

Falcon Laboratories Vs The Director, Drug Control Administration

Court: Andhra Pradesh High Court

Date of Decision: Oct. 16, 1995

Acts Referred: Constitution of India, 1950 " Article 226
Drugs and Cosmetics Rules, 1945 " Rule 49A, 50A

Citation: (1995) 3 ALT 432

Hon'ble Judges: G. Bikshapathy, J

Bench: Single Bench

Advocate: K.V. Satyanarayana, for the Appellant; Govt. Pleader for Medical and Health, for the Respondent

Final Decision: Dismissed

Judgement

@JUDGMENTTAG-ORDER

G. Bikshapathy, J.

The petitioner seeks declaration that there is no validity constituted licensing authority in A.P. from 1-2-1989 to 20-2-1990 and for further declaration that all the sanctions for prosecution accorded during the said period are illegal and void.

2. The petitioner is a manufacturer and distributor of drugs holding valid licence under the provisions of Drugs and Cosmetics Act, 1940. Among

other drugs the petitioner has been manufacturing "FENOPRIN" S.S. tablets during February, 1989 to September, 1989. The drug authorities

have seized certain samples of the tablets and found that they are not upto the prescribed standard. One Sri G.S.R.C.V. Prasad Rao, in-charge

Director during the relevant period accorded sanction for prosecution of the petitioner. The said Mr. Prasad functioned in such capacity from 1-2-

1989 to 20-2-1990. He cancelled the licence issued to the petitioner. Aggrieved by the said order the petitioner filed W.P. No. 14777/89 and the

same was allowed by the order dt. 30-6-1991, Palcon Laboratories v. Director, Drugs Control (Administration): 1991 (2) An.W.R. 322. In the

present petition the petitioner is seeking the declaration that the said officer is not competent to accord sanction as he did not possess the requisite

qualifications to act as Licensing Officer or Controlling Officer.

3. The learned Counsel for the petitioner - Sri K.V. Satyanarayana submits that Mr. Prasad, who was in-charge Director, Drug Control

Administration was not qualified to be appointed as the Licensing Authority or Controlling Authority as he did not possess the requisite

qualifications as prescribed under Rule 49-A and 50-A of the Drugs and Cosmetics Rules, 1945 and, therefore, he is incompetent either to cancel

the license or accord sanction for prosecution of the petitioner for violation of the provisions of the Drugs and Cosmetics Act (for short the Act).

4. The learned Government Pleader submits that the Rules 49-A and 50-A were introduced with effect from 12-4-1989 and by that time Mr.

Prasad was already notified as Licensing Authority,. Approving Authority and Controlling Authority vide Notification in G.O.Ms. No. 129, dated

13-2-1989 and hence Mr. Prasad continued to be validly constituted authority. The amendment has no retrospective effect. Thus he contends that

the writ petition is liable to be dismissed.

5. For proper appreciation of the issue, it is necessary to extract Rules 49-A and 50-A of the Drugs and Cosmetics Rules, 1945. They read thus:-

49-A: Qualification of a Licensing Authority: No person shall be qualified to be a Licensing Authority under the Act unless:-

(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialisation in clinical pharmacology or microbiology from a

University established in India by law; and

(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years:

Provided that the requirement as to the academic qualification shall not apply to Inspectors appointed under this Act and who are in position on the

date of commencement of the Drugs and Cosmetics (Ninth Amendment) Rules, 1989.

50-A: Qualification of a Controlling Authority:

(1) No person shall be qualified to be a Controlling Authority under the Act unless:-

(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialisation in Clinical Pharmacology or microbiology from a

University established in India by law; and

(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years:

Provided that the requirement as to the academic qualification shall not apply to Inspectors appointed under this Act and who are in position on the

date of commencement of the Drugs and Cosmetics (Ninth Amendment) Rules, 1989.

6. The amendments were admittedly introduced with effect from 12-4-1989. It is also not in dispute that on the said date i.e., 12-4-1989 Mr.

Prasad was not possessing the requisite qualifications to act as Licensing Authority or Controlling Authority. As already stated, the petitioner filed

W.P. No. 14777/89, when its licence was cancelled on 16-6-1989. The Court allowed the writ petition on the ground that Mr. Prasad was not

qualified to act as Licensing Authority as on the date of cancellation. The relevant paragraphs are extracted below (1 supra):

It is not disputed that the 2nd respondent has the requisite qualification required by the first part of the Rule, namely, that he should be a Graduate

in Pharmacy or Pharmaceutical Chemistry. The 2nd respondent is a Master in Pharmacy and he possesses the necessary academic qualification.

