

(2011) 03 KL CK 0003

In the High Court Of Kerala

Case No : Criminal M.C. No's. 4997 of 2010 and 541 of 2011

Reckit Benckiser (India) Ltd.

APPELLANT

Vs

State of Kerala

RESPONDENT

Date of Decision : 24-03-2011

Acts Referred:

Criminal Procedure Code, 1973 (CrPC) — Section 482
Drugs and Cosmetics Act, 1940 — Section 18, 27, 3
Drugs and Cosmetics Rules, 1945 — Rule 123, 65

Citation : (2011) CriLJ 2815 : (2011) 3 Crimes 454 : (2011) 270 ELT 25 :
(2011) 2 ILR (Ker) 293 : (2011) 2 KLJ 546 : (2011) 2 KLT 213

Hon'ble Judges : Thomas P. Joseph, J

Bench : Single Bench

Advocate : Madhu Radhakrishnan, for the Appellant; K.J. Mohamed Anzar, Public Prosecutor, for the Respondent

Final Decision : Allowed

Judgement

Thomas P. Joseph, J.—Is exhibiting, stocking, selling or distributing "Dettoi", a product of M/s. Reckitt Benckiser (India) Ltd, the first Petitioner herein without a license issued under the Drugs and Cosmetics Act, 1940 (for short, "the Act") punishable u/s 27(b)(ii) of the said Act?. The answer depends on whether Dettoi is a "Disinfectant" as contended by Petitioners.

2. Short facts necessary for a decision of the question are:

Second Respondent, the Drug Inspector, Kozhikode searched premises of the second Petitioner/first accused, a partnership firm on 18.8.2006 and found Dettoi stocked and exhibited for sale in large quantity. The third Petitioner/second accused who is the Managing Partner of the said firm could not produce any license issued under the Act for stocking, exhibiting and sale of Dettoi. On the premise that Dettoi required a license for its stocking, exhibiting and sale, the Drug Inspector filed complaints against accused 1 to 3. It is alleged in the complaints that the first Petitioner/third accused manufactured and sold Dettoi to

Petitioners 2 and 3/accused 1 and 2 (hereinafter referred as accused) who had no license to deal with the same and accused 1 and 2 stocked and exhibited for sale the said product without license under the Act. It is alleged that the accused violated the prohibition contained in Section 18(c) of the Act and thereby committed offence punishable u/s 27(b)(ii) of the said Act. Learned Judicial First Class Magistrate-I, Kozhikode took cognizance of the said offence, filed C.C. No. 491 of 2009 and 717 of 2009 and issued process to the accused. The complaints, orders taking cognizance and proceedings in the said cases are challenged by the accused in these proceedings u/s 482 of the Code of Criminal Procedure (for short, "the Code"). Learned Counsel for accused 1 to 3 contended that Dettol being a "Disinfectant" does not require a license under the Act since it came within the exempted category under Item No. 12 of Schedule K of the Drugs and Cosmetics Rules, 1945 (for short, "the Rules"). Learned Counsel has invited my attention to an unreported decision of the Division Bench of this Court in Reckitt Benckiser (India) Ltd. Vs. Commissioner, Commercial Taxes and Others, and another unreported decision of the Andhra Pradesh High Court in Vijayakumar and Ors. v. Drug Inspector (Crl. Petition. No. 3400 of 2005) in support of his contention that Dettol is a "Disinfectant". Learned Public Prosecutor would contend that Dettol does not have the characteristics of a "Disinfectant", it is only an "Antiseptic" though, it may be used as a "Disinfectant" also, Item No. 12 of Schedule K referred above only exempted "Insecticides" and "Disinfectants" and hence Dettol is not exempted by the Act and Rules from the necessity to obtain license for its stocking, exhibition and sale. Learned Public Prosecutor has invited my attention to the Complete Drug Reference, 32nd Edition, Page 1097 as to the meaning of "Disinfectant" and "Antiseptic".

3. It is not disputed that accused 1 and 2 are not having license under the Act to stock, Ext. or sell Dettol. Section 18 coming under Chapter IV of the Act deals with prohibition of manufacture and sale of certain drugs and cosmetics from the date notified by the State Government in the Official Gazette. The said provision says:

18. 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 this behalf-

(a)....

(b)....

