

formulating their defence as the records pertaining to the relevant period were not available with the petitioners in the year 2016, when the impugned notices of demand were issued by the respondents.

2. The chronology of events leading to filing of the present writ petition would be relevant for appreciating the rival contentions. On 06.01.1995, respondent No.1 issued Drugs (Price Control) Order 1995 (DPCO 1995) by exercising power under Section 3 of the Essential Commodities Act, 1955. The First Schedule appended to DPCO 1995 specified the bulk drugs and formulations for which the respondent No.1 fixed ceiling price in accordance with paragraph 9 of DPCO 1995. For the present case, inclusion of 'Theophylline' in the First Schedule is relevant. The aforesaid DPCO 1995 consisted of 27 paragraphs, *inter alia*, providing for definitions of various terms used therein and also specified the powers of the respondent No.1 to fix retail price, ceiling price and to recover overcharged amounts from the entities in the business of manufacture and marketing of such bulk drugs and formulations.

3. The petitioner No.1 claims that it was exempted under a Notification dated 02.03.1995 issued by the respondent No.1, meant for small scale units. On 06.11.1995, the respondent No.1 issued Notification, fixing ceiling prices for various formulations of Theophylline. The petitioner No.1 was manufacturing Theophylline CR 300 mg tablets. Since the Notification issued by the respondent No.1, fixing ceiling prices for various formulations of Theophylline did not include Theophylline CR 300 mg tablets, the petitioner No.1 proceeded on the basis that there was no ceiling price. It is to be noted that certain variants of tablets were added by way of subsequent specific Notifications issued on 09.08.1996, but the aforesaid formulation of the petitioner No.1 was not included. Therefore, the petitioner No.1

proceeded on the basis that the ceiling price did not apply to the variant of Theophylline CR 300 mg tablet, as it was never notified by the respondent No.1.

4. After about 9 years, by issuing Notification dated 03.10.2006, the respondent No.1, for the first time, introduced ceiling prices for the variant Theophylline (CR/SR) 300 mg tablets. However, by this time, the petitioner No.1 had discontinued manufacturing its brand of Theophylline CR 300 mg tablet i.e. Phylobid CR 300 mg tablet.

5. Respondent No.1 claims that on 02.06.2008, it had issued a notice to the petitioner No.1 about alleged overcharging with regard to the said Phylobid CR 300 mg tablet i.e. brand name of the said petitioner for Theophylline CR 300 mg tablet. According to the petitioner No.1, it never received the said notice. We find that the documents placed on record by the respondent No.1 in this petition also do not support the assertion of the said respondent that the said notice was ever served upon the petitioner No.1.

6. There was no further action taken by the respondent No.1 and after about 9 years, on 18/20.02.2015, the respondent No.1 issued notice to the petitioner No.1, alleging that the said petitioner had manufactured and marketed Phylobid CR 300 mg tablets between May 2004 and February 2006, without applying for price approval despite knowing that the said product was under 'controlled price category'. The said notice was issued on the basis that the entire amount received by the petitioner No.1 for sale of the said Phylobid CR 300 mg tablets was payable as the petitioner No.1 had failed to apply for price approval.

7. Thereafter on 15.02.2016, the respondent No.1 issued a demand notice to the petitioner No.1 and one Vapi Care Pharma Private Limited, which had manufactured the said product under licence from the

petitioner No.1. In this demand notice, the earlier notice dated 18/20.02.2015 was superseded and it was claimed that the petitioner No.1 was liable to pay amount for having charged over and above the ceiling price fixed for the aforementioned product. On 14.03.2016, the petitioner No.1 responded to the demand notice, stating that in the year 2006, it had discontinued manufacturing the said product i.e. Phylobid CR 300 mg tablet. On 09.05.2016, the petitioner No.1 sent a detailed response to the demand notice of respondent No.1, specifically stating that the earlier alleged notice / letter dated 02.06.2008 was never received. It was specifically stated that the amended Notification under DPCO 1995 fixed ceiling price only for Theophylline SR 300 mg tablets and not for Theophylline CR 300 mg tablets (sold by the petitioner under its brand Phylobid CR 300 mg tablet). On this basis, it was stated that the petitioner No.1 was not liable to pay the alleged overcharged amount.

8. On 08.11.2016, the respondent No.1 sent another communication to the petitioner No.1, calling upon it to provide documentary proof of quantity of formulation rejected / defected, quantity used for sampling and unsold quantity. On 02.12.2016, the petitioner No.1 responded by stating that it had discontinued manufacturing Phylobid CR 300 mg tablet in the year 2006 itself, further reiterating that it was exempted from any ceiling price on a proper reading of relevant notification. The petitioner No.1 further stated that as per its Standard Operating Procedure (SOP), since it was required to retain records only for five years, the record pertaining to the relevant period was not available and it was destroyed.

