

Cipla Limited and Others Vs. Union of India and Others

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Court : Delhi

Decided On : Nov-24-2015

Judge : Badar Durrez Ahmed & Vibhu Bakhru

Appeal No. : W.P.(C).Nos. 4374, 4805, 4877, 4883, 4888, 4897, 4907, 4917-18, 4948, 4959, 4964-65, 4969, 4998-99, 5031, 5063, 5129-30, 5229-30, 5290, 5292, 5295, 5638, 5991, 6373, 7802 of 2013, 8566 of 2014 & CM Nos. 10106, 11985, 11079, 11089, 11107, 11988, 11125, 11139, 11141, 11176, 11204, 11211, 11214, 11986, 11227, 11281, 11285-86, 11346, 11409, 11542, 11544, 11734, 11736, 11845, 11848, 11854, 11066, 12467, 13196, 13927-28, 16587 of 2013, 19765 of 2014 & 21360-61, 22977, 24092-93 of 2015

Appellant : Cipla Limited and Others

Respondent : Union of India and Others

Judgement :

Badar Durrez Ahmed, J. (Oral)

1. We have heard the learned counsel for the parties on the writ petitions as well as on the pending applications. Initially, the grievance of the petitioners was with regard to the proviso to paragraph 13 (1), Proviso to paragraph 24(1) and part of paragraph 16(4) of the Drugs (Price Control) Order, 2013 (hereinafter referred to as DPCO, 2013'). There was also a challenge to the notification dated 26.06.2013.

2. The focus of the petitions was on the drugs manufactured prior to the date of the notification for which a new and lower ceiling price had been prescribed. In this connection, one of the counter-affidavits filed in WP(C) 4888/2013 (Micro Labs Limited and Another v. Union of India and Others) is relevant. The stand taken by the respondents was indicated in paragraph 53 thereof as under:-

53. It is submitted that the manufacturers are required to issue price lists in accordance with paragraph 24 of the DPCO, 2013. As aforementioned, in implementation of ceiling price fixed by the Government, no person can sell essential medicines at a price higher than the price mentioned in current price list or label whichever is less. It is submitted that manufacturers can do stickering, reprinting or labeling if they do desire to comply with the provisions of DPCO, 2013. However, for stocks manufactured prior to the issuance of the respective notifications there would be sufficient compliance if the manufacturers issue price list/revised price list and follow paragraph 24 of DPCO, 2013 towards that end. If for their own convenience or otherwise, manufacturers desire to restick/re-label to avoid any confusion, purported or conceived, the notification dated 26.06.2013, to allay the apprehensions of the manufacturers, was issued. (underlining added)

Paragraph 56 of the very same affidavit would also be relevant and the same reads as under:-

56. In view of the above, the manufacturers are required to issue price list in implementation of notified price in respect of stocks manufactured prenotification. In case the manufacturers choose to do relabeling, restickering they are also exempted from the provisions of excise as well as Legal Meteorology Act, 2009. The whole exercise is aimed to provide the essential medicines to the consumers at a reduced price. (underlining added)

3. On a plain reading of the said paragraphs, it is evident that the stand of the respondents is that if the manufacturers, for the stocks manufactured prior to the date of issuance of the respective notifications, issue price lists / revised price lists in terms of the notifications, then such manufacturers would be in sufficient compliance of DPCO, 2013, provided they follow the procedure given in paragraph 24 of DPCO, 2013. It is also indicated in the said counter-affidavit that if for their

own convenience, the manufacturers desire to restick/re-label the drugs in question, to avoid any confusion, the notification dated 26.06.2013 was issued to allay the apprehensions of the manufacturers. It is evident that relabeling of manufactured stocks prior to the date on which the notifications are issued, is not obligatory. What is necessary is that the pharmaceutical preparations be sold at the revised price or the labelled price, whichever is lower. This is also evident from paragraph 26 of the DPCO, 2013 which specifically provides as under:-

26. Control of sale prices of formulations.- No person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.
(underlining added)

4. We may also take note of the Supreme Court decision in the case of Glaxosmithkline Pharmaceuticals Limited v. Union of India: (2014) 2 SCC 753. In that case, one of the arguments put forth on behalf of the manufacturers concerning paragraph 15 of the DPCO, 1995 was that it was incumbent upon them to print the maximum retail price on the product and that too indelibly and that there was no provision for reprinting of the labels or of return of drugs once they leave the factory premises. The argument was that in such eventuality, the batches, which had been manufactured and stamped with old prices, could continue to be sold at those prices. We may note that paragraph 24(2) of DPCO, 2013 also requires the manufacturer of a scheduled formulation to display in indelible print mark on the label of the container of the formulation, the maximum retail price of that formulation based on the ceiling price notified in the official Gazette or ordered by the Government in this behalf. But, in the present case, the argument of the petitioners is not that they can continue to sell the formulation at the old price, but that they would not be in a position to recall or relabel the formulations although they are and have abided by the notification issued under DPCO, 2013 with regard to issuance of a price list in terms of the new notification.

