SUPREME COURT OF INDIA

Union of India

Vs.

M/s. Ranbaxy Laboratories Ltd.

C.A.No.3497 of 2008

(S.B. Sinha and V.S. Sirpurkar JJ.)

24.04.2008

JUDGMENT

S.B. Sinha, J.

1. Leave granted.

2. First respondent is a pharmaceutical company and is engaged in the manufacture, inter alia, of the bulk drug Pentazocine in the formulation of Pentazocine injection with the brand name `Fortwin'. Sale and marketing of the said drug is controlled by the *Drugs (Price Control) Order, 1995 (1995 Order)*. The said order has been made by the Central Government in exercise of its powers under Section 3 of the *Essential Commodities Act, 1955 (1955 Act)*. We may notice some interpretation clauses in the 1955 Act, which are as under:-

> "2. (a) "bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the *Drugs and Cosmetics Act, 1940 (23 of 1940)*, and which is used as such or as an ingredient in any formulation;
>
> 2. (c) "ceiling price" means a price fixed by the Government for scheduled formulation in accordance with the provisions of para. 9.
>
> 2(f) "Drug" includes-
>
> (i) ....
>
> (ii) ....
>
> (iii) Bulk drugs and formulations;

2(l)"manufacture" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drugs with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly;

2(r) "price list" means a price list referred to in paragraphs 14 and 15 and includes a supplementary price list;

2(s) "retail price" means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price;"

3. The drug in question is one of the scheduled bulk drugs being at Sl. No.43 in the First Schedule.

4. The Central Government in exercise of its powers conferred upon it by paragraph 23 of the 1995 Order issued guidelines for the purpose of grant of exemption in terms of paragraph 25 specifying that a manufacturer who had been given a price exemption for bulk drug should submit an application in prescribed forms for fixation of price of suck bulk drug and formulation four months before the expiry of the period of the exemption. It was furthermore stipulated:-

"However, if there is an existing notified price for bulk drug or ceiling price for formulations, the manufacturer shall follow the same on the expiry of the exemption and obtain price approval for non-ceiling packs of formulation (s) based on that bulk drug."

5. A similar provision has been made for grant of exemptions in respect of New Delivery System, in terms whereof a manufacturer is required, where there is an existing notified price, to follow the same on the expiry of the exemption.

6. The exemption granted in favour of the first respondent had expired on 31st October, 1999.

7. First respondent was asked to show cause as to why an amount of Rs.2,59,76,070/- should not be recovered from it and why action should not be taken under paragraphs 21 and 24 of 1995 Order read with Section 10 of the 1955 Act by a notice dated 29th April, 2002. In response thereto the first respondent inter alia contended that it had not overcharged price from any customer and no amount towards any alleged over charge was payable by it. It was furthermore contended that the company had furnished all the informations, as and when asked for by the prescribed authorities of the appellant.

8. As the said reply was found to be unsatisfactory, the first respondent was asked to deposit the alleged over charged amount with interest @ 15% per annum as provided under Section 7A of the 1955 Act.

9. A writ petition was filed thereagainst by the first respondent before the Delhi High Court. The said writ petition was dismissed by a learned Single Judge of the said High Court by an order dated 20th May, 2004.

10. A Letters Patent Appeal was filed thereagainst which has been allowed by a Division Bench of the said Court by reason of the impugned judgment and order dated 19th December, 2005.

The High Court opined that the exemption Notification dated 29th August, 1995 clearly show that the same related to drugs manufactured by 31st October, 1999 and thus the same would apply even if the drugs have been sold after the said date.

11. Mr. Gopal Subramaniam, learned Additional Solicitor General of India appering on behalf of the appellant would submit:-

> "i) That the High Court committed a serious error in passing the impugned judgment in so far as it failed to take into consideration that 1995 Order is concerned with distribution and not manufacture.
>
> ii) An exemption Notification must be strictly construed and so construed, it must be held that no benefit could be claimed by the first respondent beyond the period of 31st October, 1999 as by reason of the said exemption Notification it could sell the drug at any price and not at the stipulated one and thus, as soon as the period of exemption expired, the price provided for under the 1999 Order was required to be charged.
>
> iii) As a manufacturer the first respondent could sell its products but the exemption was in regard to sale only and not to manufacturer, the impugned judgment cannot be sustained."