9. In this backdrop, on 30.10.2017, the respondent No.3 Tahsildar issued 'notice of demand to a defaulter' under Section 267 of the MLR Code, demanding amount of Rs.1,25,22,416/- within 20 days,

threatening that in case of failure, property belonging to the petitioner No.1 would be attached and sold for satisfying the demand. Aggrieved by the same, the petitioners filed the present petition. On 22.11.2017, the instant petition was taken up for consideration urgently, when a statement was made on behalf of the respondents that warrant of attachment was yet to be served on the petitioners and that, no further coercive steps would be taken till the next date of hearing. It is an admitted position that the said statement has continued to operate and hence, the impugned demand notice has not been acted upon by the respondents.

10. On 01.06.2018, the respondent No.1 filed its reply affidavit. It relied upon various judgements of the Supreme Court, stating that ceiling prices for essential drugs were issued in public interest and that DPCO 1995 was the source of power for fixing such ceiling prices. It was submitted that since scheduled formulation could not be sold without prior approval and ceiling price was already fixed for Theophylline SR 300 mg tablet, the same applied to the product of the petitioner No.1, and therefore, the said petitioner was not liable to pay the overcharged amount. Respondent Nos.2 and 3 filed their reply affidavit, stating that a certificate of recovery was received in respect of the dues payable by the petitioner No.1 and that the said respondent No.3 was bound to issue the impugned demand notice as per the provisions of the MLR Code. On this basis, the respondents contended that the petition deserved to be dismissed.

11. Mr. Sharan Jagtiani, learned senior counsel appearing for the petitioners submitted that the tenor of the reply affidavit filed on behalf of the respondent No.1 shows that it was seeking to fall back on its first notice dated 18/20.02.2015, whereby it was claimed that since the petitioner No.1 had failed to apply for price fixation, the entire price

charged by the petitioner No.1 for its aforesaid formulation Phylobid CR 300 mg was payable as dues. This was clearly contrary to the second demand notice dated 15.02.2016 issued by the respondent No.1, whereby it superseded the first notice dated 18/20.02.2015. On this basis, it was submitted that the approach of the respondent No.1 was self-contradictory and unsustainable.

12. Even with regard to the second demand notice dated 15.02.2016, it was submitted that the same was clearly unsustainable in the light of the fact that the formulation Theophylline CR 300 mg (brand name of the petitioner No.1 being Phylobid CR 300 mg) was never included in the Notification issued by the respondent No.1, fixing ceiling price for various formulations. It was submitted that while the respondent No.1 did issue amended Notification on 09.08.1996 (including Theophylline SR 300 mg tablets), for fixing ceiling prices and specifying such ceiling prices, no such amended notification was issued in respect of Theophylline CR 300 mg tablets. It was further submitted that the formulation of Theophylline CR 300 mg tablets was, for the first time, included by a Notification issued after about 10 years on 03.10.2006. The very fact that such a specific amended Notification was required to be issued for fixing ceiling prices, specifically for the formulation Theophylline CR 300 mg tablets, demonstrates the fallacy in the stand of the respondent No.1 that ceiling price fixed for Theophylline SR 300 mg tablets was applicable to Theophylline CR 300 mg tablets.

13. It was further submitted that a recent judgement of this Court in the case of *Pfizer Limited and another Vs. Union of India and others*, **2025 SCC OnLine Bom 3821** took into consideration the difference in various drug delivery systems such as controlled release, sustained release, delayed release, extended release etc., while holding that each such distinct drug delivery system is to be specified as a formulation for

fixing ceiling prices. It was submitted that although the said judgement was concerned with subsequent Drugs (Price Control) Orders, the observations made in the said judgement would inure to the benefit of the petitioners also. In this regard, reliance was also placed on judgement of the Delhi High Court in the case of *Modi-Mundipharama Pvt. Ltd. Vs. Union of India and others*, **2018 SCC OnLine Del 9904**.

