HIGH COURT OF HIMACHAL PRADESH
Bench: Ajay Mohan Goel, J.

Date of Decision: 22.12.2023

CWP No. 4391 of 2023

ANIKETH JAIN – PETITIONER

Vs.

STATE OF HIMACHAL PRADESH AND ANOTHER — Respondent

Sections, Acts, Rules, and Articles Mentioned:

Drugs and Cosmetics Act, 1940

Drugs and Cosmetics Rules, 1945

Indian Penal Code: Sections 420, 467, 468, 471

Rule 79 of the Drugs and Cosmetics Rules, 1945

Section 18 of the Drugs and Cosmetics Act, 1940

Section 3(b) and 3(f) of the Drugs and Cosmetics Act, 1940

Subject of the Judgement:

Quashing of rejection orders for a drug manufacturing license application.

Headnotes :

License Rejection Arbitrariness: Rejection of drug manufacturing license by Assistant Drug Controller and Appellate Authority found arbitrary and not in accordance with Rule 79 of the Drugs and Cosmetics Rules, 1945. [Para 15, 1415]

Inspection Protocol NonCompliance: Licensing Authority failed to comply with the mandatory inspection protocol as per Rule 79, leading to an unjustified rejection of the application. [Para 1214]

Legal Interpretation Irrelevance of FIR and Pending Complaints: Court held that FIR against petitioner and complaints against previous unit on the same plot were irrelevant for license rejection, emphasizing statutory requirements for decisionmaking. [Para 1415]

Judicial Remedy Direction for Fresh Processing: Orders of rejection set aside, with directions to Licensing Authority to reprocess the application strictly per Rule 79. [Para 16]

Referred Cases with Citations:

There are no specific cases or citations mentioned in the judgement provided.

Representing Advocates:

Petitioner's Advocate: Not specified in the provided text.

Respondent's Advocate: Learned Law Officer (specific name not mentioned in the provided text).

JUDGMENT

Ajay Mohan Goel, Judge (Oral) By way of this writ petition, the petitioner has prayed for quashing of order dated 16.04.2022, passed by Assistant Drug ControllercumLicensing Authority, Baddi, District Solan, H.P. in terms whereof, an application submitted by the present petitioner for grant of Drugs Manufacturing license was rejected, as also the order passed by the learned Appellate AuthoritycumPrincipal Secretary (Health), to the Government of Himachal Pradesh, under the Drugs and Cosmetics Act, 1940 and Rules framed there under, in terms whereof, the appeal filed by the present petitioner against the order passed by Assistant Drug ControllercumLicensing Authority, was dismissed.

2. The case of the petitioner is that he has established a Unit in Plot No. 32, Industrial Area, Kala Amb, District Sirmaur, Himachal Pradesh, in the name and style of Dutch Formulations for the purpose of manufacturing drugs under the Drugs and Cosmetics Act, 1940. He applied for grant of drugs manufacturing licence after complying with all the codal formalities.

3. Respondent No. 2 rejected the application of the petitioner on the grounds that the petitioner had applied for grant of drugs manufacturing licence in the premises situated at Plot No. 32, Industrial Area, Kala Amb, District Sirmour, H.P. where previously a firm in the name and style of M/s Vardhman Pharma was running, which was raided by the Drugs Control Department of Himachal Pradesh for manufacturing of spurious drugs and two complaints filed against it were still pending in the High Court and a letter from SHO, Police Station, Kala Amb, was received by respondent No. 2, with respect to FIR No. 24/2022, dated 25.02.2022, under Sections 420, 467, 468 and 471 of the Indian Penal Code, informing that the same was still under investigation.

4. Feeling aggrieved, the petitioner preferred a statutory appeal before the Appellate Authority. The Appellate Authority dismissed the appeal of the petitioner by affirming the findings returned by the 2nd respondent, hence the petition.

5. Learned Senior Counsel appearing for the petitioner has argued that the orders passed by the 2nd respondent as well as the Appellate Authority are perverse as while rejecting the application filed by the petitioner both the authorities erred in not appreciating that the application of the petitioner was required to be processed in accordance with the procedure laid down in Rule 79 of the Drugs and Cosmetics Rules, 1945, whereas the application of the petitioner stood rejected by respondent No. 2 on grounds totally extraneous, which had got nothing to do with the scheme of the Rule and Appellate Authority also, without any due application of mind, upheld the said order without realizing that the application of the petitioner was rejected in a completely arbitrary manner by taking into consideration extraneous facts which could not have been taken into consideration. Accordingly, he has prayed that the petition be allowed, impugned orders be set aside and a direction be issued to the respondents to issue a manufacturing licence in favour of the petitioner.

6. Learned Law Officer, while defending the act of the respondents, has submitted that as it is clearly borne out from the record that there were two criminal cases still pending against the manufacturing Unit, which was previously manufacturing medicine on the plot wherein the petitioner has set up his Unit and further as it was a matter of record that there was an FIR registered against the petitioner, pending investigation, therefore, there is no infirmity in the impugned order and for these reasons, the present petition is liable to be dismissed.

