

IN THE HIGH COURT OF JUDICATURE AT PATNA
Civil Writ Jurisdiction Case No.16943 of 2018

Achewta Nand Singh Son of Late Shyam Sunder Singh, Prop M/s Kiran Pharma having place of business at Prop- M/s Kiran Pharma Babutola Lane, Behind Janta Hotel, Govind Mitra Road, P.S.- Pirbahor District- Patna.

... .. Petitioner

Versus

1. The State Of Bihar through the Principal Secretary, Health Department, Government of Bihar, Patna
2. The Assistant Drug Controller, New Gardiner Road, Hospital, Patna
3. The Drug Inspector, 9 New Gardiner Road Hospital, Patna.
4. The Appellate Authority, Drugs and Cosmetics Act, Patna.

... .. Respondent/s

Appearance :

For the Petitioner/s : Mr.Jitendra Kumar, Advocate
For the Respondent/s : Mr.Mujtabul Haque -GP12

CORAM: HONOURABLE MR. JUSTICE RAJEEV RANJAN PRASAD
ORAL ORDER

5 01-07-2019 The challenge in the writ application is to the order dated 06.08.2018 (Annexure P/4) passed in Appeal Case No. 03 of 2018 by the Appellate Authority under the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder (hereinafter referred to as the 'Act of 1940' and the 'Rules of 1940') whereby the appellate authority has dismissed the appeal preferred by the petitioner and affirmed the order dated 21.12.2017 passed by the Assistant Drug Controller cancelling the license of the medicines shop of the petitioner.

Facts revealed from the records are that the petitioner in this case was running the medicine shops for more than 20 years and his license was valid up to 31.03.2021. A search



operation was conducted by Police on 2nd June, 2017. In the search operation one medicine Dicloson vial 30 ml. Manufactured by Zedcare Pharmaceuticals India Ltd. which is said to be a banned medicine was seized from the shop. The raiding party prima facie was of the view that it is a spurious drug, thereafter, the sample of Dicloson, Diclone & Dicloson (Diclofenac Sodium Injection I.P.) 30 ml vial were said to have been sent to the Government Analyst, Central Laboratory, Government of India at Kolkada. The test report was received in Form No. 13 dated 19.09.2017 showing that the medicines were not of standard quality.

The Drug Inspector vide his letter no. 5471 dated 25.11.2017 wrote to the petitioner that the report of the Laboratory has been received which shows that the medicines were not of standard quality and therefore, by enclosing the Form '13' and the purchase invoice, the Drug Inspector called upon the petitioner to submit his reply, failing which lawful action shall be taken. He also called for certain information from the petitioner.

It appears that the letter no. 5471 dated 25.11.2017 of the Drug Inspector was replied by the petitioner vide letter dated 13.12.2017 as contained in Annexure '3' to the writ application.



It contains the copy of the proof of dispatch of the letter by speed post. In his reply he took a plea that he has been falsely implicated in the case. According to him, no seizure was made under Section 22 (1) (c) of the Act of 1940, no sample was taken in accordance with law and the averments made in the letter under reply that along with the so called test report copy of bill is being enclosed was denied saying factually there were test reports contained in three pages but there was no bill enclosed for purchase. It was, thus, his specific stand that the medicine was not purchased from his shop and the allegation that the medicine was prima-facie looking spurious was not correct. He denied selling of any such medicine.

While the aforesaid reply was submitted on 13.12.2017 to the Drug Inspector, it is a matter of record that the Assistant Drug Controller called for the copy of the test report from the Drug Controller vide his letter dated 08.12.2017 and in response thereto the Drug Inspector made available the Form No. 13 i.e. the test report of the Laboratory to the Assistant Drug Controller on 20.12.2017. On the very next day i.e. on 21.12.2017 the impugned order as contained in Annexure '1' to the writ application was passed by the Assistant Drug Controller whereby he cancelled the license.