14. Apart from this, a very serious challenge was raised to the impugned notices issued by the respondent No.1 on the ground that in the present case, principles of natural justice stood violated. It was submitted that the respondent No.1 issued its first notice to the petitioner on 18/20.02.2015, raising demand for sale of the said formulation of the petitioner No.1, for the period from May 2004 to February 2006. It was submitted that the said notice was issued after a long period of nine years. The said notice was superseded by a subsequent notice dated 15.02.2016, thereby demonstrating that the impugned action was undertaken on the basis of the second demand notice, which was issued a full 10 years after the subject period was over. By referring to the said chronology of events, it was submitted that the entire action stood vitiated as the petitioner No.1 was prevented from raising its own defence as the relevant records were no longer available. It was further submitted that the respondent No.1 could not be permitted to rise from its slumber after a decade to call upon the petitioner No.1 to make good the allegedly overcharged price for the aforesaid formulation. In support of the said contention, reliance was placed on the judgements of this Court in the cases of *Parekh Shipping Corporation Vs. Assistant Collector of Customs, Bombay*, **1995 SCC OnLine Bom 622**; *Anil Nemichand Bafna and others Vs. State of Maharashtra*, **2010 SCC OnLine Bom 704**; *Zuari Agro Chemicals Limited and another Vs. Union of India and others* (judgement dated **21.01.2014** passed in **Civil Writ Petition No.11794 of 2013**); *Mahindra and Mahindra Limited Vs.*

Union of India and others (order dated **19.11.2024** passed in **Writ Petition No.4339 of 2024**); and *JKC General Trading Company Vs. Union of India and others* (judgement and order dated **01.12.2025** passed in **Writ Petition No.15775 of 2025**). In this context, reliance was also placed on judgements of the Supreme Court in the cases of *State of Madhya Pradesh Vs. Bani Singh and another*, **1990 (Supp) SCC 738** and *Kranti Associates Private Limited and another Vs. Masood Ahmed Khan and others*, **(2010) 9 SCC 496**.

15. The learned senior counsel further relied upon judgements of the Supreme Court in the cases of *S. L. Kapoor Vs. Jagmohan and others*, **(1980) 4 SCC 379** and *Airports Economic Regulatory Authority of India Vs. Delhi International Airport Limited and others*, **(2024) 15 SCC 345**, for the proposition that the respondent No.1 was under a duty to act fairly even when its administrative act was being tested. It was further submitted that the respondent No.1 was also under a duty to record proper reasons and to give a hearing to the petitioners before the drastic action of seeking to recover alleged overcharged amount as arrears of land revenue. In this regard, reliance was placed on the aforementioned judgement of the Supreme Court in the case of **Kranti Associates Private Limited and another Vs. Masood Ahmed Khan and others** (*supra*).

16. On the other hand, Mr. Khandeparkar, learned senior counsel appearing for respondent No.1 refuted the claims made on behalf of the petitioners. It was submitted that on a proper reading of DPCO 1995, particularly definitions of the expressions 'bulk drug' and 'formulations', it was evident that once the drug / formulation Theophylline was included in the First Schedule to DPCO 1995, the respondent No.1 was entitled to call upon the petitioner No.1 to make good the amount overcharged for the said formulation. Reliance was

placed on the power with the respondent No.1 to fix ceiling prices for such essential drugs and formulations. Although it was conceded that the respondent No.1 did not have any documents to show that notice dated 02.06.2008 was ever served upon the petitioner No.1, it was submitted that letter of the same date was served upon the licensee of the petitioner No.1 i.e. Vapi Care Pharma Private Limited, and therefore, it was not believable that the petitioner No.1 was not served. It was emphasized that the subsequent notice dated 18/20.02.2015 was indeed served upon the petitioner No.1 on the same address, thereby falsifying the claim of the said petitioner. It was submitted that no fault could be found with the respondent No.1 insisting upon payment of the overcharged amount by treating the ceiling price fixed for Theophylline SR 300 mg as the basis for the formulation manufactured and sold by the petitioner No.1.

17. It was submitted that the contentions pertaining to violation of principles of natural justice raised on behalf of the petitioners by placing reliance on a plethora of judgements, are wholly misplaced because the petitioner No.1 was granted ample opportunity to explain its conduct of overcharging the consumers. Since no plausible explanation was given, the consequential action of recovering the overcharged amount as arrears of land revenue was clearly justified.

18. Much emphasis was placed on judgement of the Supreme Court in the case of *T. C. Healthcare Private Limited and another Vs. Union of India and others*, (2020) 15 SCC 117, to contend that the Supreme Court in the context of DPCO 1995 had categorically held that it was for the manufacturers like petitioner No.1 to have approached respondent No.1 for fixing of ceiling price. The omission of petitioner No.1 to do so cannot inure to its benefit when the respondent No.1 found the act of overcharging on behalf of the petitioner No.1. It was submitted that the approach sought to be adopted by the petitioner No.1 goes against the

position of law clarified by the Supreme Court with regard to the power of the respondent No.1 to fix ceiling prices for essential drugs and formulations in series of judgements, including judgement in the case of *Union of India Vs. Cynamide India Limited, (1987) 2 SCC 720* and other such judgements. It was further submitted that it would be against public interest to allow the petitioner No.1 to escape liability despite a clear case of overcharging made out against it.

