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(1980) 07 PAT CK 0016

In the Patna High Court

Case No : Civil Writ Jur. Case No. 3326 of 1979

Dr. (Miss) Aletta Grace Bell — APPELLANT

Vs

Dr. (Miss) S. Tirkey and Another — RESPONDENT

Date of Decision : 17-07-1980

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 18, 3
Drugs and Cosmetics Rules, 1945 — Rule 123

Citation : AIR 1981 Patna 17 : (1981) 29 BLJR 45 : (1981) PLJR 92

Hon'ble Judges : K.B.N. Singh, C.J;P.S. Sahay, J

Bench : Division Bench

Advocate : B.K. Banerjee and Sachchidanand Choudhary, for the Appellant; R.B. Mehta, A.A.G. and A.P. Singh Jr. Counsel, for the Respondent

Final Decision : Dismissed

Judgement

P.S. Sahay, J.—The petitioner has moved this Court for quashing the letter sent by respondent No. 1 dated 19-9-1979 as contained in Annexure-2 directing the petitioner to obtain licence u/s 18 Sub-clause (c) of the Drugs and Cosmetics Act (hereinafter referred to as the Act). The sole point for consideration in this application is whether hospitals are exempted from taking out licence for the manufacture and distribution of drugs which they compound and dispense in the hospital.

2. Duncon hospital was established at Raxaul about half a century ago which is run by Emmenuel Hospital, which has hospitals also in Uttar Pradesh, Madhya Pradesh, Assam, Maharashtra besides Bihar and Petitioner is the Medical Sup-crintendent-cum-Senior Administrative Officer of the hospital at Raxaul. There are about two hundred beds in the hospital. Intravenous Injection (hereinafter to be referred as I. V. Solutions) which are prepared by compounding of glucose or sodium chloride compounded with distilled water are given to the patients in the hospital. These solutions are prepared under the guidance of competent person. On 2-5-1979, the Drug Inspector, Motihari, visited the hospital and sealed the

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Laboratory and took an understanding from the petitioner that I. V. Solutions will not be manufactured in the hospital. Thereafter, the petitioner learnt that a First Information Report has been lodged by the said Inspector on 6-5-1979, alleging offences under the Act a copy of the First Information Report has been filed and marked as Annexure-5, the main ground being that the petitioner manufacturing the aforesaid drug without licence and without there being proper facilities for the same. A number of officers of the Health Department had visited the hospital earlier but none of them complained about this and it was only Sri Anand Kumar Agrawal, Inspector of Drugs, when he visited the hospital and lodged this case in order to harass the petitioner. In this connection, a written complaint was also filed against the conduct of the aforesaid Inspector on 6-6-1979; a copy of the same has been filed and marked Annexure-1, Respondent No. 1, by letter dated 19-9-1979, directed the petitioner to take licence u/s 18(c) of the Act; a copy of the letter has been filed as Annexure-2. On 8-10-1979 the petitioner sent a letter informing respondent No, I the circumstances under which the I. V. Solutions were compounded and administered to the patients and for that no licence was necessary and the hospital was exempted and it was also prayed in the aforesaid letter that the direction to obtain licence should be withdrawn; a copy of the letter has been filed and marked as An-nexure-3, But unfortunately the petitioner did not receive any reply. Again on 23-10-1979, reminder was sent to respondent No. 1 which was also not acknowledged; a copy of the letter has been filed and marked as Annexure-4. Being aggrieved by the letter as contained in Annexure-2 the petitioner has moved this Court under Articles 226 and 227 of the Constitution of India.

3. Learned Counsel appearing for the petitioner has contended that the petitioner''s hospital is not a manufacturer as defined u/s 3(f) of the Act and, therefore, it was not necessary to obtain licence. Secondly it has been contended that under Rule 123 of the Drugs and Cosmetics Rules framed under the Act certain establishments have been exempted from the operation of the Act and the petitioner also was entitled to that benefit. Learned Additional Advocate General, appearing on behalf of the State, has contended that there is no dispute that the hospital of the petitioner has been manufacturing drugs and it is necessary to obtain licence and such establishments are not entitled to any exemptions. Counter-affidavit has been filed on behalf of respondent No. 1, which has been sworn by Sri Anand Kumar Agrawal, Inspector of Drugs, who had reported the matter to the authorities, on which it has been ordered that the hospital has to obtain a licence under the Act. It has also been stated that a num- ber of complaints had been received that the I. V. solution, which was prepared by the petitioner''s hospital, was of sub-standard quality. It has also been stated that On report that the solutions, which are manufactured were sub-standard, they were actually seized and sent for chemical analysis. It has also been stated that the hospital has been charging Rs. 7/- per bottle for the solution of five hundred milliliters and thus hospital has been making a profit out of it. Reply to the counter-affidavit has also been filed in which it has been stated on

