* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% **Judgment reserved on: 01 September 2022**
Judgment pronounced on: 22 September 2022

\+ W.P.(C) 7946/2018, CM APPL. 30490/2018 (Stay)

BHARAT SERUMS AND VACCINES LIMITED ..... Petitioner

Through: Mr. Rohan Shah, Advocate

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Kirtiman Singh, CGSC and Ms. Srirupa Nag, Advocate for UOI

AND

\+ W.P.(C) 8190/2018, CM APPL. 31389/2018 (Stay)

BHARAT SERUMS AND VACCINES LIMITED ..... Petitioner

Through: Mr. Rohan Shah, Advocate

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Mr. Kirtiman Singh, CGSC and Ms. Srirupa Nag, Advocate for UOI

AND

\+ W.P.(C) 9090/2020, CM APPLs. 29370/2020, 9966/2022

BARD HEALTHCARE INDIA PRIVATE LIMITED THROUGH ITS AUTHORIZED SIGNATORY NITIN SHARMA ..... Petitioner

Through: Mr. Amit Sibal, Sr. Adv. with Ms. Krishna Sarma, Mr. Jayakrishnan K.R, Mr. Navnit Kumar and Ms. Archita Phookun, Advs.

versus

UNION OF INDIA THROUGH SECRETARY MINISTRY OF CHEMICALS AND FERTILIZERS & ORS. ..... Respondents

Through: Mr. Anurag Ahluwalia, CGSC with Mr. Danish Khan, Adv. for R-1 to 3.

CORAM:
HON'BLE MR. JUSTICE YASHWANT VARMA

J U D G M E N T

A. INTRODUCTION

1. These three writ petitions which revolve around Para 20 of the **Drugs (Price Control) Order, 2013**[1] assail demand notices issued by the respondent **National Pharmaceutical Pricing Authority**[2] holding the petitioners guilty of overcharging and thus liable to deposit the overcharged amount together with interest thereon. **Bharat Serums** the petitioner in W.P.(C) 7946/2018 and 8190/2018 challenges the demand notices dated 26 June 2018 and 05 July 2018. The two demand notices relate to non-scheduled formulations named Histoglob and U-Tryp. **Bard** the petitioner in W.P.(C) 9090/2020 has challenged identical demand notices dated 07 November 2019 and 22 October 2020 in respect of 82 medical devices which were produced and distributed by the said petitioner.

2. Insofar as **Bharat Serums** is concerned, the respondents have held it to be in violation of Para 20 with respect to the sale and distribution of Histoglob for the period February 2014 to July 2018. The allegation of

[1] 2013 DPCO
[2] NPPA

overcharging in respect of U-Tryp covers the period May 2015 to July 2018. Insofar as **Bard** is concerned, the respondents allege that medical devices were overcharged during the period January 2015 to January 2018.

3. In order to appreciate the issues which arise, it would, at the outset, be apposite to advert to the provisions of Para 20 which reads thus: -

> **"20. Monitoring the prices of non-scheduled formulations.–**(1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten per cent of maximum retail price during preceding twelve months and where the increase is beyond ten per cent of maximum retail price, it shall reduce the same to the level of ten per cent of maximum retail price for next twelve months.
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> (2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty."

4. **Bharat Serums** has been found to have overcharged and thus liable for penal action under Para 20 in respect of the two non-scheduled formulations noticed above. It asserts that in the period under scrutiny, it had not overcharged prices and had merely rounded off the price of its drug. Insofar as **Bard** is concerned, it has taken the stand that the overcharging of medical devices occurred on account of a lack of clarity in respect of the format in which price disclosures were to be made and that the overcharging was neither deliberate nor intentional. Both the writ petitioners have also challenged the interpretation accorded to Para 20 by the respondents and the consequential quantification of overcharging by NPPA. Bard has also questioned the levy of interest asserting that it would be liable to pay the same on the overcharged amount only from the date of the demand being raised as opposed to the date when the overpricing

occurred.

5. Both the writ petitioners assail the correctness of the view taken by the respondents that in case a manufacturer is found to have overcharged and thus acted in breach of Para 20, it would stand denuded of the right to claim a periodic increase which is envisaged under the said provision of the 2013 DPCO. As would be evident from a reading of Para 20 of the 2013 DPCO, a manufacturer of a non-scheduled formulation is entitled to increase the **Maximum Retail Price**[3] of a drug provided that such increase does not exceed 10% of the MRP which held the field in the preceding twelve months. The said provision further stipulates that when a manufacturer transgresses the maximum limit of 10%, it shall be liable to reduce the price of the drug to the level which prevailed in the preceding twelve months and maintain it at that level for the next twelve months. Additionally, and in terms of Para 20(2), in case a manufacturer is found to have overcharged and violated the prescriptions contained in Para 20(1), it is liable to deposit the overcharged amount along with interest thereon from the date of increase in price.

6. The respondents while dealing with the issue of overcharging have essentially taken the position that once a manufacturer is found to have violated the restrictions placed in Para 20, it would become disentitled to claim the 10% annual increase till such time that the manufacturer reduces the MRP of the non-scheduled formulation to bring it within the band of the permissible MRP and hold the same for the next twelve months. Dealing

[3] MRP

with the case of **Bharat Serums**, the NPPA in its impugned order of 26 June 2018, has recorded the following conclusions: -

> "4. Your company has submitted photocopy of CA certified quantitative data for the formulation mentioning quantity manufactured / sold for the period from April 2013 to Jan 2018 of above referred formulation. From data submitted it is seen that the company has increased the MRP of the formulation from Rs.82.50/- to Rs.91/- from batch No.A07415001 manufactured in Feb. 2015 which resulted into increase of MRP by more than 10% within a period of twelve months in contravention to provisions of Para 20 of DPCO 2013.
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> 5. The Company's contention that for calculating overcharging amount NPPA should consider 10% increase year on year basis is not correct. As per provisions of Para 20 (1) of DPCO 2013, "no manufacturer increases the maximum retail price of a drug more than 10% of maximum retail price during preceding twelve months and where the increase is beyond 10% of MRP, it shall reduce the same to the level of 10% of MRP for next twelve months. In view of the same, 10% increase is not permissible in respect of above said formulation to the Company year on year basis until the Company shall reduce the MRP of said formulation to the level of 10% of MRP for next twelve months (i.e. reduce the MRP to Rs. 90.75).
>
> 6. On the basis of photocopy of CA certified quantitative data for production/ sales submitted by company, it is found that the company has overcharged Rs.1,70,85,024/- (Rupees One Crore Seventy Lakh Eighty Five Thousand and Twenty Four only) in respect of above said formulation.
>
> 7. In addition, the company is also liable to pay interest of Rs. 34,twelve,743/- (Rupees Thirty Four Lakh Twelve Thousand Seven Hundred and Forty Three only) @ 15% per annum on the overcharged amount under Section 7A of Essential Commodities Act, 1955 calculated up to 31.07.2018."

Similar reasons were assigned for holding **Bharat Serums** having violated Para 20 in respect of U-Tryp as would be evident from the following extracts of the order dated 05 July 2018 which are extracted hereinbelow: -

"4.Your company has submitted CA certified quantitative data for the formulation mentioning quantity manufactured / sold for the period from July 2013 to Feb 2018 of above referred formulation. From data submitted it is seen that the company has revised the MRP of the formulation from Rs. 2453/- to Rs. 2450.13/ from batch No. A13315001 manufactured in March, 2015 and again revised it to Rs.2700 from batch No. A13315003 manufactured In May, 2015 which resulted into Increase of MRP by more than 10% within a period of twelve months in contravention to provisions of Para 20 of DPCO 2013.

5.On the basis of CA certified quantitative data for production/sales submitted by company, it is found that the company has overcharged Rs.4,11,65,841/ (Rupees Four Crore Eleven Lakh Sixty Five Thousand Eight Hundred and Forty Oneonly) in respect of above said formulation.

6. In addition, the company is also liable to pay interest of Rs. 69,43,968/ (Rupees Sixty Nine Lakh Forty Three Thousand Nine Hundred and Sixty Eight only) 15% per annum on the overcharged amount under Section 7A of Essential Commodities Act, 1955 calculated up to 31.07.2018.

7. Thus, the company is liable to deposit Rs. 4,81,09,809/- (Rs. Four Crore Eighty One Lakh Nine Thousand Eight Hundred and Nine only) being the overcharged amount alongwith interest thereon as per annexure enclosed, by way of demand draft in favour of "The Pay and Accounts Officer (NPPA), Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi" within 30 days from the date of issue of this letter. If the company fails to deposit the above amount within the stipulated time the matter will be referred to Collector to recover the overcharged amount, along with penalty and Interest thereon, as arrears of Land Revenue under the Essential Commodities Act, 1955, without further communication with the company."

7. In the case of **Bard**, the NPPA in its order of 22 October 2020 has observed as follows: -

"5. The submissions made by the company have been examined carefully and found not tenable in view of the following reasons:

(a) As per the provisions of Para 20 of the DPCO, 2013, no manufacturer can increase the maximum retail price of a 'drug' more than ten percent of maximum retail price in preceding twelve months and where the increase beyond ten percent of maximum retail price by whatsoever reasons, it shall reduce the same to the level of ten percent of maximum retail price and maintain the same for next twelve

months to become eligible for next increase in MRP as per prescribed limit.

Considering above provision, any subsequent increase in MRP after the default, whether increase is within permissible limit or not, would not be allowed until and unless MRP is revised downward within the prescribed limit of 10% and maintain the same for next twelve months. Thus, overcharging would be considered from the date of default to the date of compliance of this provision. Hence, contention of the company for subsequent notional increases is liable to be rejected.

As far as the judgment of M/s Obsurge is concerned, it is informed that the contention of the Company does not seem to be correct. It may be noted that the question of subsequent notional interest was not the substantial or direct question involved in the M/s Obsurge and therefore the Hon'ble High Court did not consider the same in its Order. The judgment of Hon'ble High Court of Delhi in the above referred case as stated in the **Para 13** is reproduced hereunder:

> *"I need not consider the above submission as in any case, the case of the Respondents is not that it has allowed the Petitioner the subsequent increase of MRP by exercising its power under Paragraph-20(2) of the DPCO, 2013. Therefore, the said question would not be relevant in the present case".*

(b) Interest on overcharged amount is levied under Para 20(2) of the DPCO, 2013 read with Section 7A of the Essential Commodities Act, 1955. The above provision provides mandatory levying of interest on overcharged amount from the date of default

As far as the applicability of the judgment of M/s T.C Healthcare is concerned, the Court judgment quoted by the company is not applicable in the instant case due to the different and explicit provisions of the DPCO, 2013 from DPCO, 1995. The above referred judgment is applicable for DPCO, 1995. Para 20(2) of the DPCO, 2013 read with Section 7A of the Essential Commodities Act, 1955 provides mandatory provision of levying interest on overcharged amount from the date of default. Therefore, the contention of the Company with respect to the applicability of M/s T.C Healthcare in this present case is misconstrued and inconceivable. Hence, the same is also liable to be rejected.

(c) As regard the contradiction in applicability of the provisions of Para 20(2) of the DPCO, 2013 and Section 7A of Essential Commodities Act, 1955 is concerned, it is informed that the interpretation suggested by the Company is misconceived and

untenable. There is no contradiction in the aforesaid provisions, in fact; they are complimentary to each other.

The rule of *Harmonious construction* shall be applicable in this situation. In other words, the Para 20(2) of DPCO, 2013 prescribes Overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

Section 7A of Essential Commodities Act, 1955 comes in the case of default committed by the company in non-compliance of the Orders issued under the provisions of Para 20(2) of DPCO, 2013. Therefore, both the provision are complimentary to each other and the contention of the company with regards to the contradiction of the provisions of DPCO, 2013 and Essential Commodities Act, 1955 is misconceived and untenable hence liable to be rejected.

(d) In view of the above, the computation of demand submitted by the company by taking subsequent notional increases is not acceptable and hence liable to be rejected.

Based on the above cited reasons, the contention of the company is not acceptable, hence rejected. It was obligatory for the company to follow the provision of Para 20 of the DPCO, 2013 in letter and spirit.

6. Thus, the demand of the Company is hereby increased to Rs. 7,60,01,777/- from Rs. 7,10,93,042/- on account of increased interest for the subsequent period up to 31.10.2020. Accordingly, the company is hereby directed to deposit the balance demand amount of Rs. 6,28,69,572/- (Rs. 7,60,01,777/- minus Rs. 1,31,32,205/- amount deposited) within 21 days of issue of the Order and comply with the direction given in the Demand Notice dated 7th November 2019 and subsequent letter dated twelveth February 2020 issued by this Office failing which the matter would be referred to Collector to recover the Government dues as Land Revenue without any further notice to the company **(Annexure-I)."**

B. FACTS - BARD

8. Before proceeding ahead, the following facts insofar as **Bard** is concerned may be briefly noticed. The case of **Bard** principally is that the respondents had failed to put in place a mechanism for disclosure of prices in respect of medical devices. It was argued that the 2013 DPCO as well as the attendant forms essentially dealt with pharmaceutical formulations. It

was also contended that up to 24 January 2017 the respondents had also not constructed a database for monitoring of prices of medical devices nor did the industry itself have a mechanism to report price data. On 24 January 2017 a proforma for price list (Form V) for drugs falling under Schedule II of the 2013 DPCO came to be notified. The aforesaid notification was followed by an **Office Memorandum**[4] of 12 May 2017 issued by the NPPA requiring medical device manufacturers to provide pricing data with respect to 19 medical devices. Para 3 of the said O.M. recorded that NPPA had developed a format for submission of data and had shared the same with medical device companies and associations. **Bard** contends that it was in terms of the aforesaid O.M. that NPPA for the first time lent clarity with respect to medical devices to which the 2013 DPCO would be applicable and sought pricing data from manufacturers.

9. On 13 February 2018, the petitioner was served with a show cause notice for alleged violation of Para 20 with respect to 89 products pertaining to the year 2015-2016. In response to the said show cause notice, the petitioner in terms of its letter of 5 March 2018 submitted a detailed reply along with statements setting out the batch wise import data of 89 products, sales details and corresponding MRPs' for the years 2013-14 to 2017-18. The petitioner while replying to the show cause notice also highlighted the fact that they were unaware that medical devices would stand covered under the definition of "*formulation"* and thus fall within the ambit of the 2013 DPCO. NPPA thereafter issued another notice dated 20 April 2018 seeking monthly and year wise data for the years 2013-14 to

[4] O.M.

2017-18 along with corresponding MRPs. The aforesaid information as sought was duly supplied by the petitioner in terms of its letter of 04 May 2018. NPPA thereafter on 07 November 2019 issued a demand notice holding the petitioner guilty of having overcharged and requiring it to deposit a sum of Rs. 6,92,69,798/- together with interest thereon.

10. The petitioner questioned the mechanism adopted by the respondents for calculation of the principal overcharged amount as well as the interpretation accorded to Para 20. In terms of its reply of 13 January 2020 it also raised issues with respect to the levy of interest on the principal overcharged amount. By its subsequent communication, the petitioner also sought an opportunity of personal hearing which was acceded to and granted by NPPA and the representatives of the petitioner were ultimately heard on 11 August 2020. On 24 August 2020, the petitioners deposited a sum of Rs. 1,31,32,205/- which according to them, represented the overcharged amount that they were liable to pay in terms of Para 20. The impugned order of 22 October 2020 thereafter came to be passed and the final overcharged amount was computed by NPPA to be Rs. 7,60,01,777/- along with interest up to 31 October 2020. It is thereafter that **Bard** approached this Court and filed the present writ petition.

