
(2013) 08 BOM CK 0206
In the Bombay High Court
Case No : Writ Petition No. 299 of 2013

Jenburkt Pharmaceuticals Limited

APPELLANT

Vs

Union of India and Another

RESPONDENT

Date of Decision : 08-08-2013

Acts Referred:

Citation : (2014) 2 ABR 216

Hon'ble Judges : S.J. Vazifdar, J;M.S. Sonak, J

Bench : Division Bench

Advocate : Arshad Hidayatullah and Mr. Ricab Chand, Levi Rubens, Mr. Ketan Dave and Mr. Yohaana Rubens, for the Appellant; G.R. Sharma and Mr. D.P. Singh and Mr. A.K. Shah, Director, N.P.P.A., for the Respondent

Judgement

S.J. Vazifdar, J.—Rule. Rule is made returnable forthwith and the Writ Petition is heard finally. Respondent No. 2 is the National Pharmaceutical Pricing Authority (hereinafter referred to as the "NPPA"). The petitioner has challenged communications dated 22nd June, 2012, 26th September, 2012 and 6th December, 2012, addressed by the NPPA and a demand notice dated 29th January, 2013 calling upon the petitioner to deposit a sum of Rs. 16,45,16,431/-.

2. The petitioner challenged the above communication and orders on various grounds, including on merits. We did not permit Mr. Hidayatullah to address us on the merits of the case as we find that the NPPA was not entitled to exercise the power of review. The case in short is this.

(A) Prior to the impugned action, a show cause notice dated 16th March, 2010, read with a further notice dated 20th March, 2011, was issued to the petitioner alleging, inter-alia, that the petitioner had sold its formulation in excess of the price stipulated in SO 616(E) dated 29th June, 2001. The petitioner, in its reply, contended that SO 616(E) did not apply in its case and proceeded on the basis that SO 372(E) dated 30th January, 2009, would apply to its formulations. The NPPA, by an order dated 20th December, 2011, stated that after examining the matter in detail, it had been decided to fix the petitioner's liability for over-

charging only after the issue and implementation of SO 372(E) dated 30th January, 2009. The NPPA, therefore, called upon the petitioner to furnish details of the formulation manufactured or marketed after 30th January, 2009 i.e. the date of SO 372(E). Pursuant thereto, the manufacturer of the formulation, in fact, paid the said amount. The matter, including the issue as to whether SO 616(E) applied to the petitioner's case or not, stood concluded by virtue of the order dated 20th December, 2011.

(B). The impugned action sought to re-open the entire matter. As will be indicated later, the communication expressly states that the impugned action is in supersession of the earlier order dated 20th December, 2011, and that by the impugned action, the NPPA had rejected the earlier order. It was alleged that the earlier order was passed through inadvertence on the part of the previous officer without considering the necessary aspects.

The power of review is contained in paragraph 22 of the Drug (Price Control) Order, 1995 (hereinafter referred to as the "DPCO"). It is the Central Government that is entitled to entertain an application for a review of a Notification or order. The Central Government has, in fact, by an order dated 4th September, 1997, permitted the NPPA to exercise the functions of the Central Government in respect of various paragraphs of the DPCO. However, paragraph 22 i.e. the power of review is not mentioned in this order. Indeed, the Government is not entitled to direct its powers under paragraph 22 to be exercisable by any officer or authority, including the NPPA. Under paragraph 26, the Government may, by notification in the Official Gazette, direct that all or any of the powers conferred upon it by the DPCO "other than those contained in paragraph 22 ..." shall be exercisable by such officer or authority. The petitioner is, therefore, entitled to succeed on this ground alone.

4. In or about August, 2005, the petitioner started manufacturing Nervijen multi-vitamin injections and continued to do so till February, 2009. The last batch was manufactured in December, 2008.

5. Respondent No. 1, in exercise of powers under the Drugs (Price Control) Order, 1995, issued SO 616(E) which fixed the price of the formulations mentioned therein. The relevant entry reads as under:-

According to the petitioner, this SO does not apply to it as the formulation marketed by it does not conform to the above specifications. The petitioner's formulation is as under:-

Mr. Hidayatullah, the learned senior counsel appearing on behalf of the petitioners stated that the drug methyl cobalamine was approved only on 13th February, 2002, whereas this SO is of 29th June, 2001. The Central Drugs Standard Control Organization lists methyl cobalamine as a drug approved on 13th February, 2002 (Exhibit-BB to the petition)

Mr. Hidayatullah also relied upon Annexure-A to the rejoinder which is a

compendium of the prices of scheduled drugs fixed/revised by NPPA as on 31st March, 2011, to contend that the respondents themselves considered the petitioners formulation to be different from cyno cobalamine which is a drug mentioned in column 3 of SO 616(E). Entry No. 222 of the compendium refers to multi-vitamin injection containing the following drugs.

