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ISHWAR SINGH BINDRA & ORS.

v.

THE STATE OF U.P.

May 2, 1968

B [M. HIDAYATULLAH, C.J., C. A. VAIDALINGAM AND
A. N. GROVER, JJ.]

Drugs Act, 1940 s. 3(b)(i)—Definition of 'drug'—Scope of—Medicines and substances used or prepared for use in accordance with Ayurvedic or Unani systems—When excluded.

C The Inspector of Drugs, Agra Region, filed a complaint in July 1963 before a Magistrate at Mathura alleging a preparation called anti-phlogistic plaster was manufactured and sold by a firm of which the first two appellants were partners and the third appellant was the Manager; the label on the plaster showed the constituents to be three drugs which are to be found in pharmacopoeias prescribed under the Drugs Act, 1940 but did not bear a manufacturing licence number and other particulars required to be given under r. 96 of the Drug Rules, 1945. As the drug fell within the mischief of s. 17(e) of the Act, it must be deemed to be 'misbranded'. Moreover the label of the plaster showed that it was a Unani preparation which was apparently a false and misleading claim. Accordingly, it was alleged that offences had been committed under s. 18(a)(ii) read with ss. 27(a) and (b) of the Act for selling a misbranded drug as per s. 17(f) and s. 17(e) respectively of the Act and under s. 18(b) read with s. 27(b) of the Act for selling the same drug which had been manufactured without a licence required for the purpose under the Act.

E The appellants filed a petition under s. 561A of the Criminal Procedure Code in the High Court in March 1964 and claimed *inter alia* that the plaster was not a drug as defined in the Act and praying that the entire proceedings pursuant to the complaint be quashed. It was contended that in the definition of a drug in s. 3(b)(i) of the Act in the expression "other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani Systems of medicine" the adverb "exclusively" governed the word "use" only and did not govern the words "prepared for use". The High Court was of the view that the intention of the legislature appeared to be to exclude from the definition of drug such medicines and substances which were used exclusively in accordance with the Ayurvedic or Unani system of medicine or which were prepared for use exclusively in accordance with the aforesaid system; but it declined to go into the disputed questions of fact as to whether the plasters in question fell within the exception as this was required to be determined on expert evidence.

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On appeal to this Court by certificate,

HELD : dismissing the appeal :

H The expression "substances" in the definition of drug contained in s. 3(b) means something other than "medicines". The word "and" used in the definition of drug in s. 3(b)(i) between "medicines" and "substances" is to be read disjunctively. [225 F—G]

The scheme of cl. (i) of s. 3(b) is to take in all medicines or substances with the exception of such medicines or substances which are

exclusively used or prepared for use in accordance with the Ayurvedic or Unani system of medicines. The exception made in the case of the latter class of medicines or substances was essentially meant to cover only such medicines or substances which were used in the Ayurvedic or Unani system or were prepared for use in accordance with those systems. [226 A—B]

Medicines or substances have to be taken as a whole and in the present cases it would have to be decided by the trial court whether the plasters in question are medicines which are exclusively used or which have been prepared for use exclusively in accordance with the Ayurvedic or Unani system of medicine. The High Court was right in its view that the adverb "exclusively" must be taken to govern the words "used" as well as "prepared for use"; but each individual ingredient or component of the preparation in question will not be the decisive or determining factor and what the court will have to decide after recording such evidence as may be produced will be whether the plasters satisfy the above test. If they fulfil that test they would be excluded from the definition of drug as contained in s. 3(b)(i). [226 E—G]

Chimanlal Jagjiwandas Sheeth v. State of Maharashtra, [1963] Supp. 1 S.C.R. 344; *Stroud's Judicial Dictionary* 3rd Ed. 135 and *Maxwell on Interpretation of Statutes*, 11th Ed. referred to.

CRIMINAL APPELLATE JURISDICTION : Criminal Appeals Nos. 190 and 191 of 1965.

Appeals from the judgment and order, dated July 20, 1965 of the Allahabad High Court in Criminal Mis. Cases Nos. 562 and 563 of 1964.

Bishan Narain and Harbans Singh, for the appellants.

G. N. Dikshit and O. P. Rana, for the respondents.

The Judgment of the Court was delivered by

Grover, J.—These are two companion appeals by certificates from the judgment of the High Court of Judicature at Allahabad dismissing two petitions under s. 561A of the Criminal Procedure Code in which the sole question raised related to the true and correct interpretation of s. 3(b)(i) of the Drugs Act 1940, as it stood before the enforcement of the Drugs (Amendment) Act 1962 (Act XXI of 1962) and the Drugs and Cosmetics (Amendment) Act 1964 (Act XIII of 1964).