19. On this basis, it was submitted that the writ petition deserved to be dismissed and the respondents need to be relieved of the statement made on 22.11.2017 before this Court.

20. The aforesaid rival contentions raised on behalf of the petitioners on the one hand and on behalf of the respondents on the other, demonstrate that the specific issues pertaining to violation of principles of natural justice, have been raised on behalf of the petitioners, in the context of delay of more than 10 years on the part of respondent No.1 in taking up the issue of alleged overcharging by the petitioner No.1 for the aforementioned formulation of Theophylline CR 300 mg (brand name Phylobid CR 300 mg), the duty on the part of the respondent No.1 to act fairly in its administrative action of issuing show cause notice and the necessity of recording reasons for issuing the demand notice for huge amount, without recording any reasons and/or granting hearing to the petitioners. Apart from this, the petitioners have also raised issues on merits, to challenge the impugned action of the respondents.

21. We have considered the rival submissions on the aspect of the date when the petitioner No.1 was first made aware about its liability to make good the amount overcharged for sale of the said formulation bearing its brand name Phylobid CR 300 mg. In this regard, the record shows that the first such notice/letter was issued by respondent No.1 on 18/20.02.2015. Although the respondent No.1 claimed that an earlier

notice dated 02.06.2008 was issued to the petitioners, it failed to place on record anything to demonstrate that such a notice was ever served upon the petitioner No.1. During the course of arguments, it was conceded on behalf of respondent No.1 that no such material was available.

22. The submission that such a notice was received by a licensee of the petitioner i.e. Vapi Care Pharma Private Limited, can be of no consequence and it cannot be the basis to presume that notice dated 02.06.2008 was served upon petitioner No.1. In any case, the said Vapi Care Pharma Private Limited had responded on 18.06.2008, through its letter received by respondent No.1 on 23.06.2008, stating that even it had stopped manufacturing the said product from the year 2005 as the license was cancelled. Thus, the first notice was issued and served upon the petitioner on 18/20.02.2015, concerning allegations of illegal charging of unregulated price for the said formulation Phylobid CR 300 mg, for the period from May 2004 to February 2006. In other words, the notice was issued after 9 years of the alleged illegal action of the petitioner No.1.

23. The aforesaid notice dated 18/20.02.2015 alleged that the petitioner No.1 had sold the said product without applying for price approval from respondent No.1 or the authority under its control i.e. National Pharmaceutical Pricing Authority (NPPA). On this basis, it was claimed that petitioner No.1 was liable to deposit the entire amount of sale of the said product from May 2004 to February 2006 as 'unauthorized sale proceeds' to the tune of ₹ 1,66,03,556, being the amount with interest upto 10.03.2015.

24. Thereafter, on 15.02.2016, the respondent No.1, through NPPA, issued demand notice to the petitioner No.1, claiming that it had overcharged the consumers in respect of the said product. On this

occasion, it was stated that this was a case of overcharging, thereby indicating that the entire sale proceeds were not being treated as unauthorized sale proceeds. A statement of overcharging for the period from May 2004 to February 2006, was annexed to the demand notice giving the basis for the allegation of difference in price and overcharging on the part of petitioner No.1. In this notice, it was specifically stated that the same was in supersession of the aforementioned notice dated 18/20.02.2015, issued by NPPA. Thus, demand notice dated 15.02.2016 made a complete departure from the basis of issuance of the first notice/letter dated 18/20.02.2015. The said demand notice dated 15.02.2016 was issued more than 10 years after the period from May 2004 to February 2006, concerning the alleged illegal action on the part of petitioner No.1.

25. On the basis of the aforesaid huge time gap, the petitioners have specifically raised the contention pertaining to delay, resulting in depriving the petitioners from effectively defending their position. In this regard, reliance is placed on the response dated 14.03.2016 of petitioner No.1 to the said notice dated 15.02.2016, wherein it was specifically stated that manufacturing of the product Phylobid CR 300 mg was discontinued by the the said petitioner in the year 2006 itself. It was specifically stated that the said petitioner was unable to retrieve data from the existing record as it was very old.

