

**M/s. Searle India Limited, 21 Damodaradas Sukhadvala Marg, Bombay-400
001 and Dr. K.K. Maheswari Vs The State by the Drug Inspector, Park
Range-II Range**

Court: Madras High Court

Date of Decision: June 7, 2002

Citation: (2002) 2 LW(Cri) 730

Hon'ble Judges: A. Packiaraj, J

Bench: Single Bench

Advocate: S. Anbumani for M/s. V. Vibhishanan C.A. No. 149 of 1996 and Mr. Perumbulavil Radhakrishnan, for the Appellant; I. Subramaniam, Public Prosecutor for Respondent, for the Respondent

Final Decision: Dismissed

Judgement

A. Packiaraj, J.

The accused 1 and 2, M/s. Searle India Limited Dr. K.K. Maheswari, have preferred the appeal, while the accused 3 to 7 have preferred revisions out of the same judgment rendered by the Special Judge (Essential Commodities Act, Madras, in STC No.2 of 1987).

2. When the matter was about to be heard, it came to light that the accused 3 to 7 have preferred revisions instead of appeal. The counsel for the

accused 3 to 7 pleaded that due to inadvertence, it has been done so and requested that as the accused 1 and 2 have preferred an appeal against

conviction, the revisions also should be heard alongwith them and they may be treated as appeals.

3. Considering the fact that question of law is involved in the matter and the matter having been admitted by the High court, as early as 1996, and

in the interest of justice, I am inclined to entertain them and hear them along with C.A. No. 149 of 1996.

4. The accused were charged for violation of Para-20 of The Drugs (Price Control) Order 1979, punishable u/s 7(l)(a)(ii) of the Essential

Commodities Act read with Section 3(2)(c) of the said Act. In effect the offending part is only Paragraph 20 of The Drugs (Price Control) Order

1979 and the other sections relate only to the Penal Clause.

5. The prosecution case need not be stated in detail mainly because, as far as the facts are concerned the accused have admitted the same.

a) A complaint had been filed by the Drugs Inspector, Park Town II Range, Office of the Assistant State Drugs Controller Zone-1, against all the

accused of whom the first accused is the manufacturing firm of the Drug Haloperidol Tablet;

the second accused is the production manager of M/s. Searle India Limited Bombay;

the third accused is the firm by name Mahaveer Pharma Agencies, who had purchased sold and stocked the drug Haloperidol Tablets

manufactured by A-1 Company;

the fourth accused is the partner by name Padamchand Chordia representing the accused firm namely Mahaveer Pharma Agencies;

the fifth accused is the firm by name Sri Mahaveer Pharma Distributors who purchased, sold and stocked Haloperidol Tablet;

the sixth accused is the partner by name Padam Chand Chordia of M/s. Mahaver Pharma Distributors (A-5) who purchased, sold and stocked the

drug Haloperidol and

the seventh accused Raghavan is the Proprietor of the firm M/s. Sripathy Distributors Madras, who purchased and sold Haloperidol Tablet.

b) The then Drugs Inspector on 29.11.1985, inspected Sri Mahaveer Pharma Agencies namely A-3 firm and found 68 bottles containing 100

Tablets each of Haloperidol, 5 mg Tablets, B.P. Lot 060, which was Manufactured in March 1985 by Searle India Limited, Bombay (A1) and

found that the bottles do not contain the label indicating the maximum retail price of the Drug as contemplated under the Drugs Control Order.

Order 1979. The said bottles were frozen on 29.11.1985 and at the same time, he also found that there were no purchase details for the purchase

of the said bottles. Acknowledging the same, A-4 submitted a letter (Ex.P1) stating that the labels do not indicate the maximum retail price and that

they agreed to furnish the purchase and sale details of Haloperidol 5 mg Tablets. On 2.12.1985, the Drugs Inspector drew samples from the

bottles under Form No. 17, marked as Ex.P-3, attested by P.W.3. Based on the above, show cause notices were sent to the respective firms and

on the replies from the accused and the reports from the analyst, he has filed the complaint as aforesaid.

c) To establish the above, the prosecution had examined 4 witnesses on its side and marked Ex.P-1 to Ex.P-25.