As the point involved is common to both the appeals the facts in Cr. Appeal No. 190 of 1965 may be shortly stated. The first two appellants are the partners and the third appellant is the manager of Bindra's Chemical Corporation which carries on the manufacture of medicines and substances in accordance with the Ayurvedic and Unani systems of medicines at Delhi, Shahdara. The Inspector of Drugs, Agra Region, filed a complaint dated July 2, 1963 in the court of Magistrate, First Class, at Mathura alleging *inter alia* that on September 20, 1962 when he was carrying out the inspection of the shop of M/s Frontier Gupta Medical Stores, Mathura, he came across a preparation

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- A called Antiphlogistic Plaster manufactured by the aforesaid Corporation. On examining the label it was discovered that although the names of three drugs *i.e.* Glycerine, Kaolin and Boric Acid which are to be found in Pharmacopoeias prescribed under the Act were mentioned as constituents of the plaster, the label did not bear manufacturing Licence Number and other particulars
- B with which a drug was required to be labelled in accordance with Rule-96 of the Drug Rules 1945. According to the Inspector this drug fell within the mischief of s. 17(e) of the Act and was to be deemed to be misbranded as it had not been labelled in the prescribed manner. Moreover the label of the plaster in question showed that it was a Unani preparation which was apparently a false and misleading claim. A sample was sent to the Government Analyst who gave a certificate dated October 25, 1962 to the effect that it contained Glycerine, Kaolin and Boric Acid and that Glycerine and Boric Acid were pharmacopoeal drugs which were not exclusively Ayurvedic or Unani medicines. According to the Inspector, the Antiphlogistic Plaster was a misbranded drug as per s. 17(e) & (f) of the Act. It was alleged that offences had been committed under s. 18(a)(ii) read with ss. 27 (a) and (b) of the Act for selling Antiphlogistic Plaster, a drug "misbranded" as per s. 17(f) and s. 17(e) respectively of the Act and under s. 18(b) read with s. 27(b) of the Act for selling the same drug which had been manufactured without a licence required for the purpose under the Act, to M/s Frontier Gupta
- C Medical Stores, Mathura.

- F On March 24, 1964 the appellants filed a petition under s. 561A of the Code in the High Court raising a number of points including the question of the jurisdiction of the Court at Mathura to entertain the complaint as also that the Antiphlogistic Plaster was not a drug as defined in the Act and praying that the entire proceedings pursuant to the complaint be quashed. In the affidavit accompanying the petition it was stated that the ingredients used in the preparation of Bindra's Antiphlogistic Plaster were in accordance with the Unani system of medicine. These ingredients were (i) Glycerine, (ii) Kaolin *i.e.* Gule Armani or Chikaimati, (iii) Bora *i.e.* Boric, (iv) Oil of Winter green *i.e.* Java, (v) Oil of Eucalyptus, and Safeda. It was asserted that all the six components were medicines recognised under the Unani system and merely because one of the components was used in the Allopathic system also the medicine would not become a drug when the whole preparation itself was an Ayurvedic medicine. Reference was made to certain books like Ramooz-Ul-Taba, Kitabul Davaiya and Kaniz-Ul-Taba which were well known books of the Unani system of medicine in which Glycerine and Boric were recognised as medicines used in that system. The other components of the plaster were, it is stated, of Unani origin and frequently used for preparations in accordance with Ayurve-
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dic and Unani system. The Inspector of Drugs filed a counter affidavit in which it was pointed out that Glycerine, Kaolin and Boric Acid were drugs which were to be found in the British Pharmaceutical Codex 1958. The "monographs" of Glycerine, heavy Kaolin, light Kaolin and Boric Acid containing the formulæ according to which these drugs were prepared were given. It was also alleged that Bindra's Antiphlogistic Plaster had been prepared in accordance with the Allopathic system of medicine since its composition resulted in a preparation known as Kaolin Poultice given at page 359 of the British Pharmaceutical Codex 1958. Glycerine, Boric Acid, Kaolin and oil of winter green Methyl Salicylate were the main components of Bindra's Antiphlogistic Plaster and those were medicines which were not exclusively used in accordance with either the Ayurvedic or the Unani system of medicine. In the further affidavit filed by the appellants it was maintained that Glycerine and Kaolin and Boric Acid were being used in the Unani system in the same way as many other things such as Honey, Rosewater, Boric or Sohaga, Sulphur *i.e.* Gandhak, Arsenic *i.e.* Sankhia, Alum *i.e.* Phtkari which were mentioned in the British Pharmaceutical Codes but it did not follow that they could not be used in a preparation made according to the Ayurvedic system. It was pointed out that the medicine known as Kaolin Poultice was entirely different from Bindra's Antiphlogistic Plaster.