26. Thereafter, on 09.05.2016, the said petitioner further sent a communication to NPPA, specifically stating that it had never received the alleged letter dated 02.06.2008. Specific grounds were raised to defend its position by stating that although notification dated 09.08.1996 fixed the ceiling price for Theophylline SR 300 mg, no such price was ever fixed for Theophylline CR 300 mg and there was no question of overcharging. Nevertheless, the said petitioner annexed a statement with

the aforesaid letter, to give the details of the quantity sold for the period from May 2004 to June 2005, as per the available record.

27. Thereupon, on 08.11.2016, the respondent No.1 called upon petitioner No.1 to give documentary proof of quantity of the formulation rejected/defected quantity used for sampling and unsold quantity along with disposal/fate within a period of 10 days of receiving the said letter. On 02.12.2016, the petitioner sent a letter to respondent No.1, through NPPA, clearly stating that as per its SOP for destruction and maintenance of record, the records were retained only for a period of 5 years and since such details were being demanded for the period from May 2004 to February 2006, it was not possible for the said petitioner to furnish the same. Copy of the SOP was annexed to the said letter.

28. Thus, it becomes evident that from the very beginning, the petitioner No.1 expressed its handicap in defending its position, as allegation pertaining to overcharging was levelled against the said petitioner after a huge delay of more than 10 years, by which time the relevant data and record for the period from May 2004 to February 2006 was not available. This was not even taken into account by the respondents, when the impugned notice of demand to defaulter dated 30.10.2017, was issued under section 267 of MLR Code. We find substance in the contention raised on behalf of the petitioners that the respondents could not be permitted to rise from their slumber after more than a decade, to allege overcharging on the part of the petitioner No.1 in the context of the sale of the aforesaid product. Such delayed action amounts to violation of principles of natural justice, as even under statutory provisions, the authorities are expected to initiate action within a reasonable period of time. This Court has considered such a scenario on a number of occasions and it has been laid down that gross delay in initiating proceedings and the act of issuing show cause notice in such

situations, can be quashed on the ground of delay itself.

29. In the case of **Parekh Shipping Corporation vs. Assistant Collector of Cus., Bombay** (*supra*), this Court held as follows:-

- ‘4. Shri Venkateswaran, learned counsel appearing on behalf of the petitioners, submitted that the provisions of Section 116 of the Customs Act should not be exercised after a passage of more than 12 years from the date of vessel leaving Port of Bombay. The learned counsel submitted that it is impossible for the Agents of Foreign Vessel to show cause as to whether the goods were short-landed, 12 years before the date of show cause notice. In our judgment, the submission is correct and deserves acceptance. It surpasses our imagination as to what prompted respondent No. 1 to wait for a duration of 12 years to issue show cause notice.

5. The exercise of powers under Section 116 of the Customs Act, if necessary, must be undertaken within a reasonable time. Shri Venkateswaran submitted that the Customs Excise and Gold Control Tribunal has held that show cause notice issued beyond the period of five years from the date of vessel leaving the Port is arbitrary and unreasonable. In our judgment, the period of five years is more than reasonable. Indeed, the bond executed by the Agents should also be for a duration of five years and in case the respondents desire to proceed against the Agents, action must be taken before the expiry of the period. The bond should not be kept alive for all time to come and must be limited for a duration of five years from the date of execution. For these reasons, the show cause notice issued by respondent No. 1 cannot be sustained and petition must succeed.’

30. In the case of **Mahindra and Mahindra Ltd. vs. Union of India and others** (*supra*), while considering an action sought to be undertaken by the competent authority under the provisions of Customs Act, 1962, this Court held that even where the statute is silent on limitation, the concerned authority is expected to initiate proceedings within a reasonable period of time on a holistic reading of the scheme of the statute. It was held that the show cause notice issued after gross delay,

deserved to be quashed on that very ground itself.

31. We find that in the present case, the gross delay of more than 10 years in itself could be a ground for setting aside the impugned show cause notice, demand notice and notice of demand to defaulter issued under the MLR Code. In this case, in its response to the notices sent by respondent No.1 through NPPA, after more than 10 years, the petitioner No.1 had specifically stated that the data and record for the relevant period was not available as more than a decade had gone by. Reference was also made to the SOP of the said petitioner of maintaining its record, stating that the record was destroyed after 5 years. The respondent No.1 and NPPA have not come forward to explain in any manner as to what prevented them for more than 10 years from taking action against the said petitioner for the alleged overcharging for the said product.