With regard to the second qualification required, the petitioner states that the 2nd respondent did not have experience in manufacturing or testing of

drugs of enforcement of the provisions of the Act for a minimum period of five years. Sri Ramkrishna Raju, learned Government Pleader contends

that the requirement, of the minimum period of five years experience is only with regard to the enforcement of the provisions of the Act, but not

with regard to the manufacture or testing of drugs. The rules cannot be interpreted in the way Sri Raju did. If the said interpretation is accepted,

even a day's experience in the manufacture or testing of drugs could be held to be sufficient to hold that the 2nd respondent is qualified. I do not

think that interpretation given by Sri Raju is the correct interpretation of the rule in question, The rule requires that a person should have experience

in manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years. The said minimum period of five

years equally applies, either to the manufacturing of drugs or to the testing of drugs or to the enforcement of the provisions of the Act. Admittedly,

the 2nd respondent did not have the minimum period of five years experience either in the manufacture or testing of drugs or in the enforcement of

the provisions of the Act.

For the aforesaid reasons, it should be held that the 2nd respondent was not qualified to be a Licensing Authority on the date when he passed the

impugned order. The impugned order is therefore quashed along with all its consequential actions. It is brought to the notice of the Court that the

2nd respondent was subsequently replaced by a qualified person. This order, therefore, will not preclude the first respondent to take such steps as

may be open to him in accordance with law, if it is deemed necessary. The writ petition is allowed.

7. The order in the writ petition became final. Further the petitioner also filed CrI.M.P. No. 1793/94 challenging the prosecution proceedings

launched by Mr. Prasad. This Court by orders dated 7-9-1994 relying upon the Judgment rendered in the Writ Petition No. 14777/89 dated 30-

8-1991 held that since the appointment of Mr. Prasad as Director of Drug Control Administration was held to be illegal, all actions initiated by Mr.

Prasad were also held to be illegal and incompetent. Therefore, the prosecution proceedings were quashed. In view of the pronouncements of this

Court, it is clear that Mr. Prasad has no power to function as Licensing Authority or Controlling Authority. Incidentally, the qualifications

prescribed for both Licensing Authority and Controlling Authority are one and the same. When once it is found that Mr. Prasad did not possess

the qualifications to act as a Licensing Authority it has to be necessarily held that he also cannot function as Controlling Authority. Hence his actions

shall be deemed to be incompetent and without jurisdiction.

8. The learned Government Pleader submits that the Government Order has no retrospective effect and hence the notification already issued prior

to the amendment of Rule 49-A and 50-A of the Rules notifying Mr. Prasad Rao as Licensing Authority and Controlling Authority must be

deemed to be in operation. To this contention, the learned Counsel cited the decision rendered by the Punjab and Haryana High Court in Punjab

Chemists Association (Regd.) Kapurthala v. State of Punjab, 1991 Drag Cases 184 wherein it was held that no person including already notified

licensing authority cannot exercise the powers of Licensing Authority with effect from 12-4-1989 unless he possesses the qualification under Rule

49-A. I am not inclined to go into the aspect whether the amendment has prospective or retrospective effect. This Court while considering the

action of Mr. Prasad Rao no in respect of cancellation of the Licence, it was held that he did not fulfil the qualification under Rule 49-A and hence

the cancellation was held to be bad. Even the criminal proceedings initiated by him were quashed on the same ground. The Government did not

contend that the amendment has no effect on the authorities already constituted prior to 12-4-1989 either in the writ petition or in the Criminal

Miscellaneous Petition. Since already a finding was recorded by the Court with regard to the non possessing of qualification and the action taken

or initiated by Mr. Prasad Rao held to be illegal and invalid, it is not open for the Government now in this writ petition to contend that the

amendment does not apply to the appointments already made. I cannot allow such a contention at this belated stage, as it leads to anomalous

situation.

9. Under these circumstances, I am inclined to hold that Mr. Prasad Rao was not holding the qualification to function as Controlling Authority after

12-4-1989. The fact another officer was designated as Licensing Authority and Controlling Authority after the amendment would further reinforce

the finding that Mr. Prasad Rao cannot validly function as Controlling Authority. Therefore, it has to be declared that the permission accorded after

12-4-1989 for prosecution of the petitioner by Sri Prasad Rao in the capacity of Controlling Authority is quashed. The writ petition prayer is

couched in general terms. I am not inclined to grant such a relief. The writ petition is accordingly dismissed to the extent stated above. No costs.