedly the case that national regulations required by the Conventions are subject to review under EU law to ensure that implementation does not create an "uneven playing field" for legitimate intra-EU trade, such considerations cannot apply to national rules which permit unrestricted availability to the public of "Schedule I" substances.

85. The principle of free movement of goods does not support national laws or practices which derogate from the basic requirement in Article 7 of the 1971 Convention. Any derogation which permits unrestricted sale of hemp oil containing THC can only have legal consequences within a Member State where this is permitted.

86. There is no acceptable evidence before this Court that any Member State has taken such a course. It may be that that hemp oil containing THC within this tolerance is

available to the public in other Member States as a result of either absence of regulation or a decision not to enforce. The agreed EU position as embodied in the Council Decision is evidence that no Member State has adopted laws permitting unrestricted availability of hemp oil containing THC. Even if there had been such evidence, it could not impact on the conclusions.

87. Wilfried Wolf v Hauptzollamt Düsseldorf (C-221/81) ECLI:EU:C:1982:363 related to whether the Federal Republic of Germany could charge customs duties on cocaine illegally smuggled into West Germany and not seized at point of entry. The European Court considered that a customs debt did not arise because the goods were imported otherwise than through economic channels strictly controlled by the competent authorities. At Para.8 of its judgment the court considered that drugs such as cocaine "… display special features in so far as their harmfulness is generally recognised and their importation and marketing are prohibited in all the Member States, except in trade which is strictly controlled and limited to authorised use for pharmaceutical and medical purposes."

88. The court went on to point out at para. 9 of its judgment that such drugs are subject to the provisions of the Single Convention and that Article 4 of the Single Convention committed the parties "…to take all measures necessary to limit exclusively to medical and scientific purposes the production, manufacture , export, import, distribution of, trade in, use and possession of drugs." The Court concluded in para.10 of the judgment that, "…drugs which are not confined within channels of distribution strictly controlled by competent authorities for use for medical and scientific purposes are subject, by definition, to a total prohibition on importation and distribution in all the Member States."

89. Any abandonment of strict control by a Member State which unilaterally chooses to allow preparations containing THC to be made generally available to the public cannot affect the general applicability of the rule set out by the European Court in C-221/81 Wolf.

90. The judgment of the European Court dated 16 December 2010 (Second chamber) in Marc Michel Josemans v Burgemeester van Maastricht (Case C-137/09) ECLI:EU:C:2020:774 illustrates this point . A local ordinance in Maastricht prohibited coffee shop owners from admitting foreigners into their shops. The ordinance was an effort to reduce drug tourism from neighbouring Member States. This marketing of cannabis in coffee shops was not within a legal regime where narcotic drugs were marketed under strict control. The activity was tolerated as a concession. The court held that a coffee shop owner could not rely on the concession to establish a right based on freedom of intra-EU trade to market cannabis to foreign visitors in his shop.

91. The applicant submits that it follows from the judgment in Case C-663/18 (Marketing of Cannabidiol (CBD)) "Kanavape" that Irish legal restrictions on importation and marketing to the public of CBD oil containing THC must be disapplied as in conflict with

Articles 34 and 36 of the TFEU if there is no health risk associated with its unrestricted use.

92. He contends that the question answered by the European Court determined this issue as the judgment related to cannabidiol with a THC content. He submits that as it is lawful to "produce" and "market" such a product in other Member States if it has a maximum THC content not in excess of 0.2%.

93. Case C-663/18 (Marketing of Cannabidiol (CBD)) "Kanavape" related to legality of marketing in France of e-cigarettes containing CBD oil lawfully produced in another Member States from hemp cultivated from EU approved seed varieties. The marketers of the product were prosecuted and convicted of an offence.

94. The issue framed by the French referring court to the European Court was whether a derogation allowed in Article 1 of an order of 22 August 1990 which restricted lawful growing and industrial and commercial use of cannabis to stalks and seeds of plants of varieties having a delta-9-THC content not exceeding the EU limit of 0.2% was compatible with EU law.

95. The French trial court considered the CBD in the Kanavape unlawful because it was extracted from the whole Cannabis plant. As the evidence in this case make clear, hemp oil is extracted from the leaves and flowers. These areas are also the source of the psychoactive agents.

96. The ingredients of the offence did not require that it be established that "Kanavape" contained psychoactive substances. A conviction was obtained in France on the basis of evidence that the substance was prohibited by a French law because that law limited authorisation to importation and industrial and commercial use of fibre and seeds of the cannabis plant grown from varieties with a THC content not exceeding 0.2%

97. The French order provided for double-lock security against misuse of cannabis plants. Two keys were needed to open the lock. The first key was a requirement that the plant variety THC content was within a 0.2% threshold. The second key was a requirement that the activity was restricted to parts of the plant which were not likely to yield psychoactive drugs (stalks and seeds).

