Supreme Court of India
Mac Laboratories (Pvt.) Ltd. vs The Collector Of Central Excise, ... on 22 November, 1994
Equivalent citations: AIR 1995 SC 510, 1994 ECR 625 SC, 1994 (74) ELT 769 SC, JT 1994 (7) SC 496, 1994 (4) SCALE 1018, (1995) 2 SCC 56, 1994 Supp 5 SCR 621
Bench: R Sahai, N Singh
ORDER

1. Whether Kemicetine Vaginal Suppositories (KVS), a patent and proprietary medicine which contained the antibiotic chloramphenicol (CAF) was 'chloramphenicol and its esters for oral and potential use' with in the meaning of Notification No. 116/69 -CE dated 3.5.1969 as amended by the Notification No. 106/80-CE dated 19.6.1980 issued in exercise of powers conferred by Sub-rule (1) of Rule 8 of Central Excise Rules, 1944 was answered against the appellant by Customs, Excise and Gold (Control) Appellant Tribunal.

2. The appellant is a manufacturer of KVS of two different strengths viz., 0.25 grams and 0.50 grams of chloramphenicol antibiotic contents. These suppositories are introduced in the Vagina by hand. Its wax like material containing antibiotic chloramphenicol melts at the temperature of the Vagina and the melted medicine then gets absorbed into the system through the epitheliums or mucous preparation lining the Vagina. The administration of this medicine is not against any topical or local infection but is directed at the internal infection of Vagina resulting from the oral functional system. By absorption into the system its effect is to remove the vaginal infection. It is primarily used to cure vaginal discharge resulting from oral functioning of the system. It acts like oral antibiotic.

3. The appellant was being granted exemption on the suppositories by the department till five notices were issued on 11th June 1980, 17th June 1980, 9th October 1980,24th January 1981 and 8th May 1981 raising demand for the period 1st September 1979 to 31st May 1980, 1st January 1979 to 31st August 1979, 1st June 1980 to 31st August 1980, 1st September 1980 to 31st December 1980 and 1st January 1981 to 30th April 1981 respectively. The basis for the notices for short levy was that the medicine produced by the appellant was neither for oral nor potential use. In reply it was claimed that, Kemicetine Vaginal Suppositories were treated by the Drug Control authorities as life saving drug. And the produce was classified by the department for confessional rate of duty at 2-1/2% ad valorem since it was specified at serial No. 14 of the Schedule. But after the drug became wholly exempt from duty the department erroneously has taken the view that the medicine which was in tablet form and was meant for potential use was not entitled to exemption since it was not administered through oral route. It was claimed that the word 'potential' was very wide and it could not be confined to use of injections only. The appellant objected to notices so far they were for period beyond six months prior to the date of notice. The Assistant Collector did not find any merit in the objection raised by the appellant and confirmed all the five notices issued by the Superintendent, Central Excise. The order was maintained by the appellate authority. In further appeal to the Tribunal it was not disputed that the medicine manufactured by the appellant contained chloramphenicol. Nor there was any dispute that in terms of pharmacology potential is understood to refer to such medication as is applied in such a manner that it by-passes the alimentary canal which has its opening point in the mouth and ends in the anus. The dispute centered round whether use of suppositories through vagina was potential use. The Tribunal after

examining affidavits filed on behalf of both the parties, the text books and various dictionaries and papers on this subject found 'potential refers to introduction of a medicine by route other than alimentary canal. The Tribunal further held that there were three methods of administering drugs and medicines one by putting it in mouth and swallowing it; second, by injecting either intramuscularly or intravenously; and third by local application on surface of the body and its absorption. The Tribunal did not agree with the claim of the appellant that any medicine which is not administered through mouth would be potential. The Tribunal found potential administration of medicine refers to method that involved absorption into the body fluids and system of the drug by active therapeutic effect. It further held that even through the Drug Control Authority had classified the medicine other than potential it was covered in the Notification. However, it rejected the claim of appellant. But it allowed the appeal in part and confined the demand notice to six months before the date of notice.

