SUPREME COURT OF INDIA

Drugs Inspector

Vs.

Fizikem Laboratories Pvt. Ltd.

Crl.A.No.533 of 2008

(A.K.Mathur and Altamas Kabir,JJ.)

24.03.2008

JUDGMENT:

A.K. Mathur, J.

1. Leave granted.

2. This appeal is directed against the order passed by learned Single Judge of the Andhra Pradesh High Court in a batch of petitions under Section 482 of the Code of Criminal Procedure (hereinafter to be referred to as the CrPC) whereby the learned Single Judge has held that the Drugs Inspector appointed under Section 21 of the Drugs and Cosmetics Act, 1940 (hereinafter to be referred to as the Act) had no jurisdiction to launch prosecution under Section 32 of the Act for alleged offences said to have been committed under this Act in connection with manufacture and sale of Ayurvedic drugs Ozomen capsules and Ozomen forte.

3. The brief facts which are necessary for disposal of this appeal are that the Inspector of Drugs inspected some of the business premises of these respondents where Ozomen capsules and Ozomen forte were available for sale. He took the samples and after taking the sample he sent the same to the Government Analyst, Hyderabad for analysis. The Government Analyst submitted his report declaring that Ozomen capsules under different batches contained 45.2 mg of sildenafil citrate per capsule. The persons from whom the samples were taken were called upon to disclose the name of manufacturer and on disclosure of the name of manufacturer, prosecution was launched against the respondents for contravention of Sections 18), 18(a) (i) read with Section 17B(d) of the Act namely, prohibition of manufacture and sale of certain drugs and cosmetics which are misbranded, spurious and substituted wholly or in part by another drug or substance and the Central Government prohibited manufacturer etc. of the drugs and cosmetics in public interest under notification issued under Section 26-A, vide notification No.GSR 577(e) dated 23.7.1983 punishable under Sections 27(b)(ii), 27(c), 27(d) and 28-B of the Act. It is this action initiated by the Drugs Inspector which was challenged. The respondents were arrayed as accused for the aforesaid offences because they had no licence for the manufacture of Ayurvedic drug

sildenafil citrate and they were mislabeling the Ayurvedic drugs. The sildenafil citrate is a new drug and it is patent and proprietary medicine. It is an allopathic drug used for erectile dysfunction. The respondent-accused company was holding Allopathic as well as Ayurvedic licence but the company does not hold the licence to manufacture sildenafil citrate. The information was received by the Drugs Inspector that sildenafil citrate manufactured by these companies for various medical establishments in the State of Andhra Pradesh had no licence to manufacture sildenafil citrate. Ozomen forte capsule contained 33.9 mg to 46.82 mg of sildenafil citrate per capsule. Therefore, the question was whether the respondent- company which are manufacturing Ayurvedic drug and had no licence for manufacturing sildanefil forte could be prosecuted under Chapter IV or not.

4. Before the Learned Single Judge it was submitted that since the respondents are being prosecuted for contravention of Section 18, Section 19(a) (i) read with section 17B (d) and Section 17(b) of the Act the accused had no licence for manufacture of the sildenafil forte which is one of ingredient of Ozomen forte i.e. Ayurvedic drug, therefore, the respondent can be prosecuted under this section or not. The submission of the respondents was that they have been holding licence for the Ayurvedic preparation and for any Ayurvedic preparation of spurious or misbranded nature, the Inspector appointed under Chapter IVA alone is competent to launch prosecution and not Inspector appointed under Chapter IV.

5. In order to appreciate the contention raised by learned counsel for the parties, it will be appropriate to refer to relevant provisions of the Act. The Act defines Ayurveducm Siddha or Unani drug under Section 3(a) which reads as under :

> " (a) "Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb system of medicine, specified in the First Schedule;"
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> Section 3(e) defines Inspector which reads as under :
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> (e) "Inspector" means
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> (i) in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and
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> (ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;"

Section 3(h) defines patent and proprietary medicine which reads as under:

> "(h)" patent or proprietary medicine" means,-(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha

or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

(ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;

Section 13 deals with offences. Chapter IV deals with Manufacture, sale and distribution of drugs and cosmetics. Section 16 under this Chapter deals with standard and quality. As per Section 16, all drugs complies with the standard set out in the second schedule. Section 17 deals with misbranded drugs which reads as under:

"17. Misbranded drugs.- For the purposes of this Chapter a drug shall be deemed to be misbranded,-

(a) if it is so coloured, coated, powered or polished that damage is concealed or if it is made to appear or better or greater therapeutic value than it really is; or

(b) if it is not labeled in the prescribed manner; or

(c) if it is label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Section 17A deals with adulterated drugs which reads as under : 17A. Adulterated drugs- For the purposes of this Chapter, a drug shall be deemed to be adulterated,-

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Section 17B deals with spurious drugs, Section 17C deals with misbranded cosmetics and Section 17D deals with spurious cosmetics. Section 18 which deals with prohibition of manufacture and sale of certain drugs and cosmetics, is relevant for our purpose and reads as under :

"18. Prohibition of manufacture and sale of certain drugs and cosmetics. 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-

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute-

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(ii) any cosmetic which is not of a standard quality or is misbranded or spurious;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities, thereof;

(iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) 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;

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 or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality."