6. The prosecution through P.W.I, the Drug Inspector at the relevant time, has stated about the status of the accused, which is not disputed and

consequently, I may not go deep into it. The evidence of P. W. 1 is that he visited the premises of A-3 on 29.11.1985 and found 68 bottles of

Haloperidol 5 mg Tablet containing about 100 Tablets each, without the label which indicates the maximum retail price. With regard to the same, a

letter was given by A-4, the partner of A-3 firm, marked as Ex.P-1, admitting the fact that Maximum Retail Price column has not been furnished

on the label of the bottle and the details regarding the purchase of the bottles will be furnished. Hence P.W. 1 had frozen the articles and had given

Ex.P-2, giving out the details about the consignment. In continuation of his inspection made on 29.11.1985, he again inspected the premises of A-3

firm again on 2.12.1985 at about 9.30 a.m. and after observing all the formalities, seized the samples of Haloperidol Tablet under Ex.P-3, attested

by P.W.3. Ex.P-4 is the list, detailing about the prices of 4 bottles of Haloperidol obtained from A-3 firm. M.O.1 series (68 bottles of

Haloperidol) have been recovered under mahazar Ex.P-5, attested by P.W.4. The Delivery Chalan/Invoice for the goods delivered from A-1 firm

to A-3 firm containing the product name Haloperidol, was recovered under Ex.P-6. The recovered articles were sent to the Court with the

requisition under Ex.P-7 to keep them in safe custody. He also made arrangements to send the M.O.2 Series (2 bottles of Haloperidol Tablet) for

analysis through Form No. 18, marked as Ex.P-8. Show cause notices were sent to A-1 and A-3 firm under Ex.P-9 and Ex.P-10 respectively. A-

4 on behalf of A-3 has sent a letter dated 3.12.1985 about the purchase details with regard to 30 bottles of Haloperidol Tablet, marked as Ex.P-

11. Apart from the above, A-4 on behalf of A-3 has also sent a reply to the show cause notice, marked as Ex.P-12, wherein A-4 had stated that

they expressed their regrets and that by mistake they have not noticed the label of the drug, which does not show the maximum retail price and

requested P.W.I to kindly condone the mistake and oblige. Thereafter, P.W.I having come to know mat A-5 firm was also involved in the

purchase and sale of Haloperidol, issued a show cause notice under Ex.P-13 dated 10.1.1986 and A-5 sent a reply of which Ex.P-15 is the

verbatim copy of Ex.P-12, admitting that they had not noticed the absence of maximum retail price in the bottle and requested him to condone the

mistake and oblige. He had also come to know by virtue of Ex.P-15 that 15 bottles have been sold to A-7 and on the basis of Ex.P-16, the copy

of the bill, show cause notice was issued to A-7, marked as Ex.P-17. Ex.P-18 is the reply sent by A-7 and in addition to his notice, had also

supplied the bills, on the basis of which he had purchased Haloperidol from A-3. After receiving the replies from the respective accused and after

obtaining the sanction, P.W. 1 had filed the complaint.

7. It is an undisputed fact that the recoveries have been made at the respective firms and hence it may not be necessary for me to dwell upon the

issue. However, the specific case of the accused is that Haloperidol is available in its generic sense and when it is sealed, packed and distributed in

the brand name, it is named as Serenas Tablets. In other words, according to the accused, it is not the case of the prosecution that the tablet was

either misbranded or does not confirm with the quality prescribed, but the only infringement is that the maximum retail price has not been printed on

the bottle. They would further claim that the Drug has been marketed and sold in the generic name Haloperidol, exclusively for hospital supplies

and the cost of it has been printed in the price list. The same product is marked as Serenas by its brand name for retailers in strips of 10 in

Aluminium foil. Hence in short their claim is that the bottle need not contain the maximum retail price, if the Tablets in generic form namely as

Haloperidol has been supplied to hospitals and only in the case of the Drug being sold in the trade name Serenas, the maximum retail price should

be mentioned. This appears to be the substratum of the argument of the learned counsel appearing for all the accused.