(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 an in accordance with the conditions of, a license 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.

4. Section 3(b) of the Act defines "drug" as under:

(i)...

(ii) such substance (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 are also includes in the definition of "drug".

As per the said definition, any substance intended to be used for the destruction of vermin or insects which cause disease in human being or animals as may be specified from time to time by the Central Government by notification in the Official Gazette is also brought within the definition of "drug". A "Disinfectant" is therefore, a "deemed drug" as Section 3(b)(ii) of the Act would say and should normally come within the prohibition contained in Section 18 . of the Act.

5. Now the question is whether "Dettol" is a "Disinfectant" and hence exempted from Section 18 of the Act as contended by the accused. Part XI of the Rules deals with exemptions. Rule 123 falling in the said part says:

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.

In Schedule K, Item 12 is,

Class of Drugs

12. Substances intended to be
used for destruction of vermin or
insects which, cause disease in
human being or animals, viz.

Antiseptics and Disinfectants.

Extent and Conditions of Exemption

The provisions of Chapter IV of the Act
(taking in Section 18 of the Act) and Rules thereunder,
which require them to be covered by a sale

license (subject to the condition that provision of condition (17) of Rule 65 of the Drugs and Cosmetics Rules, 1945 are complied with by the persons stocking or selling such substances.

Condition No. 17 of Rule 65 relates to stocking or sale of the drug after the date of expiration of potency recorded on its containers, label or wrapper or in violation of statement or direction recorded on such container label or wrapper. Prosecution of the accused in these cases is not based on any violation of Condition No. 17 and hence that question is not required to be adverted to in these proceedings.

6. I referred to Item 12 of Schedule K of the Rules where the expression used is substances intended to be used for destruction of vermin or insects which cause disease in human beings or animals viz, Insecticides and Disinfectants. The expression "viz" means "namely", "that is to say" (See Law Lexicon by P. Ramanatha Aiyar). The word "namely" is a term which imports interpretation that is it includes what is included in the previous term. That word imports enumeration of what is comprised in the preceding clause. It ordinarily serves the purpose of equating what follows with the clause described before (See The State of Bombay Vs. Bombay Education Society and Others,). If Dettol is a "Disinfectant", it falls in Item 12 of Schedule K in which case by virtue of Rule 123 of the Rules, Dettol should be held to be exempted from Section 18 of the Act which comes under Chapter IV of the said Act.

7. Learned Counsel for the accused has given me a copy of label of the product in question - Dettol where it is stated that it is an Antiseptic germicidal and the following are its use mentioned.

- i. Pre-operative Preparation of Patient's Skin
- ii. Antisepsis in Obstetrics and Midwifery
- iii. Cuts and Wounds (Also bites, scratches and insect stings)
- iv. Instrument Sterilisation
- v. General Disinfection: Wards and Theatre, Hands, Face, Masks, Soiled HospitalLinen, etc.
- vi. Bathing and Irrigation of Abscesses and Boils
- vii. Epidemics
- viii. Dandruff
- ix. Gargle
- x Bath

It is cautioned that the product is meant "for external use only". The active ingredients of Dettol are:

i. Chloroxylenol I.P.4.8% w/v

it TerpeneolB.P.9.0% v/v

iii. Alcohol Absolute (Denatured) 13.1% v/v

It Contains Caramel LP. as colour.

8. In "Infection Control" relied on by the accused, use of Disinfectant and Antiseptic is given as below:

Disinfectant used on inanimate objects to kill or prevent the growth of micro organisms.

Antiseptic- used on living tissue to kill or prevent the growth of micro-organisms

The unreported decision of Andra Pradesh High Court referred above held that "Savlon" is a Disinfectant. In the unreported decision of the Division Bench of this Court Reckitt Benckiser (India) Ltd. Vs. Commissioner, Commercial Taxes and Others, referred above though dealing with the question regarding liability under the Kerala Value Added Tax, 2003 it is observed in para.7:

Appellant has no case that the above Disinfectant, that is Dettol. is able to prevent or cure any disease. It externally kills germs and is used for various purposes referred to in the leaflet attached to it which includes even washing.

(emphasis supplied)

In the view of the Division Bench, Dettol is a Disinfectant.

9. In "Complete Drug Reference" relied on by the learned Public Prosecutor, it is stated at page 1097:

There is often confusion between the terms disinfectant and antiseptic.