5. It is pertinent to note that, in the context of the argument raised in the case before the Supreme Court, it was observed by the Supreme Court as under:-

47. The Senior Counsel for the manufacturer contends that under paragraph 15 of the 1995 DPCO, it is incumbent to print the maximum retail price on the product and that too indelibly. There is no provision for reprinting of the labels or of return of drugs once they leave the factory premises. Thus, the batches which have been manufactured and stamped with old prices can continue to be sold at those prices. We do not find any merit in the argument. The DPCO defines 'dealer', 'distributor', 'manufacturer', 'retailer' and 'wholesaler'. The provisions contained in paragraphs 3, 8, 9 and other relevant provisions clearly show that DPCO effectively covers the chain from manufacture of the bulk drug by the manufacturer to sale of formulation to consumer though there may be several persons in the distribution chain. The ultimate object of the DPCO is that there is no deception to a consumer and he is sold the formulation at a price not exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less. Logically it follows that there cannot be two prices at the end point of the distribution chain depending on the batch number. A consumer approaching a chemist/retailer can hardly be offered two prices for the very same product based only on the difference in batch numbers. Consumer must get the benefit of the notified price. That is the ultimate objective of DPCO. The batch number cannot override the benefit to which a consumer is entitled on price reduction of a formulation. A fair reading of DPCO leaves no manner of doubt that a formulation cannot be sold to the consumer at the higher price (for earlier batch numbers). In this view of the matter, we find merit in the submission of the learned Additional Solicitor General that the provisions of DPCO requires not just the end point sale to be at the notified price, but also every sale within the distribution chain must be at the notified price, if such sale is made after the date on which sale price is operative. (underlining added)

6. From the above extract, it is evident that the Supreme Court held that the ultimate object of the DPCO was that there should be no deception to a consumer and that he is sold the formulation at a price not exceeding the price specified in the current price list or the price indicated on the label of the container or pack thereof, whichever is less. It is further clear from this that there could be a situation during the period of transition, where the price list indicates a price different from that which has been indelibly marked on the container or pack in respect of

formulations manufactured just prior to the dates of the notifications. Whatever be the situation, this much is clear that the consumer cannot be charged a price higher than what is indicated in the current price list or what is marked on the container, whichever is less. We may also point out that the proviso to paragraph 24(1) of DPCO, 2013 requires a manufacturer to ensure that within a period of forty-five days of the date of the notification, the maximum retail price of the concerned formulation does not exceed the ceiling price (plus local taxes as applicable). But, paragraph 26 also makes it clear that no person, which includes the manufacturer, wholesaler, dealer and retailer, shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.

7. In this context, all the petitioners have stated that they issued the revised price list to all their distributors and retailers, as required under the new notifications. The learned counsel also state that all the manufacturers have done whatever they could do to ensure that the formulations are sold at the revised prices or the prices marked on the containers, whichever are lower.

8. It has also been brought to our notice that in most of the writ petitions, demand notices have been sent by the Director NPPA (National Pharmaceutical Pricing Authority) raising demands in respect of various formulations. One such demand notice is dated 02.07.2015 and is in connection with the scheduled formulation "Acivir 200 DT Tablet". For the sake of convenience, the said demand notice is reproduced herein below:-

F.No. 25(11)2013/Div.IV(OC-II)/NPPA

National Pharmaceutical Pricing Authority

Department of Pharmaceuticals

Ministry of Chemicals and Fertilizers

Government of India

5th /3rd Floor,

YMCA Cultural Centre Building,

No.1, Jai Singh Road,

New Delhi-110 001

Date: 02.07.2015

To

M/s Cipla Limited M/s Cipla Limited

Mumbai Central, Kumrek, Rangpo,

Mumbai - 400 008, Sikkim-737 132,

(MAHARASHTRA) (SIKKIM)

DEMAND NOTICE

Sub: DPCO, 2013: Manufacturing/marketing of scheduled formulation 'Acivir 200 DT Tablet' at a price higher than notified price- reg.