32. As a matter of fact, the notification dated 03.10.2006, for the first time, included Theophylline CR 300 mg under the regime of price fixing. By this time, the petitioner No.1 had already stopped manufacturing its product Phylobid CR 300 mg containing the said formulation. The respondent No.1 waited for 9 years to issue the first notice dated 18/20.02.2015. Subsequently, after one year, the respondent No.1 chose to supersede the said notice and on 15.02.2016, issued a demand notice, more than 10 years after the period during which the petitioner No.1 had allegedly overcharged, while selling its product. We find substance in the contention raised on behalf of the petitioners that in the absence of any explanation as to why respondent No.1 failed to proceed within reasonable period of time and waited for a period of more than 10 years to issue the demand notice, the impugned action deserves to be set aside.

33. Apart from this, we find substance in the contention raised on behalf of the petitioners that respondent No.1, as a department of the

State and its authority i.e. the NPPA, were expected to act in a fair and reasonable manner, while undertaking the impugned actions. The Supreme Court, in the case of **S. L. Kapoor vs. Jagmohan and others** (*supra*), held that the distinction between a judicial act and an administrative act had withered away and that even in the context of an administrative action, the concerned authority was expected to act in a fair manner. A strict adherence to natural justice was emphasized upon and this necessarily encompassed the requirement of granting a fair hearing and recording reasons for taking the ultimate action, particularly when severe and on occasions, penal consequences are inflicted upon the aggrieved person.

34. In the case of **Airports Economic Regulatory Authority of India vs. Delhi International Airport Limited and others** (*supra*), the Supreme Court again commented upon the fact that there was no longer any difference between a quasi judicial function and an administrative function, as both required a duty to act fairly on the part of the concerned authority, as principles of natural justice were read into administrative action also. The relevant portion of the said judgement reads as follows:

“50. In *Ridge v. Baldwin*, Lord Reid observed that the judicial character of the duty must be inferred from the nature of the duty itself. Since the decision in *Ridge*, Courts have inferred the duty to act judicially, that is, in compliance with the principles of natural justice based on whether the decision adversely affects legal rights. Over time, courts have abandoned the classification between quasi-judicial and administrative functions because the duty to act fairly, in compliance with the principles of natural justice has been read into administrative actions as well. M. P. Jain and S. N. Jain in their treatise on Administrative Law elucidate the reasons for the blurring of this distinction:

‘Differentiation between quasi-judicial and administrative seems to be merely an artificial formality, as many a time such a distinction is elusive and mostly a

manner of judicial policy. Also, since the functions of the Administration have been expanding adversely affecting the rights and interests of individuals, the courts are convinced that it is essential to concede the right of hearing on a broader scale, but, at the same time, it may be artificial to call a function as quasi-judicial as it may have *no judicial element involved*. Or, in a situation, the court may feel that the function of the Administration is such that it is susceptible to the application of only a few but not all the elements of natural justice. [...] Further, when a proceeding is characterised as administrative, the person whose interests are adversely affected thereby maybe left with no effective means of redress of his grievances as he could claim no procedural safeguards. To overcome these difficulties, the new trend has emerged. The advantage is that procedural fairness can be imposed on a large number of decision-making bodies without having to characterise their functions as quasi-judicial. *This approach has resulted in applying hearing procedure to a large chunk of administrative process. The nexus between hearing and quasi-judicial no longer exists in administrative process. This approach does away with the conceptual approach of calling a function as quasi-judicial when not much of judicial element is discernible there. [...] The emphasis is now placed on the element of injury to the concerned person by the administrative action in question to concede hearing to the affected person.*'

(emphasis supplied)"

35. Applying the said position of law to the facts of the present case, we find that respondent No.1 was expected to act fairly, which included the necessity of acting within reasonable period of time and not waiting for more than a decade to call upon the petitioner No.1 to explain the alleged overcharging for the said product. Such delayed action prejudiced the said petitioner in raising its defence as the relevant data and records were no longer available. Apart from this, a perusal of the communications in response given by the petitioner No.1 on 14.03.2016, 09.05.2016 and 02.12.2016, sufficiently demonstrated that specific grounds were raised to resist the proposed action to be taken by respondent No.1. This was despite the handicap faced by the petitioner No.1 due to the delayed action

undertaken by the respondent No.1.

36. The petitioner No.1 specifically raised the ground about non-applicability of the ceiling price fixation to its product concerning the formulation Theophylline as it was never notified by respondent No.1. The petitioner No.1 had also specifically relied upon its registration as a small scale industry, exempting it from operation of DPCO 1995 and other such grounds. Respondent No.1 failed to consider the said grounds specifically raised on behalf of petitioner No.1. It is an admitted position that petitioner No.1 was never given hearing, despite such specific grounds of challenge raised on its behalf and respondent No.1 directly proceeded to claim the alleged overcharged amount as arrears of land revenue. This resulted in the impugned demand of notice to defaulter dated 30.10.2017 being issued by the Tahsildar under section 267 of MLR Code.