C. FACTS IN BHARAT SERUMS

11. Turning then to the facts pertaining to **Bharat Serums,** the Court at the outset notes that the principal allegation of overcharging as laid by the respondents against this particular petitioner, essentially flows from its action of having rounded off the price of its drugs. It would be pertinent to note that the two non-scheduled formulations in respect of which an

allegation of overcharging came to be laid were Histoglob and U-Tryp. On 03 January 2017, the NPPA issued a preliminary notice observing that **Bharat Serums** had increased the MRP of Histoglob by more than 10% during the period September 2014 to September 2015. It accordingly called upon the said petitioner to respond and to submit the requisite records. The allegations in this preliminary notice were based on the respondents noting that while the price of Histoglob in September 2014 stood at Rs. 82.50/-, in September 2015 the same had come to be raised to Rs. 91/-. Another notice dated 09 January 2017, thereafter came to be issued in respect of U-Tryp. Here too the allegation leveled was of a MRP having breached the permissible 10% during the period January 2015 to December 2016. **Bharat Serums** while responding to the aforesaid notices pointed out that the MRP for Histoglob after factoring in the permissible 10% increase would have come to Rs. 90.75/-. It submitted that since it would have been impossible for a consumer to pay the aforesaid price, it had merely rounded it off to Rs. 91/-. It its written submissions, **Bharat Serums** has placed a comparative chart indicating the permissible price under the 2013 DPCO, the price actually charged by it and the permissible MRP which has been taken note of by NPPA in the impugned demand notice which came to be issued. The two charts relating to Histoglob and U-Tryp are set out hereinbelow: -

"Histoglob

Period	As per the DPCO 2013	Actual – as charged by the Petitioner	As per the impugned Demand Notice.
Feb 2014	82.50	82.50	82.50

Feb 2015	90.75	91.00	90.75
Feb 2016	99.825	100.00	90.75
Feb 2017	109.808	110.00	90.75
Feb 2018	120.788	110.00	90.75
Oct 2018	120.788	120.00	90.75
Dec 2019	132.858	131.00	90.75
			90.75 (For twelve months from the date of revising the MRP)

U-Tryp

Period	As per the DPCO 2013	Actual – as charged by the Petitioner	As per the impugned Demand Notice.
May 2015	2698.30	2700.00	2698.30
Sep 2016	2968.13	2967.00	2698.30
Dec 2017	3264.94	3234.00	2698.30
July 2019	3591.43	3541.00	2698.30
			2698.30 (For twelve months from the date of revising the MRP)"

12. On 11 May 2018, the respondents called upon **Bharat Serums** to furnish information with respect to batch wise production and sales in respect of U-Tryp. The aforesaid information was duly provided by **Bharat**

Serums along with an auditor's certificate. It provided to the respondents all details pertaining to production and sales for the period April 2013 to March 2018. On 20 April 2018 NPPA issued a show cause notice alleging that **Bharat Serums** had violated the provisions of Para 20 insofar as Histoglob was concerned, since it had sold the said drug at a price of Rs. 91/- against the permissible maximum retail price of Rs. 90.75/-. It accordingly called upon the said petitioner to show cause why it not be held to be liable to pay a sum of Rs. 2,04,59,109/- for the period July 2015 to March 2018 along with interest. It would be pertinent to note that no show cause notice is stated to have been issued to **Bharat Serums** insofar as U-Tryp is concerned.

13. Replying to the said show cause notice, **Bharat Serums** vide its letter of 22 May 2018 pointed out that during the period under scrutiny the petitioner had charged a MRP which was even lesser than what was permissible and it asserted that this would be evident from the MRP for Histoglob which was fixed between July 2014 and January 2015. It reiterated its original stand that it had never intended to overcharge or violate the provisions of Para 20 and that it had only rounded off the MRP bearing in mind the practical difficulties which would have been faced by consumers if they were asked to pay a retail price running into decimals. On 26 June 2018, the NPPA issued a demand notice calling upon **Bharat Serums** to pay a sum of Rs. 2,04,97,767/- towards the overcharging of Histoglob. A similar demand notice came to be issued in respect of U-Tryp with the respondents alleging that **Bharat Serums** would be liable to pay an aggregate sum of Rs. 4,81,09,809/-. It is these two demand notices,

which have been challenged by Bharat Serums in its two writ petitions. To complete the narration of facts, it may be additionally, noticed that this Court by its orders of 31 July 2018 and 06 August 2018 had placed the impugned demand notices in abeyance.

D. SUBMISSIONS OF BARD

14. Appearing for **Bard**, Mr. Sibal, learned senior counsel has addressed the following submissions. Mr. Sibal contended that the interpretation accorded by the respondents on Para 20 is not only erroneous but also contrary to the express language of that provision. Learned senior counsel contended that the manner in which the provisions of Para 20 have been interpreted and enforced by the respondents, would clearly amount to a rewriting of the provision itself. The aforenoted submissions were advanced in light of his contention that Para 20 nowhere envisages a forfeiture of the right of the manufacturer to claim a 10% increase over the MRP which may have prevailed in the preceding twelve months. Mr. Sibal submitted that the right to claim that periodical increase does not stand effaced or taken away merely because a manufacturer may have overcharged.

15. He further submitted that where a manufacturer increases the MRP beyond 10% of the price prevailing in the preceding year, Para 20 only empowers the respondents to recover the overcharged amount and to require the manufacturer to roll back the price of the drug at a level which was prevalent prior to the date of the infraction and to hold that price for the next twelve months. Learned senior counsel argued that Para 20 nowhere contemplates the rolled back price being frozen till such time as the infraction is cured. According to learned senior counsel, the respondents

have committed a patent error in interpreting Para 20 as mandating the revised price being liable to be maintained till such time as the overcharging is cured. According to Mr. Sibal, the view expressed by the respondents in the impugned order effectively amounts to a rescripting of Para 20 and the creation of a penalty which is not even envisaged therein.

16. Mr. Sibal submitted that Para 20 spells out the consequences which a manufacturer would have to face in case it breaches the 10% maximum permissible limit. It was urged that in such a situation the manufacturer becomes not only liable to deposit the overcharged amount, it is also obligated to deposit the said amount along with interest. It was his submission that once Para 20 had provided for the penal consequences which would ensue an act of overcharging, it was not permissible for the respondents to additionally introduce the concept of the rolled back price being maintained till the breach comes to be ultimately rectified.

17. It was then submitted that Para 20 essentially confers a power on the respondents to *"monitor"* the price of drugs and in case Para 20 were to be understood in the manner as the respondents have, it would essentially amount to the respondents being recognized to be invested with the power to fix the price of non-scheduled formulations. Stress was laid by Mr. Sibal on the admitted position that in terms of the 2013 DPCO, the respondents can fix the price of scheduled formulations only. Learned senior counsel contended that the direction requiring the petitioner to freeze the MRP at the level prevailing prior to the overcharging till such time as the contravention is rectified would in essence amount to fixing the price of non-scheduled formulations. That according to learned senior counsel

would be in clear violation of the express intent of the 2013 DPCO.

18. It was then submitted that as a result of the impugned demands, the petitioner has been held liable to revert to the price which was prevailing in the twelve months preceding the date of the contravention and to continue to hold the same for twelve months beyond the issuance of the orders by the respondents. It was in the aforesaid backdrop that learned counsel submitted that the action of the respondents has resulted in the petitioner being forced to keep the price of its drugs unchanged right from January 2015 to January 2018.

19. Turning then to the manner in which the overcharged amount has been calculated, learned senior counsel submitted that while computing the same, the respondents have proceeded on the basis that once a manufacturer is found to have breached the 10% annual increase which is permitted, it stands deprived of the right to seek a 10% annual increase which is otherwise contemplated and duly sanctioned under the first part of Para 20. Mr. Sibal would submit that once the manufacturer has held the price of the drug at the levels which were existing on the date of the infraction and for twelve months thereafter, any computation of overcharging must be calculated taking into consideration the periodic revision in the MRP which is permitted under Para 20.

20. In order to amplify the aforesaid submission, learned senior counsel has referred to the following illustration which forms part of the written submissions which were tendered: -

"S.No.	Period	Petitioner Price	Allowed MRP	Overcharge, if any
1.	01.04.2015-31.03.2016	INR 100	INR 100	No
2.	01.04.2016-31.03.2017	INR 125	INR 110	Yes – INR 15
3.	01.04.2017-31.03.2018	INR 125	INR 121	Yes – INR 4
4.	01.04.2018-31.03.2019	INR 125	INR 132	No
5.	01.04.2019-31.03.2020	INR 125	INR 145	No"

21. As would be evident from an analysis of the aforesaid illustration, **Bard** firstly asserts a right to periodically revise the MRP of a particular drug every twelve months. It is the assertion of the said petitioner that the price which may have been ultimately charged by it and in order to ascertain whether the 10% limit as prescribed under Para 20 was violated, must necessarily be considered in conjunction with the same. It was submitted that the respondents have incorrectly assumed that merely because a manufacturer may have overcharged in a particular block period, it would stand disentitled to any price revision. Mr. Sibal highlighted the fact that the respondents in the case of **Bard** have calculated the overcharged amount on the basis of a notionally reduced MRP for the entire period from January 2015 to January 2018. Learned senior counsel laid stress on the fact that while calculating the overcharged amount, **Bard** has been held liable for violations of Para 20 based on the price which was applicable in 2015 and without considering the 10% increase to which the petitioner was otherwise entitled as per Para 20.

22. Mr. Sibal while addressing submissions on the scope and ambit of Para 20 of the 2013 DPCO also placed reliance upon the following observations as entered by a learned Judge in **Obsurge Biotech Ltd. v. Union of India**[5]:-

> "8. The consequence of a manufacturer having increased the MRP and having obtained certain amounts because of the same from the consumers is in the sub paragraph-(2) of paragraph 20, wherein the manufacturer is being made liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the 'penalty'.
>
> 9. Clearly by denying the petitioner increase in the MRP which he is otherwise entitled to, would amount to a penalty being imposed even in paragraph 20 (1), which does not flow from a bare reading of the provision nor intended.
>
> 10. Paragraph 20(1) of the DPCO in no unambiguous terms provide that a manufacturer would be entitled to increase the MRP of the drug by a maximum of 10% of the MRP during the 'preceding' twelve months and incase the manufacturer is found to have increased the MRP beyond the limit of 10%, the Government would be entitled to direct reduction of the same to the level of 10% for the period of next twelve months from the date when the manufacturer became entitled to such increase.
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> 11. To put it differently and explaining it by an example, if the MRP of a drug is Rs. 100 for the period from 2013-14, the manufacturer would be entitled to increase the MRP of the drug to a maximum of Rs. 110 for the period 2014-15 and incase it is found that the manufacturer has increased the MRP beyond the ceiling limit, the Government can direct the manufacturer to reduce the MRP to the level of Rs. 110 for the period 2014-15 whereafter again, the manufacturer will be entitled to increase the MRP of the drug by a maximum of another 10% of Rs. 110."

23. Learned senior counsel apprises the Court that while the aforesaid judgment stands challenged in L.P.A No. 310/2020 in which its operation and effect has been placed in abeyance, the principles enunciated in that decision would persuade this Court to take a similar view insofar as Para 20 is concerned. Mr. Sibal then argued that the case of overcharge against the

[5] 2020 SCC OnLine Del 1744

petitioner is based on a demand notice of 07 November 2019. The demand was ultimately finalized in terms of the order of 22 October 2020. It was submitted that merely because the alleged infraction was noticed in 2019 and further action in terms of Para 20 initiated thereafter, it would be wholly illegal for the respondents to command the petitioner to revise the price of its medical devices for the block period commencing from the date of transgression and right up to the initiation proceedings under the 2013 DPCO. Learned senior counsel further submits that for the very same reasons the stand taken by the respondents of the petitioner being liable to hold the price of its medical devices at the revised levels for the twelve months post the initiation of that action is also liable to be quashed and set aside.

24. Turning then to the issue of interest payable on the principal overcharged amount, Mr. Sibal argued that the levy of interest from the date of overcharging is in clear violation of the provisions of the **Essential Commodities Act 1955**[6]**.** It was submitted that holding **Bard** liable to pay interest @ 15% from the date of contravention till November 2019 is clearly illegal. Learned senior counsel would contend that interest can be charged only from the date of default of payment of any amount that may be computed and demanded by the respondents. Learned senior counsel drew the attention of the Court to the provisions made in Section 7A of the Act to submit that a manufacturer becomes liable to pay interest only if it fails to pay an amount quantified in terms of an order that may be made under Section 3 and defaults in paying or complying with a consequential

[6] the Act

demand that may be raised. Reliance in this respect was placed on the decision rendered by the Allahabad High Court in **M/s T.C. Healthcare Pvt. Ltd. vs. Union of India**[7], where the following observations came to be made: -

> **"**The liability to pay interest has been specifically provided under Section 7-A of the Essential Commodities Act, 1955. Section 7-A(1) of the Essential Commodities Act, 1955 is quoted as below : -
>
> "7-A. Power of Central Government to recover certain amounts as arrears of land revenue [or as a public demand]. (1) Where any person, liable to -
>
> (a) pay any amount in pursuance of any order made under Section 3, or
>
> (b) deposit any amount to the credit of any Account or Fund constituted by or in pursuance of any order made under that section,
>
> makes any default in paying or depositing the whole or any part of such amount, the amount in respect of which such default has been made shall [whether such order was made before or after the commencement of the Essential Commodities (Amendment) Act, 1984, and whether the liability of such person to pay or deposit such amount arose before or after such commencement] be recoverable by Government together with simple interest due thereon computed at the rate of [fifteen per cent] per annum, from the date of such default to the date of recovery of such amount, as an arrear of land revenue [or as a public demand]."
>
> Section 7A of the Essential Commodities Act, 1955 contemplates recovery by Government with simple interest on the due amount in case any default is committed in payment by a person liable to pay any amount. The order has been passed in this case by respondent No. 2 directing for deposit of overcharge amount by orders dated 12th September, 2008 and 24th October, 2008. The said orders direct deposit of the said amount within fifteen days from issue of the letter failing which recovery proceedings under the provisions of the Essential Commodities Act, 1955 were to be initiated. The default of the petitioner to pay overcharge amount shall arise after fifteen days from issue of the order. The liability to pay simple interest shall arise after a default is

[7] 2010 SCC OnLine All 834

> committed as per Section 7A(1). Thus no interest could have been charged prior to issue of the order dated 12th September, 2008 and 24th October, 2008. The orders dated 12th September, 2008 and 24th October, 2008 insofar as it demands respective amount towards interest cannot be sustained.
>
> In the second writ petition an interim order was passed on 10th February, 2009 providing that no coercive action shall be taken by the respondents against the petitioners in the meantime. Subsequently by an order dated 28th May, 2009 after hearing the respondents the stay application was disposed of modifying the interim order dated 10th February, 2009 to the extent that subject to petitioners depositing 50% of the amount as determined by orders dated 12th September, 2008 and 24th October, 2008 further recovery against the petitioners shall remain stayed. After passing of the interim orders, the petitioners claim to have deposited an amount of Rs. 9,01,45,215/- by demand draft dated 18th June, 2009.
>
> In view of what has been said above, the overcharge amount to be recovered from the petitioners in the second writ petition needs to be recalculated in the light of the observations made above. The respondents while re-calculating the amount of overcharge to be realised from the petitioners shall adjust the amount already deposited by the petitioners indicated above."

25. Mr. Sibal also apprised the Court that the aforesaid decision of the Allahabad High Court was unsuccessfully challenged by the respondents therein and the judgment consequently attained finality upon dismissal of Civil Appeal No. 10687/2011 as well as Review Petition (Diary No.) 14300/2020 which was dismissed on 15 November 2019 and 05 August 2020 respectively. Learned senior counsel has also referred to the decisions rendered by this Court in **Best Laboratories Pvt. Ltd. v. Union of India**[8] as well as **Amkay Laboratories Pvt. Ltd. v. Union of India**[9] which had followed the principles enunciated in **T.C. Healthcare** and held that interest can be levied only once a manufacturer defaults in payment of the

[8] 2011 SCC OnLine Del 2487

[9] 2018 SCC OnLine Del 11943

overcharged amount in terms of a demand that may be issued.

26. In **Best Laboratories**, the Court observed as under: -

> "Interest under Section 7A EC Act
>
> As regards charging interest under Section 7A EC Act, the Division Bench of the Allahabad High Court in T.C. Healthcare pointed out that the liability to pay simple interest shall arise after a default is committed in making payment of the demanded amount within the time stipulated therein. The wording of Section 7A EC Act makes it clear that the interest has to be paid in the event of default committed by the drug manufacturer in not paying the demand within time. When a fixed time is prescribed for making payment of demand, as has been done in the instant case by the impugned demand letter dated 27th November, 2008 which requires BLPL to make payment by 5th December, 2008, the failure to pay the amount will arise only after the expiry of that date and not earlier. In the instant case therefore interest in terms of Section 7A EC Act could have been charged only for the period after 5th December, 2008. This conclusion is consistent with the decision in *T.C. Healthcare* and *Ranbaxy Laboratories Pvt. Ltd…"*

27. Taking an identical view, this Court in **Amkay Laboratories** held thus:-

> **"**25. A Coordinate Bench of this Court in *Best Laboratories Pvt. Ltd.* v. *Union of India*, 2011 (124) DRJ 390 had observed that the liability to pay interest would arise only once a default is committed in making a payment of the demanded amount within the time stipulated therein. The Court also referred to a similar view expressed by the Division Bench of the Allahabad High Court in *T.C. Healthcare Pvt. Ltd.* v. *Union of India* (supra). The Court had also referred to Section 7A of the Essential Commodities Act, 1955 and observed that the said provision made it explicit that interest would be payable in the event of default was committed in not paying the amount demanded within time.
>
> 26. In the present case, the demand was raised for the first time by the impugned order dated 20.01.2009 and the petitioner was called upon to pay the amount demanded within a period of fifteen days from the date of the said letter. Thus, the liability to pay interest would only arise with effect from 04.02.2009 (that is, on expiry of fifteen days after the date of the impugned letter)."