The definition of "drug" contained in s. 3(b) is in the following terms :—

- "(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 disease in human beings or animals other than medicines and substances exclusively used or prepared for use in accordance with Ayurvedic or Unani systems of medicine.
- (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 contention of the appellants before the High Court was that in the last part of cl. (i) the adverb "exclusively" governed the word "used" only and did not govern the words "prepared for use". The other argument raised was that the legislature intended to except from the definition of drug medicines and sub-

- A stances which were common to Ayurvedic or Unani system of medicine and other systems. The High Court was of the view that the intention of the legislature appeared to be to exclude from the definition of drug such medicines and substances which were used exclusively in accordance with the Ayurvedic or Unani system of medicine or which were prepared for use exclusively in accordance with the aforesaid system. In other words it was held that the adverb "exclusively" governed "use" as well as "prepared for use". The High Court declined to go into the disputed questions of fact as to whether Bindra's Antiphlogistic plaster fell within the exception and was not a drug and observed that the question as to whether a medicine or a substance was used exclusively or prepared for use exclusively in accordance with the Ayurvedic or Unani system of medicine was a question of fact, the decision of which would hinge *inter alia* on expert evidence.

- D It has been urged by Mr. Bishan Narain that on a true interpretation of the words embodying the exception a medicine which has been prepared for use in accordance with the Ayurvedic or Unani system would fall within the exception notwithstanding the use of certain medicines like Glycerine, Boric Acid etc. which are used in the Allopathic system as also in the Ayurvedic or Unani systems. By way of illustration, in the Unani system fat was being used in preparation of certain medicines and instead of fat being used now Glycerine is being used. This, according to Mr. Bishan Narain, will not take the entire preparation of the Antiphlogistic Plaster as such outside the scope of the exception in the definition of drug in the Act. An attempt has, also been made to show, by reference to certain provisions of the Act, that the Government Analyst to whom the sample of the plaster was sent, was not qualified and indeed could not be qualified to express any opinion about medicines used or prepared for use in accordance with the Ayurvedic and Unani systems.

- G The position taken up on behalf of the State is that in fact and substance all the drugs and medicines mentioned in the British Pharmaceutical Codex have been employed in the preparation of Bindra's Antiphlogistic Plaster. It is strenuously contended that by a simple device of calling it a Unani or Ayurvedic preparation in which admittedly Glycerine, Kaolin, Boric Acid etc. have been used, which find place in British Pharmaceutical Codex and are clearly drugs, the appellants cannot escape the consequences of infringement of the provisions of the Act.

- H At this stage it would be useful to refer to some of the important provisions of the Act. It was enacted to regulate the import, manufacture, distribution and sale of drugs. The definition of drug as given in s. 3(b) was made as wide as it could be and the only exception related to the medicines and substances

used or prepared for use exclusively in the Ayurvedic or Unani system.

Chapter IV contains provisions relating to manufacture, sale and distribution of drugs. Section 16 says, the expression "standard quality" when applied to a drug means that the drug complies with the standard set out in the Schedule. Section 17 relates to misbranded drugs. Section 18 prohibits manufacture and sale of sub-standard drugs including misbranded drugs. Sections 20 & 21 provide for the appointment of Government Analysts and Inspectors, the procedure to be followed by them and the reports of Government Analysts. Section 27 contains the penalty for manufacture, sale etc. of drugs in contravention of Chapter IV; the punishments provided being quite severe.

A number of amendments were made by Act XIII of 1964 some of which may be noticed. These are strictly not relevant for our purposes except for understanding the legislation on the subject. In cl. (i) the words "other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani system of medicine" were deleted. Before clause (aa) the following clause was inserted :

(a) "Ayurvedic (including Siddha) or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment mitigation or prevention of disease in human beings, mentioned in, and processed and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic (including Siddha) and Unani Tibb) system of medicine, specified in the First Schedule."

Chapter IV-A was added containing provisions relating to Ayurvedic including Siddha and Unani drugs. According to s. 33(e) in that Chapter, from such date, as may be fixed by the State Government by notification in the official gazette no person shall himself or by any other person on his behalf sell or stock or exhibit for sale, or distribute, any Ayurvedic (including Siddha) or Unani drug other than that manufactured by a manufacturer licensed under this Chapter. Penalties were provided for the infringement of the provisions contained in the Chapter.