222. Multi-Vitamin Injection

Each 2ml contains

Thiamine HC1-100mg

Pyridoxine HC1-00 mg

Niacinamide-100 mg

D-Panthenol-50 mg

Cyanocobalamin-1000 mcg.

The relevant SO is stated to be 616 (E).

On the other hand, entry No. 243 of the same Compendium also refers to multi-vitamin injection but containing the following drugs:-

243. Multi-Vitamin Injection

Each 2ml contains

Thiamine Hydrochloride-100 mg

Pyridoxine Hydrochloride-100 mg

Mecobalamin-1500 mcg

Nicotinamide-100 mg

D-Panthenol-50 mg

Benzyl Alcohol-2% v/v (as preservative)

The relevant SO number of this formation is stated to be SO No. 869 (E). Moreover, the Compendium refers to the petitioner as the formulator of this multi-vitamin injection at entry No. 243. The petitioner's name is not mentioned as the formulator in the table against entry No. 222. The petitioner, therefore, submits that even according to the respondents it was not covered by SO No. 616 (E). The impugned action, however, is on the basis that the petitioner's formulation is covered by SO No. 616(E).

6. On 30th January, 2009, SO 372 (E) was issued. It expressly stated that NPPA notified that formulations/compositions not covered in the table of standing orders issued by it that have any standard drugs as one of their ingredients, shall be subject to the price ceiling mentioned in the respective serial number of the respective notification, as the case may be, unless the manufacturer has

subsequently got a specific price fixed by the NPPA for that formulation/ composition.

The petitioner proceeds on the basis that its case would be covered with effect from the date of this SO as one of the ingredients of its formulation is a scheduled drug. The petitioner has, in any event, not manufactured or marketed its said product after 30th January, 2009 i.e. the date of SO No. 372.

7. The NPPA issued a notice dated 16th March, 2010, calling upon the petitioner to furnish reasons for non-compliance with the ceiling price in respect of its said product. The notice alleged that the petitioner had not followed the price schedule fixed by the NPPA in respect of its said formulation. The notice referred to SO No. 616 (E) dated 29th June, 2001 and SO 372 (E) dated 30th January, 2009.

The said show cause notice dated 16th March, 2010, was followed by a further notice dated 21st March, 2011. This letter was in furtherance of the show cause notice dated 16th March, 2010. This letter also alleged that the petitioner had been selling the said product at prices higher than the ceiling prices notified in SO 616(E). The letter once again called upon the petitioner to furnish details in respect of the sales of the said product. It is alleged that the petitioner had charged Rs. 11,81,36,058/- during the period from August, 2005 to July, 2010 in excess from the consumers in respect of the said product which had been manufactured by M/s. Star Drugs & Research Laboratories Limited and marketed by the petitioner. The petitioner was, therefore, called upon to show cause why the said excess amount together with interest ought not to be recovered from it.

8. It is important, therefore, to note that both the show cause notices dated 16th March, 2010 and 21st March, 2011, alleged that the petitioner had sold the products at prices higher than those stipulated in SO 616(E).

9. The petitioner's formulation was covered by SO 869(E) dated 16th April, 2010. However, by that time, the petitioner had stopped marketing the same.

10. The petitioner was awarded a personal hearing by respondent No. 2-NPPA on 7th September, 2011. NPPA passed an order dated 20th December, 2011 in respect of the said show cause notices dated 16th March, 2010 and 21st March, 2011. The relevant part of the notice reads as under:-

I am to refer the correspondence resting with your letter no. SM-C/2011-12/00620 dated 21.09.2011 on the above subject furnishing your written submissions in pursuance of Personal Hearing held on 07.09.2011 with Chairman NPPA. The matter has been examined in detail and it has been decided to fix the liability of overcharging in r/o. above formulation for the period only after issue and implementation of the notifications S.O. No. 372 (E) dated 30.01.2009.

You are, therefore, once again directed to submit the batch-wise quantitative details in respect of the said formulation sold either by the manufacturing or marketing company after implementation of S.O. No. 372(E) dated 30.01.2009

duly certified by an independent Chartered Accountant/Cost Accountant in the following format with in 15 days from the receipt of this letter to NPPA positively failing which NPPA shall be constrained to initials appropriate section under the provisions of DPCO as & EC Act, 1955 on the basis of data available with us.

