Kerala High Court
Cadila Pharmaceuticals Ltd. vs State Of Kerala And Ors. on 2 April, 2002
Equivalent citations: AIR 2002 Ker 357
Author: G Sivarajan
Bench: G Sivarajan
ORDER G. Sivarajan, J.

1. The question that arises for consideration in this case is as to whether EC 350 (Vitamin E and Vitamin C capsules) and Cecure (Multi-Vitamin Capsules) manufactured by the petitioner and sold in the market through medical shops as "Dietary Supplements" falls within the definition of "drug" requiring licence under the Drugs arid Cosmetics Act, 1940 (hereinafter referred to as 'the Act').

2. The petitioner is a limited company engaged in the business of manufacture, distribution and sale of branded formulations, generic and oncocare products, animal health and natural products, dietary supplements, biotech products, chemicals, etc. Their registered office is at Navrangpura, Ahmedabad in Gujarat State, They are having licence for the manufacture, storage, distribution and sale of 'dietary supplements' to be manufactured at its factory at Navi Kadi, District Mehsana, Gujarat under Licence No. 3071/1977 issued by the Assistant Commissioner, Food and Medicine Administration, Mehsana, Gujarat, under Edible Things Adulteration Prevention Act produced as Ext. P1. They are also having licences issued by the Commissioner, Food and Drugs Control Administration, Gujarat State for the manufacture of drugs at its factory at Village Dholka, Ahmedabad District, under the Drugs and Cosmetics Act, 1940 evidenced by Ext. P2.

3. The petitioner has been marketing, distributing and selling its dietary supplements 'EC-350 and Cecure' which according to them are essentially Vitamin based in the State of Kerala from April, 1998 and April, 2001 respectively. The said dietary products are sold all over the country and were developed by the petitioner as a supplement which would induce general well being among the customers. The petitioner received letters (Ext. P3) from various medical shops in Palghat and Trichur Districts which had been selling the dietary supplements of the petitioner intimating the petitioner that they are returning their stocks of the said dietary supplements to the petitioner based on the orders of respondents 3 and 4. The petitioner had also obtained copies of the said orders issued by respondents 3 and 4 from medical shops, evidenced by Ext. P4.

4. According to the petitioner, the abovementioned products are not 'medicines' or substances meant for internal or external use of human beings intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings and were only meant as 'dietary supplements' intended to induce general well being among its consumers and that the said products did not fall within the definition of 'drug' as defined by Section 3(b) of the said Act. Respondents 3 and 4, on the other hand, have taken the stand that the two products mentioned above contain the ingredients which are coming under the definition of 'drug'. Respondents 3 and 4 had accordingly issued Ext. P4 series notices to the petitioner, dealers/distributors/medical shops directing them not to sell or distribute the said products until further orders. They were also directed that the balance stock of these products shall be reported in their reply. The petitioner is aggrieved. Hence the writ petition. Petitioner seeks to quash Ext. P4 communication issued by the

3rd and 4th respondents. They seek other consequential reliefs also.