4. Notification No. 1 16/69-CE dated 3rd May 1969 was issued in exercise of powers conferred by Sub-rule (1) of Rule 8 of the Central Excise Rules, 1944 exempting patent or proprietary medicines falling under item 14 of the 1st Schedule of the Central Excises and Salt Act, 1944 (Act 1 of 1944) and containing one or more of the ingredients specified in the Schedule annexed from so such of the duty of excise livable thereon as was in excess of 2-1/2% ad valorem. In the Schedule serial No. 14 read as under:

14. Chloramphenicol and its esters for oral and potential use;

5. On 19th June 1980 column 2 of the Schedule was amended and the amended entry provided that in the said notification for the words and figures, 'that from so such of the duty of excise leviable thereon as is in excess of 2-1/2% ad 'valorem the words, 'from the whole of the duty of excise leviable thereon' shall be substituted. Therefore any patent or proprietary medicine if it fell in item No. 14 of the Schedule it became wholly exempt from payment of duty.

6. For exemption two conditions were required to be satisfied one, that the patent and proprietary medicine should have been produced out of one or more ingredients specified in the Schedule and that it should have been for oral and potential use. Since the ingredient used in production of KVS was chloramphenicol it satisfied the first requirement as provided in the notification of being a patent or a proprietary medicine in manufacture of which one of the ingredients as specified in the Schedule was used. But that alone was not sufficient for exemption as it was further required to satisfy that the medicine was for oral and potential use. The appellant did not claim that KVS manufactured by it could be used orally. Therefore, the only question that arises for consideration is whether it was for potential use or not.

7. In Pharmaceutical Handbook edited by A. Wade 'potential' is defined as, Not by way of the alimentary tract; administered by a route other than that of the alimentary tract.

8. The Faber Medicine Dictionary explains the word as, Outside the intestinal tract; relating to administration of a substance by a way other than that of the alimentary tract, e.g. by subcutaneous, intramuscular or intravenous injection.

9. In Black's Medical Dictionary by William A.R. Thomson the word is defined as, administration of drugs by any route other than by the mouth or by the bowel.

10. Churchill Livingstone's Pocket Medical Dictionary defined the word as, Not via the alimentary tract.

11. Lewis's Pharmacology by James Cross land explains 'potential administration' as under:

The term potential administration (par-beyond, enteral intestinal) implies that the drug is given by a route which takes it directly into the body fluids, by passing the preliminary process of transport through the intestinal wall or pulmonary alveoli which is necessary when drugs are ingested, inhales or placed in the rectum. With all forms of potential administration, sterile precautions are necessary.

12. In Remington's Pharmaceutical Sciences it is stated as under:

The term potential (GK, para enter on = beside the intestine) refers to the route of administration of drugs by injection under or through one or more layers of skin or mucous membrane.

13. In the same chapter while discussing administration of potential preparations it was observed, drugs can be administered potentially when they cannot be given orally because of the unconscious or uncooperative state of the patient, or because of inactivation or lack of absorption in the intestinal tract.

14. The author while discussing potential products has observed that potential preparations could be divided in three factors-one, drug pellet absorption; two solution absorption; and three, potential dispersion absorption. It is explained in 'the Basis of Pharmacology, Second Ed. by Avram Goldstein, Lewis Aronow and Summer M. Kalman' as under:

The possible routes of drug entry into the body may be divided into two classes enteral and potential. In enteral administration the drug is placed directly in the gastrointestinal tract by placing it under the tongue (sublingual), by swallowing it (oral), or by rectal administration. In potential administration the gastrointestinal tract is by-passed. There are many potential routes. The commonest are subcutaneous (s.c), intramuscular (i.m.), and intravascular: but drugs may also be applied to the skin or injected intradermally, for local effect or to be absorbed percutaneously: they may be inhaled for direct action on the bronchial tree or to be absorbed into blood at the alveoli: they may be injected into or near the spinal canal: they may be introduced intravaginally.