[emphasis supplied]

The order dated 20th December, 2011, states that the matter had been examined "in detail". It further states that it had been decided to fix the liability of over-charging in respect of the said formulation "for a period only after issue and implementation of the Notification SO 372 (E) dated 30.01.2009". In other words, it was not the respondent's case that the manufacture and sale of the said product by the petitioner prior to the Notification No. 372(E) dated 30th January, 2009 violated any of the SOs, including SO 616 (E) dated 29th June, 2001.

11. The first paragraph of the order refers to the petitioner's letter dated 21st September, 2011. A copy thereof was furnished to us. The copy furnished to us is the one addressed by the manufacturer M/s. Star Drugs & Research Laboratories Limited. It is important to note that the letter was in reply to the show cause notice dated 21st March, 2011 which, as we noted earlier, was in furtherance of the show cause notice dated 16th March, 2010. Apart from dealing with the case on merits, it was expressly contended that SO 616 (E) did not apply in the present case as it did not deal with the said product. For instance, in paragraph 4, it is stated that SO 616 (E) dated 29th June, 2001, does not cover the said formulation; that the cost of mecobalamin could not have been considered in SO 616 (E) as that drug was approved only on 13th February, 2002 and that the said product/formulation was not covered by SO 616 (E). This contention was obviously accepted by the said order. This is clear from the last sentence of the first paragraph quoted above in which it is held that the matter had been examined in detail and it had been decided to fix the liability of over-charging in respect of the formulation "for the period only after issue and implementation of the Notification SO 372(E) dated 30.01.2009". In other words, it had been held in favour of the petitioner that there was no over-charging in respect of the said formulation for the period prior to SO 372(E). Accordingly, the petitioner's case that SO 616 (E) was not applicable to the formulation was accepted by the NPPA.

12. The excess amount as per the said order dated 20th December, 2011 was paid on 9th March, 2012, by the manufacturer.

13. The matter as regards the said show cause notice dated 16th March, 2010, read with the further letter dated 21st March, 2011, thus stood concluded. The present dispute started thereafter.

15(A). The impugned action commenced with the issuance by respondent No. 2, of a letter dated 22nd June, 2012. The very first paragraph states that the written submissions of the petitioner and the manufacturer including the said letter dated 21st September, 2011, had been examined and it had been found

that the formulation had been sold at a price, ten times the price notified in SO 616(E) dated 29th June, 2011. It was also contended that the petitioner's product was similar to the composition mentioned in SO 616 (E) and that the use of one extra ingredient did not put the formulation out of price control; that the footnote thereto required the manufacturer to approach the NPPA for approval/fixation of specific price for different packing material for any special feature claimed; that the validity of the notes had been upheld by various High Courts and the Supreme Court. It is important to note that in paragraph 9, it is expressly stated that the said order dated 20th December, 2011, passed by respondent No. 2 in respect of the earlier show cause notice had been superseded (wrongly typed as "suppression"). It was stated that in supersession of the said order dated 29th December, 2011, the petitioner was required to furnish the details of the production and sale of the said product from the date of the SO 616 (E) to date.

(B) Respondent No. 2 by a further letter dated 26th September, 2012, stated as under:-

(iv) Before communicating NPPA's decision vide letter dated 20.12.2011, duly approved by the then Member Secretary, the matter was examined by the Technical Officer of NPPA as a normal practice. There is no separate Technical Report on the subject which was approved by NPPA.

(v) While examining the contents of M/s. Star Drugs & Research Lab's letter dated 09.03.2012. NPPA observed that certain issues were not inadvertently considered before conveying the decision vide aforesaid letter dated 20.12.2011. The matter was reviewed and accordingly, another letter of even number dated 22.08.2012 in supersession of the earlier letter dated 20.12.2011 was issued with approval of the present Chairman, NPPA and then Member Secretary, NPPA who also approved the earlier letter dated 20.12.2011.

(emphasis supplied)

(C) These letters were followed by a show cause notice dated 26th September, 2012. By the impugned communication dated 6th December, 2012, the NPPA went into the entire matter afresh and held that the petitioner was liable to deposit the amount over-charged in respect of the said product under SO 616 (E) for all the production and sales made after the date of SO 616 (E) i.e. 29th June, 2011. The petitioner was called upon to furnish the details of the sales.

15. The petitioner, by a letter dated 9th January, 2012, dealt with all the contentions on merits, in detail. For the purpose of this judgment, however, it is important to note that in paragraphs 3.1, 3.2 and 3.3 the petitioner expressly contended that the impugned communications were illegal, unlawful and without jurisdiction in view of the fact that the matter had already attained finality by virtue of the said order dated 20th December, 2011 which dealt with the earlier show cause notice and that the NPPA did not have the power of reviewing the same. The power of review was only with the Central Government.