98. The purpose of these restrictions was to reduce the possibility that leaves, and flowers of plants would be misused for psychotropic drugs. Commercial use of Cannabis leaves and flowers to make preparations containing cannabidiol was not permitted. If cannabidiol is a harmless substance which can be extracted from Cannabis leaves and marketed to the public elsewhere in Europe; then why not in France?

99. The European Court was provided with an explanatory circular from the French Ministry of Justice dated 23 July 2018 from which the following extract was quoted at para.27 of the judgment: "Contrary to the argument sometimes put forward by establishments offering cannabidiol-based products for sale, the authorised delta-9-

tetrahydrocannabinol content of the 0.2% applies to the cannabis plant and not to the finished product resulting from it… It should be noted that cannabidiol is found mainly in leaves and flowers of the plant, and not in the fibre and seeds. Consequently, as the applicable legislation stands , it does not appear possible to extract cannabidiol under conditions consistent with the Public Health Code...” This guidance said nothing about THC in preparations produced as a result of this extractive process.

100. The evidence was that the CBD oil product was produced in the Czech Republic and had a level of THC which was below what the court described as the “…legally permitted threshold…” in France: see para. 31 of the judgment. The only evidence of a threshold for THC content was that set by the EU for plant varieties eligible for subsidies under the CAP. This was adopted by French law as one of the criteria for determining the legality of manufacturing and other economic activities relating to use of cannabis in France.

101. The French authorities decided not to prosecute for marketing a product above “the legal threshold of 0.2%, since an analysis conducted by the Agence nationale de sécurité du médicament et des produits de santé (the ANSM) … had established that the threshold had not been reached.” (see para.15. of the opinion of Advocate General Tanchev delivered on 14 May 2020.) What this means is that in order to prove the offence it was only necessary for the French authorities to establish that the leaves of the plant were processed to make hemp oil. The quantity of THC in the product had no relevance to proof of the offence.

102. It was taken as a “given” by the referring court that as hemp was marketed lawfully in other Member States where it contained THC at a threshold value of 0.2%, as was the case in the main proceedings, CBD could not be classified as a “narcotic drug”: see para.37 of the judgment.

103. This conclusion of the referring court seems to have followed from a view that the laws of France and of the Czech Republic were aligned in allowing products from hemp varieties which were within the 0.2% THC threshold. The premise was that as the laws of France and the Czech Republic were the same on threshold THC content within Kanavape, no issue of free movement of goods could arise on the basis that France treated THC content in the product differently to the Czech Republic.

104. The European Court made the following observation at the end of para. 37 of its judgment: “Indeed, according to the judgments of 26 October 1982, Wolf (C-221/81, EU:C:1982:263), and of 28 March 1985, Evans Medical and Macfarlan Smith (C-324/93, EU:C:11995:84) only a product whose harmfulness is demonstrated or generally recognised and whose importation and marketing is prohibited in all Member states may be classified as such.”

105. The term “narcotic drug” was being used by the court in para.37 in the same sense in which that term was used in the judgments cited by the court.

106. In this context it is important to note that C-221/81 Wolf concerned unregulated trade in drugs recognised to be harmful and scheduled as such by the Conventions. These substances are tightly regulated by rules which do not differentiate between large and small amounts or give general exemptions where they are contained in particular "products" capable of being used or misused for human consumption. Any "products," be they preparations, tinctures, extracts, or pills, which contain "Schedule 1" psychoactive substances are generally proscribed, except to the extent that they are allowed by special exemptions permitted in accordance with the Conventions.

107. The evidence presented by the referring court relating to the risks to health from CBD is set out in paras. 34 and 72 of the judgment: "(34) The referring court explains that CBD does not appear to have any 'recognised psychoactive effects.' Indeed, it notes that the World Health Organisation (WHO), in a 2017 report, recommended removing it from the list of doping substances, that CBD is not listed as such in the Single Convention , that the ANSM concluded, on 25 June 2015, that there were insufficient data to classify it as 'harmful' and, last, that the expert appointed in connection with the criminal inquiry giving rise to the proceedings instituted against the applicants in the main proceedings concluded that it had 'little or no' effects on the central nervous system. Moreover, CBD is not expressly referred to either in the texts applying to industrial hemp or in those relating to cannabis as a narcotic drug… (72) However, it must be observed that it follows from the elements of the file before the Court, which are summarised in paragraph 34 of the present judgment, that the CBD at issue in the main proceedings does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data. Moreover, according to those elements in the file, the cannabis variety from which that substance was extracted, which was grown in the Czech Republic lawfully, has a THC content not exceeding 0.2%."

108. The referring court also considered that the public health objective was already taken into consideration in the EU rules relating to use of hemp seeds and prescribing a 0.2% threshold in respect of THC content of Hemp.

109. In light of these matters the European Court reformulated the question posed by the referring court and answered that question. Question (para. 44 of the judgment): "Although the referring court refers, in the wording of its question, to limiting 'the cultivation, industrialisation and marketing of hemp solely to fibre and seeds,' it is apparent from its own explanations that the question can be asked relevant to the main proceedings only to the extent that it concerns the conformity with EU law of national legislation which prohibits the marketing of CBD when it is extracted from the Cannabis sativa plant in its entirety and not solely from its fibre and seeds."

