

THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 22.10.2019

CORAM

THE HONOURABLE MR.JUSTICE V.BHARATHIDASAN

W.P.NO.20553 OF 2009

Universal Pharmaceutical Limited,
having its Registered Office at
No.1, GLSC Vaidyanathan Street,
Chennai 600 081 and factory at
18th Cross, PIPDIC Indl. Estate,
Mettupalayam, Pondicherry 9

... Petitioner

/vs/

1. The Union of India, through the Secretary,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
Shastri Bhavan, New Delhi 110 001.
2. National Pharmaceutical Pricing Authority,
Ministry of Chemicals & Fertilizers,
5th/3rd floor, YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi -110 001.
rep. by its Director

.... Respondents

PRAYER : Petition filed under Article 226 of the Constitution of India, to issue a writ of Certiorarified Mandamus directing the respondents to call for the records pertaining to the impugned order in F.No.21(1405) 2008/DIV.IV/N.PPA, dated 23.09.2009 passed by the 2nd respondent and quash the same and consequently to forbear the respondents by themselves, their servants and agents, officers and subordinates from enforcing the notification S.O.1056 (E) dated:11.07.2006 against the petitioner's formulation viz., LCF Cough Formula having R.Salbutamol as bulk drug or taking any action pursuant to or in furtherance of the implementation of the provisions of DPCO 1995, with respect to said formulations of the petitioner containing R-Salbutamol with costs.

For Petitioner : Mr.P.S.Raman,
Senior Counsel,
for Mr.T.D.Selvan Babu

For Respondents : Mr.G.Karthekeyan, SCGSC

O R D E R

This writ petition has been filed challenging the order passed by the second respondent on the ground that there is a variation in price fixation of the drug manufactured by the petitioner.

2. According to the petitioner, the petitioner company is engaged in the business of manufacturing and marketing various pharmaceutical preparations including the formulation "LCF Cough Formula" made from and using the molecule named "R.Salbutamol", which has been introduced in India in the year 2004 with other ingredients. The formulations of LCF Cough Formula are used for the treatment of Asthma and Chronic Obstructive Pulmonary disease. The petitioner is engaged only in the manufacture of the said formulations and not in the manufacture of any bulk drug. R-Salbutamol is also known as Levosalbutamol and the petitioner-company is not using the bulk drug "Salbutamol", which is covered in the impugned order passed by the second respondent. According to the petitioner, the Salbutamol and R-Salbutamol are different and distinct drugs. The manufacturing process and the ingredients used for deriving Salbutamol and R-Salbutamol are distinct and different. The bulk drug R.Salbutamol is not derived from Salbutamol and the origin of R.Salbutamol is relatively very recent within about 5 years of period. The respondents also exercised the power in fixing the ceiling price in respect of such bulk drug and formulations containing Salbutamol and also issued a notified ceiling price for one of the formulations under Notification S.O.1056(E) dated 11.07.2006, as per the said notification, the price fixed as follows:

Sl. No	Name of the Formulation	Strength	Pack Size	Ceiling Price (Rs.)
1.	Salbutamol Sulphate + Ambroxol Hydrochloride + Guaiphenesin Liquid	(Each 5 ml contains) Salbutamol Sulphate eq. to Salbutamol 1mg Ambroxol Hydrochloride 15 mg Guaiphenesin 50 mg	100 ml Bottle with M.Cup	16.66

The above notification does not apply to R.Salbutamol used as an ingredient in the drug manufactured by the petitioner. Hence, the above price fixation notification is not applicable to the petitioner. Earlier the second respondent has issued a show

cause notice to the petitioner on 31.03.2009 stating that the petitioner-company is not following the price fixed by the Government and directed the petitioner to explain the reason for non-compliance of the ceiling price and also directed them to file production and sales details. For which, the petitioner had sent a detailed reply dated: 16.04.2009, thereby explained the formulation of LCF Cough Formula is different composition compared to the formulations, for which the price has been notified by notification S.O.1056 (E) dated 11.07.2006, they have also given their formula and composition, they have also explained in detail regarding the chemical composition used by the petitioner, and stated that the drug manufactured by the petitioner will not fall under the said notification. Thereafter, the impugned order dated 23.09.2009 came to be passed by the second respondent without considering the objection raised by the petitioner and come to a conclusion that the formulation of "LCF Cough Formula" manufactured by the petitioner-company is duly covered by the notification S.O.1056 (E) dated 11.07.2006 and directed the petitioner to furnish all the details regarding production and sales. Now, challenging the impugned order dated 23.09.2009, the present writ petition has been filed.