5. A statement was initially filed on behalf of respondents 2 to 4. It is stated therein that the Drugs and Cosmetics Act, 1940 was enacted to regulate manufacture, sale and distribution of drugs and the main object is to make available standard quality medicines to the consumers, that the Act is said to be an effective tool in the hands of the Regulatory Agencies for quality managements and periodic checking and inspection, that it is the natural instincts of the manufacturers to circumvent the provisions of the law so as to cut the cost of production and other statutory obligations, that if the dietary supplements EC 350 and Cecure are manufactured and marketed as drugs, the petitioner has to use pharmaceutics grade raw materials costing manifold, more than food grade, keep strict quality measures under the Act and even for the capsules, standards are to be followed and that in such cases the department officials do draw samples of the 'drugs' at regular intervals for quality check, whereas Food Inspectors will not care these products under the impression of being drugs. It is also stated that Sodium Chloride (common salt) cost only Rs. 6/- per kg., whereas the pharmaceutical grade Sodium Chloride cost Rs. 250/-in the market because the purity and standards are very high. The Sodium Chloride 0.9% solution known as normal saline is used as a "drip solution" administered to the human body and, therefore, purity and quality cannot be diluted in pharmaceutical products, but in food grade the quality management is not strictly looked into and hence the tendency to manufacture food supplements circumventing the laws. It is further stated that the so-called food supplement EC 350 contains Vitamin E Acetate 200 Mg. and Vitamin C-150 Mg. with dosage 1-2 caps a day and that Cecure contains Vitamin B6 (Pyridoxine) 10 Mg. Vitamin B12 (Cynocobalamin) 500 Mg. and Folic Acid-1 Mg. in addition to the combination of the EC 350 with dosage-one softgel with water or as directed by the physician. They have also produced the labels of the two products as Exts. R2 and R2(a). It is further stated that the Indian Pharmacopia (IP), defines standards and limits for Vitamin C such as description, solubility, identification, specific rotation, light absorption, PH clarity, heavy metals, sulphated ash, assay, etc. and all these parameters should be passed for the raw materials to be used in a drug formulation; similarly for Vitamin E, IP gives specification for description, solubility, standards, identification, refractive index, acid value, free tocopherol, sulphated ash, assay, etc. and all these tests should be passed before the manufacture of capsules IP, page 49 (Vitamin C), 141 (Vitamin B12), 430 (Vitamin B6), 221-22 (Folic Acid) and 523 (Vitamin-E) are submitted as Ext. R2 series defining the standards and limits of these vitamins as drugs; in dietary supplement grade, no such stringent quality checks monitored; the M.R.P. of the products being very much at par with all other licensed drugs of same nature, the extent of profit margin by applying food-grade can be assessed. The relevant portion of the Indian Pharmacopia are also produced as Ext. R2(b).

6. Referring to Section 3 of the Act it is stated that whether an article, substance or device is a drug or not is decided by the intention of the use of the same, that the word 'drug' has an inclusive definition and all medicines are drugs, but 'medicine' is not defined in the Act, that medicine is a common man's word, a capsule is a medicine for any common man and that one of the basic difference between food and drug is that drug has a definite dosage, but food has not. They have also referred to Indian Drug Review (IDR) published for July-August, 2001 which is stated to be the reference book of the pharmaceutical people about the drugs formulation in the market which shows the therapeutic index of the Vitamins. It is stated that the name of EC 350 is published in page 519

in the subheading of 'preparations of Vitamin E' and also stated that there are many other preparations of the similar drug combinations manufactured by different manufacturers under valid drugs manufacturing licences and that Indication of Vitamin C is given as for the treatment of Scurvy, Anaemia, Dental Caris, Capillary Fragility, etc. There is also reference to Cecure News Volume-I published by the IJCP Academy of CME and brought by Cadila Pharmaceuticals Ltd., Ahmedabad (Ext. R2(d)), All these are produced to show that the two products in question are intended and marketed for certain disease conditions in human beings and hence these are nothing but drugs. The statement also refers to Schedule V of the Act which depicts the standards of patent and proprietary medicines which clearly defines the therapeutic, prophylactic and paediatric doses of the Vitamins in particular. It is also stated that these Vitamins cannot be taken as food without any control and hypervitaminosis will cause other toxicity and that fat solube vitamin such as Vitamin E once absorbed into the body will not be excreted, and overdose is highly detrimental and that overdosage of Vitamin B6 causes sensory pollneurtpathy, as explained in the Davidson's Principle and Practice of Medicine. It is further stated that so-called dietary supplements are manufactured by the petitioner under Ext. P1 licence which is intended for manufacture of food grade products and that the petitioner has no case that Ext. P2 drug manufacturing licence of the petitioner includes these two items. It is Issued in respect of other formulations. It is also stated that the petitioner has printed the dosages of the drugs on the labels of the drugs themselves whereas for food items no dosage is known and that Horlicks and Complan are food which were exempted under Rule 123 of the Drugs and Cosmetics Rules, 1940 under Clause 10 in Schedule K wherein preparations of condensed milk, powdered milk, cereal preparations fortified with Vitamins are exempted from the provisions of the Act. It is also stated that Section 17(c) of the Act is also attracted.