28. Continuing along this line, Mr. Sibal further urged that the power to levy interest principally flows from Section 7A of the Act. It was contended that since the 2013 DPCO is a piece of subordinate legislation notified under Section 3 of the Act, it must necessarily yield to the provisions of Section 7A. In light of the position which would flow from Section 7A, learned senior counsel submitted that the question of levy of interest is liable to be decided accordingly.

29. Mr. Sibal lastly urged that **Bard** had neither knowingly nor willfully violated the provisions of Para 20 of the 2013 DPCO. It was his submission that it was essentially a case of inadvertent overcharging of medical devices which occurred during the period 2014-2016. Elaborating on this aspect, Mr. Sibal submitted that during the period in question there was confusion and a lack of clarity with respect to the disclosures and price declarations which were to be submitted by manufacturers of medical devices. It was also pointed out that during that period even the Government had no database for monitoring prices of medical devices. Mr. Sibal submitted that the proforma for price list in respect of medical devices was formulated and notified only on 24 January 2017. Prior to the said notification, Mr. Sibal argued, that there was a complete lack of clarity amongst manufacturers of medical devices with respect to the applicability of the 2013 DPCO. It was further highlighted that it was only in terms of the O.M. of 12 May 2017 that the respondents for the first time issued directives seeking the pricing data with respect to 19 medical devices. Drawing the attention of the Court to the aforesaid O.M., it was pointed out that it was in terms of Para 3 thereof that the respondents for the first time developed a format for

submission of data and shared the same with companies engaged in the manufacture of medical devices. For the aforesaid reasons, it was the submissions of Mr. Sibal that the demand as raised and impugned in the writ petition are liable to be set aside and quashed.

E. CONTENTIONS -BHARAT SERUMS

30. Mr. Rohan Shah, learned counsel appearing for Bharat Serums, firstly drew the attention of the Court to the **National Pharmaceuticals Pricing Policy 2012** which came to be notified on 07 December 2012. Learned counsel highlighted the key principles which were enumerated and adopted in terms of that Policy and which were explained to be the essentiality of drugs, control of formulation prices and the regulatory regime moving to a market-based pricing system as opposed to a cost-based pricing formula which formed the foundation for the **Drug Price Control Order 1995**[10] . Mr. Shah laid emphasis on Para 4(xii) of the Policy and submitted that it embodied a clear intent of the respondents to leave non-essential drugs out of the price control regime with their prices being liable to be fixed as per market forces. Mr. Shah submitted that the ultimate provisions which form part of Para 20 are an adoption of the Policy measures which were formulated in Para 4(xii). The aforesaid paragraph is reproduced hereinbelow: -

> **"4. (xii) Non-price Control Drugs**: … In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of

[10] 1995 DPCO

above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next twelve months."

31. Turning then to the provisions of Para 20 itself, Mr. Shah contended that it is evident that a manufacturer of non-scheduled formulations is entitled to increase the MRP of drugs annually subject to the singular rider of ensuring that the increase does not exceed more than 10% of the MRP which had prevailed in the preceding twelve months. According to Mr. Shah, this right which stands so conferred on a manufacturer of non-scheduled formulations is not made dependent upon the manufacturer in any particular year overcharging or exceeding the band of 10% as fixed under Para 20. In other words, learned counsel would submit that the manufacturer does not stand deprived of the right to claim such periodic revisions merely because he may have violated that stipulation in a particular year. It was pointed out by Mr. Shah that the consequences which a manufacturer must suffer are clearly set out in the latter part of Para 20 which stipulates that in case it has overcharged, the manufacturer would have to reduce the price of the drug to bring it at par with the MRP which had prevailed in the preceding twelve months. Mr. Shah points out that the said provision additionally prescribes that the manufacturer as a consequence of overcharging, would also have to hold the price of the particular drug at the reduced price for the next twelve months. Mr. Shah submits that the third consequence which stands attached to overcharging is the liability of the manufacturer to deposit the overcharged amount along with interest. It was the submission of learned counsel that the phrases *"preceding twelve months"* and *"next twelve months"* as are employed in

Para 20 are critical to understanding its scope and intent. According to learned counsel it is these two phrases which constitute the pivotal and focal points for the purposes of understanding the liability which may come to be imposed upon a manufacturer as a consequence of overcharging.

32. Mr. Shah submitted that it must be borne in mind that insofar as non-scheduled formulations are concerned, they are not subject to the price control regime which otherwise stands embodied in the 2013 DPCO. According to Mr. Shah the power to monitor can only be understood as empowering the respondents to oversee and ensure that manufacturers of non-scheduled formulations do not increase retail prices of such drugs beyond the permissible 10%. According to Mr. Shah, the right of the manufacturer to increase the price of non-scheduled formulations is separate and distinct and not subject to the penal consequences which are comprised in the latter part of Para 20. Learned counsel explains the right of a manufacturer to increase the price of drugs in accord with the provisions of Para 20 to be *"continual"* and *"sequential"*. According to learned counsel even if a manufacturer were to transgress the provisions made in Para 20, it would always be open to NPPA to take immediate action and call upon the manufacturer to roll back the price of the drug in question. It was vehemently urged that even if an infraction of Para 20 comes to be discovered many years after the date of the alleged transgression it is the twin phrases *"preceding twelve months"* and *"next twelve months"* which would govern the issue of liability of a manufacturer. The submission in essence was that even if a manufacturer has infringed the injunct placed by Para 20, it would not take away its right to claim a

continual and sequential increase of the MRP of a drug. It was additionally argued that the price revision which would have to be mandatorily made by the manufacturer would also have to be with reference to the date of alleged violation and the "preceding twelve months" and "next twelve months" being calculated in conjunction with that date. Mr. Shah argued that the respondents would, in any case, not be justified to freeze the price of a particular drug for the preceding and the next twelve months from the date when an infraction may come to be discovered.

33. Mr. Shah then invited the attention of the Court to the decision rendered in **Alembic Pharmaceuticals Limited *v.* Union of India and Others**[11] to submit that the Court had clearly held that the power to monitor non-scheduled formulations as envisaged in Para 20 cannot extend to the recognition of a power inhering in the respondents to fix the MRP of a non-scheduled formulation. It would be apposite to notice the following pertinent observations as made in **Alembic Pharmaceuticals:**

> "13. It is clear from the plain reading of the provisions of the DPCO that *NPPA's case* is fundamentally flawed. Sub-paragraph (1) of Paragraph 14 of the DPCO, 2013 enables the NPPA to fix ceiling price of 'scheduled formulations'. Paragraph 14 of the DPCO, is set out below:—
>
> **"14. Fixation of ceiling price of scheduled formulations**.-
>
> (1) The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.
>
> (2) Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable)

[11] 2019 SCC OnLine 7040

fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging."

14. It is clear from the above that the NPPA has no power to fix the ceiling price or the MRP of any formulation other than a scheduled formulation. Concededly, the Formulation had ceased to be a 'Scheduled formulation' with effect from 10.03.2016. Consequently, the power of the NPPA to fix a ceiling price for the Formulation had also ceased with effect from 10.03.2016.

15**.** Having stated above, it is also necessary to refer Paragraph 20 of the DPCO, which reads as under:—

"20. Monitoring the prices of non-scheduled formulations.-

(1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

(2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty."

16. It is clear from the plain language of Sub-paragraph (1) of Paragraph 20 of the DPCO that the Government is required to monitor the MRP of all drugs, including the non-scheduled formulations. However, the same does not empower NPPA (the Government) to fix a MRP for a non-scheduled formulation. The only restriction placed by virtue of Paragraph 20 of the DPCO is that a manufacturer cannot increase the MRP of any drug by more than 10% of the MRP as prevailing during the preceding twelve months. Thus, in terms of Paragraph 20 of the DPCO, the NPPA would be well within its rights to ensure that the petitioner does not increase the MRP of the Formulation for a period of twelve months."

34. Mr. Shah submitted that viewed in that light the action of the respondents which has called upon the petitioner to freeze the price of drugs, for not just the months preceding the issuance of the demand notice and also thereafter, clearly amounts to the respondents exercising a price

fixation power. Mr. Shah argued that the power to monitor prices as conferred on authorities under various statutes has never been recognised to extend to or be equated with a price fixation power. In support of his submission, reliance was placed on the following observations as made by this Court in **Petroleum and Natural Gas Regulatory Board v. Indraprastha Gas Ltd.**,[12]

> "11. We are of the opinion that none of the aforesaid clauses can be construed as prescribing price control/regulation as a function of the Board. Clause (a) supra while prescribing protection of interest of consumers limits the same to, by fostering fair trade and competition amongst entities engaged in distributing, dealing, transporting, marketing gas. The function of the Board thereunder is of regulating the inter se relationship of entities under the Act and not to regulate/control the relationship between the entities under the Act and the consumers. Similarly, Clause (f) while prescribing function of monitoring prices limits the same to taking corrective measures to prevent restrictive trade practices by the entities. Thus only if the Board finds that the marketeers of gas in a particular area have formed a cartel or are indulging in any other restrictive trade practices, is the Board empowered to monitor prices. Such is not the case of the Board in the present instance. The petitioner even though till date the exclusive marketeer of gas in Delhi, has not been accused of any restrictive trade practice and the power exercised also is not in the name of monitoring price. Another sub-clause of clause (f) of Section 11 confers function on the Board to ensure display of information about Maximum Retail Price. Again, had the intent of the legislature been to confer the power on the Board to fix the Maximum Retail Price, nothing prevented the legislature from providing so expressly. Instead, functions of enforcing retail service obligations and marketing service obligations only have been conferred by the legislature. The definition of retail service obligations and marketing service obligations in Sections 2(zk) and (w) also do not include obligation to sell at the prices fixed by the Board.
>
> 12. That brings us to the question as to whether prices can be fixed/regulated/controlled and if so, how. Prices are generally governed/regulated by market forces. Price fixation/regulation/control is essentially a clog on the freedom of trade and commerce conferred the status of a fundamental right. However wherever the circumstances so

[12] 2012 SCC OnLine Del 3215

justify, the same has been treated as a reasonable restriction. However such restriction on fundamental right has to be by legislative mandate only. The Supreme Court recently in DLF Universal Ltd. v. Director, Town and Country Planning Department, Haryana (2010) 14 SCC 1, finding no provision in the statute (Haryana Development and Regulation of Urban Areas Act, 1975) empowering the Director to fix the sale price, held directions fixing the sale price to be beyond the limits laid down by the empowering Act and suffering from lack of power and void. It was observed that an order which is not within the powers given by the empowering Act, has no legal legs to stand on and is a nullity. It was further held that a power of imposing restrictions on profit percentages, time limit on construction and handing over of such construction does not encompass within itself the right to exercise power in manner that inhibits terms of contract and freedom granted therein. Similarly, in O.N.G.C. v. Association of Natural Gas Consuming Industries of Gujarat AIR 1990 SC 1851 it was observed that price fixation is a legislative function. Even the seven Judge Bench of the Supreme Court in Prag Ice & Oil Mills v. Union of India (1978) 3 SCC 459 had observed that unless by the terms of a particular statute, price fixation is made a quasi-judicial function, it is really legislative in character. The Supreme Court in Transmission Corporation of Andhra Pradesh Limited v. Sai Renewable Power (P) Ltd. (2011) 11 SCC 34 also opined that fixation of tariff is a statutory function, to be performed by a statutory authority in furtherance of the provisions of the relevant laws; finding the Electricity Act, 2003 to be requiring the appropriate Commission to determine the tariff, it was held to be empowered to do so. In contrast, the Board with which we are concerned in the present case, as aforesaid is not found to have been assigned the function of fixing the Network Tariff or the Compression Charges as it has purported to do. The Supreme Court in U.P. Power Corp. Ltd. v. NTPC Ltd. (2009) 6 SCC 235 has held that regulatory provisions are required to be applied having regard to the nature, textual context and situational context of each statute.

13. Coming back to the PNGRB Act, Section 12 thereof while conferring jurisdiction on the Board to entertain complaints and of resolution of disputes also does not mention complaints of sale beyond any retail price as may be fixed by the Board, but only mentions contravention of display of retail price at retail outlets. Similarly, Section 46 of the Act while prescribing punishment for unauthorized activities does not deal with punishment if any for sale beyond the retail price fixed by the Board. Section 52 while prescribing the obligations of entities as the petitioner does not require them to sell gas at the prices fixed by the Board.

14. The aforesaid analysis of the PNGRB Act does not show the Board to have been conferred power to regulate the Maximum Retail Price of gas. In the absence of any provision to the said effect in the Act, the mention

> in the Preamble to the Act to regulation of marketing and sale of natural gas is to be necessarily read as without the power to fix the Maximum Retail Price. Price fixation being a restriction on fundamental right, such a power cannot be inferred by conjectures and has to be expressly conferred. As aforesaid no such power/function has been conferred on the Board and the learned ASG also during the arguments has struggled to dig out such a power in the Board by seeking to extrapolate different provisions of the Act.
>
> 15. The Supreme Court in DLF Qutab Enclave Complex Educational Charitable Trust v. State of Haryana (2003) 5 SCC 622 held that a regulatory Act must be construed having regard to the purpose it seeks to achieve and a statutory authority cannot ask for something which is not contemplated under the statute. The statute in that case relating to regulation of user of land was construed to be not imposing any limitation prohibiting transfer of land not affecting its user. It would thus be seen that the powers of regulation under a statute were held to be not unlimited and a right of regulation was held to be confined to the language of the statute and not all pervasive. The basic rule of interpretation of statutes that the Court shall not go beyond the statute unless it is absolutely necessary so to do and that purposive construction would be resorted to only when literal interpretation leads to manifest injustice or absurdity, was applied. In our view the principle applied therein holds good in the facts of the present case also. Merely because the Board has been conferred with regulatory powers will not be interpreted to empower the Board to exercise powers which the statute has not conferred on it."

35. Turning then to the facts of Bharat Serums itself, Mr. Shah submitted that there was no intent to violate the provisions of Para 20. It was submitted that the exercise of rounding off was adopted only to arrive at a convenient MRP which could be paid by consumers. It was contended that the exercise of rounding off was itself based on the decision taken by NPPA in its meeting held on 12 April 2016 where while dealing with Agenda Item No.5 (ii) relating to overcharging, the NPPA had resolved thus:

> **"Agenda item no 5(ii):**- Overcharging on account of fixation of ceiling price for formulation upto two decimal points based on WPI of preceding financial years.
>
> 5.2. The agenda point was discussed. It was decided that NPPA would

> not pursue those overcharging cases which arose out of purely mathematical calculation due to rounding off decimal points as per the general mathematical practice and no other mala fide intention on the part of the company was evident."

36. Mr. Shah further drew the attention of the Court to the Resolution of the Ministry of Chemicals and Fertilizers dated 29 August 1997 pursuant to which the NPPA itself came to be constituted. The attention of the Court was further drawn to the notification of 30 May 2013 issued by that Ministry transferring the powers of the Union Government as embodied in Paras 4 to 30 and 32 of the 2013 DPCO upon NPPA. Mr. Shah submitted that NPPA has been conferred pivotal authority, duties and obligations under the 2013 DPCO. In light of the statutory conferral of authority on the NPPA and by virtue of the said body being designated as the key regulator, Mr. Shah would contend that Bharat Serums cannot be held to have infracted Para 20 since it was in essence acting in accord with that decision.

37. It was lastly urged by Mr. Shah that while Agenda Item 5(ii) may on a facial examination appear to apply to scheduled formulations only, there exists no rationale or justification to deny the benefits of rounding off to manufacturers of non-scheduled formulations. This, more so, in light of the fact that while scheduled formulations are subject to price control, insofar as non-scheduled formulations are concerned, the respondents only exercise the power of monitoring. Mr. Shah also placed reliance on the following observations as were made by the Court in **Obsurge Biotech**:

> "
>
> xxx
>
> 14. As far as the rounding up of the MRP is concerned, the submission of the learned counsel for the respondents cannot be accepted.

