Gaikwad RD

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CIVIL APPELLATE JURISDICTION
WRIT PETITION NO. 2419 OF 2023

DKT INDIA,
A society registered under the Societies Registration Act, 1860, having its address at Shop No. 12, 22-23, Bldg No. Y, Rajlaxmin Commercial Complex, Mane Farm House, Opp Durgesh Park, Kather, Bhiwandi, District Thane 421 302 & Having its head office at Hem-Dil, 67 A, Linking Road, Opp St Lawrence High School, Santacruz (W), Mumbai 400 054 **…Petitioner**

~ VERSUS ~

1. **STATE OF MAHARASHTRA,**
Through the Ministry of Food & Drug Administration, Mantralaya, Churchgate, Mumbai 400 020

2. **OFFICE OF THE JOINT COMMISSIONER,**
Food & Drugs Administration, State of Maharashtra, Vardan (MIDC) Building, 1st & 9th Floors, Road No. 16, Wagle Estate, Thane 400 606 **…Respondents**

APPEARANCES

FOR THE PETITIONER	**Mr Rashmin Khandekar**, *with Dhruva Gandhi, Deepak Deshmukh, Vivek Dwivedi & Hrishikesh Nadkarni, i/b Naik Naik & Co.*
FOR RESPONDENT-STATE	**Mr PJ Gavhane, AGP.**

CORAM : G.S.Patel & Neela Gokhale, JJ.

DATED : 3rd April 2023

ORAL JUDGMENT (*Per GS Patel J*):-

1. **Rule**. Rule returnable forthwith.

2. The order in original was of 10th January 2022. The cancellation order in appeal w24th January 2023. Then a revised order of 27th January 2023 came to be issued notifying a suspension for 90 days instead of the cancellation. The reliefs are in the nature of a certiorari and a mandamus.

3. The Petitioner is a society under the Societies Registration Act, 1860. It is non-profit organization established in 1992 and works *inter alia* with the government in family planning and HIV prevention. At first, the Petitioner focused on birth control measures including contraceptives, especially for distribution amongst the poor. After 2001, the Petitioner expanded the range of family planning and maternity health products to include IUCDs, birth control pills, injectable contraceptives and other treatments as well. The Petitioner claims that its initiatives have received wide government support and appreciation. The Petitioner has, as part of its work, a series of agreements with the central government.

4. Given the nature of these activities. the Petitioner applied to the 2nd Respondent under the Drugs and Cosmetics Act, 1940 and the applicable Rules and two licenses came to be issued to the Petitioner on 29th August 2001 with a validity until 31st December 2027. The Petitioner uses these licenses to purchase various items such as condoms, drugs, devices and so on from various manufactures and then sales them to DKT Healthcare India Pvt Ltd which, in turn, sells and dispatches these products through a network of distributors. DKT Healthcare India Pvt Ltd is not the manufacturer of these products nor is the Petitioner.

5. On 3rd August 2021, the 2nd Respondent conducted an inspection of the Petitioner's godown at Bhiwandi. An inspection report was prepared. This contained various allegations against the Petitioner regarding non-compliance. A show cause notice of 16th November 2021 followed asking the Petitioners why its licenses should not be suspended or cancelled. The Petitioner replied on 25th November 2021. A personal hearing was afforded on 10th December 2021. Despite this, the 2nd Respondent passed a cancellation order effective from 16th May 2022 on 10th February 2022. The grounds for cancellation were that the Petitioner had not maintained Form 35; that for two of its products that the Petitioner did not send the same number of tablets to the head office; of four batch numbers, randomly chosen, the 2nd Respondent found that for one batch the Petitioner had sent 10 tablets to the head office whereas for the other two batches it had sent 15 and 20; that the Petitioner and DKT Healthcare India Pvt Ltd had nominated the same person as the nominee or competent person under their licenses; and, most surprisingly, that the Petitioner had not filed a FIR with the police authorities for the loss in transit of some 85 kits by a third party transportation agency, ATS Cargo Pvt Ltd.