Section 18 prohibits any person from manufacturing for sale or for distribution or sell or stock or exhibit or offer for sale or distribute any drug which is not of a standard quality or is misbranded, adulterated or spurious. Section 18) says that no person shall himself or by any other person on his behalf 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. Section 21 deals with Inspectors. The Inspectors can be appointed by the Central Government or the State Government by notification in the Official Gazette having the prescribed qualifications and they may perform such duties for drugs or classes of drugs,or cosmetics or classes of cosmetics and they shall be public servant within the meaning of Section 21 of the Indian Penal Code. Section 22 lays down the powers of the Inspectors. The Inspector has power to inspect any premises wherein any drug or cosmetic is being manufactured. He has the power for testing the drugs or cosmetics. He has also power to search and such other powers which are necessary for enforcement of the provisions of the Act. Section 23 deals with procedure which is to be employed by the Inspectors. After taking all necessary samples and obtaining report from the Drugs Analyst he can also launch prosecution with the previous sanction. Punishment has been prescribed under Section 27. Any person who manufactures for himself or by any other person on his behalf, manufactures for sale or for distribution, or sells or stocks or exhibits or offers for sale or distributes any adulterated, spurious or misbranded drugs then he shall be punished under Section 27. Chapter IVA which was introduced with effect from 1.2.1969 deals with provisions relating to Ayurvedic, Siddha and Unani drugs. Here also identical provisions are there. Section 33E deals with misbranded drugs, Section 33 EE deals with adulterated drugs and Section 33EEA deals with spurious drugs and it is punishable under Section 33-I. Section 33 G deals with the Inspectors which says that the Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having certain prescribed qualifications and it has laid down their duties, functions who could launch prosecution for breach of any of the provisions."

6. The provisions in Chapter IV and Chapter IVA are almost identical. Chapter IVA deals with special branch of medicines like, Ayurvedic, Siddha and Unani drugs whereas Chapter IV deals with branches other than Chapter IVA. Learned Single Judge has taken the view that since Ozomen capsules had a component like sildenafil citrate, therefore, they may be misbranded, spurious or adulterated for which the prosecution could only be launched by the Inspector authoricsed under Chapter IVA. But the prosecution in this case was launched under Chapter IV. Therefore, learned Single Judge came to the conclusion that the Inspector

under Chapter IV had no jurisdiction to launch the prosecution and it is only the Inspector who has been appointed under Chapter IVA could have launched the prosecution against the accused for breach of the provisions of the Act for adulteration, misbranding in the Ayurvedic drugs.

7. Learned counsel for the appellants submitted that it is not the case that only Chapter IVA is involved but the offence has also been committed under Chapter IV also. Learned counsel for the appellants submitted that Ozomen capsules and Ozomen forte had a component of sildenafil citrate and this medicine does not fall under Chapter IVA. Therefore, learned counsel for the appellants submitted that use of this medicine in the Ayurvedic medicines is also punishable under Chapter IV as accused has no licence to deal with this drug. The accused had to mix this drug with other Ayurvedic drugs, therefore, the accused can also be prosecuted for selling Allopathic drug like sildanefil citrate when licence is required under Section 18. Learned counsel for the appellants submitted that sildenafil citrate is a new drug and it is an Allopathic drug. This cannot be used for the Ayurvedic medicines without displaying in the prescribed manner on the label or container thereof or list of active ingredients contained in it together with the quantities thereof. It is also punishable under Section 18 (a)(iii) read with Section 27 (d) of the Act. Learned counsel for the appellants also pointed out that the respondents also manufactured and sold this spurious Ozomen capsules containing sildenafil citrate violating section 18(a) which is punishable under Section 27(d) of the Act. The sum total of the submission of learned counsel for the appellants was that the very fact of dealing with sildenafil citrate drug and distributing the same after making a different component of Ayurvedic drug itself constitutes an offence. Therefore, it is erroneous to say that since the accused is dealing with Ayurvedic drugs therefore, only the Inspector who is authorized under Chapter IVA could launch the prosecution and not the Inspectors appointed under Chapter IV. The accused has used sildenafil citrate which is an allopathic drug. Sildenafil citrate is a white to off-white crystalline power with a solubility of 3.5 mg/ml in water and molecular weight of 666.7 . Viagra (sildenafil citrate) is formulated as blue, film-coated rounded-diamond shaped tablets equivalent to 25mg, 50 mg and 100 mg of sidenafil for oral administration. In addition to the active ingredient, sildenafil citrate, each tablet contains the following inactive ingredients; microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide,lactose, triacetin and FD & C Blue No.2 aluminum lake. The brand name is Viagra and generic name is sildenafil citrate. This is an allopathic drug and by no stretch of imagination it can be said as an Ayurvedic drug. Therefore, learned counsel for the appellants appears to be justified that since it is an allopathic drug and it cannot be used by anybody else unless a person who holds the licence for it. It is an admitted position that the accused does not possess the licence. Therefore, the very fact of selling this drug as one of the ingredients in the Ozomen capsule and not displaying the name in the prescribed manner in the drugs will also constitute an offence under Section 18 (a), (b) & (c) punishable under Section 27(b) (ii). The submission of learned counsel for the appellants is justified and we are of opinion that the view taken by learned Single Judge of the High Court is not correct and the High Court should not have proceeded to quash the whole proceedings under Section 482 of the Code of Criminal Procedure when serious issues were involved in the matter.

8. In the result, we allow this appeal and set aside the order passed by the High Court and direct that the Inspector appointed under Chapter IV is competent to launch prosecution for the aforesaid sections against the accused. We have also been informed in the alternative prosecution has also been launched against the accused under Chapter IVA. Both the prosecution can be tagged together and the learned trial court should proceed with the matter. However, any observations made by us in disposing this appeal will not prejudice the rights of either parties