

IN THE HIGH COURT OF JUDICATURE AT PATNA
Civil Writ Jurisdiction Case No.5568 of 2015

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M/s. Deo Pharma, Rahul Market, Govind Mitra Road, Patna through its proprietor - Suresh Prasad. S/o Late Kesho Ram. Resident of village/Mohalla - Malahi Pakari, P.S.- Kankarbagh, District - Patna.

.... Petitioner

Versus

1. The State of Bihar.
2. The Principal Secretary, Health Department, Government of Bihar, Patna.
3. The State Drug Controller cum Chief Licensing authority, Govt. of Bihar, Patna.
4. The Drug Inspector, Patna, District - Patna.

.... Respondents

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Appearance :

For the Petitioner/s : Mr. Ram Shankar Das, Advocate
For the Respondent/s : Mr. Md. Nadim Seraj, G.P.5
Mr. Shailesh Kumar, A.C. to G.P.5

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CORAM: HONOURABLE MR. JUSTICE RAMESH KUMAR DATTA
ORAL ORDER

8 23-08-2016 Heard learned counsel for the petitioner and learned counsel for the State.

The petitioner seeks quashing of the order dated 31.12.2014 passed, in Appeal No. 01/2014 by the appellate authority-cum-Health Minister, Government of Bihar, by which the order of cancellation of Drug selling licence of the petitioner vide order dated 18.07.2014 has been confirmed as also for setting aside the said order dated 18.07.2014 of the Drug Controller-cum-Chief Licensing authority and for consequential relief.

The petitioner is a wholesale licensee for as many as seven drugs and is carrying out his business with proper licence



for the last 30 years. The premises of the petitioner were inspected on 24.10.2013 by the Drug Inspector, wherein it was found that the bills and registers are not maintained with regard to phensedyl cough syrup. An F.I.R. was lodged in that regard on the allegation that the petitioner was selling the same, which is also used as intoxicant without proper accounting. Thereafter, a show cause notice dated 02.06.2014 was issued to the petitioner as to why his six drug licences be not cancelled for the said irregularities for which the petitioner filed his reply on 18.06.2014 stating that his computer was out of order and the computer operator was also not available. Since the system was not in order, the computer was giving out incorrect figures but subsequently on the rectification of the computer, the correct figure was available.

By the impugned order dated 17.7.2014, the State Drug Comptroller-cum-Chief Licensing Authority, found the explanation of the petitioner unsatisfactory as the petitioner could not produce the genuine document with regard to the sale and purchase of Phensedyl cough syrup which is also misused for the purpose of intoxication, which makes it violative of Rule 65 (5) (1) of the Drugs and Cosmetic Act and it was further found that the petitioner had been directed to produce the sale and purchase documents with regard to Phensedyl cough syrup by 25.10.2013



but he could not produce the same even till the date of the order; therefore he cancelled the licence of the petitioner. Aggrieved by the same, the petitioner filed an appeal against the said order which has been rejected by the impugned order dated 31.12.2014 of the Minister of Health Department-cum- Appellate Authority. Before the Appellate Authority, the petitioner was again directed to produce relevant documents, which were produced on 11.02.2014. The verification of the same was done from seven drug selling institutions as per the details given in the documents but it was found that all the invoices were forged and fabricated.

Learned counsel for the petitioner submits that under the provisions of Rule 66 of the Drugs and Cosmetic Rules, 1945, the drug licence can be cancelled by the licensing authority, whereas in the case of the petitioner, it has been done by the State Drug Controller-cum-Chief Licensing Authority. It is submitted that different notifications were issued by the State Government by which the licensing authorities have been appointed for different areas of the State and thus there was no occasion for the State Drug Controller-cum-Chief Licensing Authority to have passed the order in the matter.

It is submitted that the action of the Chief Licensing Authority is also contrary to the observations made by this Court



by order dated 04.12.2008 passed in C.W.J.C. No.13488 of 2008 wherein it was observed that when the licences were granted by the Regional Licensing Authority, who was available, why the matter was reported straight to the State Drugs Controller was not known and ordinarily should not be resorted to.