6. The Petitioner filed an Appeal No. 954 of 2022 before the 1st Respondent on 9th May 2022.

7. Among the grounds the Petitioner took was that the non-maintenance of Form 35 was at best an irregularity; that batches of various drugs had been sent for testing to independent laboratory; the size or quantity difference for different tablets was immaterial; there was no prohibition or proscription against one individual being nominated as the competent person under multiple licenses; that the Petitioner had in fact submitted the appropriate documents and an explanation for the missing 85 kits; that the resultant order was disproportionate; that the order was unreasoned.

8. Since the Appeal was not being taken up urgently, the Petitioner filed Writ Petition No. 6061 of 2022. On 13th May 2022, the Petitioner was informed that the 1st Respondent had temporarily stayed the impugned order until it was heard. In view of that, the Writ Petition that the Petitioner had filed required no further orders.

Court clarified on 13th May 2022 that the 1st Respondent would pass a speaking order and if it was adverse to the Petitioner, it would not be implemented for another two weeks. While the Appeal was pending before the 1st Respondent the Petitioner applied for a renewal of its licenses. There was some change in the constitution. Some correspondence followed in that behalf and a clerical mistake was sought to be rectified. Specifically, the Petitioner was being wrongly classified as a private limited company although it is a registered Society. In any case that renewal application was allowed, and the drug licences stood renewed.

9. On 11th November 2022, the Petitioner received a notice that the Appeal before the 1st Respondent would be taken up on 14th November 2022. The Petitioner sought a short adjournment. But since there was no response to that request, the Petitioner appeared before the 1st Respondent and personally sought a rescheduling. The Petitioner was directed to file written submissions. It was pointed out that a hearing was required under the order of the High Court. There was no response to this letter either. The Petitioner on a without prejudice basis filed its written submissions and then received a fresh notice that the Appeal would be heard on 28th November 2022. That hearing took place. The 1st Respondent ultimately passed an order upholding the grounds for cancellation. The 2nd Respondent has then, pursuant to the appellate order, passed a revised order suspending (in lieu of cancelling) the Petitioner's licences for 90 days from 1st March 2023 to 29th May 2023. One month of that suspension has already gone.

10. The trouble with both the orders is that they suffer, prima facie, from a complete non application of mind, take into account all manner of irrelevant circumstances and fail to take into account relevant material. Chief amongst these is that the Petitioner is really not the manufacturer of the products. It is a second level collector. It does not even distribute the product directly. It has simply set up a scheme by which it is allowed to hold the medicinal products in question and then sends them out for further distribution. Rule 66 of the Drugs and Cosmetics Rules, 1945 is invoked with specific reference to 66(1)(b) alleging that the Petitioner or its agent employee has been guilty of an act or omission within the preceding 12 months. This is a reference to the loss in transit of a certain amount of cargo by a third party transporter. It is difficult to understand how the Petitioner could be held responsible for a third party carrier loss. The allegation that the failure to file an FIR constitutes so grave a charge as to warrant even a suspension (let alone a cancellation) is only to be stated to be rejected.

11. More importantly, while we have before us a copy of the grounds of appeal, we do not find from the appellate order any consideration of these grounds at all. The discrepancy in the two batches was explained and it was shown that the relevant portions of Rule 65 could not have been violated. Those Rules only require a licence holder to maintain records of the date of purchase, the name, address and licence number of the person from whom the drugs were purchased, the name of the drugs, quantity, batch number and the name of the manufacturer. This was in fact done. A discrepancy in the actual kits in stock and those purchased is not *per se* actionable under Rule 65.

