REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO.6178 OF 2009

GLAXO SMITHKLINE PHARMACEUTICALS LTD. & ANR. .. **APPELLANT(S)**

Versus

UNION OF INDIA & ORS. .. **Respondent(s)**

J U D G M E N T

R.F. NARIMAN, J.

The present appeal arises on the true construction of paragraph 28 of the Drugs (Prices Control) Order, 1987, read with exemption notification dated 28th February, 1992. Paragraph 28 of the DPCO, 1987, reads as under:

> **"28. Power to exempt- (1) The Government may, having regard to the factors mentioned in sub-paragraph (2) and subject to such conditions, if any, as it may specify, by order in the Official Gazette, exempt any drug manufacturing unit or a class of such units from the operation of all or any of the provisions of this order and may, as often as may be, revoke or modify such order.**
>
> **(2) While granting exemption under sub-paragraph (1), the Government shall have regard to all or any of the following**

factors relating to the drug manufacturing unit or a class of such units, namely;

a) Number of workers employed;

b) Amount of capital invested;

c) Range and type of products manufactured;

d) Sales turnover;

e) Production of bulk drug basic stage by process developed through indigenous Research and Development".

Under paragraph 28, an exemption notification was issued for the period mentioned to Glaxo India a manufacturer of a bulk drug which is Betamethasone Disodium Phosphate. The exemption notification with which we are directly concerned is set out hereunder:

> **"S.O. 166 (E) – In exercise of the powers conferred by sub-paragraph (1) of Paragraph 28 of the Drugs (Prices Control) Order, 1987, the Central Government, having regard to the factors specified in clause (e) of sub-paragraph (2) of paragraph 28 of the said Order and also having been satisfied for the need to do so in public interest, hereby exempts the bulk drugs and formulations based, thereupon specified in column 2 of the Table below 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 and sub-paragraph (1) of paragraph 9 of the said Order, upto the period as indicated in column 4 thereof."

TABLE

Sl No	Name of the bulk drug	Name of Company	Period upto which the exemption is granted
1.	Povidone Iodine	Wockhardt Ltd.	31.12.1995
2.	Betamethasone Disodium Phosphate	Glaxo India Ltd.	31.12.1994

A lot of correspondence took place between the appellant before us and the Union of India which ultimately culminated in a show cause notice dated 10th June, 1997. The said show cause notice referred to an earlier letter written by the appellant, finding that there was a differential in the price charged for the goods manufactured during the exemption period stated thereunder. A sum of Rs.1.90 crores was payable in the following terms:

"2. Government had exempted Betamethasone disodium Phosphate based formulations of

your company for only the period 28.2.92 to 31.12.94 vide notification SO No. 166 dated 28.2.92. Accordingly, you were required to follow the prices fixed by the Government for the formulation pack immediately on expiry of the exemption period i.e. from 1.1.95. Your contention that an application for fresh cost study had been made in October 1994 itself, merely did not give the right to the company to charge own prices, a Government fixed price was prevailing as on that date. A case of violation of the provisions of the para 9(3) of the DPCO '87 has accordingly been established and it has been decided to invoke the provisions of para 13 of the DPCO'95, for recovery of overcharged amount as assessed below:

Period of overcharging	Tentative sales (no. of packs)	Overcharging per	Tentative amount of overcharging
1.1.95 to 24.1.95	19,20,624	Rs. 1.52	Rs. 29,19,348
25.1.95 to 17.7.95	1,39,24,524	Rs. 1.16	Rs. 1,61,52,447
		Total	Rs. 1,90,71,795

This was replied to by the appellant, after which an order was passed on 9th April, 1999, by which the said show cause notice was confirmed, and a sum of Rs.2.04 crores including interest was demanded. Since the appellants were

aggrieved by the said demand, they filed a Writ Petition No.1266 of 1999 before the High Court at Bombay, which culminated in the impugned judgment dated 16th February, 2004, dismissing the aforesaid writ petition.

Shri S.Ganesh, learned senior counsel, appearing on behalf of the appellant, has placed great emphasis on the fact that both paragraph 28 as well as the exemption order, read with the Central Government Guidelines of 14th February, 1989, lead to only one conclusion that it is "manufacture" and not sale that is relevant. According to the learned counsel, since the period of exemption ends on 31st December, 1994, it is open to the appellants to charge a price which is not a price under the DPCO at any subsequent point of time. According to him this has not been correctly appreciated by the High Court, as a result of which the High Court, in going into various other provisions of the DPCO and reading them along with the exemption provision, has gone wrong and mixed up price with

manufacture.