15. A reading of the DPCO would clearly show that the same, in fact, is intended to regulate the pricing of the essential drugs. The same is also evident from the 'National Pharmaceuticals Pricing Policy, 2012'. The objectives of the Policy are stated as under:

> *"**2. OBJECTIVES OF THE PRESENT POLICY***
>
> *As stated above in its present form, the Drug Policy of 1994 needs to be modified in the context of changed global environment for industry as well required changes in the mechanism to make available essential medicines to the masses. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines - "essential medicines" - at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all. The reasons are further elaborated later in the Policy Document."*

16. The drugs that have been placed in the National List of Essential Medicines (NLEM) have been incorporated by the respondents in form of the Schedule to the DPCO. The pricing of such drugs is regulated and, in fact, fixed under the control price regime under the DPCO. For the Non-Schedule Formulation, paragraph 20 allows the manufacturers of drugs to fix the MRP based on the market conditions, however, such prices are to be monitored by the Government and the only condition imposed is that the increase in the MRP should not be more than 10%. Therefore, keeping in view the objective of the DPCO and the Policy, it cannot be accepted that the decision taken in the meeting as referred hereinabove would be confined only to the Schedule Formulations. If the Schedule Formulations would be entitled to round of the pricing to the next whole number, then the same benefit cannot be denied to a Non-Schedule Formulation who, otherwise, are allowed liberty to fix the MRP keeping in view the market conditions. Such interpretation, therefore, would be absurd and is to be avoided.

17. Even otherwise, the Minutes of Meeting reproduced hereinabove are for determination of 'ceiling price' for 'formulation'. 'Ceiling price' is also determined in paragraph 20(1) of the DPCO and the Non-Schedule Formulation is also a 'formulation' under the meaning of the terms in the DPCO. Therefore, there is absolutely no justification for excluding the Non-Schedule Formulations from the scope of the decision taken in the meeting and was, in fact, never so intended.

18. In view of the above, the Impugned Demand Notices cannot be sustained and are set aside, leaving it open to the respondents, if so

advised, to re-initiate an enquiry based on the observations as laid down by the present judgment."

F. THE RESPONSE OF NPPA

38. Countering the aforesaid submissions, Mr. Kirtiman Singh, learned CGSC, firstly submitted that in matters concerning the procurement and availability of essential medicines, it is the interest of the consumer which has to be accorded primacy and the regulatory regime must be interpreted accordingly. Mr. Singh submitted that the principal objective underlying Section 3 of the Act and the various orders which have come to be promulgated thereunder is to secure the equitable distribution of essential commodities and to ensure availability thereof at fair prices. Learned counsel submitted that it is the interest of the consumer and not the producer which must be countenanced as being the determinative factor for the purposes of interpreting the provisions of the 2013 DPCO. Proceeding along these lines, Mr. Singh submitted that the theme and ethos of the **Essential Commodities Act, 1955**[13] and the various Control Orders which have come to be promulgated thereunder were lucidly explained by the Supreme Court in **Shree Meenakshi Mills Ltd. v. Union of India**[14] in the following terms: -

> "65. If fair price is to be fixed leaving a reasonable margin of profit, there is never any question of infringement of fundamental right to carry on business by imposing reasonable restrictions. The question of fair price to the consumer with reference to the dominant, object and purpose of the legislation claiming equitable distribution and availability at fair price is completely lost sight of if profit and the producer's return are kept in the forefront. The maintenance or increase of supplies of the commodity or the equitable distribution and availability at fair prices are the

[13] The Act

[14] (1974) 1 SCC 468

> fundamental purposes of the Act. If the prices of yarn or cloth are fixed in such a way to enable the manufacturer or producer to recover his cost of production and secure a reasonable margin of profit, no aspect of infringement of fundamental right can be said to arise."

39. He also drew the attention of the Court to the following principles as laid down by the Supreme Court in **Prag Ice & Oil Mills v. Union of India,[15]:-**

> "21. All the tests of validity of the impugned price control or fixation order are, therefore, to be found in Section 3 of the Act. Section 3 makes necessity or expediency of a control older for the purpose of maintaining or increasing supplies of an Essential Commodity or for securing its equitable distribution at fair prices the criteria of validity. It is evident that an assessment of either the expediency or necessity of a measure, in the light of all the facts and circumstances which have a bearing on the subjects of price fixation, is essentially a subjective matter. It is true that objective criteria may enter into determinations of particular selling prices of each kilogram of mustard oil at various times. But, there is no obligation here to fix the price in such a way as to ensure reasonable profits to the producer or manufacturer. It has also to be remembered that the object is to secure equitable distribution and availability at fair prices so that it is the interest of the consumer and not of the producer which is the determining factor in applying any objective tests at any particular time. Hence, the most important objective fact in fixing the price of mustard oil, which is consumed generally by large masses of people of limited means, is the paying capacity of the average purchaser or consumer.
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> xxxx xxxx xxxx
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> 59. The basic rule of construction in these matters, as observed in *Vrajlal Manilal & Co. v. State of M.P.* [(1969) 2 SCC 248 : (1976) 1 SCR 400, 409] is that a mere literal or mechanical construction is not appropriate where important questions such as the impact of an exercise of a legislative power on constitutional provisions and safeguards hereunder are concerned. In cases of such a kind, two rules of construction have to be kept in mind: (1) that courts generally lean towards the constitutionality of a legislative measure impugned before them upon the presumption that a legislature would not deliberately flout a constitutional safeguard or right, and (2) that while construing such an enactment the court must examine the object and the purpose of the

[15] (1978) 3 SCC 459

> impugned Act, the mischief it seeks to prevent and ascertain from such factors its true scope and meaning.
>
> xxxx xxxx xxxx
>
> 60. Section 3(1) of the Essential Commodities Act, 1955, empowers the Central Government to fix the prices of essential commodities if it is of the opinion that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at a fair price. Sub-section (2)(c) of Section 3 provides that without prejudice to the generality of the power conferred by sub-section (1), an order made under that sub-section may provide for controlling the price at which any essential commodity may be bought or sold. The dominant purpose of these provisions is to ensure the availability of essential commodities to the consumers at a fair price. And though patent injustice to the producer is not to be encouraged, a reasonable return on investment or a reasonable rate of profit is not the sine qua non of the validity of action taken in furtherance of the powers conferred by Section 3(1) and Section 3(2)(c) of the Essential Commodities Act. The interest of the consumer has to be kept in the forefront and the prime consideration that an essential commodity ought to be made available to the common man at a fair price must rank in priority over every other consideration."

40. Mr. Singh submitted that in **Union of India v. Cynamide India Ltd.,**[16]**,** the Supreme Court pertinently observed that while profiteering by itself is evil**,** when it comes to essential commodities and life saving drugs, it is a menace which must be curbed and curtailed. He referred to the following important observations as made by the Supreme Court in the aforesaid decision which are extracted hereinbelow: -

> "2. Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life-sustaining foodstuffs and life-saving drugs is diabolic. It is a menace which has to be fettered and curbed. One of the principal objectives of the Essential Commodities Act, 1955 is precisely that. It must be remembered that Article 39(b) enjoins a duty on the State towards securing "that the ownership and control of the material resources of the community are so distributed as best to subserve the common good". The Essential Commodities Act is a legislation towards that end. Section 3(1) of the Essential Commodities Act enables the

[16] (1987) 2 SCC 720

Central Government, if it is of opinion "that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair price", to "provide for regulating or prohibiting by order, the production, supply and distribution thereof and trade and commerce therein": In particular, Section 3(2)(c) enables the Central Government, to make an order providing for controlling the price at which any essential commodity may be bought or sold. It is in pursuance of the powers granted to the Central Government by the Essential Commodities Act that first the Drugs (Prices Control) Order, 1970 and later the Drugs (Prices Control) Order, 1979 were made……..

xxxx xxxx xxxx

9. In *Shree Meenakshi Mills Ltd. v. Union of India* [(1974) 1 SCC 468] a notification fixing the ex-factory price of certain counts of cotton yarn was questioned on the ground that the price had been arbitrarily fixed. After referring *to Harishankar Bagla v. State of M.P.* [AIR 1954 SC 465 : (1955) 1 SCR 380 : 1954 Cri LJ 1322] , *Union of India v. Bhana Mal Gulzari Mal* [AIR 1960 SC 475 : (1960) 2 SCR 627 : 1960 Cri LJ 664] ; *Sri Krishna Rice Mills v. Joint Director (Food)* [(1974) 1 SCR 418] , *State of Rajasthan v. Nath Mal and Mitha Mal* [AIR 1954 SC 307 : 1954 SCR 982] , *Narendra Kumar v. Union of India* [AIR 1960 SC 430 : (1960) 2 SCR 375] , *Panipat Cooperative Sugar Mills v. Union of India* [(1973) 1 SCC 129] . *Anakapalle Cooperative Agricultural & Industrial Society Ltd. v. Union of India* [(1973) 3 SCC 435] and *Premier Automobiles Ltd. v. Union of India* [(1972) 4 SCC (N) 1 : AIR 1972 SC 1690 : (1972) 2 SCR 526] , a Constitution Bench of the court observed that the dominant object and the purpose of the legislation was the equitable distribution and availability of commodities at fair price and if profit and the producer's return were to be kept in the forefront, it would result in losing sight of the object and the purpose of the legislation.

xxxx xxxx xxxx

27. …..In the present case, the enquiry contemplated by paragraph 3 of Drugs (Prices Control) Order is to be made for the purposes of fixing the maximum price at which a bulk drug may be sold, with a view to regulating its equitable distribution and making it available at a fair price. The primary object of the enquiry is to secure the bulk drug at a fair price for the benefit of the ultimate consumer, an object designed to fulfil the mandate of Article 39(b) of the Constitution. It is primarily from the consumer public's point of view that the government is expected to make its enquiry. The need of the consumer public is to be ascertained and making the drug available to them at a fair price is what it is all about...."

41. Mr. Singh also laid stress upon the fact that the power of price fixation which the respondents exercise under the 2013 DPCO is legislative in character and essentially driven by the need to ensure the availability of essential commodities at a fair price. In **Glaxosmithkline Pharmaceuticals Ltd. v. Union of India,**[17] the decision which was referred to by Mr. Singh in this regard, the Supreme Court observed as follows: -

> "43. One finds, therefore, that the price fixation by the Central Government under the DPCO is in the nature of legislative measure and the dominant object and purpose of such price fixation is the equitable distribution and availability of commodities at fair price. The whole idea behind such price fixation is to control hoarding, cornering or artificial short supply and give benefit to the consumer. The regulation of drug price being ultimately for the benefit of the consumer, we must now consider the effect of Paras 14(1), (2) and (3), Para 16(3), Para 19 and Form V.
>
> 50. In *Cynamide India Ltd. [Union of India v. Cynamide India Ltd.,* (1987) 2 SCC 720] , though the Court was concerned with challenge to the notifications issued by the Central Government fixing the maximum prices at which various indigenously manufactured bulk drugs could be sold under the 1979 DPCO but the prefatory statement made by this Court in para 2 is worth noticing. In para 2 of the Report, the Court observed : (SCC p. 733)
>
> > "2. Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life-sustaining foodstuffs and life-saving drugs is diabolic. It is a menace which has to be fettered and curbed. One of the principal objectives of the Essential Commodities Act, 1955 is precisely that. It must be remembered that Article 39(b) enjoins a duty on the State towards securing 'that the ownership and control of the material resources of the community are so distributed as best to subserve the common good'."
>
> 51. We are of the considered view that if an interpretation of Paras 14(1), (2) and (3), Para 16(3) and Para 19 of the 1995 DPCO results in frustrating its object and leads to denial of the benefit of current notified price to the consumer, then such interpretation must be avoided. We,

[17] (2014) 2 SCC 753

> therefore, find it difficult to accept the construction put to the above provisions by Mr. S. Ganesh."

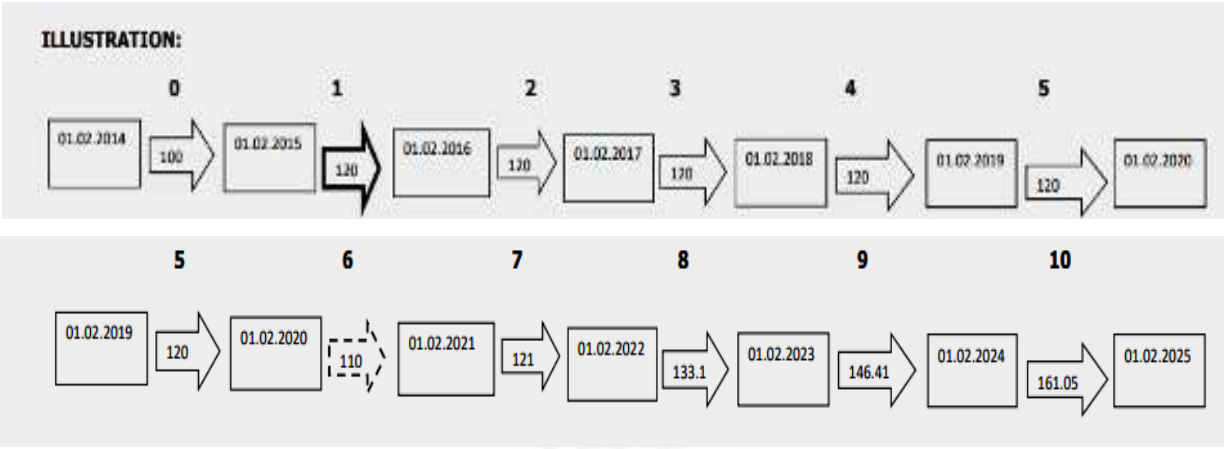
42. The submission in essence was that the provisions of the 2013 DPCO must be interpreted in a manner which subserves the essential objectives of the Act, the legislative power of the respondents to control the price of essential commodities and ensuring that the benefits which are envisaged therein flow to the ultimate consumer. It was contended that it is the interest of the consumers which is of significance and import and that the same would clearly override any right or interest which a manufacturer of an essential commodity may claim. According to Mr. Singh, Para 20 has to therefore necessarily be interpreted bearing in mind the fundamental precepts which have been noticed above. Mr. Singh would contend that the fundamental objective of Para 20 is to essentially act as a deterrent upon manufactures from acting contrary to the interest of consumers. It was submitted that the said provision has been promulgated in order to prevent manufacturers from overcharging consumers in respect of non-scheduled formulations. Mr. Singh would submit that the moment a manufacturer is found to have transgressed the maximum parameters which are placed under Para 20, it would lose the right to seek an upward revision of the MRP.

43. Mr. Singh in support of the aforesaid contention also referred to the judgment rendered by a learned Judge of the Court in **Terumo Penpol Private Limited vs Union of India**[18] where the Court explained the import of Para 20 in the following terms: -

[18] 2019 SCC OnLine Del 7366

> "12. The language of paragraph 20(1) of the DPCO, 2013 is unambiguous. It proscribes the manufacturer from raising a Maximum Retail Price (MRP) beyond 10% of the MRP as existing during the preceding twelve months. There is no scope for the petitioner to make any adjustment on account of the preceding periods for which MRP has not been raised. It is also relevant to observe that the National Pharmaceutical Pricing Policy, 2012 brought about a paradigm shift in the administration of the ceiling prices from a cost based price regime to a price determined by the market force. Although, in terms of the DPCO, 2013, the ceiling prices are required to be fixed only for scheduled formulations, the prices of other drugs are also required to be monitored. This monitoring of the prices is also based on the market forces, and a manufacturer is free to fix the MRP with the restriction that the same cannot be increased beyond 10%, over and above the MRP fixed in the preceding twelve months. This is to ensure that the there is no runaway increase in the prices of the drugs. Thus, in cases where a manufacturer is compelled to peg up the MRP on market forces, it would militate against the very object of paragraph 20(1) of DPCO, 2013 to permit such a manufacturer to increase a price beyond 10%, taking into account the period for which such manufacturer was constrained to peg the MRP at a price below the permissible increase."

44. Mr. Singh further apprised the Court that while the Union has challenged the judgment in **Terumo Penpol** on other related aspects, insofar as the interpretation accorded to Para 20 is concerned and as was enunciated in that decision, it is the stand of the respondents that the said judgment correctly expounds the intent of the said provision. Continuing along this thread, Mr. Singh argued that the moment it is found that a manufacturer has violated the maximum permissible increase as contemplated under Para 20, it would necessarily result in a deprivation of the right to seek periodic increases under that provision. For the purposes of elucidating the aforesaid submission, Mr. Singh has also placed on the record a chart showing the consequences of default as per the respondents which is extracted hereinbelow: -



45. Mr. Singh submitted that in terms of the aforesaid illustration, a manufacturer which breaches the maximum permissible increase of 10% would be liable to be viewed as being in continued violation of Para 20 until the default is ultimately remedied. It was submitted that the moment a breach of Para 20 is discovered, the price of the non- scheduled formulation would have to be necessarily rolled back to the permissible MRP and from the year of default till the transgression is ultimately cured, the manufacturer would be liable to hold prices at that level. It was the categorical case of the respondents, and one which was also explained in the illustrations extracted above, that the liability of a manufacturer to revise and roll back prices of a particular drug would have to revert to the year of default and the price thereafter maintained for the entire period till the default may be ultimately cured or a demand raised. According to Mr. Singh, during this period where the manufacturer is statutorily obliged to rectify its conduct, it cannot claim a notional increase of the MRP by 10%.