12. In any case, there is the question of the application of the principles both of Wednesbury unreasonableness and the doctrine of proportionality. See: *Union of India v G Ganayutham*,[1] referencing and analysing *Associated Provincial Picture Houses v Wednesbury Corporation*[2] and *Council of Civil Service Unions v Minister for the Civil Service ("**CCSU**").*[3] The two doctrines received an elucidation in *Om Kumar & Ors v Union of India*,[4] and *Kerala State Beverages (M&M) Corporation Ltd v PP Suresh & Ors*.[5] The scope of the proportionality principle came to be examined in *Coimbatore District Central Cooperative Bank v Coimbatore District Central Cooperative Bank Employees Association & Anr*.[6] As the Supreme Court itself noted, the proportionality principle is a test of whether the decision-maker has achieved the correct balance: *Chairman, All India Railway Recruitment Board & Anr v K Shyam Kumar & Ors*.[7]

13. At least one decision of the Supreme Court reviews more recent thinking in England that the doctrine of proportionately has supplanted *Wednesbury* unreasonableness but our Supreme Court held that there is no such clear-cut division: *Jitendra Kumar & Ors v State of Haryana & Anr*.[8] In given cases both will apply. *Wednesbury*

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1 (1997) 7 SCC 463.

2 *Associated Provincial Picture Houses Ltd v Wednesbury Corporation*, [1948] 1 KB 223

3 [1983] UKHL 6 : [1984] 3 All ER 935 : [1984] 3 WLR 1174.

4 (2001) 2 SCC 386.

5 (2019) 9 SCC 710.

6 (2007) 4 SCC 669.

7 (2010) 6 SCC 614.

8 (2008) 2 SCC 161 : "We, with greatest respect, do not have any such problem. This Court not only has noticed the development of law in this field but applied the same also."

unreasonableness will speak to the rationality of a decision-making process. It has distinct components. One of these is a test of procedural irregularity. Another test is one of reasonableness, to test whether the decision is of a kind that no reasonable person could ever take. In the words of Diplock LJ in *CCSU*, the Wednesbury principle, formulated by Lord Greene, is whether the decision is so outrageous in its defiance of law or logic that it cannot possibly be sustained. Proportionality will speak to, as the Supreme Court said in *All India Recruitment Board*, examining if the decision achieves the required balance.

14. On an application of either of these principles, we find that the impugned orders cannot possibly be sustained. There is nothing in the show cause notice itself that even prima facie indicates that the alleged defaults, and we do not accept that there were in fact defaults because that would imply a lack of an explanation, were so egregious as to warrant even a suspension let alone a cancellation. The non consideration of the material and the lack of reasoning in the appellate order is directly in violation of the High Court order which specifically called for a reasoned order to be passed.

15. Accordingly, the petition succeeds, and rule is made absolute in terms of prayer clauses (a) and (b) which read thus: "a. Issue a writ of certiorari or any other appropriate orders or directions calling for the records of the case pertaining to the Order dated 24th January 2023 as passed by Respondent No.1 and Order dated 27th January 2023 passed by

Respondent No.2, (which Orders have been annexed at **Exhibits A** and **C** to this Petition), and after perusing the legality and propriety of the process, be pleased to quash and set aside both the orders, and in particular, the direction to suspend the Petitioner's licenses bearing Nos. MH-TZ5-267574 and MH-TZ5-267575;

> b. Issue a writ of mandamus or a writ in the nature of mandamus or any other appropriate directions or orders in the nature of mandamus declaring the suspension of the Petitioner's licenses bearing Nos. MH-TZ5-267574 and MH-TZ5-267575, as carried out vide Orders dated 24th January 2023 and 27th January 2023 passed by Respondent Nos. 1 and 2 respectively, to be illegal, arbitrary, disproportionate and in contravention of the Drugs and Cosmetics Rules, 1945."

16. No costs.

(Neela Gokhale, J) **(G. S. Patel, J)**

RAJU DATTATRAYA GAIKWAD Digitally signed by RAJU DATTATRAYA GAIKWAD Date: 2023.04.05 17:29:45 +0530