The sheet anchor of Shri Ganesh's case is a judgment delivered by this Hon'ble Court in *Union of India* vs. *Ranbaxy Laboratories Limited and Others,* (2008) 7 SCC 502 in which the selfsame problem arose before this Court under *pari materia* provisions of the DPCO of 1995. This Court has unequivocally held in favour of the construction suggested by Shri Ganesh, namely that all manufacturers of exempted goods, upto the last date of exemption, would be entitled, at any subsequent point of time, to charge a price which is not controlled by the DPCO.

Shri Rana Mukherjee, learned senior counsel appearing on behalf of the Union of India, has tried to support the High Court's judgment, and has referred us to Guideline No. (viii) of the Central Government Guidelines, and paragraph 16(3) of the DPCO of 1987. According to him, a subsequent judgment of this Court in *Glaxosmithkline Pharmaceuticals Ltd.* vs. *Union of*

India and Others **(2014) 2 SCC 753 has correctly distinguished the earlier judgment in Ranbaxy's case, and would therefore, squarely cover the present facts.**

Having heard learned counsel for the parties, the point with which we are concerned is in a very narrow compass. If paragraph 28, which is set out hereinabove is perused, it is clear that the exemption relates to drug manufacturing units or classes of such units. The very exemption order which has also been set out by us (supra) again refers only to bulk drugs and formulations based thereupon which are "manufactured" by the company. Further, a reading of the guidelines of 1989 also makes it clear that the exemption only relates to manufacture and has no reference to sale whatsoever. The Guidelines of 1989 are set out hereunder:

GOVERNMENT OF INDIA

MINISTRY OF INDUSTRY
DEPARTMENT OF CHEMICALS & PETROCHEMICALS
(OFFICE OF THE DEVELOPMENT COMMISSIONER)

New Delhi, the 14th February, 1989

GUIDELINES NO. 1/ 1989

In exercise of the powers conferred by Paragraph 25 of the Drugs (Price Control) Order, 1987, (hereinafter called the "said Order"), the Central Government hereby issue guidelines for the purpose of grant of exemption under Para 28 of the Order to such bulk drug manufacturing unit from the provisions of Para 3 of the said Order, in respect of such bulk drugs) as is/are produced by that unit from the basic stage by a process of manufacture developed through its own Research and Development effort, for a specified period not exceeding five years reckoned from the date of commencement of commercial production of such bulk drug(s) subject to the following, namely:-

(i) The process development activities are registered with the Department of Scientific and Industrial Research (hereinafter referred to as DSIR) and a certificate is issued by DSIR to the effect that the manufacture has developed the process of manufacture through its own R&D efforts.

(ii) The process so developed is significantly different from the known/available technology in the country leading to import substitutions/cost reduction, etc.

(iii) The manufacturer shall make an application to the Government within 30 days of commencement of commercial production of such bulk drug or within 30 days of the date of issue of these guidelines in the case of bulk drugs already under production, as the case may be, along with the information as per the Annexure, and such other information as may

be required by the Government and/or such additional information as the company may voluntarily furnish.

(iv) The Government if satisfied with the application mentioned above, may by a Notification in the official Gazette, exempt a manufacturer from fixation of price or compliance with the price already fixed if any for such a bulk drug under the provisions of the said Order.

(v) In case of bulk drugs which are already being produced from the basic stage by a process of manufacture developed through indigenous Research and Development, the period which has already elapsed since it came into commercial production by this process, shall count towards determining the said limit of five years prescribed under this Order.

(vi) In case of processes developed by National Laboratories and purchased and actually made use of by a manufacturer, such activity shall also be taken into consideration for the purpose of granting exemption.

(vii) The Government shall have the liberty to withdraw the exemption so granted at any time.

(viii) After expiry of the period of exemption, the manufacturer shall submit application(s) in Form I of the Drugs (Prices Control) Order, 1987 for fixation of price of such a bulk drug(s)under the provisions of the said Order.

Sd/-

(R.S. Mathur)
Joint Secretary to the Govt. of India

It will be noticed that the reference is to the date of commencement of commercial production of a bulk drug which has reference to manufacture alone. However, Shri Mukherjee, referred us to sub-clause (viii) of the aforesaid guidelines in order to argue that after the expiry of the period of exemption, the manufacturer has to submit an application for fixation of the price of a bulk drug under the provisions of the DPCO.

Sub-clause (viii) cannot be read in isolation but must be read as a part of the entire scheme of the guidelines. All that sub-clause (viii) says is that after the period of exemption, which is after the period which has reference to manufacture and not sale of goods, such goods as are manufactured after the exemption will be subject to the drill of sub-clause (viii). Read in this light, we do not find any difficulty in rejecting Shri Mukherjee's arguments based on this sub-clause.