110. Answer (para.97 of the judgment): "…Articles 34 and 36 TFEU must be interpreted as precluding national legislation which prohibits the marketing of cannabidiol (CBD) lawfully produced in another Member State when it is extracted from the Cannabis sativa plant in its entirety and not solely from its fibre and seeds, unless that legislation

is appropriate for securing the attainment of the objective of protecting public health and does not go beyond what is necessary for that purpose..."

111. Cannabidiol is not listed as a psychotropic substance by the 1971 Convention. It followed that the issue which was presented to the court for consideration was whether cannabidiol came within the Single Convention. Had the Court concluded that cannabidiol was caught by the Single Convention it would not have mattered that the Czech authorities permitted its production using hemp leaves and allowed it to be marketed freely to the public.

112. In order to answer the question posed, the court analysed whether cannabidiol came within the categories of cannabis and cannabis resin within the intent of the Single Convention. The issue was whether cannabidiol was a narcotic in the light of established law (judgment of 16 December 2010, Josemans C-137/09, EU:C:2010:774) that "…narcotic drugs which are not distributed through such strictly controlled channels are prohibited from being released into the economic and commercial channels of the European Union, persons who market those products cannot rely on the freedoms of movement or the principle of non-discrimination, in so far as concerns the marketing of cannabis…." (paras 62 and 63 of the judgment)

113. The court concluded on the evidence available from the French referring tribunal, "…which it is for the referring court to verify, it must be held that, since CBD does not contain a psychoactive ingredient in the current state of scientific knowledge recalled in paragraph 34 of the present judgment, it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of "drugs" within the meaning of that convention as a cannabis extract." (para. 75 of the judgment)

114. The European Court did not conclude as a fact that THC is not a harmful drug or a harmful "product" or that the 1971 Convention permitted marketing to the public "Schedule I" psychoactive drugs in preparations which contain small quantities of such drugs.

115. This Court is only bound to follow conclusions of law of the European Court which it must apply to the facts established by the evidence in this application. The evidence in this application establishes that the hemp oil which the applicant wishes to import and sell to the public is a preparation containing THC. It follows that the Article 7 of the 1971 Convention applies to that preparation. Irish law conforms with a mandatory requirement of Article 7 which does not permit such a course.

116. It follows that the applicant is not entitled to rely on Article 34 of the TFEU as requiring that he be permitted to import hemp oil containing TFC and sell it to the public.

117. For the same reason the applicant is not entitled to an order compelling the Minister to revisit the current restrictions. The State is precluded by Article 7 of from permitting what the applicant seeks.

118. Even if Article 34 of the TFEU were to be treated as presumptively applicable to the selling hemp oil containing THC in the State on the basis that this is allowed in other Member States, the evidence demonstrates the dangers associated with this and that the present regulatory regime is justified.

119. Finally, the explanation for delay in instituting judicial review to challenge validity of seizure and forfeiture of the vials is unconvincing and does not show sufficient grounds for extending time. The applicant knew that the vials had been seized and the reason for the seizure shortly after 21st October 2021. The notice of seizure explained that the vials tested positive for THC. He knew what this meant.

120. This notice set out the procedure for contesting the seizure and stated that in the absence of a claim within 30 days the goods were deemed by law to be forfeit.

121. The applicant gave no notice of claim. He did not intend at that stage to make any challenge to the seizure. The judgment of the European Court in Case C-663/18 (Marketing of Cannabidiol (CBD)) "Kanavape" was issued on 19 November 2020. His affidavit omits to state when he first became aware of this decision. It is clear from the affidavit of his solicitor that he was aware of this development when he first sought legal advice. At that stage the bird of time was already well on the wing.

122. He indicates that he went to his solicitor on 13 December 2020. A letter from his solicitor dated 12 January 2021 to the Customs section of the Revenue Commissioners referred to EU Regulation 1307/2013 and sought return of the vials on the basis that the "traces of THC" were within lawfully permitted parameters. This letter made no reference to the judgment in Case C-663/18, ECLI:EU:C:2020:938 (Marketing of Cannabidiol (CBD)) "Kanavape" which obviously inspired it. The applicant had available at that stage all of the materials which are exhibited in his application for judicial review.

123. His solicitor wrote a more detailed letter to the Minister and the Revenue Commissioners dated 15 February 2021 claiming that the seizure was invalid and demanding an immediate amendment of the 1977 Act. Engagement in the correspondence exhibited did not operate to buy extra time for the applicant and is not a sufficient excuse for failure to apply for judicial review within the prescribed time limit.

124. Even after making allowances for difficulties in getting advice over the Christmas period, this Court does not accept that the applicant has established a sufficient basis to justify extending the time limit for judicial review of the customs seizure to 19 April 2021 on grounds specified in O.84 r.21(3) of the of the Rules of the Superior Courts.