Further submission of learned counsel for the petitioner is that the original order is of the incompetent authority and it is non est in the eye of law.

Learned counsel also submits that the respondents are not justified in cancelling the entire licence of the petitioner which was for different items, whereas the irregularity, if any, was found only with respect to one of the items, namely, Phensedyl Cough Syrup and thus even in the worst circumstances, the licence for the same alone could have been cancelled and not the entire drug licence.

In support of the same, learned counsel for the petitioner relies upon a decision of this Court in the case of Universal Drug House Pvt. Ltd. vs. State of Bihar and Ors.: 2003 (3) PLJR 771, in paragraph Nos. 10 to 15 of which it has been held as follows:-

“10. I find substance in the submissions of Mr. Husain. It may be noted 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 tablets. 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 anyone of the items covered by 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 the licensee. Whether the licence would be liable to cancellation partly or wholly would depend upon the facts and circumstances of each case. But the point to be emphasized is that the power to cancel licence must be exercised with proper discretion and not mechanically or arbitrarily.

11. At this stage, it would be apposite to take a look at rule 66 (1) of the Drugs & Cosmetic Rules which is reproduced below:

“66 (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 licence 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 licence or with any provisions of the Act or Rules thereunder.” (emphasis added)

12. It is to be noted that the provision of the rule itself envisages a partial suspension/revocation of the licence in respect of the items with reference to which the violation (s) was committed.

13. I am supported in the view taken by me by the decision in Wyeth Lederle Limited (supra).

14. On hearing counsel for the parties and on going through the writ petition, the impugned order and the counter affidavit, it appears to me that in the facts and circumstances of the case the licensing authority acted mechanically and without a proper application of mind in cancelling the entire licence of the petitioner. In this case having regard to the fact that till 17.2.2003 the patent preparation with two Ayurvedic ingredients was in the list of approved substances in the manufacturing licence issued in favour of the petitioner by the licensing authority in West Bengal, the irregularities alleged against the petitioner with regard to the two specified items under its licence do not appear so grave or serious as to render the entire licence liable to cancellation.

15. Therefore, the impugned order in so far as it cancels the petitioner's licence as a whole and with regard to the items other than Ocimal Linctus with Codeine and parafen tablets is quashed and the licensing authority is directed to restore the petitioner's licence with regard to its other items."

It is also the submission of learned counsel for the petitioner that the case of the petitioner is covered by the proviso to Rule 66, under which the licence could not have been cancelled for the act or omission on the part of the petitioner.

Learned counsel also submits that the petitioner was not required to maintain any such register with regard to any formulation except before 01.03.2014 while an amendment had been made essentially for Schedule-H1 drugs.

Learned counsel for the State, on the other hand, submits that the action of the petitioner was a grave infringement of the conditions of the licence and the provisions of the Drugs & Cosmetic Act and Rules. It is further submitted that there is clear a finding of the Inspecting Team on 24.10.2013 that the petitioner was not maintaining proper records with regard to the registers regarding Phensedyl syrup.

It is further submitted that the petitioner failed to produce



any such explanation even before the State Drug Controller-cum-Chief Licensing Authority during the course of hearing when an opportunity was given to him nearly eight months after the inspection was made. Further when an opportunity was provided by the appellate authority, the petitioner produced the documents but on verification of seven of such invoices, it was found that seven invoices were forged. The same were thus forged and fabricated documents. In view of such violation by the petitioner in maintaining the records with regard to Phensedyl syrup, his licence has been cancelled and further explanation submitted by the petitioner regarding forged and fabricated document having been found to be not satisfactory, there is no justification that the orders passed by the licensing authority as also by the appellate authority regarding cancellation of the entire licence of the petitioner should be interfered with by this Court.

It is also submitted by learned counsel that the powers of the licensing authority provided under Section 66 of the Rules can equally be exercised by the State Drug Controller-cum-Chief Licensing Authority and there is nothing in the Act which prevents such exercise of power that has been duly delegated to him.