We are of the view that the matter is no longer *res-integra.* In Ranbaxy's case, cited by Shri Ganesh, the relevant exemption provision under the DPCO of 1995, referred to in paragraph 19 of the judgment, is almost a verbatim reproduction of the earlier exemption provision i.e. paragraph No.28 of the DPCO of 1987, with which we are directly concerned. Even the exemption notification mentioned in paragraph 20 of the aforesaid judgment, like the exemption notification in the present case, refers only to bulk drugs and formulations "manufactured" by the company. After hearing arguments from both sets of counsel, the Court answered the question that was before it thus:

> **"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 up to 31-10-1999 or manufactured and sold up to 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 the learned Additional Solicitor General that the drug could be manufactured up to 31/10/1999 but on and from 1/11/1999 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 31-10-1999, some time 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 including the process of marketing and sale. The exemption order dated 29-8-1995 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 correlated 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 dispatched to the distributor. The distributor may dispatch it to the wholeseller. 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 the light of the object and purport of the Act. Thus, the decisions relied upon by the learned Additional Solicitor General in *Union of India* v. *Cynamide India Ltd.*; *Prag Ice & Oil Mills* v. *Union of India*, *Shree Meenakshi Mills Ltd.* v. *Union of India* and *Panipat Coop. Sugar Mills* v. *Union of India* will have no application.

28. It is true that the 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.

29. Not only in terms of the Essential Commodities Act, 1955 but also under various others, for example, Customs and Central Excise Act and the Weights and Measures Act (if applicable) several informations are required to be furnished. If the submission of Mr. Gopal Subramanium that the first respondent was bound not only to manufacture but also to sell at a price up to 31-10-1999 is correct, the same in our opinion would lead to an absurdity. Such an anomaly and absurdity must be avoided."

Not to be deterred by the plain language

of the aforesaid judgment, Shri Mukherjee referred us to a later judgment in the Glaxosmithkline case, referred to hereinabove. The issue in that case concerns a price notification issued under the later DPCO of 1995. In the course of arguments, counsel for the appellants relied upon the Ranbaxy Laboratories case, in order to buttress his submission on the facts of that case. However, the Court distinguished the Ranbaxy judgment in paragraph-60 thereof as follows:

> **"60. The issue before us is quite different and, in our view, the judgment of this Court in *Ranbaxy Laboratories* does not apply to the present controversy for more than one reason. First, in *Ranbaxy Laboratories*, the Court was concerned with the exemption notification issued under Para 25 of the 1995 DPCO whereas in the present matters, the issue centres around Paras 14, 16 and 19 of that DPCO. Second, the notification under consideration in *Ranbaxy Laboratories* was an exemption notification and not a notification for fixation of price. Third, the exemption notification is relatable to the manufacturer of the drugs whereas price fixation notification is related to sale of drug/formulation at a given price."**

It can be seen that the issue that arose in the Glaxosmithkline case was completely different from the issue that arose in Ranbaxy's case and the present case. Ranbaxy's case and the present case are directly concerned only with an exemption notification, and not a notification for fixation of price. Also, what is relevant for an exemption notification is the manufacture of drugs, whereas what is relevant for a price fixation notification relates to sale and not manufacture. Obviously, therefore, the Glaxo-smithkline decision would have no relevance to the facts of the present case. Coming to Shri Mukherjee's arguments based on paragraph 16(3) of the DPCO of 1987, we first set out the said provision:

> **"16(3)- Every manufacturer or importer shall give effect to the price of a bulk drug or formulation, as the case may be, as fixed by the government from time to time within 15 days from the receipt by such manufacturer or importer of the communication in this behalf from the government and issue a supplementary price list in this regard to the dealers, state drugs controllers and the government and indicate necessary reference to such price fixation."**

Shri Mukherjee has based his argument on the fact that there cannot be two prices for the same bulk drugs or formulation, which is why the period of 15 days is mentioned in paragraph 16(3) so that one price may be fixed by the Government for each bulk drug and formulation from time to time. This argument also need not deter us, for the simple reason that there will only be one price that is fixed for all goods that are manufactured by the appellant upto 31st December, 1994, and that price will be a price unilaterally determined by the appellant and will not be fixed under the DPCO.

This being the case, we allow the present appeal and set aside the judgment of the High Court.

.....J.
[ROHINTON FALI NARIMAN]

.....J.
[SANJAY KISHAN KAUL]

NEW DELHI,
JULY 18, 2017.