

DR. (MISS) ALETTA GRACE BELL

v.

DR. (MISS) S. TIRKEY AND ANR.

NOVEMBER 8, 1995

[MADAN MOHAN PUNCHHI AND SUJATA V. MANOHAR, JJ.]

Drugs and Cosmetics Act, 1940 :

Ss.18(C) and 33(2)—Drugs—‘Manufacture for distribution’—Prohibition on—Requirement of application for licence-forms to be prescribed—Actually no forms prescribed nor any conditions laid down—Hospital manufacturing drug for distribution to its patients—Held, in absence of any forms prescribed and conditions laid down, the requirement leaves a vacuum and its benefit must go to hospital which could not be required to obtain a licence on the date of alleged offence.

The appellant was Medical Superintendent-cum- Administrative Officer of a Hospital in the State of Bihar. On 2.5.1979, the Drug Inspector noticed that the hospital was engaged in the manufacture of a drug, referred to as I.V. Solution, for administration to patients in the hospital. The Drug Controller, Bihar served on the appellant a letter stating that for manufacture and distribution of I.V. Solution the hospital was required to obtain a licence under the provisions of the Drugs and Cosmetics Act, 1940, and for default it had to suffer prosecution. The appellant filed a writ petition before the High Court contending that the product was manufactured not for sale, but for distribution in the hospital and the Act of manufacture for distribution required no licence. The High Court dismissed the writ petition holding that the hospital was required to obtain licence under S.18(c) of the Act. Aggrieved, the appellant filed the present appeal by special leave.

Allowing the appeal and setting aside the judgment of the High Court, this Court

HELD : 1.1. The scheme of chapter IV of the Drugs and Cosmetics Act, 1940 and particularly the provisions of S.18(c) and S. 33(2) indicate that Government is required to frame rules and prescribed form of licence for "manufacture for sale or for distribution" of drugs as also the form of ap-

A plication for such licence, the conditions subject to which such licence may be issued, and the authority empowered to issue the same. [845-C, 846-B]

B 1.2. Prior to amendment of S.18(c) of the Act with effect from 1.2.1983 only two forms of licence namely (i) for the manufacture for sale and (ii) for sale, of drugs and cosmetics, were prescribed as the two activities were distinct, and separate licences were required for the respective activities. The significant change effected by the amendment is that "manufacture for sale or for distribution" is now one composite activity and would require a licence. Significantly, no form of licence for 'manufacture for distribution' of drugs or cosmetics has been provided. Nor any condition has been laid subject to which such licence may be issued. The requirement in that regard leaves a vacuum which for reasons best known to the Executive has remained unfilled and its benefits must go to the appellant. [845-H, 846-C-F]

D 1.3. The appellant has been able to successfully plead and prove that in the absence of the requisites laid down in Sections 18(c) and 33 of the Act, she and hence the hospital could not be required to obtain a licence for manufacture and distribution of the drug on the date when the offence was allegedly committed. [846-F]

E CIVIL APPELLATE JURISDICTION : Civil Appeal No. 85 of 1981.

From the Judgment and Order dated 17.7.80 of the Patna High Court in C.W.J.C. No. 3326 of 1979.

F K.D. Prasad and (Mr. R.P. Singh) (NP) for the Appellant.

D. Goburdhan for the Respondents.

The following Order of the Court was delivered :

G This is an appeal against the judgment and order of a Division Bench of the Patna High Court passed in Civil Writ Jurisdiction Case No. 3326 of 1979, on 17-7-1980.

H The appellant - Dr. (Miss) Alette Grace Bell, as Medical Superintendent-cum-Administrative Officer of the Duncan Hospital at Raxaul in the State of Bihar, was served with a letter from the Drug Controller Bihar

to the effect that the hospital being in the manufacture and distribution of a drug referred to as I.V. Solution, was required to take a licence under the provisions of the Drugs and Cosmetics Act, 1940, for the default of which it had to suffer prosecution. Challenging the same before the Patna High Court, the appellant contended that since its product was a preparation by compounding of glucose or sodium with distilled water and administered to patients in the hospital, this solution was manufactured not for sale but for distribution, and the act of manufacture for distribution required no licence. The High Court on examining the various provisions of the Act, came to hold that the appellant's hospital was required to obtain licence under clause (c) of Section 18 of the Drugs and Cosmetics Act, 1940. This view of the High Court has led to this appeal.

When leave was granted, interim order of stay was vacated. We are therefore not aware whether any prosecution of the appellant followed or not. Be that as it may, we must state the legal position. The offence was committed on 2.5.1979 when the Drugs Inspector on his usual visit, discovered the appellant engaged in the manufacture of I.V. Solution for administration to patients in the hospital. The provision requiring licence, being Section 18(c) of the Act then read as follows :

"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 person on his behalf manufacture for sale, or sell, 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."

With effect from 1.2.1983, the provision reads :

"..... manufacture for sale or for distribution, or sell, or stock or exhibit or offer 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."

As is evident, prior to the amendment, manufacture for sale of any drug or cosmetic, as a composite activity required a separate licence. Likewise, distribution of any drug or cosmetic required a separate licence. The significant change effected by the amendment is that "manufacture for sale or for distribution" is now one composite activity and would require a

A licence. If distribution of any drug or cosmetic is a separate activity unconnected with manufacture, then as of before, it requires a separate licence. In all situations licence must be obtained to carry out activity on the conditions given under Chapter IV of the said Act of which Section 33 is a part, empowering the Central Government to make rules. Section 33 is laid in the usual format. Clause (e) of Section 33(2) says that Rules to be framed by the Government may prescribe the forms of licences for the manufacture for sale or for distribution (the relevant words added after the amendment) and *inter alia* for the distribution of drugs etc. as also the form of application for such licences, and the condition subject to which such licences may be issued, and the authority empowered to issue the same etc.

C etc. Significantly, no form of licence for manufacture for distribution of drugs or cosmetics has been provided. No conditions has been laid subject to which such licence may be issued. Only two forms stood prescribed prior to the amendment. Those were for obtaining licence (i) for the manufacture for sale and (ii) for sale of drugs and cosmetics. Now after the

D amendment the form is for the manufacture for sale or for distribution of drugs or cosmetics. In the absence of the requisite form of licence being part of the rules as per requirements of Section 18(c), it is difficult to conceive as to how the appellant was obligated to apply for obtaining the requisite licence, and before which authority and in which form and subject to which conditions. It thus appears clear to us that the requirement in that

E regard leaves a vacuum which for reasons best known to the Executive has remain unfilled. The obligation of the appellant and her sequel prosecution being founded on the supposed requirement of Section 18(c) of the Act, not only the provision, but the rules which carry out its purpose have to be viewed strictly. When there is a vacuum, as spelled out before, its benefit

F must go to the appellant. She thus has been able to successfully plead and prove that in the absence of the requisites laid down in Sections 18(c) and 33 of the Act, she and hence the hospital could not be required to obtain a licence for manufacture and distribution of the drug on the date when the offence was allegedly committed.

G Thus, for the aforesaid reasons, we differ from the view taken by the High Court, and upset its judgment and order granted the writ to the appellant, as prayed. There shall be no orders as to costs.

R.P.

Appeal allowed.