37. We find substance in the contention raised on behalf of the petitioners that the aforesaid approach adopted by respondent Nos.1 and 3 violated the principles of natural justice as the said respondents did not act in a fair manner. No reasons were recorded for the drastic action of seeking to recover the huge amount of ₹ 1,25,22,416 as arrears of land revenue and no hearing was given to petitioner No.1 at any point in time.

38. We find substance in reliance placed on behalf of the petitioners on the judgement of the Supreme Court in the case of **Kranti Associates Private Limited and Masoon Ahmed Khan and others** (*supra*). In the said judgement, the Supreme Court held that it was necessary for recording reasons for executive actions. After referring to a number of earlier precedents, including certain English judgements, the Supreme Court in the said judgement, summarised that if a decision of an administrative authority prejudicially affects anyone, reasons must necessarily be recorded. It was held that this operates as a valid restraint on any possible arbitrary exercise of administrative power and that it had been taken on relevant grounds, instead of extraneous considerations. It was held that

recording reasons facilitates judicial review of the administrative action and that it encourages transparency.

39. We find that respondent No.1, in the facts of the present case, fell short of satisfying the aforesaid requirements, while taking the administrative action of issuing the impugned notices and demands against the petitioners. The said aspect was reiterated in the judgement of this Court in the case of **Zuari Agro Chemicals vs. Union of India and others** (*supra*), wherein it was held that even if there is no specific provision for a personal hearing and issuance of a speaking order under provisions of the statute, the principles of natural justice are required to be read into the statute, to ensure that they are followed. It was further reiterated that reasons are the soul of the orders and that such requirements apply to administrative and executive actions also with equal force. We do find substance in the said contentions raised on behalf of the petitioners, to the effect that the manner of exercising power on the part of the respondents, in the facts and circumstances of the present case, demonstrated flagrant violation of principles of natural justice, thereby vitiating the entire action and justifying the prayer made on behalf of the petitioner for setting aside the impugned notices and demands.

40. On the merits of the matter, the respondents relied upon judgment of the Supreme Court in the case of **T. C. Healthcare Private Limited and another vs. Union of India and another** (*supra*). It was contended that the petitioner, in terms of DPCO 1995 ought to have approached respondent No.1 for approval of price for the aforesaid product Phylobid CR 300 mg. In this context, reliance was placed on the definitions of the expressions 'bulk drug', 'ceiling price', 'formulation', 'schedule', 'scheduled bulk drug' and 'scheduled formulation'. Reliance was also placed on paragraph Nos.3, 8 and 9 of the DPCO 1995 in the context of the aforesaid submission.

41. We find that in the light of respondent No.1 itself having superseded

its earlier notice dated 18/20.02.2015 by the subsequent demand notice dated 15.02.2016, it cannot place reliance on the said judgment of the Supreme Court and the contents of the DPCO 1995, in order to insist that the impugned notices and demand are justified, as the petitioner No.1 failed to apply to respondent No.1 for approval of price for the said product. In the first notice dated 18/20.02.2015, the respondent No.1 had stated that the petitioner No.1 was liable to deposit the entire amount of 'unauthorized sale proceeds' in respect of the said product Phylobid CR 300 mg. The said notice was evidently issued on the basis that since the petitioner No.1 had failed to apply for price approval of the said product, it ought to deposit the entire sale proceeds. This is evident from paragraph No.3 of the said notice dated 18/20.02.2015. But the moment the respondent No.1 superseded the said notice by the subsequent demand notice dated 15.02.2016, the very basis for claiming that the petitioner No.1 was liable to deposit the entire amount towards 'unauthorized sale proceeds', was taken away. As a matter of fact, the subsequent demand notice dated 15.02.2016 reduced the liability of petitioner No.1 from ₹ 1,00,95,317 to ₹ 42,90,626 and restricted the liability to 'overcharged amount'. The statement of overcharging annexed to the aforesaid demand notice dated 15.02.2016 shows that the difference or the amount towards overcharge, was calculated on the basis of the ceiling price fixed for Theophylline SR 300 mg, treating the same equivalent to Theophylline CR 300 mg (brand name of the petitioner's product being Phylobid CR 300 mg). In other words, the case against the petitioner No.1 of failure in applying for fixation of price was consciously given up by respondent No.1 and therefore, the said contention of respondent No.1 is rendered unsustainable.