Thereafter, the petitioner preferred the appeal but the appeal was also dismissed saying that the appellant-petitioner could not produce any material which could have shown that the order of the Assistant Drug Controller is not in accordance with law.

Learned counsel for the petitioner has assailed the impugned order by taking this Court through the letter no. 1160 dated 21.12.2017 (Annexure 1). It is submitted that without going into any other contentions or dispute at this stage, the impugned order is liable to set aside on a bare perusal of the same as it would be evident from the averments made therein that the test report of the Laboratory was sent to the office of the Assistant Drug Controller on 20.12.2017, thereafter, on the very next day he passed the impugned order without giving any opportunity to show cause to the petitioner. It is submitted that apart from the fact that the petitioner has emphatically stated in his reply dated 13.12.2017 that neither the medicine in question was purchased from him nor the purchase invoice was sent to him with the letter dated 25.11.2017 and the samples were also not made in accordance with law, the fact remains that even the said reply of the petitioner as contained in Annexure '3' to the writ application was never considered either by the Drug



Inspector or by the Assistant Drug Controller while passing the impugned order. The order as contained in Annexure '1' nowhere talks of the reply of the petitioner dated 13.12.2017 which was sent to the Drug Controller.

Learned counsel submits that a bare perusal of Rule 66 of the Drugs and Cosmetic Rules, 1945 would show that the licensing authority may take action towards suspension or cancellation of the license only after giving the licensee an opportunity to show cause as to why such an order should not be passed by an order in writing stating the reasons therefor. Therefore, it is mandatory for the licensing authority i.e. the Assistant Drug Controller to give the licensee an opportunity to show cause which has not been done in the present case as the impugned order was passed on the very next day.

Learned counsel further submits that even the appellate authority has not looked into the grounds raised by the petitioner and the appeal was dismissed without consideration of the material available on the record. He has relied upon the judgment of the Hon'ble Supreme Court in the case of **M/s. North Bihar Agency and others v. The State of Bihar and others** reported in **AIR 1981 Supreme Court 1758** and the judgment of the Hon'ble Division Bench of this Court in the



case of **Universal Drug House Pvt. Ltd. vs. State of Bihar and others** reported in **AIR 2004 Patna 86**.

Learned counsel for the State has opposed the writ application. It is submitted that the Drug Inspector inspected the shop of the petitioner and upon finding the irregularities the impugned action was taken. A statement has been made in the counter affidavit that in terms of Rule 66 (1) of the Rules of 1945, the petitioner was directed to file a reply within 7 days otherwise an ex-parte order shall be passed as per Rules. Annexure 'A' to the counter affidavit is the copy of show cause notice dated 10.06.2017. Annexure 'B' is another letter dated 24.06.2017 addressed to the petitioner which states that the earlier letter dated 10.06.2017 was returned unserved by the postal peon with an endorsement "always door locked". The letter dated 24.06.2017 addressed to the petitioner was without any house number or the name of the locality.

It is the contention of the State that despite show cause notice issued to the petitioner, he failed to submit any reply. The counter affidavit though refers to the letter dated 25.11.2017 issued by the Drug Inspector to the petitioner but it is totally silent about the reply of the petitioner dated 13.12.2017 which is enclosed with the writ application as



Annexure '3'.

In his rejoinder the petitioner has stated that pursuant to the FIR lodged on the date of inspection he was arrested by Police and since 02.06.2017 to 28.08.2017 he remained in jail, therefore, there was no question of service of notice upon him. He has denied service of Annexure 'A' and Annexure 'B' because during those period he was in jail.