46. Mr. Singh then submitted that the submission addressed on behalf of the Petitioners that there was no intent to violate Para 20 in light of the perceived uncertainty in the legal position is wholly untenable. He would

contend that a transgression of Para 20, which essentially constitutes the breach of a civil obligation, does not require *mens rea* to be proved or established. Mr. Singh referred to the following pertinent observations as made by the Supreme Court in **SCM Solifert Ltd. v. CCI,[19]:-**

> "23. There was no requirement of mens rea under Section 43-A or an intentional breach as an essential element for levy of penalty. The Act does not use the expression "the failure has to be wilful or mala fide" for the purpose of imposition of penalty. The breach of the provisions of the Act is punishable and considering the nature of the breach, it is discretionary to impose the extent of penalty. Mens rea is important to adjudge criminal or quasi-criminal liability, not in case of violation of the civil statutory provision.
>
> 24. In *SEBI v. Shriram Mutual Fund* [SEBI v. Shriram Mutual Fund, 2006 5 SCC 361] , with respect to the failure to comply with the civil obligation this Court has laid down thus : (SCC pp. 371 & 376, paras 29 & 35)
>
> > "29. In our opinion, mens rea is not an essential ingredient for contravention of the provisions of a civil act. In our view, the penalty is attracted as soon as contravention of the statutory obligations as contemplated by the Act is established and, therefore, the intention of the parties committing such violation becomes immaterial. In other words, the breach of a civil obligation which attracts penalty under the provisions of an Act would immediately attract the levy of penalty irrespective of the fact whether the contravention was made by the defaulter with any guilty intention or not. This apart, unless the language of the statute indicates the need to establish the element of mens rea, it is generally sufficient to prove that a default in complying with the statute has occurred … the penalty has to follow and only the quantum of penalty is discretionary.…
> >
> > ***
> >
> > 35. In our considered opinion, penalty is attracted as soon as the contravention of the statutory obligation as contemplated by the Act and the Regulations is established and hence intention of the parties committing such violation becomes wholly irrelevant. … We also further held that unless the language of the statute indicates the need to establish the presence of mens rea, it is wholly unnecessary to ascertain whether such a violation was

[19] (2018) 6 SCC 631

> intentional or not. On a careful perusal of Section 15-D(b) and Section 15-E of the Act, there is nothing which requires that mens rea must be proved before a penalty can be imposed under these provisions. Hence, once the contravention is established then the penalty is to follow."
>
> 25. The imposition of penalty under Section 43-A is on account of breach of a civil obligation, and the proceedings are neither criminal nor quasi-criminal. Thus, a penalty has to follow. Discretion in the provision under Section 43-A is with respect to quantum. Thus, we find that in view of the submissions made by the learned counsel for the appellants no case for our interference is made out."

47. He also drew the attention of the Court to the following principles as were laid down in **Director of Enforcement v. M.C.T. M. Corpn. (P) Ltd.,**[20]**:-**

> **"6.** The High Court, while dealing with the first question opined that Section 23 is a "penal provision" and, the proceedings under Section 23(1)(a) are "quasi-criminal" in nature and therefore, unless 'criminality' is established, the penalty provided under Section 23(1)(a) of the Act cannot be imposed on any person. The High Court thus held the existence of "mens rea" as a necessary ingredient for the commission of an 'offence' under Section 10 of the Act and in the absence of a finding about the presence of "mens rea" on the part of the offenders, no punishment under Section 23(1)(a) of FERA, 1947 could be imposed. For what follows, we cannot agree.
>
> **7.** "Mens rea" is a state of mind. Under the criminal law, mens rea is considered as the "guilty intention" and unless it is found that the 'accused' had the guilty intention to commit the 'crime' he cannot be held 'guilty' of committing the crime. An 'offence' under Criminal Procedure Code and the General Clauses Act, 1897 is defined as any act or omission "made punishable by any law for the time being in force". The proceedings under Section 23(1)(a) of FERA, 1947 are 'adjudicatory' in nature and character and are not "criminal proceedings". The officers of the Enforcement Directorate and other administrative authorities are expressly empowered by the Act to 'adjudicate' only. Indeed they have to act 'judicially' and follow the rules of natural justice to the extent applicable but, they are not 'Judges' of the "Criminal Courts" trying an 'accused' for commission of an offence, as understood in the general context. They perform quasi-judicial functions and do not act as 'courts'

[20] (1996) 2 SCC 471

but only as 'administrators' and 'adjudicators'. In the proceedings before them, they do not try 'an accused' for commission of "any crime" (not merely an offence) but determine the liability of the contravenor for the breach of his 'obligations' imposed under the Act. They impose 'penalty' for the breach of the "civil obligations" laid down under the Act and not impose any 'sentence' for the commission of an offence. The expression 'penalty' is a word of wide significance. Sometimes, it means recovery of an amount as a penal measure even in civil proceedings. An exaction which is not compensatory in character is also termed as a 'penalty'. When penalty is imposed by an adjudicating officer, it is done so in "adjudicatory proceedings" and not by way of fine as a result of 'prosecution' of an 'accused' for commission of an 'offence' in a criminal court. Therefore, merely because 'penalty' clause exists in Section 23(1)(a), the nature of the proceedings under that section is not changed from 'adjudicatory' to 'criminal' prosecution. An order made by an adjudicating authority under the Act is not that of conviction but of determination of the breach of the civil obligation by the offender.

8. It is thus the breach of a "civil obligation" which attracts 'penalty' under Section 23(1)(a), FERA, 1947 and a finding that the delinquent has contravened the provisions of Section 10, FERA, 1947 that would immediately attract the levy of 'penalty' under Section 23, irrespective of the fact whether the contravention was made by the defaulter with any "guilty intention" or not. Therefore, unlike in a criminal case, where it is essential for the 'prosecution' to establish that the 'accused' had the necessary guilty intention or in other words the requisite "mens rea" to commit the alleged offence with which he is charged before recording his conviction, the obligation on the part of the Directorate of Enforcement, in cases of contravention of the provisions of Section 10 of FERA, would be discharged where it is shown that the "blameworthy conduct" of the delinquent had been established by wilful contravention by him of the provisions of Section 10, FERA, 1947. It is the delinquency of the defaulter itself which establishes his 'blameworthy' conduct, attracting the provisions of Section 23(1)(a) of FERA, 1947 without any further proof of the existence of "mens rea". Even after an adjudication by the authorities and levy of penalty under Section 23(1)(a) of FERA, 1947, the defaulter can still be tried and punished for the commission of an offence under the penal law, where the act of the defaulter also amounts to an offence under the penal law and the bar under Article 20(2) of the Constitution of India in such a case would not be attracted. The failure to pay the penalty by itself attracts 'prosecution' under Section 23-F and on conviction by the 'court' for the said offence imprisonment may follow.

11. The Constitution Bench then laid down that though the administrative authorities functioning under the Sea Customs Act had the jurisdiction to

confiscate gold illegally brought into the country, and levy penalty on the defaulter, nonetheless the authorities were not trying a criminal case but deciding only the effect of a breach of the obligations by the defaulter under the Act. On a parity of reasoning, what holds true for the adjudicatory machinery under the Sea Customs Act holds equally true for the administrative or adjudicatory machinery, designed to adjudge the breach of a civil statutory obligation and provide penalty for the said breach, under the FERA, 1947, whether the breach was occasioned by any guilty intention or not is irrelevant.

12. In *Corpus Juris Secundum,* Vol. 85, at p. 580, para 1023, it is stated thus:

> "A penalty imposed for a tax delinquency is a civil obligation, remedial and coercive in its nature, and is far different from the penalty for a crime or a fine or forfeiture provided as punishment for the violation of criminal or penal laws."

13. We are in agreement with the aforesaid view and in our opinion, what applies to "tax delinquency" equally holds good for the 'blameworthy' conduct for contravention of the provisions of FERA, 1947. We, therefore, hold that mens rea (as is understood in criminal law) is not an essential ingredient for holding a delinquent liable to pay penalty under Section 23(1)(a) of FERA, 1947 for contravention of the provisions of Section 10 of FERA, 1947 and that penalty is attracted under Section 23(1)(a) as soon as contravention of the statutory obligation contemplated by Section 10(1)(a) is established. The High Court apparently fell in error in treating the "blameworthy conduct" under the Act as equivalent to the commission of a "criminal offence", overlooking the position that the "blameworthy conduct" in the adjudicatory proceedings is established by proof only of the breach of a civil obligation under the Act, for which the defaulter is obliged to make amends by payment of the penalty imposed under Section 23(1)(a) of the Act irrespective of the fact whether he committed the breach with or without any guilty intention. Our answer to the first question formulated by us above is, therefore in the negative."

48. It was then submitted that insofar as drug manufactures are concerned, it cannot possibly be assumed that they were unaware of the applicable legal and regulatory framework. Mr. Singh sought to drew sustenance in this respect from the following observations as made in

Union of India v. Cynamide India Ltd.[21]:-

> "28. .....Manufacturers of any bulk drug are either one or a few in number and generally they may be presumed to be well informed persons, well able to take care of themselves, who have the assistance of accountants, advocates and experts to advise and espouse their cause. In the context of the drug industry with which we are concerned and in regard to which the Control Order is made we must proceed on the basis that the manufacturers of bulk drugs are generally persons who know all that is to be known about the price fixed by the Government."

49. Controverting the contentions addressed on the question of interest and the decision in **T.C. Healthcare**, Mr. Singh argued that Para 20 in unambiguous terms prescribes that interest would be leviable on the overcharged amount from the date of such overcharge. According to Mr. Singh, Para 20(2) in unequivocal terms employs the phrase "*from the date of increase in price*". In view of the aforesaid, Mr. Singh would submit that there is neither justification nor interpretative space to hold that interest under Para 20 is liable to be computed only from the date when a demand may come to be raised by the NPPA. It was his submission that the decision in **T.C. Healthcare** proceeded on the basis of the provisions contained in the 1995 DPCO whereas the provisions made in the 2013 DPCO insofar as they relate to interest are clearly distinct. It was argued that penal consequences which follow a transgression of Para 20 and the liabilities created in terms thereof, are not premised on a notice of demand. In view of the above, it was his submission that the decisions relied upon by the petitioners in this respect would not apply.

50. Turning then to the arguments addressed at the behest of **Bharat**

[21] (1987) 2 SCC 720

Serums in relation to rounding off, Mr. Singh submitted that Agenda Item No. 5(ii) as considered by the NPPA in its Meeting of 12 April 2016 can have no application to a non-scheduled formulations. Mr. Singh submitted that as is explicit from the Agenda Item itself, NPPA in that meeting was dealing with the overcharging of scheduled formulations. This according to Mr. Singh is evident from the usage of the terms "*ceiling price*" and Wholesale Price Index [WPI] in that Agenda. Mr. Singh further pointed out that the principle of rounding off essentially flows from the provisions contained in the **Legal Metrology (Packaged Commodities) Rules, 2011**[22]. Drawing the attention of the Court to the 2011 Rules, Mr. Singh pointed out that the expression "*maximum or maximum retail price"* has being defined in Section 2(m) to mean the price of a commodity inclusive of all taxes *"after taking into account the fraction of less than fifty paise to be rounded off to the preceding rupee and fraction of above fifty paise and up to ninety five paise to the rounded off to fifty paise"*. Mr. Singh submitted that while the aforesaid Rules specifically incorporate and adopt the principles of rounding off, no provision under the 2013 DPCO empowers a manufacturer of formulations to follow the same route. It was further pointed out that the aforesaid Rules in any case would have no application bearing in mind the provisions made in Rule 26 thereof and in terms of which drugs covered under the 2013 DPCO have been specifically excluded from the ambit of those rules.

51. It was further submitted that the decision of the NPPA as embodied in Para 5.2 of the Minutes of the Meeting held on 12 April 2016 merely

[22] The 2011 Rules

represents a principled decision taken by the said authority to not pursue prosecutions where overcharging may have occurred solely on account of rounding off of decimal points as per general mathematical practice. It was submitted that while resolving as such, the NPPA had placed a further rider that the aforesaid decision would only apply to those cases where there was no other mala fide intent on the part of a manufacturer. The argument essentially was that the decision of the NPPA which is sought to be relied upon was only permissive and applicable to those cases which could be said to fall within the ambit of Agenda Item 5.2. In any case, Mr. Singh would contend even Agenda Item 5.2 cannot be construed or understood as entitling a manufacturer to round off the prices of non-scheduled formulations as a matter of right.

G. DRUG PRICE CONTROL- A BRIEF HISTORY

52. Before proceeding to rule on the rival contentions which have been noticed above, it would be appropriate to briefly advert to and recapitulate the price control regime insofar as drugs are concerned. Price control measures in respect of medicines and drugs came to be introduced as an aftermath of the Chinese aggression when for the first time the Drugs (Control of Prices) Order, 1963 came to be promulgated in exercise of powers conferred under the Defence of India Act, 1915. In terms of the aforesaid, the prices of drugs came to be frozen at the levels at which they stood on 01 April 1963. Subsequently, a series of Drug Price Control Orders came to be notified, namely, in 1966, 1970, 1979, 1987 and 1995. It would be relevant to note that the aforesaid Control Orders came be issued under the Act. The 1995 DPCO was framed in light of the Drug Policy of

1994. The aforesaid Control Order followed the principle of cost of production with allowances relating to post production expenses being permitted to be taken into consideration. It was these two factors which were essentially taken into account while fixing the price of drugs. The 1995 DPCO created a list of 76 bulk drugs and various formulations based on those drugs which at the time of the announcement of the NPPP 2012 stood at approximately 1577.

53. The Union, thereafter, introduced a new Pharmaceutical Pricing Policy in 2002. In terms of this policy the turnover limit for the purposes of price control was raised from Rs. 4 crores to Rs. 25 crores. It also excluded drugs whose unit price did not exceed Rs. 2 from the ambit of price control. The aforesaid policy, however, came to be challenged before the Karnataka High Court which by its order of 12 November 2002 stayed the implementation thereof. The aforesaid order was ultimately challenged by the Union before the Supreme Court which while vacating the stay vide its order dated 10 March 2003 observed that the Union would consider and formulate an appropriate criterion for ensuring essential and life saving drugs not falling out of price control and to further review drugs which may fall in the category of essential and life saving medicines.

54. In the interregnum, the Ministry of Health and Family Welfare which had in 1996 also catalogued a **National List of Essential Medicines**[23] revised the same in 2003. The Government is, thereafter, stated to have constituted a Task Force to undertake a comprehensive review in respect of

[23] NLEM

price control and other related issues and to make recommendations to make life saving drugs available at reasonable prices. That Task Force is stated to have submitted its report in 2005. The NLEM came to be revised and notified in 2011. The Government upon an overall review and consideration of the aforesaid, then proceeded to announce the **National Pharmaceuticals Pricing Policy 2012**[24]. The key principles for regulation of prices under the NPPP 2012 were spelt out in Para 3 which reads as follow: -

> "**3. KEY PRINCIPLES OF NATIONAL PHARMACEUTICALS PRICING POLICY 2012**
>
> The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:
>
> (1) Essentiality of Drugs
> (2) Control of Formulations prices only
> (3) Market Based Pricing"

55. The guiding principles for price control of drugs as enunciated in Para 4 read as under: -

> "**4. PRINCIPLES FOR DRUGS PRICE CONTROL AND DETERMINATION IN NPPP-2012**
>
> (i) Price regulation would be on the basis of 'Essentiality' of the drug as laid down in the "National List of Essential Medicines - 2011" declared by the Ministry of Health and Family Welfare, and modified time to time, in public interest under Drug Price Control Order.
> (ii) Price regulation would be applied only to formulations, i.e. the medicine actually used by the consumers, and not to any upstream products such as bulk drugs and intermediates.
>
> (iii) The Span of Price Control shall be as per the dosages and strengths as listed in NLEM- 2011.
>
> (iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of

[24] NPP 2012

the total market turnover of that medicine, will be as per the formula below:

(Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of the medicine)

(v) The formulations will be priced only by fixing a **Ceiling Price (CP)**. Manufacturers would be free to fix any price for their products equal to or below the CP. The CP's would be fixed on the dosage basis, such as per tablet / capsule / standard injection volume as listed in NLEM-2011.

(vi) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/ evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockist level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers.

(vii) For drugs not in the IMS data, NPPA would collect data by commissioning the same.

(viii) For the medicines where there is no reduction of price due to absence of competition, the overall percentage reduction in the price of same molecule with other dosage and strength will be applied; otherwise the overall percentage reduction in the price of medicines in the same therapeutic category will be applied.