7. An additional statement was also filed on behalf of respondents 2 to 4, wherein it is stated that edible things are either food or drug, that there is no category called 'dietary supplement', that no standards are fixed for Vitamins under the Prevention of Food Adulteration Act, while stringent standards are provided under the Drugs and Cosmetics Act, that the quality of food is assessed by the consumer himself, whereas in the case of drugs quality is beyond the assessment of consumer and that the dose of Vitamin A and Vitamin E are fixed in International Units, which is not a food measure. It is pointed out that there are high level bodies comprised of experts in the field of Drugs and Pharmaceuticals and Doctors like Drugs Consultative Committee, Drugs Technical Advisory Board. Pharmacopoeial Committee, etc. to fix standards of drugs and that water, sodium chloride, oxygen, etc. are drugs depending upon the intention with which they are used.

8. Later a counter-affidavit is also filed on behalf of respondents 2 to 4. It is stated that E.C. 350 capsules and Cecure capsules are manufactured by a Pharmaceutical Company, distributed by their authorised distributors, stored and sold along with other drugs under the same invoices, promoted through medical representatives, advertised through medical journals like Indian Drug Review and through promotional literature like Cecure News, prescribed by Doctors, sold through retail medical stores and consumed by patients only to the knowledge of the respondents. The petitioner very well know that they are drugs and that they haVe violated the provisions of Drugs and Cosmetics Act and Drugs (Prices Control) Order and only tries to escape prosecution. Even if empty gelatin capsules are packed and labelled, it is 'drug', that drugs called placebos, without any active ingredients, are

prescribed to patients and so when Vitamins are filled inside capsules there need not be any doubt, that they are drugs. It is also stated that in India we have either 'drugs' or 'food', that 'dietary supplement' is a new terminology in India, and that the licence produced is only a food licence. Various other circumstances are also stated.

9. The petitioner has filed a detailed reply and also produced additional documents. It is stated therein that the petitioner's dietary supplement products were never intended to be used as components of drugs or as drug itself. It is also stated that the raw materials that go into the manufacture of the dietary supplement products are tested and conform to the standards and specification provided in the pharmacopoeias and that empty geletin capsules are brought within the definition of 'drugs' only when it is used as a component of a drug and not otherwise. It is further stated that the publications mentioned by the respondents are only private publications which contains only opinions of the Editor. Various other averments in the statements and in the counter-affidavit of the respondents to the extent it is against the averments in the Original Petition and in the, reply are stated as incorrect and denied.

10. I have heard Sri. Rajiv A. George, the learned Counsel appearing for the petitioner and Sri. George Mecheril, learned Senior Government Pleader appearing for respondents. The question to be decided, as already noted, is as to whether 'EC 350' and 'Cecure' Vitamin Capsules manufactured and distributed by the petitioner and sold in the market through Medical Shops fall within the definition of 'drug' requiring licence under the Drugs and Cosmetics Act, 1940. Section 3(b) of the Act defines 'drugs' as follows :

"3(b) "drug includes-

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board."

The definition of 'drug' would show that it took within its fold 'medicines' as well as 'substances' used for treatment, mitigation or prevention of disorders in human beings as well as in animals. Under clause (1) all medicines for internal or external use of human beings or animals and all

substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body for the purpose of repelling insects like mosquitoes are drugs. Thus it would be clear that a substance intended to be used for mitigation or prevention of any disease or disorder in human beings is a 'drug' notwithstanding the fact that it is not a 'medicine' which is to be applied for diagnosis or treatment of diseases. It is also relevant to note that a preparation applied on human body for the purpose of repelling Insects like mosquitoes is also a drug under clause (i). Under clause (ii) substances "other than food" intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Gazette is also a 'drug'. Under clause (iii) all substances intended for use as components of a drug including empty gelatin capsules is a 'drug' and as per clause (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Gazette after consultation with the Board are also 'drug'. Thus it is clear that the definition of 'drug' is wide enough to comprehend all medicines and substances for external or internal use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or in animals except food. The term 'food' is not defined in the Act.

11. Let me now examine whether the two products of the petitioner, viz., EC 350 (Vitamin E) and Vitamin C capsules (Multi-Vitamin capsules) fall under the definition of 'drug' under Section 3(b) of the Act. Here, it must be noted that food items are specifically excluded from the said definition. Hence it is worthwhile to first consider as to whether the aforesaid two items can be treated as 'food'. As already noted, the term 'food' is not defined in the Act. In Collins Cobuild English Dictionary for Advanced Learners Major New Edition (3rd Edition, 2001) the meaning of the word 'food' is shown as follows : "Food is what people and animals eat. Enjoy your food. N-MASS food-supplies of food and water..... Emergency food aid.... Frozen foods". Section 2(v) of the Prevention of Food Adulteration Act defines 'food' as any article used as food or drink for human consumption other than drugs and water and Includes (a) any article which ordinarily enters into, or is used in the consumption or preparation of, human food, (b) any flavouring matter or condiments, and (c) any other article which the Central Government may, having regard to its use, nature, substance or quality, declare, by notification in the Official Gazette, as food for the purposes of the said Act.