8. In order to substantiate the above through the Control Order, the learned counsel for the accused drew my attention to the answers given by

P.W.I in cross examination, wherein according to Pharmacopea, Haloperidol is the generic name and the Trade Name is Serenas. Ex.P-21-A is

the price list in which the price of Serenas 5 mg has been marked. The price relates to 10 tablets and the price of which is Rs. 21.14 ps.

9. The learned counsel for the accused has further stated that if the consignment is only for the hospital use, the price would not be shown on the

consignment. However, there is no positive evidence to the same, nor has any suggestion been put to the witness. All that has been done on behalf

of the accused is that the witness have been confronted with the reply to the show cause notice, wherein they have stated as above. It is important

to note that it is not admitted by the Drugs Inspector that if a drug is supplied to a hospital the consignment need not contain the maximum retail

price. Therefore, though the accused in their replies on earlier occasions as shown earlier has admitted the fact that these consignments do not

contain the maximum retail price and they had requested the Drug's Inspector to condone the mistake would in the first instance, make it appear

that they know fully well the implications of Para-20 that it must contain the maximum retail price and the consignment which has been frozen by

the Drug Inspector in the present case does not contain and consequently, wanted the mistake to be condoned. However, in view of the fact that

the counsel were emphatic in their arguments that merely because the accused had accepted their guilt or their mistake would not by itself establish

the ingredients of the offence. The initial burden is on the prosecution to establish that an offence has been actually committed and it is only then the

answers of the accused has to be taken into consideration.

10. True the prosecution should stand on its own legs. I do not venture to go into the evidentiary value of their replies, considering the fact that a

question of law is involved in the present case, I am constrained to ignore the replies given by the accused, in view of the fact that they had stated

that they were forced to give such replies on the assurance that no action would be taken.

11. At the risk of repetition, I once again formulate the proposition framed by the learned counsel appearing on behalf of the accused that a

manufacturer need not print the maximum retail price in case a consignment relates to hospital purpose, but it is only necessary when it is offered

for sale in retail. To answer the above, relevant provision has to be considered.

12. Before dealing with the provision, it will not be out of place for me to state that when a specific plea has been taken by the accused that in so

far as the consignment sent to the hospitals are concerned, it is not necessary for the manufacturer, or the wholesaler to incorporate the maximum

retail price, it is duty of the accused to establish the same. Such establishment can either be made by way of letting evidence, or by eliciting

answers from the prosecution witnesses. However, in the present case, the accused has not done either of these things, nor is there any suggestion

to such an effect. All that has been done by the accused, is that the witnesses have been confronted with the averments mentioned in a letter

addressed by the accused to the department on an earlier occasion and the witness namely P.W.I has stated that the letter contains such

averments. No where does the witness admits the averments to be true. Hence the counsel for the accused solely rests his arguments on the

interpretation of the sections found in the said letter, rather than adverting to any portion of the evidence.

13. Paragraph 20 of the Drug Control Order (hereinafter shall be referred to as "the order") reads as follows:

20 Retail price to be displayed on label of container:

Every manufacturer, importer or distributor of a formulation intended for sale shall display in indelible print mark on the label of the container of the

formulation or the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words "retail price not to

exceed" " preceding it, and "local taxes extra" succeeding it.

14. Upon reading the above provision, the learned counsel would persuade this Court to mean that the manufacturer, importer or distributor shall

fix the maximum retail price only when it is offered for retail sale. They would emphasize that this paragraph would apply only to cases where the

formulation is offered for retail sale and that the words offered for retail sale should be read as disjunctive from the rest of the language and this is in

contra junction to the goods being offered in a bulk to the hospital, or to a distributor for stocking purposes etc.