[Emphasis supplied]

15. The Tribunal itself found that from the definitions in different dictionaries it was apparent that potential refers to introduction of medicines by route other than the alimentary tracts. It further observed, There can be no doubt whatever from these paragraphs which have been relied upon the appellant that when speak of vaginal drug delivery by which the drug is absorbed, the drug spoken

of is a systemically active steroids hormone, and is said to be effectively absorbed through the vaginal mucus. The drug being a hormone, its effects will depend on its systematic absorption, although the administration of the progesterone was by means of a suppository. This route appears to have been explored because progesterone was found to be orally inactive. Even for the contraceptive, the article described the advantage of the continuous infusion when the vaginal route is used, as it can prevent the possibility of systemic toxicity that can result from the surging and ebbing plasma drug levels. The systemic absorption and action of the drug is beyond doub. In other words, the paragraph describes a systemic drug administration through the route of the vagina.

16. Yet it rejected the claim of the appellant as, none of the authorities who have been presented before us speak of the intravaginal route of administrations potential except when the administration is meant to be a systemic administration, the drug or medicine being systemically absorbed, and penetrates into the body lymph blood or tissues in a more or less complete manner. Whatever the area of application, the aim is the same to cause the drug to penetrate into the body system, thereto act and to be physiologically taken up and become integral with the system in such a manner that after a lapse of a period upon the speed and degree of penetration/absorption, rejection whether voluntarily or involuntarily becomes impossible.

17. The Tribunal did not disbelieve that suppositories were used even for curing typhoid. But it held that a close study of the material produced before it indicated that CAF are used to treat, local infections and inflammations of female genital tract. The absorption aimed at is clearly a local absorption of the drug for the purpose of combating and eradicating trichomoniasis not only in the mucus but also in the extra vaginal lacunae to eradicate inflammation and infection; and it needs to be understood that there is no need, for the drug to operate effectively, to penetrate and be absorbed systemieally, because, as we have seen, the infections are all local in the vulva, vagina and cervix region. The paper indeed does not suggest anywhere that one for the treatment of these maladies, there is any need for systemic absorption of the drug. The reason for this is obvious. The target areas are all superficial - that is - not inside the system but outside the internal body system, although in a protected/covered cavity or orifice. M/s. Mac Laboratories have not shown any evidence to satisfy us and to convince us that their Kemicetine vaginal suppositories are potential in their activity is to combat infecting organism which lie on the surface of the body system itself.

18. Medicines used through vaginal route could, thus, be potential if its administration according to Tribunal was for systemic absorption. But since KVS produced by the appellant was for local absorption it could not be held to be potential. Whether it approach of the Tribunal is correct or not but this appears to be certain that the word 'potential' is wide enough as bronchial inhalers have come to be included in it even though it is neither p taken orally nor it is injected nor it is meant for local use. In Goodman and Gilman's The Pharmacological Basis of Therapeutics, 'Topical Application' extends to, drugs applied to the mucous membranes of the conjunctival, nasopharynx, oropharynx, vagina, colon, urethra, and urinary bladder primarily for their local effects. Occasionally, as in the application of ant diuretic hormone to the nasal mucus, systemic absorption is the goal. Absorption through mucous membranes occurs readily. Similarly medicines taken through vaginal route meant for systemic absorption are included in it. Therefore, the word 'potential' is not confined to the injections. Yet the question is whether suppositories produced by