12. The two items in question are not food that is ate by the people and animals normally nor is it understood by the common man as food. The petitioner also has no case that these two items are used by people as a food item. The said two items also did not fall within the definition of 'food' in the Prevention of Food Adulteration Act, though it is used for human consumption in special cases. There is also no case that these two items are notified as 'food' by the Government. It is true that the petitioner has obtained a licence (Ext. P1) from the Assistant Commissioner of Food and Medi-

cine Administration, Mehsana under Edible Things Adulteration Prevention Act, 1952 and under the Prevention of Food Adulteration Act, 1954. That by itself will not make the two the Prevention of Food Adulteration Act and/or in common parlance/dictionary meaning. I have also noted that the

two Items do not satisfy the above requirement.

13. The word 'medicine' is not defined in the Act or in the Rules. It is defined in Collins Cobulld English Dictionary for Advanced Learners (Major New Edition) as (1) "Medicine is the treatment of illness and Injuries by doctors and nurses and (2} medicine is a substance that you drink or swallow in order to cure an illness". The definition of 'drug' has to be understood in this background.

14. Ext. R2(a) is the label of the product EC 350, which is stated as Vitamin E and Vitamin C capsules. It is noted that each soft gelatin capsule contains the Vitamins as noted in Ext. P1. Ext. R2(a) label which contains the instruction states thus : "Keep in a cool dry place protect from light. Dosage : One softgel with water or as directed by the physician". Similarly the label of the item 'Cecure' Multi-Vitamin Capsules Dietary Supplement states "each softgel contains Vitamin E", the vitamin noted in Ext. P1. Here, it must be noted that Ext. P1 shows the components of EC 350 as follows : "Each soft gelatin capsule contains Vitamin-E Acetate 200 mg. (Alpha Tocopheral Acetate), Vitamin C 150 mg (Ascorbic Acid) Appropriate overages added". Ext. R2 label also reveals the said fact. Similarly the item Cecure as per Ext. R2(a) label shows the following components: "Each soft gelatin capsule contains Vitamin E Acetate 200 mg (a Tocopheryl Acetate) Vitamin C 150 mg (Ascorbic Acid)-Pyridoxine HC-10 mg, Cyanocobalamin 500 mg. Folic Acid-1 mg". Ext. R2(b) which is a relevant portion of the Indian Pharmacopia shows that ascorbic acid. Vitamin C is used in the prevention of scurvy and or in the treatment of scurvy. Cyanocobalamin is used in the treatment of megaloblastic anaemia. Folic acid is also used in the same treatment, Ext. R2(c), which is the Indian Drug Review also refers to Vitamins. It also shows that Vitamin C (Ascorbic Acid) the deficiency of which develops scurvy and, therefore. Vitamin C is used for treatment of scurvy. The deficiency of Vitamin E will lead to Nausea, weakness, fatigue, headache, blurred vision, diarrhoea.

It also indicates that in premature infants exposed to high concentration of oxygen, correction of established Vitamin E deficiency, in patients at risk of developing Vitamin E deficiency. Item EC 350 is specifically shown as preparation of Vitamin E. The Indian Drug Review July-August, 2001 (Ext. R2(c)) under the head 'preparation of Vitamin E' Included E.C. 350. Cecure News (Ext. R2(d)) shows that these Vitamin preparations are used for prevention of diseases.