12. Mr. S. Ganesh, learned Senior Counsel, appearing on behalf of the first respondent, on the other hand, would submit that exemption Notification must be given a purposive meaning and so construed, the impugned judgment is wholly unassailable

13. Admittedly the drug in question is an essential commodity within the meaning of the provisions of 1955 Act.

15. Section 3(2)(c) of 1955 Act empowers the Central Government to make an order providing for controlling the price at which the essential commodity may be bought or sold.

16. Exemption clause contained in paragraph 25 of the 1995 Order vis-`- vis Notification dated 29th August, 1995 must be construed having regard to the object and purport, which 1995 Order seeks to achieve. A scheduled drug contains details not only of the maximum retail price but also the date of manufacture. The price fixed in terms of paragraph 9 of the 1995 Order shall be the ceiling price. Paragraph 3(1) empowers fixing of the maximum sale

price at which the same can be sold. The factors which were required to be considered therefore, however, are not required to be noticed.

17. In terms of clause 3 of paragraph 3 of 1995 Order, a statutory prohibition had been created in terms whereof nobody could sell the bulk price exceeding the maximum sale price fixed under paragraph 1. Clause 2 of paragraph 8 empowers the authority fix retail price of scheduled formulations in terms whereof revision in the price is permissible.

18. Clause 6 of paragraph 8 of 1995 Order reads as under:-

> "(6) No manufacturer or importer shall market a new pack, if not covered under sub-paragraph 3 of para 9, or a new formulation or a new dosage form of his existing scheduled formulation without obtaining the prior approval of its price from the Government.
>
> Thus, what is prohibited is market of a new pack without obtaining the prior approval of its price from the Government.
>
> Paragraph 9 empowers the authority to fix ceiling price of scheduled formulations.
>
> Paragraph 23 provides for the power of the Central Government to issue guidelines and directions. Such guidelines and directions, however, must be consistent with the provisions of the Order."

19. What is, thus, necessary to be taken into consideration is the power for exempting and the Notification issued therefore by the Central Government. The power of exemption is contained in clause 25 of he Order, which reads as under:-

> "25. Power to exempt.- (1) Government may, having regard to the factors mentioned in sub-paragraph (2) and subject to such conditions as it may specify by an order in the Official Gazette, exempt any manufacturer from the operation of all or any of the provisions of this Order.
>
> (2) While granting exemption under sub-paragraph (1), the Government shall have regard to all or any of the following factors,-
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> (a) Number of workers employed:
>
> (b) Amount of capital invested;
>
> (c) range/group and type of products manufactured;
>
> a) Sales turnover;
>
> b) ....

c) Production of a new drug which has not been produced elsewhere, if developed through indigenous research and development."

20. We may, at this juncture, also notice the exemption Notification dated 29th August, 1995, which reads thus:-

"ORDER

S.O. No./ 7153 (E), in exercise of the powers conferred by sub-paragraph (1) of Paragraph 25 of the Dugs (Price Control) Order, 1995, the Central Government having regard to the factors specified in the clause(e) of sub- paragraph (2) of paragraph 25 of the said order and also having been satisfied for the need to do so in the public interest hereby exempts the bulk drug and formulations based thereupon specified in column 2 of the Table bellow which is manufactured by the company specified in the corresponding entry in column 3 from the operation of price control stipulated in sub-paragraph (1) of paragraph 3, sub paragraph (1) of paragraph 8 and sub-paragraph (1) of paragraph 9 of the said order, upto the period as indicated in column 4 thereof.

TABLE

S.No	Name of the Product	Name of the Company	Period upto which the exemption is granted
1	2	3	4
1	Pentazocine and its formulations	M/s.Ranbaxy Laboratories Ltd.	31-10-1999

Sd/-
(K. MULALIDHARAN)
DESK OFFICER"

21. For issuance of an exemption Notification the Central Government is required to apply its mind. The factors which are relevant, must be taken into consideration as provided for under paragraph 2 of clause 25 of the Order.

22. The relevant considerations inter alia are the sales turnover as also production of a new drug which was not produced elsewhere, if developed through indigenous research and development.

23. Pentazocine is used for a patient suffering from traumatic pain. The Central Government must be held to have applied its mind before issuing the exemption notification.

24. What must have been taken into consideration for that purpose is that respondent No.1 fulfilled the requisite criteria. The area of exemption is from the operation of the price control. Such exemption admittedly had been granted upto 31st October, 1999. Indisputably the Central Government had the power to extend the period of exemption. It could have granted further exemption subject to any condition.