42. Even otherwise, in the said judgment of the Supreme Court, in the case of **T. C. Healthcare Private Limited and another vs. Union of India and another** (*supra*), the Supreme Court was specifically considering a challenge to a notification dated 11.07.2006, whereby the respondent No.1 had specifically fixed the ceiling price for the formulation that was the

subject matter of the said case. The Supreme Court found that under DPCO 1995, the respondent No.1 indeed had the power to fix such price and therefore, if the appellants therein wanted to claim that their drug delivery system was unique and different, it was for them to come forward and demonstrate the same. The observations made by the Supreme Court in the context of the aforesaid controversy, cannot be relied upon by respondent No.1 in the facts of the present case.

43. In this case, we find that while the respondent No.1 consciously issued subsequent notification dated 09.08.1996 to add the formulation Theophylline SR 300 mg tablets under the regime of fixation of ceiling price, the formulation Theophylline CR 300 mg tablets was not added by way of amendment. The contention of respondent No.1 that sustain release (SR) ought to be treated as equivalent to control release (CR), is unacceptable, for the reason that if that was the case, there was no necessity for issuing notification dated 03.10.2006 specifically including Theophylline CR 300 mg under the regime of ceiling price fixation. In any case, as noted hereinabove, the petitioner had stopped manufacturing its product Phylobid CR 300 mg (brand name for formulation Theophylline CR 300 mg) in the year 2006. This indicates another reason why the contention raised on behalf of respondent No.1 cannot be accepted.

44. It is to be noted that in a recent judgement of this Court in the case of **Pfizer Limited and another Vs. Union of India and others** (*supra*), although this Court was concerned with the explanation provided below the National List of Essential Medicines, 2015 (NLEM) that specifically stipulated that formulations developed through incremental innovations or novel drug delivery system could be considered included in the regime of ceiling price fixation only if specified in the list, observations made with regard to the difference in drug delivery systems in the said judgement, can be said to be relevant. It was noted in the said judgment that whenever a specific drug delivery system like sustain release or control release, other

than the ordinary tablet was intended to be covered under the NLEM, there was a specific reference to that drug delivery system and that when a particular drug delivery system stood covered by specific mention in the NLEM, by implication, the drug delivery system which was not mentioned, would have to be considered as not included in the list amenable to ceiling price fixation. To that extent, the observations made in the aforesaid judgement of this Court are relevant for the present case. For the very same reason, reliance placed on behalf of the petitioners on judgement of the Delhi High Court in the case of **Modi-Mundipharama Pvt. Ltd. Vs. Union of India and others** (*supra*), is justified.

45. In this backdrop, we find that respondent No.1 could not have treated the ceiling price fixed for drug delivery system concerning sustain release i.e. Theophylline SR 300 mg as the ceiling price fixed for the distinct drug delivery system of control release concerning the product of petitioner No.1 i.e. Theophylline CR 300 mg (brand name of the petitioner's product being Phylobid CR 300 mg). Therefore, the stand of respondent No.1 in order to justify its actions, is found to be unsustainable. In any case, as noted hereinabove, the impugned notices and demand were not only highly belated, thereby depriving the petitioner No.1 from raising its defence effectively, the same also demonstrated lack of fairness on the part of respondent No.1 and absence of a proper opportunity granted to the petitioner No.1 and total absence of any consideration of the limited stand the petitioner No.1 could take in its responses. There was no reason recorded at all as to why the respondent No.1 proceeded to issue the demand, eventually leading to 'notice of demand to defaulter' issued by respondent No.3 – Tahsildar under the provisions of MLR Code.

46. Since we have found the impugned notices and demand issued by respondent No.1 to be unsustainable for the aforesaid reasons, the consequential notice of demand issued by respondent No.3 – Tahsildar under the provisions of MLR Code, is also found to be unsustainable.

47. We also do not find substance in the contention raised on behalf of respondent No.1 by relying upon the judgement of the Supreme Court in the case of **Union of India Vs. Cynamide India Limited** (*supra*), for the reason that there cannot be any quarrel about the fact that respondent No.1 indeed has the power to fix prices and issuing ceiling price for essential products, including life saving drugs, the same can be done only in accordance with law and the provisions of the relevant drug control orders. In the present case, since we find that respondent No.1 has not been able to sustain its action under DPCO 1995, reliance on the said judgement on behalf of respondent No.1, can be of no consequence.

48. In view of the above, the writ petition is allowed in terms of prayer clauses (a) to (e). As a result, the impugned demand notice dated 15.02.2016 and notice of demand dated 30.10.2017 are quashed and set aside. Pending applications, if any, also stand disposed of.

(SHREERAM V. SHIRSAT, J.)

(MANISH PITALE, J.)

Minal/Priya