3. The respondents filed a detailed counter affidavit explaining that R-Salbutamol and Salbutamol are one and the same. R.Salbutamol is only a stereo-isomers of Salbutamol and used for the same purpose as Salbutamol.

4. The learned Senior counsel appearing for the petitioner would submit that the formulation used by the petitioner, namely, R.Salbutamol is totally different from Salbutamol and the petitioner has given a detailed explanation in the reply to the show cause notice issued by the second respondent and the second respondent without considering the same, came to a conclusion that the formula used by the petitioner is duly covered under the notification dated 11.07.2006, hence, the impugned order passed by the second respondent is in total non-application of mind and also without any valid reason. Hence, the same is liable to be set aside.

5. Per contra the learned counsel appearing for the respondents would submit that the formula used by the petitioner-company is covered under the notification dated 11.07.2006, and they have deliberately fixed higher price to the drug. That apart, Salbutamol and R.Salbutamol are one and the same. Now considering all those facts, the second respondent has passed the impugned order.

6. I have considered the rival submissions made on either side and perused the materials available on records carefully.

7. The show cause notice was issued by the second respondent on the ground that the LCF Cough Formula used by the petitioner-company fall under the notification dated 11.07.2006 and the ceiling price was fixed at Rs.16.66/-, but the petitioner is selling the drug at the retail price of Rs.44/-, hence, the petitioner was directed to submit the explanation. The petitioner has submitted a detailed explanation stating that the LCF Cough Formulation used by the petitioner is totally different from the formulation covered under the notification dated 11.07.2006 and the petitioner is only using the composition of R- Salbutamol, which is totally different from the composition of Salbutamol sulphate, for which notification has been issued. That apart, a detailed explanation was also given by the petitioner in respect of a difference between Salbutamol sulphate and R- Salbutamol. However, it could be seen from the impugned order that the second respondent without considering none of the objection, simply came to a conclusion that the formulation of LCF Cough Formula is duly covered by the notification dated 11.07.2006 and directed the petitioner to submit the details of production and sales to the respondents.

8. Considering all the above facts, I am of the considered opinion that the impugned order has been passed in total non application of mind, simply confirming the show cause notice, as if the formulation is covered under the notification dated 11.07.2006. When a detailed objection has been filed to the show cause notice, it is the duty cast upon the respondents to consider the same and pass the order by giving reasons for arriving at the conclusion that, both the formulations are one and the same. That apart, before passing the order no opportunity was given to the petitioner, thereby violating principal of natural justice.

9. In the above circumstances, without going into the merits of the case, I am inclined to set aside the impugned order passed by the second respondent, and the matter is remanded to the second respondent, the second respondent is directed to conduct a fresh enquiry by giving an opportunity of hearing to the petitioner and to submit his objection and pass a reasoned order on merits and in accordance with law. The petitioner is directed to submit a fresh objection within a period of four weeks from the date of receipt of the copy of this order, thereafter, the second respondent is directed to complete the enquiry and pass order within a period of four weeks.

10. With the above directions, this writ petition is disposed of. No costs.

Sd/-
Assistant Registrar(CS VI)

//True Copy//

Sub Assistant Registrar

mrp

To

1. The Secretary,
Union of India,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
Shastri Bhavan, New Delhi 110 001.
2. National Pharmaceutical Pricing Authority,
Ministry of Chemicals & Fertilizers,
5th/3rd floor, YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi -110 001.
Rep. by its Director

+2cc to Mr.T.D.Selvan Babu, Advocate, S.R.No.88378

+1cc to Mr.G.Karthekeyan, SCGSC, S.R.No.88082

W.P.No.20553 of 2009

PVS (CO)
CS/03/02/2020

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