15. As already noted, the definition of 'drug' In the Act clearly specifies that all, substances intended to be used for mitigation or prevention of any disease or disorder in human beings is a drug and further all substances Intended for use as components of a drug including empty gelatin capsules is a drug. Admittedly the two Items of Vitamins are filled in empty gelatin capsules. So a combined reading of clauses (i) and (iii) of Section 3(b) would show that the two Items, EC 350 and CECURE which are Vitamin E and Vitamin C and/or multi-vitamin tablets would fall within the definition of 'drugs'. The provisions of Schedule V prescribing standards for patent or proprietory medicines also support the said stand. Clause 2 thereof says that proprietory medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain vitamins in quantities not less than and not more than those specified in the said schedule in single or two divided daily dozes. As per Rule 43 of the Drugs and Cosmetics Rules drugs specified in Schedule D shall be exempted from the provisions of Chapter III of the Act and of the Rules made thereunder to the extent and subject to the conditions specified therein. The items which are exempted under Schedule D. Item 5 reads "the

following substances; which are used both as articles of food as well as drugs : (1) all condensed milk or powdered milk whether nder pure skimmed or malted, fortified with vitamins and minerals, (2) Farex, Oats, Lactose and all other similar preparations whether fotified with vitamins or otherwise excepting those that are parentoral use". Similarly Rule 123 provides that the drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the Rules made thereunder to the extent and subject to the conditions specified in that Schedule. Item 10 of Schedule K deals with condensed or powdered milk, farex, oats and other similar cereal preparations whether fortified with Vitamins or otherwise excepting those for parenteral use. This clearly indicates that but for the exemption those items would have been subjected to the licencing and other procedures under Chapters III and IV of the Act and the Rules. I have already noted that the two items in question cannot be brought within the definition of 'food' as ordinarily understood or within the scope of the definition of 'food' in the Prevention of Food Adulteration Act. 'Medicine' as already noted is a substance that one drinks or swallows in order to cure an illness. By virtue of the definition of 'drug' in the Act a substance which is swallowed for mitigation or prevention of disease in human beings or in animals is a medicine and a drug. The two products in question is not used by any person as a general dietery supplement. Vitamin deficiencies in human being may result in certain diseases in human beings. In such cases doctors prescribe these vitamin capsules of a particular dozage which is for mitigation or for prevention of such diseases. These vitamin capsules will squarely fall within the definition of 'drug' under the Act.

16. In the above circumstances, I am of the view that the two items 'EC-350' and 'CECURE' which are styled as 'dietary supplements' are 'drugs' within the definition of the said word in Section 3(b) of the Drugs and Cosmetics Act, 1940.

17. Admittedly the petitioner does not have a licence issued under the Act for manufacture and/or sale of EC 350 or CECURE. Section 18 of the Act interdicts the manufacture for sale or distribution, sale, stock or exhibit for sale or distribution of any drug except under and in accordance with the conditions of, a licence issued for such purpose under Chapter IV of the Act. Section 27 of the Act also provides for punishment for contravention of Section 18 by way of imprisonment.

18. The petitioner has obtained a licence (Ext. P1) issued under the Edible Things Adulteration Prevention Act from the Asstt. Commissioner and Local (Health) Authority in Gujarat and has been manufacturing the said products in Gujarat and are selling the said products throughout India. It is stated that the said two products are sold in Kerala from April 1998 and April 2001, respectively. The petitioner, in the reply affidavit has stated that even though it is not mandatory for them to have followed the standards set by the Indian Pharmocopoeia for the manufacture of its dietary supplement products they are following the specifications laid down in the Indian Pharmacopoeia in regard to the said materials used in the manufacture of its dietary supplement products as would be evident from the Raw Material Specification and Finished Product Specification for its various dietary supplement products and also produced Ext. P6 series reports which according to them would show that the raw materials that go into the manufacture of the petitioner's dietary supplement products are tested and conform to the standards and specifications provided in the pharmacopoeias. The respondents have no case as of now that the products in question do not conform to the standards fixed in the Indian Pharmacopoeia or under the Drugs and Cosmetics Act

and the Rules issued thereunder. In the above circumstances, I am of the view that the petitioner can be directed to approach the licencing authorities under the Drugs and Cosmetics Act, 1940 for obtaining licence under the said Act in respect of the two products in question. I am also of the view that the petitioner can be allowed to market and sell the two products, viz.; EC-350 and CECURE in the State of Kerala for a period of four months to enable them to obtain the licence mentioned above. In the meantime, the authorities under the Drugs and Cosmetics Act, 1940 and the Rules are entitled to take samples of the two products and to test whether the said products conform to the standards, if any, prescribed under the Act and the Rules. I order accordingly. If the products on such testing do not conform to the standards fixed in the Act, Rules or under notifications the respondents are free to act in accordance with law.

The original petition is disposed of as above.