With regard to reliance placed by learned counsel for the petitioner on the decision of this Court in Universal Drug House



case (supra), it is submitted by learned counsel for the State that the case of the petitioner is not similar to that of the said case wherein the violation was held to be only technical whereas in the case of the petitioner there was a violation of the Rules which has been sought to be supported by producing forged and fabricated documents which is inexcusable.

Learned counsel for the State further submits that reliance placed by the petitioner on the amendment brought about has no any substance, as the same merely provides for separate registers, which does not mean that for the prior period no records had to be maintained for the said drugs.

On a consideration of the entire facts and circumstances of the case there can be hardly any doubt that the findings recorded by the State Drug Controller-cum-Chief Licensing Authority and the Appellate Authority are unassailable. So far as the violation by the petitioner of the provisions of the Act and Rules with regard to maintenance of various sales and purchase records regarding Phensedyl syrup is concerned, the case of the petitioner is made much worse by the fact that before the appellate authority he has sought to produce forged and fabricated documents, which have been so found on the basis of verification made with regard to as many as seven of those sales invoices.



Learned counsel's further submission that the State Drug Controller-cum- Chief Licensing Authority is not a competent authority and any order passed by him is non est or without any force of law does not appear to be wholly correct. Rule 66 of the Drugs and Cosmetics Rule 1945 confers the power on the Licensing Authority to, inter alia, cancel a licence of the licensee. The State Drug Controller-cum-Chief Licensing Authority could, in such circumstances, be also the Licensing Authority and thus the order passed by him per se is not illegal. However, the fact remains that when the State Government has appointed the Licensing Authorities for different areas by specific notifications, it does not appear proper for the State Drugs Controller-cum-Chief Licensing Authority to exercise the powers, which have been conferred upon the Licensing Authority for the different areas. The said observation in this regard of this Court is of nearly eight years back in the case of Jamil Medical Hall vide order dated 04.12.2008 passed in C.W.J.C. No.13488/2008, which ought to have been kept in mind by the State Drugs Controller-cum- Chief Licensing Authority before exercising the powers which are normally to be exercised by the Licensing Authority. But that does not mean that when the State Drugs Controller-cum-Chief Licensing Authority has exercised such powers of a Licensing

Authority, the same must be held to be illegal.

In the present matter, the petitioner's case is made worse by the fact that he has not taken the plea regarding jurisdiction at the earliest stage and it is an established proposition that the issue of territorial jurisdiction has to be taken at the earliest stage and not at a subsequent stage.

The fact, however, remains, as observed by this Court in the case of Universal Drug House (supra), that whether the licence would be liable to cancellation partly or wholly would depend upon the facts and circumstances of each case and cannot be done mechanically and arbitrarily, as Rule 66 itself makes provision for cancellation of the licence either wholly or in respect of some of the substances to which it relates. In the present matter, there is no dispute that the violation was made by the petitioner only with regard to one out of the seven items, that is, Phensedyl syrup, and thus if the Licensing Authority and the Appellate Authority were of the view that the petitioner had violated the terms of the licence with regard to the same then they ought not to have cancelled the entire licence without examining as to whether the violation of the terms and conditions of the licence is of such a grave nature as to entail cancellation of the licence or it should be ordered only with regard to the item, namely, Phensedyl syrup, for which the

anomaly has been found. There does not appear to be any consideration in the impugned order regarding cancellation of licence of only phensedyl.

In the absence of such consideration, it is not open to the Licensing Authority to mechanically cancel the entire licence considering the specific provision with regard to the same in Rule 66 itself. Such consideration ought to have taken into account the fact that the petitioner had been doing his business under the Drugs Licence for the last 30 years and this is the first time that the violation has been noticed with regard to only one of the items.

Thus, in the light of the above discussions, the writ application is partly allowed and the impugned orders dated 31.12.2014 and 18.07.2014 are set aside to the extent that they relate to the cancellation of the drugs licence of the petitioner with regard to other items, except phensedyl cough syrup.

(Ramesh Kumar Datta, J)

V.P.Sinha/-

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