15. No doubt on a first glance, the above proposition appears to be attractive. But on going through the above stated paragraph, I see that the

emphasis is not on the fact on the retail price being shown only when it is offered for retail sale but if the formulation is for sale itself, whether it be

to a wholesaler or retailer. I am forced to come to this conclusion mainly on two grounds. The first being on an analytical approach namely when

the paragraph reads that every manufacturer, importer or distributor of a formulation intended for sale shall display in indelible etc., would go to

show that this paragraph relates not only to the manufacturer, but also to a importer or distributor. Now if a manufacturer has to sell the same to

another wholesaler or who in turn sells it to the hospital or sells it in a generic form, the manufacturer will not be aware as to what the third person,

namely the stockiest or the wholesaler or the distributor does it. Hence when the manufacturer is expected to fix the retail sale price, it means that

whether or not it is for a hospital purpose or for any other person, it should contain the maximum retail price. If it had been the intention of the

parliament or the law makers that the retail price shall be mentioned only when the said formulation is sold for retailers alone, then there is no

reason as to why they should include the manufacturer, importer or distributor in this paragraph.

16. Secondly the paragraph classifies as to when and what circumstances, the formulation should contain the maximum retail price. Therefore, what

is incumbent is that it must be meant for sale. May be if the same is for donation, it need not contain the Maximum retail price. This is only an

example and not exhaustive. But however, when the manufacturer has sent it from his premises as a sale, it must necessarily contain the maximum

retail price. Therefore, the language in Paragraph 20 is in my opinion not ambiguous and on a plain reading, it means that a manufacturer when he

has intended his commodity to be sold, should necessarily print the maximum retail price or the other on the consignment, the moment when it has

been dispatched from his end as a sale.

17. In addition to the above said argument the learned counsel argued that maximum retail prices are prescribed for only some products and not in

cases of tablets including Haloperidol in view of paragraph-10 of the said order. Paragraph 10 reads as follows:

10. Calculation of retail price of formulations:

The retail price of a formulation shall be calculated in accordance with the following formula, namely:

$$R.P = (M.C + CC + P.M. + P.C) \times [1 + MU] + ED/100$$

Where-

R.P"" means retail price.

MC"" means material cost and includes the cost of drugs and other pharmaceutical aids used, including averages, if any, and process loss thereon

in accordance with such norms as may be specified by the Government from time to time by notification in the official Gazette in this behalf.

CC"" means conversion cost worked out in accordance with such norms as may be specified by the Government from time to time by notification

in the official Gazette in this behalf.

P.M."" means the cost of packing material including process loss there on worked out in accordance with such norms as may be specified by the

Government from time to time by notification in the official Gazette in this behalf.

P.C"" means packing charges worked out in accordance with such norms as may be specified by the Government from time to time by notification

in the official Gazette in this behalf.

M.U"" means mark-up referred to in paragraph 11.

E.D"" means excise duty:

But this calculation mentioned above applies only to the formulations mentioned in category 1, 2 and 3 of the III Schedule and not in respect of

others and according to the counsel, Haloperidol does not come under any of these categories namely Category 1, 2 and 3 of the III Schedule of

the order and consequently, the maximum retail price need not be printed.

18. In continuation of their submissions, the learned counsel have referred to Paragraph 18 of the Order, which reads as follows:

18. Certain provisions of this Order to apply to formulations not included in Category I, Category II or Category III of the Third Schedule.

The provision of this Order, other than those contained in paragraphs 10 to 14 (both inclusive) shall apply to any formulation not specified in

Category I, Category III or Category III of the Third Schedule

19. On going through the provisions, I do agree that Paragraph 18 segregates Haloperidol and paragraph 10 does not apply to the Haloperidol. In

other words the calculation contemplated or calculated under paragraph 10 does not apply to Haloperidol which does not come under any of the

Category 1, 2 and 3 of the HI Schedule.