Sir,

This has reference, to this office notice dated 30.09.2013 followed by reminder-dated 27.08.2014 for your having manufactured/sold the above referred scheduled formulation 'Acivir 200 DT Tablet' at a price of Rs.88.50/- per strip of 10 tablets as against the ceiling price of Rs.7.30 per tablet notified vide S.O.No.1590(E) dated 14.06.2013 (i.e. Rs.73.00 for 10's tabs on pro-rata basis). The company was directed to furnish the quantitative details in respect of the subject formulation duly certified by a Chartered/Cost Accountant in the format given in the said notice.

2. Due to non-receipt of the quantitative details from the company, a Show Cause Notice was issued on 21.04.2015 based on Pharmatrac data from the period June, 2013.to February, 2015. However, NPPA has not received any response from the company after the issue of reminder till date. The said formulation was available in the market on 09th August 2013, well after the expiry of 45 days from the date of

notification of the ceiling price notified by the Govt./NPPA.

3. The OPCO, 2013 has, been issued by the Central Government in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 and any contravention at the provisions of the DPCO, 2013 is punishable in accordance with the provisions of the Essential Commodities Act, 1955.

4. It is pertinent to state here that under the DPCO, 2013, once the price notification is issued it takes immediate effect. In this connection, your attention is invited to the judgment of the Hon'ble Supreme Court dated 09.12.2013 in M/s Glaxo Stithkline vs. UOI reported in (2014) SCC VOL.II 753, wherein it was inter-alia, held that once the price notification is gazetted, it takes effect immediately in sale of all available stock in market. From the above judgment it is also clear that the companies should not sell the formulations at a price higher than the notified selling price or the label of pack whichever is less after the date of notification. As the said formulation was purchased from the market at higher MRP well after the issuance of notification for which the company is liable to deposit the overcharged amount in respect of the quantity sold during this period under the provisions of DPCO, 2013 and Essential Commodities Act, 1955.

5. Based on the available information, the overcharged amount was estimated at Rs 1,09,74,235/- (Rupees One Crore Nine Lakh Seventy Four Thousand Two Hundred And Thirty Five Only) for the period from June, 2013 to March, 2015 and the same is required to be deposited with the Government of India. In addition, the company is also liable to pay interest @15% on overcharged amount which amounts to Rs 21,99,307/- upto 20.07.2015.

6. Thus, the company is liable to deposit the total amount of Rs. 1,31,73,541/- (Rupees One Crore Thirty One Lakh Seventy Three Thousand Five Hundred And Forty One Only) consisting of overcharged amount along with interest thereon calculated upto 20.07.2015 as per Annexure-I by way of demand draft drawn in favour of The Pay and Account Officer (NPPA), Deptt. of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi within 15 days from the date of issue of this letter positively.

7. The amount indicated above is provisional and is without prejudice to any further amount that may be assessed by this office under the provisions of DPCO, 2013 based on further information. It may be noted that the company is liable to pay interest @ 15% per annum on the overcharged amount till the date of its actual deposit in the Government Account.

8. The company is also required to submit control sample of the referred formulation and price list in Form-V in support of compliance of the notified ceiling price.

9. This demand notice may not be treated as a coercive action taken by NPPA against the company. It is only an advance intimation to the company towards the liability likely to arise after the court case reaches its finality.

10. Kindly acknowledge the receipt.

Yours faithfully,

Sd/-

(A.K.KHURANA)

Director

Encl: As above

Copy to: The SDC, Maharashtra and SDC, Sikkim. (underlining added)

9. From the above notice, it can be seen that the demand that is sought to be raised is purely provisional and it has also been stated in paragraph 9 that the demand notice may not be treated as a coercive action taken by the NPPA against the company. It is only an advance intimation to the company towards the liability likely to arise after the court case (meaning thereby the present petitions) reaches its finality. But the matter did not stop here. Another set of demand notices have been issued and by way of sample, we can take the demand notice with regard to Cipladline Solution, which was issued on 17.07.2015 and the same reads as under:-

F.No. 25(63)2013/Div.IV(OC-II)/NPPA
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

5th /3rd Floor,
YMCA Cultural Centre
Building, No.1, Jai Singh Road,
New Delhi-110 001
Date: 17.07.2015

To

M/s Jeps Pharmaceuticals M/s Cipla Limited

Rampur Ghat, Mumbai Central,

Paonta Sahib, Mumbai-400 008

Distt. Sirmour-173025

(HIMACHAL PRADESH) (MAHARASHTRA)

DEMAND NOTICE

Sub: DPCO, 2013: Manufacturing / marketing of scheduled formulation Cipladine Solution at a price higher than notified price- reg.