the appellant which on the finding of the Tribunal are used for local absorption can be held to be included in it. The word 'potential' is not confined to injections. But does it include medicines used for local application. For determining this it is necessary once again to understand the distinction between 'enteral' and 'potential'. In other words what is the basis on which this classification has been made. Each medicine whether it is taken orally or injected in the body or applied locally enters the blood stream to be effective and efficacious. In enteral administration 'the drugs are absorbed from the small intestine'. Whereas the medicine injected in the body reaches in the blood stream directly. The medicine applied locally or tropically too enters the blood stream through mucous membrane or skin. The range of topical application is very wide. But the basic characteristic is that the medicine applied through this method enters the blood stream directly even though slowly. The basis characteristic of administration of drug potentially is thus satisfied. That is why the potential is described by various writers as every medicine which by-passes alimentary canal. Since the medicine either injected by needle or applied locally enter the blood stream directly it was classified as potential by Avram Goldstein extracted earlier.

19. Till now the discussion has been about understanding of the word in Pharmacology. But the Courts are concerned, primarily, how the Notification granting exemption should be construed and what was the intention in using the word potential in the Notification. The exemption claimed by the appellant was refused as the suppositories produced by the appellant were for local absorption. It has been explained that the ambit of the word 'potential' is very wide. Its use in the Notification has been in still wider sense. The use of the word 'oral' for 'enteral' and 'potential' for injections in the Notification is not without purpose. Enteral administration of medicine may be sublingual, that is, 'absorption of drugs by oral mucous membrane producing systemic effects' or oral, 'one of the most popular, routes of administering drugs in the form of tablets, capsules, mixture, powder, pills, emulsions or rectal' of local or topical, that is, the administration of drug for systemic actions specially in vomiting, unconsciousness and when intestinal absorption is to be avoided. The Government even though it was aware of the word 'enteral' decided to use the word 'oral' in the Notification obviously so that there may hot be any ambiguity. In technical sense sublingual administration may be different from oral but in the common and popular sense a medicine taken sublingually is as much oral as a tablet or capsule or mixture taken by a patient. Similarly the word 'potential' was technically understood for injections whether they are intramuscular, intravenous or intra-dermal. But in the larger sense it has come to include even inhalers as, gaseous and volatile drugs may be inhaled and absorbed through the pulmonary epitheliums and mucous membranes of the respiratory tract' (Goodman and Gilman). This widening of the ambit of word 'potential' was overlooked by the Tribunal. It was swayed by hyper-technical use of the medicine. Even assuming that it was used to remove local infection or inflammation it could not be denied that it entered the blood stream. It, therefore, satisfied the broad test of entering the blood stream directly and by-passing the alimentary canal. The two words 'oral' and 'potential' in fact appear to have been used to extend the benefit to all the medicines produced by the use of chloramphenicol Reading the notification narrowly or technically as has been done by the Tribunal, may result in denying the benefits to those medicines which are produced by use of CAF but are used locally. There can be no rationale for it. For instance a medicine produced for bilingual use cannot be denied exemption because the word 'orally' is confined technically to tablets and mixtures. Similarly exempting tablets and injections but excluding ointments would not be harmonious reading. It would result in

narrowing down and curtailment of the ambit of the notification. The Notification the construction of which is involved is an exemption notification. Therefore, the benefit of it is available to only those who fall under it. To that extent the Notification has to be construed strictly. That is the medicine must be for oral or potential use. But once it is found that a medicine falls in the category of potential medicine then the benefit cannot be denied because it falls in category of those medicines which are applied locally. Topical or medicines used for local absorption appear to be included in the word 'potential'. In fact the definitions which have been extracted earlier do support the claim of the appellant that there are only two classifications of the medicines - one, which are known as enteral, that is which passed through an alimentary canal and other potential which extends to all other medicines which are not enteral. The subsequent classification of the medicines used locally for convenience cannot take it away from the main and the broader classification of it being potential.

20. In the result this appeal succeeds and is allowed. The question raised by the appellant is decided by saying that the suppositories produced by the appellant were covered in the Notification No. 106/80-CE dated 19th June 1980 and, therefore, were entitled for total exemption. There shall be no order as to costs.