Having heard learned counsel for the parties and on perusal of the records, this Court finds that at this stage the impugned orders are liable to be set aside on the ground of non-observance of the statutory provisions as contained in Rule 66 of the Rules of 1945 which reads as under:

“66. Cancellation and suspension of license.- (1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefore, cancel a license issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the Act or rules thereunder:

⁶⁵[Provided that, where such failure or contravention is the consequence of an Act or omission on the part of an agent or employee, the license shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority—

(a) that the act or omission was not instigated or connived at by him or, if the licensee is a firm or company, by a partner of the firm or a director of the company, or



(b) that he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission, the licensee had not or could not reasonably have had, knowledge of that previous act or omission, or

(c) if the act or omission was a continuing act or omission, he had not or could not reasonably have had knowledge of that previous act or omission, or

(d) that he had used due diligence to ensure that the conditions of the license or the provisions of the Act or the rules thereunder were observed.]

⁶⁶[(2) A licensee whose license has been suspended or cancelled may, within three months of the date of order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.]”

From perusal of the records it is evident that although initial show cause notices were sent to the petitioner on 10.06.2017 and 24.06.2017 but both the show cause notices were not served upon the petitioner because he was in jail during the relevant time. The address present at Annexure ‘B’ is not complete address. It is also evident that when the petitioner received the letter dated 25.11.2017 from the Drug Inspector, he sent his reply thereto vide his letter dated 13.12.2017 to the Drug Inspector. Copy of his reply dated 13.12.2017 is Annexure ‘3’ to the writ application. This document (Anneuxre ‘3’) has neither been dealt with in the impugned order dated 21.12.2017 nor the document and the receipt thereof have been denied by



the respondents in their counter affidavit. The respondents have completely ignored Annexure '3' to the writ application. In these circumstances, when the Assistant Drug Controller called upon the Drug Inspector to make available the test report of the Laboratory and the same was made available to him on 20.12.2017, he should have issued a show cause notice with the proposed action to the petitioner in compliance of Rule 66 of the Rules of 1945. The mandate of Rule 66 is very clear and it has to be complied with which has not been in the present case. This is violation of the statutory provision which is mandatory in nature and the action of the Assistant Drug Controller, Patna seems to be in haste as he has passed the order on the very next day after receipt of the test report from the Drug Inspector.

This Court also finds that the appellate order is totally without consideration of the materials available on the record. Even the appellate authority has not looked into the reply of the petitioner dated 13.12.2017 which was sent to the Drug Inspector that was the document in which the petitioner's stand was given.

Paragraph '10' of the Hon'ble Division Bench Judgment in the case of **Universal Drug House Pvt. Ltd.** (supra) reads as under:-

"I find substance in the submissions of Mr. Hussain.



It may be noticed that in course of inspection the drug authorities noticed two irregularities, one relating to the preparation called Ocimal Linctus with Codeine and the other with the pricing of Parafen tables. The irregularities in regard to these two specified items are made the basis for cancellation of the entire licence. It is true that a single violation of the licence or a contravention of the licence with regard to any one of the items covered it may be so grave and serious as to justify the cancellation of the entire licence with regard to a number of other items as well. But all violations may not necessarily lead to cancellation of the licence as a whole. A technical or minor violation in regard to one or some of the items covered by the licence may not, in all cases, justify cancellation of the whole licence covering many other items in regard to which there is no violation of any kind. It cannot be lost sight of that the cancellation of the licence in its entirety would amount to, as in this case, a forcible shutting down of a long standing business of in licence. Whether the licence would be liable to cancellation partly or wholly would depend upon the facts and circumstances of each cases. But the point to be emphasised is that the power to cancel licence must be exercised with proper discretion and not mechanically or arbitrarily.”

In the given facts and circumstance of the case, both the impugned orders as contained in Annexure ‘P/1’ and ‘P/4’ passed by the Assistant Drug Controller, Patna and the appellate authority respectively are hereby set aside and the license is restored.

The matter is remitted to the office of the Assistant Drug Controller, Patna (respondent no. 2) to take a fresh view of the matter giving reasons within a reasonable period and on the



basis of the materials available on the record after giving an appropriate opportunity to show cause to the petitioner in terms of Rule 66 of the Rules of 1945.

This writ application is allowed to the extent indicated above.

(Rajeev Ranjan Prasad, J)

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