25. The short question which arises for our consideration is as to whether the exemption Notification would apply in respect of drugs which were manufactured upto 31st October, 1999 or manufactured and sold upto the said date. The exemption granted is in respect of what. It is in respect of a drug manufactured by a company. What is marketed for sale is the drug manufactured. Manufacture of a drug is controlled by a different statute, namely the Drugs and Cosmetics Act, 1940. Process of marketing the drug as also the maximum price which can be charged have direct relation with manufacture and also the date thereof. The wrapper/foil/containers in which the drug is marketed contains several informations for the general public; one of them being the date of manufacture and the retail price. Various other informations are also required to be furnished.

26. The contention of learned Additional Solicitor General that the drug could be manufactured upto 31st October, 1999 but on and from 1st November, 1999 it could be sold only at the price specified in the order, in our opinion, cannot be accepted. If the first respondent was entitled to avail the benefit of the exemption notification till the midnight of 31st October, 1979, sometime would be necessary for it to market the same. There must be some time lag between the period the drug is manufactured and the actual sale by a retail dealer to the customer.

27. The Court while construing an exemption notification cannot lose sight of the ground realities inclduing the process of marketing and sale. The exemption order dated 29th August, 1995 is clear and unambiguous. By reason thereof what has been exempted is the drug which was manufactured by the company and the area of exemption is from the operation of the price control. They have a direct nexus. They are co related with each other. While construing an exemption notification not only a pragmatic view is required to be taken but also the practical aspect of it. A manufacturer would not know as to when the drug would be sold. It has no control over it. Its control over the drug would end when it is despatched to the distributor. The distributor may despatch it to the whole seller. A few others may deal with the same before it reaches the hands of the retailer. The manufacturer cannot supervise or oversee as to how others would be dealing with its product. All statutes have to be considered in light of the object and purport of the Act. Thus, the decision relied upon by the learned *Additional Solicitor General in Union of India vs. Cynamide India Ltd.*[1] *,Prag Ince & Oil Mills vs. Union of India*[2] *and Sree Meenakshi Mills vs. Union of India*[3] will have no applicability.

28. It is true that 1995 Order was to control the price and not the manufacture. But there cannot be any doubt that the price is that of a manufactured drug.

> "Not only in terms of the Essential Commodities Act, 1955 but also under various others, for example Customs and Central Excise Act and Weights and Measures Act (if applicable) several informations are required to be furnished. If the submission of Mr. Gopal Subramaniam that the first respondent was bound not only to manufacture but also to sell at a price upto 31st October, 1999 is correct, the same in our opinion lead to an absurdity. Such an anomaly and absurdity must be avoided."

29. Learned counsel wants us to apply the principle of purposive construction. It may be applied so as to give full effect to the exemption notification. The exemption notification must be construed to be a workable one. In *New India Assurance Co. Ltd.. vs. Nusli Neville Wadia and another*[4] this Court opined:-

> "51. Barak in his exhaustive work on `Purposive Construction' explains various meanings attributed to the term "purpose". It would be in the fitness of discussion to refer to Purposive Construction in Barak's words:
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> "Hart and Sachs also appear to treat "purpose" as a subjective concept. I say "appear" because, although Hart and Sachs claim that the interpreter should imagine himself or herself in the legislator's shoes, they introduce two elements of objectivity: First, the interpreter should assume that the legislature is composed of reasonable people seeking to achieve reasonable goals in a reasonable manner; and second, the interpreter should accept the non-rebuttable presumption that members of the legislative body sought to fulfill their constitutional duties in good faith. This formulation allows the interpreter to inquire not into the subjective intent of the author, but rather the intent the author would have had, had he or she acted reasonably."
>
> (Aharon Barak, Purposive Interpretation in Law, (2007) at pg. 87)
>
> While referring to its decision in *Oriental Insurance Co. Ltd. vs. Brij Mohan and others*[5] it applied the doctrine of purposive construction. Applying the principle of doctrine of purposive construction, we are of the opinion that meaningful purpose could be achieved only if the construction of the notification as indicated hereinbefore is adopted and no other."

30. There is no merit in this appeal which fails and is accordingly dismissed with costs. Counsel's fee assessed at Rs.50, 000/-

[1](1987) 2 SCC 720 *[2](1978) 3 SCC 459* *[3](1973) 1 SCC 129* *[4]2007 (14) SCALE 556*
[5]2007 (7) Scale 753