The term Disinfectant is applied to a chemical agent which destroys or inhibits the growth of pathogenic micro-organisms in the non-spoting or vegetative state, Disinfectants do not necessarily kill all micro-organisms but reduce them to a level which is harmful neither to health not the quality of perishable goods. The term is applicable to agents used to treat inanimate objects and materials and may also be applied to agents used to treat the skin and other body membranes and cavities.

An Antiseptic is a Disinfectant which is used on skin and other living tissues thereby limiting or preventing infection.

Learned Public Prosecutor argues that Dettol is basically an Antiseptic though, it may be used as Disinfectant also.

10. It is appropriate to refer to the meaning of the words in the Medical

Dictionary. In Legal Medical Dictionary by Erskine Pollock and E. Raymond Clutterbuck the word "Sepsis" (the word "Septic" is its adjective) is defined as under:

The presence of pus-forming bacteria in, e.g, a wound which is festering. The index of the presence of such bacteria is the train of symptoms known as inflammation. Adj, Septic.

"Antiseptic" therefore must be something which prevents sepsis. The word "Infectious" is defined as,

capable of being transmitted from one person to another

The word "Antiseptic" is defined as,

germ-destroying.

In Dorland's Pocket Medical Dictionary the word "Antiseptic" is defined as:

- i. Preventing sepsis.
- ii. a substance that inhibits the growth and development of microorganisms but does not necessarily kill them.

Disinfectant" is defined thus:

- i. Freeing from infection,
- ii. An agent that disinfects, particularly one used on inanimate objects.

In Mosby's Medical Dictionary, the word "Antiseptic" is defined as,

- i. tending to inhibit the growth and reproduction of micro-organisms,
- ii. a substance that tends to inhibit the growth and reproduction of micro-organisms.

The word "Disinfectant" is defined as,

a chemical that can be applied to objects to destroy micro-organisms

"Disinfection" is defined as "the process of killing pathogenic organisms or of rendering them inert."

The above descriptions persuades me to hold that the function of a "Disinfectant" which is a chemical or mixture of chemicals of appropriate percentage is destruction or making inert micro organisms particularly on inanimate objects. But that does not mean that a Disinfectant could be used only on inanimate objects and (sic) oment it could be used on animate objects also, it ceases to be a "Disinfectant" (sic) an "Antiseptic". Its use on animate objects is only external with the same purp (sic) struction or making inert micro organisms.

11. I stated from the label of "Dettol" the uses to which the said product can be put to. It includes sterilisation of instruments and general disinfection of wards

and theatre, hands, face, masks, soiled hospital linen, etc (i.e., on inanimate objects). It can also be used for bathing and irrigation of abscesses and boils, not to say about its use to prevent dandruff. "Dettol" can be used for bathing as well. It is stated (on the label) that a little Dettol added to bath water is pleasant, refreshing and deodorising. A deodorant is a substance that destroys or masks odors (smell). The mere fact that "Dettol" can also be used for pre-operative preparation of patient's skin or as antiseptics in obstetrics and midwifery, on cuts and wounds (also bites, scratches and insect sting), all externally, and all for the purpose of destruction or making inert micro organisms in my view does not make "Dettol" anything other than a "Disinfectant". "Dettol" is a mixture of the chemicals I have mentioned above, from its label. Thus, going by the definition of the word "Disinfectant" and the use for which Dettol is manufactured I hold that Dettol is a "Disinfectant" used to treat inanimate objects and materials though it may also be applied to agents used to treat the skin and other body membranes and cavities (externally). Dettol contains some chemicals which are antiseptic but does not lose its character as a Disinfectant for the said reason or that it can be used to treat skin and other body membranes and cavities. "Dettol" thus comes under Item 12 of Schedule K of the Rules and hence is exempted from Chapter IV of the Act by virtue of Rule 123 of the Rules. Hence for stocking, exhibiting and sale of "Dettol" a license under the Act is not required. Prosecution against Petitioners/accused have to fail.

Resultantly these criminal miscellaneous cases are allowed. The complaints preferred against Petitioners/accused, cognizance taken thereon and proceedings against them before learned Judicial First Class Magistrate-I, Kozhikode in C.C. Nos. 401 and 717 of 2009 are quashed.