There can be no difficulty now after the amendments made by Act XIII of 1964 in the matter of medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani system of medicine provided they are processed and manufactured according to the formulae described in the authoritative books as specified in the First Schedule. The difficulty, however, remains with regard to the true import of the

A exception in the definition of "drug" in the Act. In *Chimanlal Jagjivandas Sheth v. State of Maharashtra*⁽¹⁾ the appellant had been prosecuted for an offence under s. 18 of the Act *inter alia* for manufacturing drugs which were of sub-standard quality. Certain samples of absorbent cotton wool, roller bandages and guaze which he had manufactured were seized and he had not only stored them but he was also passing them off as though they were manufactured by a firm of repute at Secunderabad. The Government Analyst had reported that only the lint was of standard quality and the other articles were not of standard quality. He had been convicted and sentenced to undergo rigorous imprisonment for three months and to pay a fine of Rs. 100 under each count by the High Court on appeal against acquittal. After setting out the definition of drug as given in s. 3(b) this Court observed :

D "The said definition of 'drug' is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. This artificial definition introduces a distinction between medicines and substances which are not medicines strictly so called. The expression 'substances', therefore, must be something other than medicines but which are used for treatment."

E The dictionary meaning of the words "medicines and substances" may be noticed. In Shorter Oxford English Dictionary the appropriate meaning of "medicine" is "medicament especially one taken internally—medicament generally". The meaning of "substance" relevant for our purposes is "any particular kind of corporeal matter—a species of matter of a definite chemical composition—a piece or a mass of particular kind of matter—a body of a specified composition or texture."

F Now if the expression "substances" is to be taken to mean something other than "medicine" as has been held in our previous decision it becomes difficult to understand how the word "and" as used in the definition of drug in s. 3(b)(i) between "medicines" and "substances" could have been intended to have been used conjunctively. It would be much more appropriate in the context to read it disjunctively. In Stroud's *Judicial Dictionary*, 3rd Ed. it is stated at page 135 that "and" has generally a cumulative sense, requiring the fulfilment of all the conditions that it joins together, and herein it is the antithesis of "or". Sometimes, however, even in such a connection, it is, by force of a context, read as "or". Similarly in Maxwell on *Interpretation of Statutes*, 11th Ed., it has been accepted that "to carry out the intention of the legislature it is occasionally found necessary to read the conjunctions 'or' and 'and' one for the other".

(1) [1963] Supp. 1 S.C.R. 344.

The scheme of cl. (i) of s. 3(b) apparently is to take in all medicines or substances with the exception of such medicines or substances which are exclusively used or prepared for use in accordance with the Ayurvedic or Unani system of medicine. The exception made in the case of latter class of medicines or substances was essentially meant to cover only such medicines or substances which were used in the Ayurvedic or Unani system or were prepared for use in accordance with those systems. In other words all medicines or substances had, under s. 16 of the Act, to comply with the standard set out in the Schedule, as it stood before the amendment made by Act XIII of 1964. In the Schedule classes of drugs and the standard which was to be complied with were set out with reference mostly to the standards maintained at the National Institute for Medical Research, London and the standards of identity, purity and strength specified in the (current edition for the time being of the British Pharmacopoeia) or the British Pharmaceutical Codex or any other prescribed pharmacopoeia, or adopted by the Permanent Commission on Biological Standardisation of the (World Health Organisation). Only one category consisting of medicines and substances used or prepared for use exclusively in accordance with the Ayurvedic or Unani system of medicine was taken out of the definition of drug before the amendments made by Act XIII of 1964. That Act, as mentioned before, deleted the exception.

In our view medicines or substances have to be taken as a whole and in the present cases it will have to be decided by the trial magistrate whether Bindra's Antiphlogistic Plaster and Bindra's Yabrooj Plaster (Belladonna Plaster) are medicines which are exclusively used or which have been prepared for use exclusively in accordance with the Ayurvedic or Unani system of medicine. As regards the adverb "exclusively" we concur in the view of the High Court that it must be taken to govern the words "used" as well as "prepared for use"; but in our opinion each individual ingredient or component of the preparation in question will not be the decisive or determining factor and what the court will have to decide after recording such evidence as may be produced will be whether the aforesaid medicines (they can hardly be called substances) were exclusively used or were prepared for use exclusively in accordance with the Ayurvedic or Unani system. If they fulfil that test they would be excluded from the definition of drug as contained in s. 3(b)(i). With these observations, however, the appeals are dismissed.