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behalf of the hospital that the I. V. Solutions are supplied to the patients on payment of Rs. 7/- per bottle which is the actual cost and it is the service charge and no profit is made out of it though in market it is priced as Rs. 9.40, Paise per bottle.

4. In order to appreciate the submission made at the Bar it will be necessary to refer to the various provisions of the Act. Manufacture and also of certain drugs are prohibited without licence and Section 18 runs thus :

"18. Prohibition of manufacture and sale of certain drugs--From such date as may be fixed by the State Government by notification in the official Gazette in this behalf, no person shall himself or by any other persons on his behalf....."

18 (c) requires licence and is as follows:

"Manufacture for sale, or sale or stock or exhibit for sale, or distribute any drug (or cosmetic), except under, and in accordance with the conditions of a licence issued for such purpose under this chapter 5.

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis :

Provided further that the Central Government may, after consultation with the Board, by notification in the official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, sale or distribution of any drug or class of drugs not being of standard quality."

Manufacture has been "denned tinder Section 3(f) of the Act and is as follows : "3 (f). ''Manufacture'' in relation to any drug (or cosmetic) includes any process or part of a process for making, al- tering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug (or cosmetic) with a view to its sale and distribution but does not include the compounding or dispensing (of any drug, or the packing of any drug or cosmetic in the ordinary course of retail business, and ''to manufacture'' shall be construed accordingly.)" Under Sections 6(2), 12 and 33 of the Act Drugs and Cosmetics Rules, 1945 has been framed, Rule 76 deals with the form of licence to manufacture drugs specified in Schedules C and C (1) and conditions for the grant or renewal of such licence, Form No, 28, which is under the aforesaid Rule, is licence to manufacture for sale of drugs specified in Schedules C R and C (1). I, V. Solutions are mentioned in Schedules C, R, of the Rules and item No. 12 is as follows 5

"any other preparation which is meant lor parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which. .....

(a) requires to be stored in a refrigerator; or

(b) does not require to be stored in a refrigerator."

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Rule 123, on which reliance has been placed by the learned counsel for the petitioner, runs as follows :

"123. 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."

Schedule K which in under Rule 123 and we are concerned with item No. 5 and this runs as follows :

Class of Drugs Extent and Conditions of the Exemption.

"5A. Drugs supplied by a hospital or dispensary maintained or supported by Government or local body or by charity or voluntary subscription.

The Provisions of Chapter TV of the Act and the Rules thereunder which require them to be covered by a sale licence, subject to the following conditions;

(1) the dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person;

(2) the premise, where drugs are supplied or stocked shall be open to inspection by an Inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take sample for test;

(3) the drugs shall be stored under proper storage conditions".

Relying on the above provision learned Counsel for the petitioner has contended that the hospital of the petitioner is exempted and he is not to obtain licence, In this connection it will be necessary to refer to Chapter IV which deals with manufacture, sale and distribution of drugs but the exemption under Schedule K, which has been referred to, is only for a licence for sale. It has been rightly contended by the learned Additional Advocate General that the hospital can be exempted from taking licence for sale but has to take licence because it has been manufacturing drugs for the pur- pose of distribution. The word ''distribution'' has not (been) defined under the Act. According to Chambers Dictionary it means delivery of something to several persons. In Webster''s Dictionary several meanings have been given : (1) to divide among several or many; to deal out a portion or allot; (2) spread out so as to cover a surface or space (3) to divide or separate especially into classes, orders, kinds or species to classify, assort, as specimen letters etc. Almost the same meaning has to be found in Concise Oxford Dictionary. According to Lexicon of Law ''distribute'' means the act of spreading of goods anywhere by whatever means that may be employed. From the facts mentioned in the application and also in the counter-affidavit it is clear that I. V. Solution, which is manufactured in the hospital, is being distributed among the patients. Our attention has been drawn to a decision of the Bombay High Court in the case of State Vs. Nathumal Damumal and Others, where the word ''distribution'' has been interpreted while construing a case under this Act. A person, who was trading at Nasik, purchased certain drugs from Calcutta and