Sir,

This has reference to this office notice dated 24.12.2013 followed by reminder dated 27.02,2014 and 09.06.2014 for your having manufactured/sold the above referred scheduled formulation 'Cipladine Solution' at a price of Rs.99.50/- for 100 ml. plastic bottle as against the ceiling price. of Rs.0.39 per ml notified vide S.O.No.1651(E) dated 14.06.2013(i.e. Rs.39.00 for 100 ml. on pro-rata basis). The Companies were directed to furnish the quantitative details in respect of the subject formulation duly certified by a Chartered / Cost Accountant in the format given in the said notice.

2. Due to non-receipt of the quantitative details from the companies, a Show Cause Notice was issued to them based on Pharmatrac data from the period June, 2013 to December, 2014. However, NPPA has not received any response from the company till date.

3. The DPCO, 2013 has been issued by the Central Government in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 and any contravention of the provisions of the DPCO, 2013 is punishable in accordance with the provisions of the Essential Commodities Act, 1955.

4. It is pertinent to state here that under the DPCO, 2013, once the price notification is issued it takes immediate effect. In this connection, your attention is invited to the judgment of the Hon'ble Supreme Court dated 09.12.2013 in M/s Glaxo Stithkline vs. UOI reported in (2014) SCC VOL.II 753, wherein it was inter-alia, held that once the price notification is gazetted, it takes effect immediately in sale of all available stock in market. From the above judgment it is also clear that the companies should not sell the formulations at a price higher than the notified selling price or the label of pack whichever is less after the date of notification. As the said formulation was purchased from the market at higher MRP well after the issuance of notification for which the company is liable to deposit the overcharged amount in respect of the quantity sold during this period under the provisions of DPCO, 2013 and Essential Commodities Act, 1955.

5. Based on the available information, the overcharged amount was estimated at Rs.1,75,14,810/-(Rupees One Crore Seventy Five Lakh Fourteen Thousand Eight Hundred and Ten only) for the period from June, 2013 to May, 2015 and the same

is required to be deposited with the Government of India. In addition, the companies are also liable to pay interest @15% on overcharged amount which amounts to Rs.33,29,406/- upto 20.07.2015.

6. Thus, the company is liable to deposit the total amount of Rs.2,08 44,217/- (Rupees Two Crore Eight Lakh Forty Four Thousand Two Hundred and Seventen only) consisting of overcharged amount alongwith interest thereon calculated upto 20.07.2015 as per Annexure- I by way of demand draft drawn in favor of "The Pay and Account Officer (NPPA), Deptt. of Pharmaceuticals,. Ministry of Chemicals and Fertilizers, New Delhi" within 15 days from the date of issue of t6s letter positively.

7. The amount indicated above is provisional and is without prejudice to any further amount that may be assessed by this office under the provisions of DPCO, 2013 based on further information. It may be noted that the companies are liable to pay interest @ 15% per annum on the overcharged amount till the date of its actual deposit in the Government Account.

8. The companies are also required to submit control sample of the referred formulation and price list in Form-V in support of compliance of the notified ceiling price.

9. If the above amount is not deposited within the stipulated period alongwith the documentary evidences, the matter will be referred to Collector for recovery of the amount as arrears of land revenue under Essential Commodities Act, 1955 without any further correspondence with the company.

10. Kindly acknowledge receipt.

Yours faithfully,

Sd/

(A.P.S.S HNEY)

Director (OC-II)

End: As above

Copy to: The SDC, Himachal Pradesh and SDC, Maharashtra - with a request to insist the company to deposit the demanded overcharged amount alongwith interest thereon with this office within the stipulated time (underlining added)

10. From the above extract, it is clear that the notice is not just a notice indicating a provisional demand but, the manufacturer has been required to deposit the amount demanded within the stipulated period along with documentary evidence otherwise the matter would be referred to the collector for recovery of the amount as arrears of land revenue under the Essential Commodities Act, 1955 without any further correspondence with the company. Similar demand notices have been issued to the other petitioners as well.

11. The learned counsel for the respondents submit that the said demand notices may be treated as show cause notices. We direct accordingly. The petitioners would, therefore, be entitled to file their replies to the said show cause notices within four weeks from today. The show cause notices shall be disposed of in accordance with law after considering the replies submitted by the petitioners as also after granting an opportunity of personal hearing to the petitioners in their individual cases. The same shall be disposed of in accordance with the observations made in this order as also the portions referred to in this order pertaining to the observations of the Supreme Court in Glaxosmithkline Pharmaceuticals Limited (supra). No coercive action shall be taken by the respondents till the disposal of the show cause notices.

12. In the view that we have taken in the backdrop of the directions given above, we do not deem it necessary to go into the question with regard to the constitutional validity of the provisions which have been challenged in these petitions. All the pending applications and the writ petitions stand disposed of.

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