(ix) The CP for a drug listed in the NLEM would be the Simple Average of Prices as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy i.e the "Appointed Date" for bringing the new Policy into effect. For a drug whose data is not available in IMS, the NPPA will commission the data within a reasonable time for determining the Simple Average Prices also on the basis of prices prevailing six months prior to the Appointed Date. Thus the Simple Average Prices data date for the drugs available in IMS data and collected by NPPA would be same. Once the Simple Average Price is fixed, NPPA would monitor its implementation on a continuous basis through a proper methodology and system.

(x) The prices of these NLEM-2011 medicines will be allowed an annual increase as per the Wholesale Price Index as notified by the Department of Industrial Policy & Promotion. It is proposed to fix the 1st April of every year as the reference date for this. Accordingly, on 1st April of every year, companies will be automatically authorized to revise their prices upto the limit of the increase in the Wholesale Price Index for the

previous year. In case of decline in Wholesale Price Index, a corresponding reduction in the ceiling price will be obligatory. The NPPA itself will also separately notify the revised ceiling prices as applicable as on the 1st of April each year, and in case any company has fixed the prices not consistent with the revised ceiling prices, the NPPA will take appropriate action to have these revised.

(xi) The Simple Average Price of all the brands of the medicine having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine - the Reference Prices for calculation of Simple Average Price - may also change on an annual basis due to changes in the MAT value. However, there would be no annual revision of Ceiling Prices on the basis of MAT. Revision of Ceiling Prices on the basis of MAT value would be carried out only once in five years or as and when NLEM is updated/revised. However, the Government will revise the ceiling price of a medicine under NLEM, if there is a significant change in the market structure of the particular medicine even in between 5 years.

(xii) **Non-price Control Drugs**: Under the existing price control regime, the prices of Non-Scheduled drugs are monitored, and in case the prices of such drugs increase by more than 10% in a year, subject to certain criteria, government fixes the prices of such medicines from time to time. In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next twelve months……."

56. To briefly step back and notice some of the salient provisions of the 1995 DPCO, it would be relevant to note that the said order dealt with the regulation of prices of bulk drugs and scheduled / non-scheduled formulations. Bulk drugs were defined to mean those which were specified in the Second Schedule to the Drugs and Cosmetics Act, 1940. A formulation was defined in Para 2(h) to mean a medicine processed out of or containing without the use of any one or more bulk drug or drugs with all pharmaceutical aids for internal or external use for diagnosis, treatment or

mitigation of disease in human beings. Scheduled bulk drugs were catalogued and specified in the First Schedule to the 1995 DPCO. A non-scheduled bulk drug was defined in Para 2(o) to mean a bulk drug not specified in the First Schedule. The 1995 DPCO defined a scheduled formulation to mean a formulation containing any bulk drug specified in the First Schedule either individually or in combination with other drugs. Similarly, a non-scheduled formulation was defined to mean a formulation not containing any bulk drug specified in the First Schedule. The provision contained in the 1995 DPCO empowered the Union to fix the maximum sale price of bulk drugs and scheduled formulations as well as to specify a ceiling price of scheduled formulations. The principles for calculation of the retail price of a formulation was set out in Para 7. The formula which came to be adopted and which embodied the cost-plus principle which was then prevalent required the authority to take into consideration material costs, conversion costs, packaging costs as well as the maximum "Aflowable Post Manufacturing Expenses". Excise duty was also factored in for the purposes of arriving at the retail price. The power to revise the price of bulk drug and scheduled formulations was spelt out in Para 10 which read as under: -

> "**10. Power to revise price of bulk drugs and formulations :**
>
> Notwithstanding anything contained in this order :
>
> (a) the Government may, after obtaining such information as may be considered necessary from a manufacturer or importer, fix or revise the retail price of one or more formulations marketed by such manufacturer or importer, including a non-Scheduled formulation, in such manner as the pre-tax return on the sales turnover of such manufacturer or importer does not exceed the maximum pre-tax return specified in the Third Schedule;
>
> (b) the Government may, if it considers necessary so to do in public interest, after calling for such information by order fix or revise the

retail price of any formulation including a non-Scheduled formulation;

(c) the Government may, if it considers necessary so to do in public interest, by order include any bulk drug in the First Schedule and fix or revise the prices of such a bulk drug and formulations containing such a bulk drug in accordance with the provisions of paragraphs 3, 7, 8 and 9, as the case may be."

57. Para 13 of the 1995 DPCO, while dealing with a power to recover overcharged amount incorporated the following provisions: -

"**13. Power to recover Overcharged Amount:**

Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importers or distributors, as the case maybe, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and under the provisions of this Order."

58. While the 1995 DPCO held the field, the Government of India in terms of a resolution of 29 August 1997 constituted the NPPA. By a subsequent notification dated 30 May 2013, the Union Government delegated its powers comprised in Para 4 to 30 and 32 of the 2013 DPCO to the NPPA. The 2013 DPCO came to be promulgated in order to implement and enforce the policy decisions which were taken by the Union and stood embodied in the NPPP 2012. The 2013 DPCO did away with the concept of bulk drugs and essentially categorized drugs into scheduled and non-scheduled formulations. A scheduled formulation was defined in Para 2 (zb) to mean one which stood included in the First Schedule referred to either by its generic description or brand name. Non-scheduled formulations were defined to mean those which were not included in Schedule One. The expression *'ceiling prices'* was defined in Para 2(d) to mean a price fixed by the Government for scheduled formulations in

accordance with the provisions of the said order. Paras 5 and 6 which spelt out the principles for calculation of the retail price of a new drug and ceiling prices of scheduled formulations stand framed as under: -

> "**5. Calculation of retail price of a new drug for existing manufacturers of scheduled formulations.–** (1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.
>
> (2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15.
>
> (ii) the retail price of such new drug shall be fixed by adding sixteen per cent margin to retailer on the price to retailer as fixed in item (i):
>
> **6. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.–** (1) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of,-
>
> (a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and
>
> (b) there are less than five manufacturers for that formulation having one per cent or more market share, the ceiling price shall be calculated as under:-
>
> (i) in the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under:
>
> **Step1:** First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:
>
> $$\mathbf{P(s) = P_m\{1-(P_{i1}+P_{i2}+\ldots.)/(N*100)\}}$$ **Where**,
>
> $\mathbf{P_m}$ = Price to Retailer of highest priced scheduled formulation under consideration.
>
> $\mathbf{P_i}$ = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of sub-paragraph (1) of paragraph (4) in the list of schedule formulations w.r.t. the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.
>
> **N** = Number of such other strengths or dosage forms or both in the list of schedule formulations

Step 2: Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step 1 hereinabove and

M = % Margin to retailer and its value = 16

(ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub-therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

$P(s) = P_m\{1-(P_{i1}+P_{i2}+….)/(N*100)\}$, Where,

P_m = Price to Retailer of highest priced scheduled formulation taken for calculating the average price to retailer of the formulation under consideration.

P_i = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category as that of the scheduled formulation under consideration w.r.t. the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same sub-therapeutic category as that of the scheduled formulation under consideration

Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s)*(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step above and

M = % Margin to retailer and its value=16

Explanation.- where the scheduled formulation under consideration is coming under more than one sub therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such sub-therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under

consideration;

(iii) in case the other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category of the scheduled under consideration, the ceiling price shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

$P(s) = P_m\{1-(P_{i1}+P_{i2}+\ldots)/(N*100)\}$, Where,

$\mathbf{P_m}$ = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

$\mathbf{P_i}$ = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 sub-paragraph (1) of paragraph 4) in same therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same therapeutic category as that of the scheduled formulation under consideration.

Step2. Thereafter, the celling price of the scheduled formulation i.e. P(c) shall be calculated as under

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 above and

M = % Margin to retailer and its value=16

Explanation.- where the scheduled formulation under consideration is coming under more than one therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration.

(2) Notwithstanding anything contained in this paragraph, where the price has been fixed and notified by the Government under the Drugs (Prices Control) Order, 1995 the provisions of sub-paragraph (1) shall not apply."

59. In terms of Para 8, the MRP of scheduled formulations was to be determined in accordance with the formula prescribed therein. Para 8 reads as follows: -

> "8. **Maximum retail price.-** (1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under
>
> **Maximum Retail Price = Ceiling price + Local Taxes as applicable**
>
> (2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:
>
> **Maximum Retail Price = Retail Price + Local Taxes as applicable**"

60. The price of scheduled formulations which also stood included in the First Schedule to the 1995 DPCO were to be fixed as per the principles contained in para 10 which is extracted hereinbelow: -

> "**10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995.-** (1) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to 30th May, 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub- paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such formulations.
>
> (2) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order,1995 after 31st May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations.
>
> (3) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to the 30th May 2013 and thereafter prices of such formulations

> shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.
>
> (4) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31st May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order."

61. Similar provisions were made in Paras 13, 14, 15 for fixation of ceiling prices and retail prices of scheduled formulations for existing manufacturers. Insofar as non-scheduled formulations are concerned, they were admittedly kept out of the price control regime and the Government only retained the power to monitor the MRP thereof in terms of Para 20 which has been noticed in the introductory parts of this judgment.

H. THE SCOPE OF PARA 20

62. Having noticed the salient provisions which were made in the 1995 DPCO and those which stand incorporated in the 2013 DPCO, the principal challenge revolving around the scope of Para 20 may then be taken up for consideration.

63. As would be evident from an *ex facie* reading of the said provision, the manufacturer of a non scheduled formulation is conferred the discretion to increase the maximum retail price of a drug subject to the condition that the said increase does not exceed more than 10% of the MRP which was prevailing in the preceding twelve months. The consequences of an infraction of the aforesaid stipulation contained in Para 20 are prescribed to be the obligation of the manufacturer to not only deposit the overcharged amount but to also reduce the price of the drug in question to that which

was prevailing immediately before the event of overcharging and was compliant with Para 20. The manufacturer is further obliged to maintain the price of the drug at that level for the next twelve months. The provisions of Para 20 directly fell for consideration before this Court in **Terumo Penpol** which too was a case dealing with the issue of overcharging. The order of the NPPA which was impugned therein was assailed firstly on the ground with the petitioners there contending that since they had not increased the MRP of their drugs for the last several years, they were entitled to raise the price cumulatively taking into account the annual increase of 10% which had not been availed of earlier. The second challenge to the order passed by NPPA was based on the assertion that since the actual sale price of the drug was below the MRP for the year 2015, no penal consequences would ensue. In **Terumo Penpol,** the petitioner also sought to assail the action of the NPPA on the ground of inordinate delay in the raising of the demand alleging overcharging. While this Court while dealing with the present batch is not directly concerned with the latter two submissions which were addressed in that matter, it would be apposite to notice what the learned Judge ultimately held with respect to the scope of Para 20. The leaned Judge observed that in terms of Para 20 a manufacturer stands restrained from raising the MRP beyond 10% of the price as existing during the preceding twelve months. It was further pertinently observed that it would not be permissible for a manufacturer to make any adjustments on account of the MRP having not been raised in the preceding periods. The spirit behind Para 20 and the periodical increase which is permissible to be availed of by the manufacturer was further expressed by the Court to be aimed at ensuring

that there is no run away increase in the price of drugs.

64. Para 20 of the 2013 DPCO thereafter fell for consideration again in **Obsurge Biotech.** While dealing with the scope and ambit of that provision, the learned Judge in **Obsurge Biotech** observed as follows: -

> "**7.** A reading of the above provision would clearly show that a manufacturer is entitled to increase the maximum retail price of a drug not more than 10% of the maximum retail price during 'preceding' twelve months. It further provides that where the manufacturer of a drug increases the price beyond 10% of the maximum retail price, 'it shall reduce the same to the level of 10% of maximum retail price for next twelve months.' The paragraph uses the word 'preceding' and 'next' and clearly, therefore, what is intended is that where the manufacturer increases the MRP by more than 10%, the Government is empowered to ensure that the manufacturer reduces the MRP to the level of maximum 10%.
>
> 8. The consequence of a manufacturer having increased the MRP and having obtained certain amounts because of the same from the consumers is in the sub paragraph-(2) of paragraph 20, wherein the manufacturer is being made liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the 'penalty'.
>
> 9. Clearly by denying the petitioner increase in the MRP which he is otherwise entitled to, would amount to a penalty being imposed even in paragraph 20 (1), which does not flow from a bare reading of the provision nor intended.
>
> 10. Paragraph 20(1) of the DPCO in no unambiguous terms provide that a manufacturer would be entitled to increase the MRP of the drug by a maximum of 10% of the MRP during the 'preceding' twelve months and incase the manufacturer is found to have increased the MRP beyond the limit of 10%, the Government would be entitled to direct reduction of the same to the level of 10% for the period of next twelve months from the date when the manufacturer became entitled to such increase.
>
> 11. To put it differently and explaining it by an example, if the MRP of a drug is Rs. 100 for the period from 2013-14, the manufacturer would be entitled to increase the MRP of the drug to a maximum of Rs. 110 for the period 2014-15 and incase it is found that the manufacturer has increased the MRP beyond the ceiling limit, the Government can direct the manufacturer to reduce the MRP to the level of Rs. 110 for the period 2014-15 whereafter again, the manufacturer will be entitled to increase the MRP of the drug by a maximum of another 10% of Rs. 110."

65. It may be noted in passing that although the ambit of Para 20 was noticed, the learned Judge in **Obsurge Biotech** did not record any specific findings in respect thereof since in that particular case, the claim of the petitioner had not been denied by the respondents on the ground that it was not entitled to a subsequent increase in the MRP. **Obsurge Biotech** ultimately came to be decided on the issue of whether the principles of rounding off could be adopted. The judgment in **Obsurge Biotech** in any case and as was noticed hereinabove, has been placed in abeyance by a Division Bench of the Court in LPA No. 310/2020.

66. The power of the NPPA to monitor the price of non-scheduled formulations as distinct from a power to fix a price for drugs which stands reserved in respect of scheduled formulations only was duly noticed and explained in **Alembic Pharmaceuticals Limited.** Dealing with the said aspect, the learned Judge held as under:-

> "14. It is clear from the above that the NPPA has no power to fix the ceiling price or the MRP of any formulation other than a scheduled formulation. Concededly, the Formulation had ceased to be a 'Scheduled formulation' with effect from 10.03.2016. Consequently, the power of the NPPA to fix a ceiling price for the Formulation had also ceased with effect from 10.03.2016.
>
> 16. It is clear from the plain language of Sub-paragraph (1) of Paragraph 20 of the DPCO that the Government is required to monitor the MRP of all drugs, including the non-scheduled formulations. However, the same does not empower NPPA (the Government) to fix a MRP for a non-scheduled formulation. The only restriction placed by virtue of Paragraph 20 of the DPCO is that a manufacturer cannot increase the MRP of any drug by more than 10% of the MRP as prevailing during the preceding twelve months. Thus, in terms of Paragraph 20 of the DPCO, the NPPA would be well within its rights to ensure that the petitioner does not increase the MRP of the Formulation for a period of twelve months."

67. In order to appreciate the conflicting submissions advanced on the

question of the correct meaning and purport of Para 20, it would be apposite to advert to the illustrations which had been relied upon and have been extracted above. As per the illustration relied upon by Bard and extracted in paragraph 20 of this decision, it has sought to explain how Para 20 must be interpreted and implemented by asserting that a manufacturer would be entitled to claim a 10% revision in the MRP every twelve months. It also explained a case of overcharging by taking the example of a drug coming to be priced at Rs. 125/- where the allowed MRP in terms of Para 20 would be only Rs. 110/-. In that scenario it is conceded that the overcharged amount would be Rs. 15/-. However, for the next year, the position is explained with the allowed MRP being fixed at Rs. 121/- and thus factoring in the 10% increase which is otherwise permissible under Para 20. The case of Bard essentially is that notwithstanding a manufacturer having transgressed the limits prescribed in Para 20 in a particular year, that would not detract from its right to claim an increase in the MRP. The submission additionally was that the amount of overcharge cannot be computed without factoring in the periodic and annual 10% increase which the manufacturer can claim.

68. The Court then turns its gaze on the illustration relied upon by Bharat Serums and which has been reproduced in paragraph 11 of this judgment. The case of **Bharat Serums** stands on a slightly distinct footing since, and as was noticed hereinabove, it has been found to have violated Para 20 on account of having rounded off the permissible MRP under the 2013 DPCO. While explaining the impact of Para 20 in respect of the drug Histoglob, **Bharat Serums** has firstly contended that mere rounding off cannot be construed as overcharging. It has been argued that if the permissible price

of Histoglob be Rs. 90.75/- in February 2015, it was clearly permissible for the petitioner to round it off to Rs. 91/-. It similarly explains the aforesaid position while taking the permissible MRP in February 2016 to be Rs. 99.825/-. It was contended that if the aforesaid price were rounded off to Rs. 100/-, it could not be said that it had violated Para 20. It has additionally taken an objection to the freezing of the price at Rs. 90.75/- which was the MRP prevailing in February 2015. It was urged that even if the infraction had firstly occurred in February 2015, its obligation to hold the price of the drug at that price could have only been for the next twelve months when computed from February 2015. It is urged that from February 2017, **Bharat Serums** must be recognized to be entitled to charge Rs. 109.808/- rounded off Rs. 110/- and that it cannot be compelled to charge only Rs. 90.75/-. It was argued that the directive issued by the respondents which essentially compels the manufacturer to roll back the price of the drug to the permissible MRP from the period of infraction and till the issuance of the impugned demand or act of rectification by the manufacturer is clearly contrary to Para 20 of the 2013 DPCO.