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transported them to Nasik. Those drugs were not found to be of standard quality by the Drugs Inspector and prosecution was launched at Nasik. A point was taken in course of trial at Nasik that the purchase was nude at Calcutta and, there-lore, the Court at Nasik had no jurisdiction. If was held that the word ''distri- bute'' was wide enough to include the repose of goods at Nasik even though the sale was completed at Calcutta. It was, further, held that the process of distribution started at Calcutta and ended at Nasik. Thus from the various provisions of the Act, referred to above, and after going through Schedule K and Chap-i ter IV of the Act, I am of the opinion I that the petitioner''s hospital can claim exemption under Rule 23 from obtain-j ing licence for sale and there is nothing in Schedule K to show that they are exempted from obtaining licence for the distribution of drugs which they manufacture. The definition of the term ''drug'' is not exhaustive and it cannot be disputed that I. V. Solutions, which is the subject matter of controversy in this application, comes within the meaning of drug. Drug has been defined u/s 3(b) which runs as follows :

"3 (b). ''Drug'' includes (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 disease in human beings or animals;

(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."

The solutions which are manufactured and distributed, are sensitive drugs and for that purpose competent persons are to be employed, and under their supervision those drugs are manufactured. The preamble of the Act says :

"Whereas it is expedient to regulate the import, manufacture, distribution and sale of drugs and cosmetics".

and it is with that object in view that licence has to be obtained. A number of conditions have been imposed on the manufacturers under Rule 78 and they are enumerated from 78 (a) to 78 (m), the sole purpose of which is to ensure that standard drugs are manufactured under the control of the licensing authority and those drugs are ultimately sold or distributed among the patients. Learned Additional Advocate General has drawn our attention to other provisions also relating to seizure and prosecution of those licensees whose drugs are found to be of sub-standard quality on analysis but it is not necessary to refer to them in this regard. Form 28, no doubt, only speaks of manufacture for sale of drugs specified in Schedules C and C (1) and word ''distribution'' does not find place as urged on behalf of the petitioner. There is no doubt that it is not happily worded but leading the provisions of the Act and Rules framed thereunder it is manifest that it is a mere omission. Chapter IV, which have been discussed earlier, not only deals with manufacture for sale but also distribution of drugs. Our attention

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has been drawn by the learned additional Advocate General to Craise on Interpretation of Statutes with particular reference to Heydon''s case in which it has been held that while contruing Statute in general four things have to be seen and considered.

1. What was the common law before making of the Act.

2. What was the mischief and defect for which the common law did not provide.

3. What remedy the Parliament hath resolved and appointed to cure the disease of the commonwealth.

4. The true reason of remedy and on a careful constructionn of those provisions the Court should come to the ultimate conclusion,

Similar observation are also to be found in Maxwell''s Interpretation of Statute (12th Edition) and Bindra''s Interpretation of Statutes at Page 452. In my opinion, these rules of interpretation are not very relevant for the decision of the instant case because there is no ambiguity at all. The relevant provisions of the Act and Rule 123 read with Sche-dule K clearly shows that licance is ex-empted for the purpose of sale and not for distribution. It is wholly immaterial whether the hospital is charging prices and making profit out of those solutions. Thus, on a careful consideration of the provisions I am of the opinion that the petitioner''s hospital has to obtain licence u/s 18(c) of the Act. No doubt the hospital in question has been serving the people of the area and I am sure that it will continue to do so even after obtaining licence. There should not be any apprehension by the petitioner that there will be undue harassment and interference by the officers of the Health Department. In that case it will, always, be open to the petitioner to make representations before the authorities concerned who, I am sure, will certainly look into the matter without any prejudice. The application is, accordingly, dismissed, but in the circumstances of the case, there will be no order as to costs.

K.B.N. Singh, C.J.

5. I agree.

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