20. The learned Public Prosecutor Mr. I. Subramaniam with his usual fairness conceded that Haloperidol does not come under this category. But

his contention is that Haloperidol is an ethical drug falling under Schedule H of the Drugs and Cosmetics Rules. This part of it has also been

admitted by the counsel appearing for the accused. Hence that this drug namely Haloperidol is an Ethical drug falling u/s Schedule H of the Drugs

and Cosmetics Rules does not come under paragraph 10 or 18, but according to the learned Public Prosecutor a separate paragraph has been

incorporated for such of these goods in the form of Paragraph 24, which is as follows:

24. Price to the wholesaler and retailer:

(1) No manufacturer, importer or distributor shall sell a formulation to a wholesaler unless otherwise permitted under the provisions of this Order

or any order made thereunder, at a price higher than:

(a) the retail price minus 14 percent thereof, in the case of Ethical drugs, and

(b) the retail price minus 12 percent thereof, in the case of non-ethical drugs

(2) No manufacturer, importer, distributor or wholesaler shall sell a formulation to a retailer unless otherwise permitted under the provisions of this

order or any order made thereunder, at a price higher than

(a) the retail price minus 12 percent thereof, in the case of ethical drugs, and

(b) the retail price minus 10 percent thereof, in the case of non-ethical drugs.

Explanation For the purposes of this paragraph-

(i) "ethical drugs" shall include all drugs specified in Schedule C. entries Nos. 1, 2, 3, 7, 8 and 9 of Schedule C (1).
Schedule E, Schedule G,

Schedule H and Schedule L, appended to the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940 (23 of 1940)

and

(ii) "non-ethical drugs" shall mean all drugs other than ethical drugs.

(3) Notwithstanding anything contained in subparagraphs (1) and (2) the Government may, by a general or special order, fix, in public interest, the

price to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order.

21. Therefore, the explanation in paragraph 24 of the order which contemplates the calculation of the retail price of ethical drugs of which

haloperidol, admittedly, falls under the said category, makes it abundantly clear that the manufacturer has to necessarily calculate the maximum

retail price of such drugs. In view of this provision, the argument advanced by the learned counsel for the accused that maximum retail price need

not be mentioned for products like haloperidol, is not acceptable.

22. It will not be out of place for me to mention that Paragraph 24 contemplates that a manufacturer, importer or distributor shall formulate to a

wholesaler, according to the retail prices which has to be calculated in the remaining part of the paragraph. In the present case, admittedly A-1 is

the manufacturer, while A-3 is the wholesaler to whom A-1 who has sold the goods and A-5 is the distributor who has received the goods from

A-3 and ultimately A-7 is the purchaser. The accused had also sold some of the Haloperidol for hospital purposes. Therefore, in the circumstances

of the case, it is not as if that A-1 has sold all the consignment only to the hospital. No doubt the price list of the invoice shows that Serenas have

also been sold on a higher price than Haloperidol and it is their own case that Serenas is in effect is Haloperidol, addressed as Serenas by trade

name and has been packed in aluminium foils and sold in strips of 10 each, consequently, the price no doubt may vary and in view of that we

cannot come to a conclusion that Haloperidol or the consignment that had been frozen in this case is solely meant for hospital purposes. At any

rate, whether or not the consignment is sold for hospital purposes, it is the duty of the manufacturer to display in indelible print mark on the label of

the container of the formulation or the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words

retail price not to exceed" preceding it, and "local taxes extra" succeeding it.

23. In the result, I find that the prosecution has clearly established that the accused have violated Paragraph 20 of the Section and consequently

found guilty by the trial Court. In the circumstances, I confirm the conviction and sentence passed by the trial Court and dismiss the appeal and the

revisions.