69. The respondents, on the other hand, contend that if a manufacturer in any twelve-month period breaches the maximum permissible increase of 10%, it must be held to be in default till the transgression is cured. That stand is explained with the aid of the exemplar which has been extracted in paragraph 44 of this decision.

70. In terms of those illustrations, Mr. Singh argued that Para 20 must be interpreted to require the manufacturer to set back the clock to the year of default, to maintain the MRP prevailing prior to the period of transgression,

to hold it that price till the infraction is cured and for twelve months thereafter. The respondents further contend that if the default is ultimately cured after six years, the manufacturer would have to go back to the price which was prevailing in the first year and thereafter continue to hold the same for the entire period of six years. According to them and as is explained by Mr. Singh with the aid of the illustration noticed above, if the default had occurred in 2015 being Year One and is ultimately cured after six years, the manufacturer would have to maintain the price of the drug at the permissible price which was prevalent prior to Year One and hold it at that level throughout the period of the succeeding six years and twelve months even thereafter. It is these rival interpretations advocated with respect to Para 20 which merit consideration.

71. Undisputedly, Para 20 of the DPCO 2013 empowers the Government to monitor the retail price of non-scheduled formulations. That authority to oversee and periodically track the price charged by a manufacturer is to ensure that no manufacturer increases the maximum retail price of a drug more than 10% over the maximum retail price that prevailed in the preceding twelve months. The first part of Para 20 thus appears to enable the manufacturer to revise the maximum retail price over a twelve-month cycle. The statute, however, places an injunct by proscribing any revision in price beyond 10% over the price prevailing in the preceding twelve-month cycle.

72. The Court has already noticed the paradigm shift with regard to price control of drugs which was ushered in by the DPCO 2013. Under the 1995 DPCO, a "scheduled formulation" was defined to mean a formulation

containing any bulk drug specified in the First Schedule either individually or as a combination. A non-scheduled formulation was defined to mean one which did not contain any bulk drug specified in the First Schedule. However, the power to fix the retail price of both the aforenoted categories of drugs stood embodied in Para 7. Insofar as scheduled formulations were concerned, while the computation of the retail price was to abide by the formulae set out in Para 7, the 1995 DPCO dealt with this category of formulations in Para 8 in order to amplify the procedure that it was bound to follow while fixing the retail price of scheduled formulations from time to time. Para 9 then conferred a power on the Government to fix a ceiling price of scheduled formulations. This too was to be guided by the provisions contained in Para 7. The power to revise the retail price of formulations including non-scheduled formulations was recognised and provisioned for in Para 10.

73. However, with the introduction of the 2013 DPCO the basis of price fixation shifted from a cost of manufacture principle to a market driven price mechanism. The second significant policy change which was ushered in with the advent of the 2013 DPCO was of the NPPA retaining the power to fix prices in respect of scheduled formulations only. Insofar as non-scheduled formulations were concerned, all that was proclaimed was that it would *"monitor"* the price of such formulations. This appears to be a result of the variation in the total number of drugs which remained under price control starting from the 1979 DPCO [347 drugs], which was then abridged to 166 in 1987 and brought further down to 142. Under the 1995 DPCO, only 76 drugs were subjected to price control. This course of abridging the

total number of drugs which would be under price control was again reviewed in terms of the NPPP 2012 which essentially took the position that all essential drugs would be under price control and as a logical corollary non-essential drugs were to be kept out of the price control regime and their prices being left to be governed by market forces. In order however to keep a check on overall drug prices, non-essential drugs were to be monitored and the restrictive price band of 10% was mooted. These proposals and policy directives which formed the backbone of the NPPP 2012, inform the provisions of Para 20 of the 2013 DPCO.

74. From the aforesaid discussion, it is evident that insofar as non-scheduled formulations were concerned, the Government took a conscious decision to leave their prices to be determined by market forces subject to the rider that the annual increase would not exceed 10% and in case of overcharging the manufacturer would have to roll back the prices to the preceding legally permissible price and preserve it at that level for the next twelve months. Viewed in that backdrop it is evident that a manufacturer of a non-scheduled formulation was entitled to fix the price of its drug subject to the singular fetter of the same being compliant with the stipulation of 10% which was sanctioned.

75. The question which then arises is whether a manufacturer who breached the 10% increase would result in the manufacturer being deprived of its right to that periodical increase and if so for what period of time. The respondents in the impugned communications take the position that any periodical increase that may have accrued to a manufacturer would stand obiterated till the revised price is reduced downwards to fall within the

bracket of the permissible 10% increase and that price then maintained for the next twelve months. The aforesaid position which is taken in Bard, is reiterated in Bharat Serum with the respondents noting that it would be ineligible to seek the benefit of the sequential increase of 10% over the prevailing retail price till the price is reduced to fall within the permissible band in terms of Para 20 and held at that level for the next twelve months. Bard while assailing the aforesaid reasoning has contended that the view taken by the respondents has resulted in the freezing of its prices since 2018. They further contend that as a result of the impugned order, they had to bring down the prices of their medical devices to the levels prevailing in 2014-2015, maintain it for the next twelve months and then commence afresh. The aforesaid grievance is liable to be considered in the backdrop of the demand notice for the period 2015-16 having been issued only in 2019. Similarly, Bharat Serum has demonstrated with the aid of the material existing on the record that it has been held liable to hold the price of its drug at the level prevailing in February 2015 right upto December 2019.

76. The respondents essentially appear to have understood Para 20 to mean that the revisions permissible annually would stand forfeited till such time as remedial action in terms of the 2013 DPCO are taken by the manufacturer. However, that interpretation rests principally not on the date when the infraction occurred but on the date when the violation of Para 20 may come to be discovered either by the respondents or when corrective action may be taken by the manufacturer itself. It is here that the dispute appears to have arisen between the parties. This is evident from a perusal of the demand notice dated 07 November 2019 in the case of Bard which

alleged violations during the period 2015-16 and the notices dated 26 June 2018 and 05 July 2018 alleging overcharging by Bharat Serum during the period February 2014 to December 2019. The question which consequently arises is whether the petitioners are liable to hold the prices of the drugs in question at the permissible retail price for a period of twelve months from the date of issuance of those notices and whether they become disentitled to the periodic increase envisaged under Para 20 for the entire period commencing from the date of overcharging till the expiry of twelve months post the issuance of the impugned notices/demands.

77. It becomes important to pause here and note that if the view as taken by the respondents were to be upheld it would essentially amount to recognizing a principle that a manufacturer would be disentitled to claim the 10% annual increase in the retail price which is guaranteed under Para 20, if it transgresses the first part of Para 20. Secondly, the manufacturer would have to be held to be obliged in law to freeze or roll back the retail price of the drug to the level which was prevailing prior to the alleged infraction not just from that crucial point in time but to hold it at that level for the entire period commencing from the date of overcharging upto the date of issuance of the demand. Additionally, the manufacturer would have to hold that retail price for the next twelve months from the date of issuance of the demand and the revision permitted thereafter would have to be a 10% increase over the permissible price which prevailed prior to the date of overcharging. It is the correctness of this view that ultimately falls for consideration of the Court.

78. Undisputedly, non-scheduled formulations are not subject to the

rigours of price control under the 2013 DPCO. That provision simply places an obligation upon the Government to monitor and oversee that the maximum retail price of such formulations does not exceed 10% of the price which was prevailing in the preceding twelve months. The salutary objective underlying this prescription is clearly manifest bearing in mind the fact that drug prices must necessarily be regulated by the Government in order to ensure that patients and consumers do not face the specter of runaway price increases and to control profiteering. However, Para 20 undoubtedly permits a manufacturer to increase the maximum retail price annually subject to the singular limitation that the price increase would not exceed 10% of the price which was prevailing in the preceding twelve months. The consequences of a breach of the aforesaid prescription is also not left open to speculation with Para 20 in clear and unequivocal terms prescribing the penalty as well as the remedial measures which must be adopted. This is evident from a reading of the latter part of Para 20 which stipulates that in such a situation, the manufacturer would have to roll back the price charged to the legally permissible price which was prevailing in the twelve months preceding the date of violation of Para 20 and to preserve it at that level for the next twelve months. The penalty is then prescribed by Para 20(2) which provides that the manufacturer would be liable to deposit the overcharged amount along with interest from the date in increase of price.

79. Significantly, however, Para 20 does not envisage a deprivation of the right to increase the retail price of a drug annually in case of overcharging. Para 20 spells out and stipulates both the consequences as

well as the penalties which would visit a manufacturer in case it were to violate its provisions. The stand taken by the respondents to the effect that the right to seek such increase would stand lost till such time as the price is revised and brought down, would not only amount to a recasting of Para 20, it would also and on more fundamental terms, result in the introduction of a penal consequence which neither flows from a plain reading of that provision nor inferentially.

80. The Court, thus, finds itself unable to read or interpret Para 20 in the manner as suggested by the respondents for the following reasons. Firstly, Para 20 does not link the sequential increase which a manufacturer can avail of in respect of a non-scheduled formulation to the corrective measures that are liable to be adopted by it if a transgression occurs. The 10% factor attached to the right of sequential increase in the first part of Para 20 is the solitary fetter placed on the manufacturer who is otherwise left free to fix the price of its formulation. Para 20 significantly does not postulate that a transgression of that particular stipulation would result in the manufacturer being deprived of the right to claim an annual revision of the MRP. All that it prescribes is that in case of a violation it must revise the MRP, roll it back to the valid price prevailing in the preceding twelve months and hold it at that level for the next twelve months. It is for the next twelve months alone that the price must remain static as per the statutory command enshrined in Para 20. However, that provision neither envisages nor mandates the right to revise the MRP being effaced beyond the next twelve-month period.

81. It would be pertinent to notice that Para 20 comprises of two separate

and distinct identifiable parts. While the former deals with the right of the manufacturer to a sequential increase of 10% annually, the latter deals with the consequences of a violation of the 10% circuit breaker. The latter part of Para 20 kicks into play the moment the manufacturer transgresses the maximum permissible limit of 10%. However, Para 20 nowhere mandates that the right to seek a periodic revision stands lost in case the manufacturer violates the limits prescribed. The Court consequently finds itself unable to accept the interpretation advocated at the behest of the respondents in light of the unambiguous prescription of the consequences of a violation of the former part of Para 20. The language employed by that provision explicitly spells out not just the consequences of a transgression, it also prescribes the period during which remedial measures are to be adopted.

82. As was rightly contended on behalf of the petitioners, the crucial expressions which would throw light on the intent of Para 20 are the expressions ***"preceding"*** and ***"next"***. The word "preceding" acts as a pointer to the date or the period which would constitute the focal point to identify the legally permissible MRP with reference to which an infraction is liable to be examined. The word "next" denotes and prescribes the period during which the MRP of the formulation must be kept static after being rolled back. For the purposes of identifying the valid MRP against which a periodic 10% increase may be claimed, it is the price prevailing in the preceding year which would govern and decide. Similarly, the period during which the MRP must be revised and kept on hold is also prescribed to be the next twelve months when computed with reference to the date or period of the infraction. Both the commencement as well as the termination

of the period during which the MRP must remain frozen has to be necessarily computed with reference to the date or the period during which the manufacturer may have overcharged.

83. The Court notes that if the view as taken in the impugned orders were to be upheld, it would not only amount to the introduction of an additional penal consequence, it would also shift the terminal point as fixed by Para 20. The interpretation of Para 20 as advocated by the respondents would clearly amount to the Court recasting that provision while undertaking an exercise of statutory interpretation and the introduction of a penalty which has neither been provided for nor contemplated. While the Court is conscious of the fact that the issues involved here relate to drugs and the paramount consideration of the said essential commodity being sold and distributed in a fair and equitable manner, it finds itself unable to introduce in or read into Para 20 a penal consequence which has otherwise not been incorporated by the authors of the statute. It is not for this Court to structure or insert a penal consequence on its own understanding or notions of righteousness. The contention of the respondents based on alleged profiteering is also negated by the penal consequences which are provided for in Para 20 itself and which requires the manufacturer to not only deposit the overcharged amount but to do so along with interest from the date of the transgression.

84. It would be pertinent to observe that Para 20 constructs a complete and comprehensive structure to enable the Government to regulate and monitor the price of non-scheduled formulations. It not only and in unambiguous terms prescribe the price band within which the maximum

retail price of such formulations can move, it also stipulates the penal consequences of transgressions. The said provision does not leave any grey area or pocket of ambiguity which may warrant an intervention by the Court or it stepping in to clear the thicket or dispel a cloud of doubt or uncertainty.

I. PARA 20 AND THE INTEREST QUESTION

85. That then takes the Court to deal with the issue of interest as was canvassed on behalf of **Bard** by Mr. Sibal. It may be noted that insofar as **Bharat Serums** is concerned, Mr. Shah, learned counsel appearing on their behalf, did not adopt those submissions. The submission relating to interest and as was advanced by Mr. Sibal proceeded along the following lines. According to Mr. Sibal, the power to levy interest on the overcharged amount principally flows from Section 7A of the Act. According to Mr. Sibal, the liability to pay interest in terms of Section 7A can commence only once a manufacturer defaults in paying an amount pursuant to an order or demand which may be raised by the respondents. It was contended that the 2013 DPCO which is essentially a piece of subordinate legislation must yield to the provisions contained in Section 7A. It was in the aforesaid backdrop that it was commended to the Court that the principles as enunciated in **T.C. Healthcare** and the various decisions which had followed the dictum laid down therein should be reiterated. This Court, however, finds itself unable to sustain the aforesaid contentions for the following reasons.

86. It must, at the outset, be noted that **T.C. Healthcare** came to be rendered in the context of the provisions contained in the 1995 DPCO. Para

13 of the 1995 DPCO which has been extracted hereinabove, made provisions for recovery of overcharged amounts. While dealing with that subject, Para 13 prescribed that the Government shall by notice require manufacturers, importers or distributors to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of the 1987 and 1995 DPCOs'. Para 13 thus prescribed and put in place a procedure in terms of which the Government was to place manufacturers, importers or distributors on notice to deposit the amounts which may have accrued due to charging of prices higher than those fixed under the Price Control Orders. However, Para 20 has been worded in a manner which is starkly distinct from Para 13. It becomes pertinent to note that Para 20(1) clearly appears to put in place a self regulatory mechanism which obligates the manufacturer to ensure that the price that it fixes for non-scheduled formulations does not exceed 10% of the price prevailing in the preceding twelve months. The penalty which would visit a manufacturer in case of a violation of the aforesaid provision is clearly and unambiguously spelt out in that provision itself when it stipulates that in case a manufacturer breaches the maximum permissible increase of 10%, it would be under an obligation to deposit the amount overcharged in excess together with interest. Significantly, the compliance with the aforesaid prescriptions is not made dependent upon or subject to an order being made by the NPPA. What places Para 20 in a position distinct from Para 13 of the 1995 DPCO is that unlike the latter which envisages interest being leviable from the date when a manufacturer fails to comply with a demand, the former is not premised on a demand being raised at all. Under Para 20, the manufacturer becomes liable to take steps for reparation the moment an

event of overcharging occurs. The trigger event under Para 20 is thus the act of overcharging itself.

87. The Court also bears in mind the duty placed upon manufacturers to issue price lists and supplementary price lists and provide the same to dealers, State Drug Controllers and the Government indicating changes that may be made from time to time in terms of Para 25(2) of the 2013 DPCO. Regard must be had to the fact that since and insofar as non-scheduled formulations are concerned, the Government has only retained the power to monitor prices of such formulations, the 2013 DPCO casts a duty upon that class of manufacturers to ensure that the price of their drugs do not breach the maximum permissible increase which is prescribed. The requirement placed by Para 25(2) is essentially a valuable aid to enable the NPPA to monitor and oversee the movement of prices of drugs. Additionally, it also acts as a constant reminder for manufacturers of their overarching obligation to maintain prices within the permissible limits and to self-regulate.