16. This Writ Petition was filed on 24th January, 2013. Thereafter, by a letter dated 29th January, 2013, the respondents called upon the petitioner to deposit a sum of Rs. 16,45,16,431/- within fifteen days.

17. Mr. Hidayatullah sought to argue the matter on merits. He invited to this Court to consider the merits of the case once and for all. We, however, did not permit him to address us on merits as we found the preliminary issue raised by him viz. that NPPA did not have jurisdiction to supersede the order dated 20th December, 2011 and to review the same, to be well founded. The petitioner is, therefore, entitled to succeed on that ground alone.

18. It was not disputed that the impugned communications and orders commencing with the letter dated 22nd June, 2012 and ending with the letter dated 29th January, 2013, raised the same issues as were raised in the show cause notice dated 16th March, 2010 and 21st March, 2011. The main contention was that the product manufactured by the petitioner fell within the ambit of SO 616 which came into force on 29th June, 2001. Accordingly, the petitioner was liable to pay the amounts charged in excess of the price stipulated therein from the date of its manufacture viz. August, 2005. The petitioner by its replies to the said earlier show cause notice contended otherwise. The petitioner and the manufacturer submitted their replies and were heard by the NPPA. It is only thereafter that the NPPA passed the said order dated 20th December, 2011. There is nothing in the order that indicates that there was any inadvertence on the part of the earlier officers who passed the order. The officer who succeeded him does not explain in the impugned communication/order as to the nature of the alleged inadvertence on the part of the earlier officer. The earlier order states that it was passed after the matter had been examined in detail. The impugned communication dated 26th September, 2012 also states in paragraph 4, reproduced by us earlier, that the earlier order dated 20th December, 2012, was duly approved by the then Member Secretary. The respondents were unable to explain why the matter was examined thereafter by a technical officer of the NPPA. Nor were they able to indicate what is alleged to be a normal practice viz. the examination of an order passed by a Director of NPPA by a technical officer subsequently.

19. It was not contended and indeed it could not be contended that in passing the impugned orders, the respondent No. 2 had, in effect, reviewed the earlier order dated 20th December, 2011. The impugned order, in fact, almost amounts to an exercise of appellate jurisdiction. Even assuming it was only a review, it would make no difference. As rightly contended by Mr. Hidayatullah, respondent No. 2 does not have the power of review. Paragraph 22 of the Drugs (Price Control) Order, 1995 reads as under:-

22. Power to review.-Any person aggrieved by any notification issued or order made under paragraphs 3, 5, 8, 9 or 10 may apply to the Government for a review of the notification or order within fifteen days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the

case may be, and the Government may make such order on the application as it may deem proper:

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer, importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government of which a review has been applied for.

20. The order dated 4th September, 1997, issued by the Ministry of Chemicals and Pharmaceuticals does not confer the power of review upon the NPPA. The order reads as under:-

MINISTRY OF CHEMICALS AND FERTILIZERS"

ORDER

New Delhi, the 4th September, 1997

S.O. 637(E).-In pursuance of Paragraph 26 of the Drug (Prices Control) Order, 1995, the Central Government hereby directs the National Pharmaceutical Pricing Authority established vide Government of India in the Ministry of Chemicals and Fertilizers Resolution No. 33/7/97-PI. 1 dated the 29th August, 1997, published in Part 1, Section (1) of the Gazette of India Extraordinary also to exercise the functions of the Central Government in respect of paragraphs 3, 4, 5, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18, 19, 20 and 21 of the said Order.

It will be noticed that the Government has not, by the said order, directed NPPA to exercise the functions of the Central Government in respect of paragraph 22 of the Drugs (Price Control) Order, 1995.

21. Regulation 26 does not entitle the Government to direct its powers under paragraph 22 to be exercisable by any officer or authority. Paragraph 26 reads as under:-

26. Delegation of powers.-The Government may, by notification in the Official Gazette, direct that all or any of the powers conferred upon it by this Order, other than those contained in paras 22, 23 and 25 shall, subject to such restrictions, exceptions and conditions, as may be specified in the direction, be exercisable also by such officer or authority as may be specified in the notification.

The NPPA is, therefore, not only not conferred with the power to review its own orders, but is expressly barred from doing so.

22. Mr. Sharma, the learned counsel appearing on behalf of the respondents was unable to indicate any other provision of law which entitled respondent No. 2 to exercise the power of review. The petitioner is, therefore, entitled to succeed on the ground alone. In the circumstances, Rule is made absolute in terms of prayer (a). There shall, however, be no order as to costs.