7. I have heard learned Senior Counsel appearing for the petitioner as well as learned Law officer. I have also carefully gone through the order passed by respondent No. 2 as well as learned Appellate Authority and also documents appended with the petition as well as relevant provisions of the Drugs and Cosmetics Act, 1940 and Rules 1945 framed there under.

8. The Drugs and Cosmetics Act, 1940, was enacted to regulate the imports, manufacture, distribution and sale of drugs and cosmetics. Section 3(b) of the same defines 'Drugs' as under:

3[(b) 'drug' includes

[(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;]

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]

[(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;]

9. Section 3(f) defines 'manufacture' as under:

'3[(f)] 'manufacture' in relation to any drug [or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug [or cosmetic] with a view to its [sale or distribution] but does not include the compounding or dispensing [of any drug, or the packing of any drug or cosmetic,] in the ordinary course of retail business; and 'to manufacture' shall be construed accordingly;]'

10. In terms of Section 18 of the Act ibid, there is a prohibition of manufacture and sale of certain drugs and cosmetics except under and in accordance with the conditions of licence issued for such purpose under Chapter III of the Act.

11. Rule 79 of the Drugs and Cosmetics Rules, 1945, as amended from time to time, provides as under:

'79. Inspection before grant or renewal of licence.Before a licence under this Part is granted or renewed the Licensing Authority or Central Licence Approving Authority, as the case may be, shall cause the establishment in which the manufacture is proposed to be conducted or being conducted to be inspected by one or more Inspectors appointed under this Act with or without

an expert in the concerned field. The Inspector or Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regard to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the 'Requirements of Good Manufacturing Practices' and the 'Requirements of Plant and Equipment' as laid down in Schedule M read with the Requirements of Maintenance of Records as laid down in Schedule U.]'

12. In terms of the provisions of this Rule, before a licence under the Drugs and Cosmetics Act is granted by the Licensing Authority or the Central Licence Approving Authority, as the case may be, the authority has to cause the establishment in which the manufacture is proposed, to be inspected by one or more Inspectors appointed under the Act with or without an expert in the field. The Inspector or Inspectors so appointed have to examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the drugs to be manufactured or being manufactured and enquire into the profession qualifications of the Technical Staff to be employed. Inspector or Inspectors so appointed have to examine and verify the statements made in the application in regard to their correctness and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the 'Requirement of Good Manufacturing Practices' and the Requirements of Plant and Equipment' as laid down in Schedule M read with the Requirements of Maintenance of records as laid down in Schedule U.

13. After the Inspector submits the report, thereafter in terms of Rule 81, the Licensing Authority acts thereupon and takes a decision as to whether the licence has to be granted or not.

14. Coming back to the facts of this case, herein after the application was submitted by the applicant for the grant of licence, the Licensing Authority i.e. respondent No. 2 did not follow the procedure prescribed under Rule 79. None was appointed to carry out the inspection of the premises. As a

consequence thereof, no report was submitted in terms of Rule 80 of the 1945 Rules and the application was rejected on the grounds totally extraneous to Rule 79 of the Rules ibid. In other words, what weighed with the Licensing Authority while rejecting the application of the petitioner was not the fact that the premises of the applicant were not fulfilling the conditions provided under Rule 79 but the fact that two complaints filed against the company which was earlier carrying out manufacturing activities in the plot, were still pending and there was also an FIR pending against the petitioner.

15. During the course of hearing of this petition, learned Law Officer could not point out that lodging of an FIR against the petitioner or pendency of complaints against another Unit, which was earlier carrying out manufacturing activities on the plot, not run by the petitioner, was an impediment in the grant of licence in favour of the petitioner provided the petitioner was fulfilling requisite statutory conditions. Therefore, this Court has no hesitation in holding that the rejection of the application of the petitioner on the grounds as are contained in impugned order Annexure P2 as well as the subsequent order of rejection of the appeal of the petitioner by the Appellate Authority, is bad in law. The application of the petitioner ought to have been processed as per Rule 79 of the 1945 Rules.

16. Accordingly, this petition is allowed. Impugned orders, i.e. order dated 16.04.2022, passed by Assistant Drug ControllercumLicensing Authority, Baddi (respondent No. 2) and order dated 29.07.2022 passed by learned Appellate Authority, are set aside. Respondent No. 2 is directed to proceed with the application of the petitioner afresh, strictly in accordance with Rule 79 of the 1945 Rules and take an expeditious decision thereupon. It goes without saying that decision by Licencing Authority on the application of the petition, would be on its merit and would not be influenced by any observation made by this Court.

The petition stands disposed of in above terms.

Pending miscellaneous application(s), if any, also stand disposed of accordingly.

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