88. More significant, however, are the provisions contained in Para 20(2). Sub Para (2) in clear and unequivocal terms mandates that interest shall be payable on the overcharged amount from the date of increase in price. The expression "*date of increase in price*" must necessarily be understood to be a categorical reference to the date or the period from which interest is ordained to be leviable. Para 20(2) thus appears to leave no room for doubt that interest has to be paid from the date of increase of such price. It may be noticed that while separate provisions have been made in Paras 22 and 23 for recovery of dues which may have accrued

under the 1979, 1989 and 1995 DPCOs', insofar as cases of overcharging which are referable to the provisions of the 2013 DPCO are concerned, they are mandated and must be understood to be governed by the provisions of Para 20 only.

89. It becomes pertinent to highlight that Para 20 neither contemplates the issuance of a notice nor does it adopt the principle of amount "accrued" as was envisaged under the 1995 DPCO. **T.C. Healthcare** and all judgments which followed thereafter were essentially construing the provisions of Para 13 of the 1995 DPCO. However, the trigger point in terms of Para 20 is not a notice or a demand but the event of overcharging itself. Secondly, sub para (2) in unequivocal terms prescribes that the interest shall be leviable from the date of increase of price. The language of Para 20(2) thus leaves no room to introduce the concept of a notice of demand being the precursor to the liability to deposit the overcharged amount along with interest.

90. The Court also finds itself unable to construe Section 7A of the Act as in any manner abridging the scope of Para 20. It would be relevant to note that the liability to pay amounts which are due together with interest is related to any sums that may be recoverable in pursuance of any order made under Section 3 of the Act. The 2013 DPCO, and of which Para 20 is an integral part, is itself an order made under Section 3 of that Act. Thus, the liability to pay interest from the date of increase of price which stands created in light of Para 20 is itself liable to be recognised as one created in terms of an order made under Section 3 itself. The Court thus finds itself unable to interpret Section 7A(1)(a) as stultifying the command of Para 20.

The submissions addressed in this respect in any case warrant negation in light of the plain and express language of Para 20.

J. THE LEGAL UNCERTAINTY AND OVERCHARGING

91. Before closing this chapter and for the completeness of the record, the submission of Bard with respect to a lack of clarity in respect of disclosures liable to be made by manufacturers of medical devices being the cause for the transgression may also be evaluated. To recall, Bard had contended that at the relevant time, there was a lack of clarity with respect to the categories of medical devices which could be said to be covered under the 2013 DPCO. It was also argued that since the respondents themselves had not put in place the requisite mechanism for reporting the prices of medical devices, the allegation of overcharging would not sustain. The Court finds itself unable to accept this submission in light of the candid concession made on behalf of the said petitioner that the medical devices in question did fall within the ambit of the expression "drug" as defined. The Court also notes that disposable hypodermic syringes/needles as well as catheters stood duly notified as drugs in terms of notifications dated 17 March 1989 and 06 October 2005.

92. There is thus a tacit admission to medical devices falling within the ambit of non-scheduled formulations under Para 20. Consequently, merely because the respondent did not call upon these manufacturers to submit a price list in a particular format, that would not absolve Bard from their obligation to ensure compliance with Para 20. The Court also bears in mind the pertinent observations made by the Supreme Court in **Cynamide** where it had observed that pharmaceutical manufacturers cannot feign ignorance

of legal and statutory obligations. Bard in any case cannot assert that it was unaware of the legal obligation to be compliant with Para 20. The reporting mechanism which was developed by NPPA in 2017 was only to aid them in the task of monitoring the price of non-scheduled formulations. The arguments addressed on this score are consequently rejected.

K. ROUNDING OFF- A WELL RECOGNISED CONCEPT

93. That only leaves the Court to deal with the issue of rounding off. It cannot possibly be disputed that the 2011 Rules clearly do not apply in light of the express exclusion of drugs from their ambit. The Court also bears in mind the submission of Mr. Singh who had contended that Para 5.2 of the NPPA Minutes of Meeting dated 12 April 2016 used the expression '*ceiling price"* and *"WPI"* and must therefore be understood to be confined to scheduled formulations only. The Court also bears in mind that the extension of the rounding off the principle was one which was considered and ruled upon in **Obsurge** and which decision presently forms subject matter of challenge in a pending LPA No. 310/2020.

94. Notwithstanding the above and without being influenced by the observations in **Obsurge**, the Court notes that Para 5.2 speaks of overcharging on account of fixation of a price for formulations. Undisputedly, the expression *'formulation'* would include both scheduled and non-scheduled formulations. The Court also bears in mind that NPPA had decided not to pursue overcharging cases which arose merely on account of the adoption of the rounding off principle and was otherwise not actuated by mala fide. **Bharat Serums** has in terms of the data placed on the record clearly established that it has been held to have overcharged

merely because it had rounded off the price of its drugs. This is evident from the disclosures made by the said petitioner where the price of Rs. 90.75 was rounded off to Rs. 91 and Rs. 109.808 was rounded off to Rs. 110. It becomes pertinent to observe that it is not the case of the respondent that the aforesaid action of **Bharat Serums** was actuated by mala fides. The issue ultimately boils down to whether the respondents would be justified in taking the position that the principle of rounding off can only apply to scheduled formulations.

95. The Court bears in mind the admitted fact that a manufacturer of non-scheduled formulations is not obliged by statute to seek the approval of the price of its drugs. In fact, that class of formulations is exempt from the rigors of price control altogether as has been noticed in the preceding parts of this decision. The Government has merely retained a power to monitor the price of non-scheduled formulations. Apart from the power of oversight which stands retained by the Government in respect of this class of drugs, the manufacturers thereof are freed from the rigors of price control and are entitled to raise and revise the prices of such formulations provided such increases are within the permissible band of 10%. The Court also cannot lose sight of the practical difficulties that may accompany the price of a drug being fixed at Rs. 99.825, Rs. 109.808, Rs. 2698.30, Rs. 2968.13 or Rs. 3591.43. The fixation of such prices would lead to serious impracticalities when evaluated from a consumer's point of view.

96. On a more fundamental plane, this Court of the firm opinion that depriving manufacturers of non-scheduled formulations of the facility of rounding off which is otherwise and generally accepted by the NPPA itself

as a well-recognized mathematical practice would be manifestly arbitrary. The respondents have failed to point out any justifiable or rationale basis on account of which the principle of rounding off would not apply to non-scheduled formulations. The Court finds no justification in the stand taken by the respondents who contend that while it would be open for a manufacturer of a scheduled formulation to round off the price of its products, that benefit should be denied to manufacturers of non- scheduled formulations. Once the NPPA had arrived at the conclusion that rounding off was a well-accepted mathematical principle, the Court finds no justification to discriminate between scheduled and non-scheduled formulations and restrict the application of that practice only to the former. The Court deems it pertinent to observe that if the argument as advanced on behalf of the respondents on this score were to be countenanced, it would not only amount to a hostile discrimination between scheduled and non-scheduled formulations, it would additionally and more fundamentally be patently arbitrary. The Court comes to this firm conclusion since the respondents have abjectly failed to indicate any valid or justifiable ground on the basis of which the principle of rounding off which as per the respondents themselves is a well recognised mathematical practice would not apply to non-scheduled formulations. The Court also bears in mind the fact that the applicability of the aforesaid mathematical practice has been accorded due recognition and acceptance by the NPPA itself. That decision taken by the apex regulatory body cannot and should not be construed as being restricted to scheduled formulations alone. It would be manifestly arbitrary and unjust to uphold an allegation of overcharging against manufacturers of non-scheduled formulations where the infraction of Para

20 is based solely on the adoption of the principle of rounding off.

L. CONCLUSIONS

97. Having traversed the issues which were raised in this batch, the Court comes to record the following conclusions: -

A. The 2013 DPCO represents a conscious decision taken by the Union to leave the price of non-scheduled formulations to be determined by market forces subject to the rider that the annual increase would not exceed 10% and in case of overcharging the manufacturer would have to roll back the prices to the preceding legally permissible price and preserve it at that level for the next twelve months.

B. Viewed in that backdrop it is evident that a manufacturer of a non-scheduled formulation was entitled to fix the price of its drug subject to the singular fetter of the same being compliant with the stipulation of 10% which was sanctioned.

C. Undisputedly, non-scheduled formulations are not subject to the rigors of price control under the 2013 DPCO. That provision simply places an obligation upon the Government to monitor and oversee that the maximum retail price of such formulations does not exceed 10% of the price which was prevailing in the preceding twelve months. The salutary objective underlying this prescription is clearly manifest bearing in mind the fact that drug prices must necessarily be regulated by the Government in order to ensure that patients and consumers do not face the specter of runaway price increases and to control profiteering.

D. However, Para 20 undoubtedly permits a manufacturer to increase the maximum retail price annually subject to the singular limitation that the price increase would not exceed 10% of the price which was prevailing in the preceding twelve months. The consequences of a breach of the aforesaid prescription is also not left open to speculation with Para 20 in clear and unequivocal terms prescribing the penalty as well as the remedial measures which must be adopted.

E. Significantly, Para 20 does not envisage a deprivation of the right to increase the retail price of a drug annually in case of overcharging. Para 20 spells out and stipulates both the consequences as well as the penalties which would visit a manufacturer in case it were to violate its provisions. The stand taken by the respondents to the effect that the right to seek such increase would stand lost till such time as the price is revised and brought down, would not only amount to a recasting of Para 20, it would also and on more fundamental terms, result in the introduction of a penal consequence which neither flows from a plain reading of that provision nor can be inferred.

F. The crucial expressions which would throw light on the intent of Para 20 are the expressions ***"preceding"*** and ***"next"***. The word "preceding" acts as a pointer to the date or the period which would constitute the focal point to identify the legally permissible MRP with reference to which an infraction is liable to be examined. The word "next" denotes and prescribes the period during which the

MRP of the formulation must be kept static after being rolled back. For the purposes of identifying the valid MRP against which a periodic 10% increase may be claimed, it is the price prevailing in the preceding year which would govern and decide.

G. Similarly, the period during which the MRP must be revised and kept on hold is also prescribed to be the next twelve months when computed with reference to the date or period of the infraction. Both the commencement as well as the termination of the period during which the MRP must remain frozen has to be necessarily computed with reference to the date or the period during which the manufacturer may have overcharged.

H. While the Court is conscious of the fact that the issues involved here relate to drugs and the paramount consideration of the said essential commodity being sold and distributed in a fair and equitable manner, it finds itself unable to introduce in or read into Para 20 a penal consequence which has otherwise not been incorporated by the authors of the statute. It is not for this Court to structure or insert a penal consequence on its own understanding or notions of righteousness.

I. Para 20 therefore must be read as providing a right to manufacturers of non-scheduled formulations to price their products subject to the rider that the increase complies with the 10% stipulation. That right of the manufacturer would be entitled to be factored in notwithstanding it having transgressed the latter part of Para 20 and overcharged.

J. The increase of 10% shall stand effaced only for the period of twelve months post the transgression of Para 20 where a manufacturer may have overcharged and violated that provision.

K. In case of a violation of Para 20 and an overcharging event having occurred, the manufacturer would be liable to roll back the price of the drug to the level at which it stood prior to the transgression and hold that price for twelve months post the date or the period of overcharge.

L. For the purposes of computing the liability that would stand raised in the case of an overcharging, the NPPA would be obliged to identity the date or the period during which the price of the drug transgressed Para 20 and require the manufacturer to revert to the price which prevailed prior to that event for a period of twelve months.

M. However the liability to roll back the price of the drug and keep it static at that level cannot extend beyond the twelve month period prescribed under Para 20 and continue up to the raising of a demand or till such time as the transgression is cured. The manufacturer in any case cannot be held liable to keep the price frozen for the period between the date or period of infraction till the date of raising of a demand or till the infraction is rectified by the manufacturer itself.

N. While calculating the liability relating to overcharge, the NPPA would have to take into consideration the legally permissible price which must be enforced over the next twelve months commencing

from the date or period of infraction, even if that may entail a notional computational exercise being undertaken.

O. In a case where the infraction is discovered many years down the line, in order to arrive at the actual liability owed, the authority would have to reverse the clock and calculate backwards in order to ascertain the legally permissible MRP which is to be enforced and the period of twelve months during which that price must be preserved.

P. However, for successive periods post the *"next twelve months"*, the manufacturer would be entitled to claim the 10% increase which is otherwise sanctioned by virtue of the first part of Para 20. The computation of liability would have to necessarily factor that into consideration while notionally computing the ultimate overcharge amount.

Q. Para 20 has been worded in a manner which is starkly distinct from Para 13. Para 20(1) clearly appears to put in place a self-regulatory mechanism which obligates the manufacturer to ensure that the price that it fixes for non-scheduled formulations does not exceed 10% of the price prevailing in the preceding twelve months. The penalty which would visit a manufacturer in case of a violation of the aforesaid provision is clearly and unambiguously spelt out in that provision itself when it stipulates that in case a manufacturer breaches the maximum permissible increase of 10%, it would be under an obligation to deposit the amount overcharged in excess together with interest.

R. Significantly, the compliance with the aforesaid prescriptions is not made dependent upon or subject to an order being made by the NPPA. What places Para 20 in a position distinct from Para 13 of the 1995 DPCO is that unlike the latter which envisages interest being leviable from the date when a manufacturer fails to comply with a demand, the former is not premised on a demand being raised at all. Under Para 20, the manufacturer becomes liable to take steps for reparation the moment an event of overcharging occurs. The trigger event under Para 20 is thus the act of overcharging itself.

S. Sub Para (2) in clear and unequivocal terms mandates that interest shall be payable on the overcharged amount from the date of increase in price. The expression "*date of increase in price*" must necessarily be understood to be a categorical reference to the date or the period from which interest is ordained to be leviable. Para 20(2) thus appears to leave no room for doubt that interest has to be paid from the date of increase of such price.

T. Para 20 neither contemplates the issuance of a notice nor does it adopt the principle of amount "accrued" as was envisaged under the 1995 DPCO. **T.C. Healthcare** and all judgments which followed thereafter were essentially construing the provisions of Para 13 of the 1995 DPCO. However, the trigger point in terms of Para 20 is not a notice or a demand but the event of overcharging itself. Secondly, sub para (2) in unequivocal terms prescribes that the interest shall be leviable from the date of increase of price. The

language of Para 20(2) thus leaves no room to introduce the concept of a notice of demand being the precursor to the liability to deposit the overcharged amount along with interest.

U. The liability to pay amounts which are due together with interest is related to any sums that may be recoverable in pursuance of any order made under Section 3 of the Act. The 2013 DPCO, and of which Para 20 is an integral part, is itself an order made under Section 3 of that Act. Thus, the liability to pay interest from the date of increase of price which stands created in light of Para 20 is itself liable to be recognised as one created in terms of an order made under Section 3 itself. The Court thus finds itself unable to interpret Section 7A(1)(a) as stultifying the command of Para 20.

V. Bard did not dispute that medical devices did fall within the definition of "drug" and would thus fall within the ambit of non-scheduled formulations under Para 20. Consequently, merely because the respondent did not call upon these manufacturers to submit a price list in a particular format, would not absolve Bard from their obligation to ensure compliance with Para 20. Bard in any case cannot assert that it was unaware of the legal obligation to be compliant with Para 20. The reporting mechanism which was developed by NPPA in 2017 was only to aid them in the task of monitoring the price of non-scheduled formulations.

W. The Court has borne in mind that insofar as non-scheduled formulations are concerned, the NPPA only exercises the power to monitor their prices. Having freed this category of manufacturers

from the rigors of price control, there appears to be no justification to restrict the applicability of the rounding off principle to scheduled formulations only.

X. The Court finds no justification in the stand taken by the respondents who contend that while it would be open for a manufacturer of a scheduled formulation to round off the price of its products, that benefit should be denied to manufacturers of non-scheduled formulations. Once the NPPA had arrived at the conclusion that rounding off was a well-accepted mathematical principle, the Court finds no justification to discriminate between scheduled and non-scheduled formulations.

Y. Depriving manufacturers of non-scheduled formulations of the facility of rounding off which is otherwise and generally accepted by the NPPA itself as a well-recognized mathematical practice would be manifestly arbitrary. The respondents have failed to point out any justifiable or rationale basis on account of which the principle of rounding off would not apply to non-scheduled formulations.

M. DIRECTIONS

97. Accordingly, and for all the aforesaid reasons, the writ petitions shall stand allowed. The impugned orders dated 05 July 2018 and 26 June 2018 pertaining to **Bharat Serums** and the order dated 22 October 2020 as well as the demand notice dated 07 November 2019 relating to **Bard** shall stand quashed.

98. The NPPA shall consequently undertake a fresh exercise of re-computation of the amounts, if any payable, by the petitioners bearing in mind the conclusions recorded hereinabove. While computing the ultimate liability of the individual petitioners, NPPA shall also take into consideration any deposits that may have been made by the petitioners during the pendency of the present litigation and pursuant to the orders which stood impugned in the present writ petitions.

YASHWANT VARMA, J.

SEPTEMBER 22, 2022
SU/rsk/neha/bh