

Kedarnath Saraf Vs The Hon"ble Minister for Health Medical Education and Department and Another

Court: Bombay High Court (Nagpur Bench)

Date of Decision: Jan. 20, 2006

Acts Referred: Drugs and Cosmetics Act, 1940 – Section 18, 19, 19(3), 34

Citation: (2006) 3 ALLMR 509 : (2006) 4 BomCR 882 : (2006) 3 MhLj 62 : (2006) 2 MhLj 62

Hon'ble Judges: J.N. Patel, J; A.H. Joshi, J

Bench: Division Bench

Advocate: B.G. Kulkarni, for the Appellant; N.S. Jog, Assistant Government Pleader, for the Respondent

Final Decision: Allowed

Judgement

A.H. Joshi, J.

Petitioner herein is a licensed Chemist and Druggist under the provisions of the Drugs and Cosmetics Act, 1940 and Drugs

and Cosmetics Rules, 1945. This Act and Rules are hereinafter referred to as "Act and the Rules".

2. Twenty Six Samples were drawn from the shop of the petitioner. Six samples were declared by the Competent Laboratory to be of sub-

standard quality while there was no objection as to the rest. When the samples were drawn, in relation to all samples including those which were

found sub-standard, the petitioner had furnished the details as to the manufacturers and invoices in regard thereto.

3. Respondent No. 2 served on the petitioner a show cause notice dated 12-9-1995, calling upon the petitioner to show cause as to why the

licence issued to the petitioner should not be suspended, alleging that the petitioner was liable for action u/s 18(a)(i) of the said Act and that the

failure complained of was punishable since petitioner had failed to take precaution and due diligence as per Section 34 of the said Act for

maintaining the standard of medicines.

4. Petitioner replied the show cause notice stating that no sooner report of Laboratory holding that the samples taken were of sub-standard quality,

the petitioner had discontinued the sale thereof and that he should not be considered to be responsible for any action whatsoever.

5. According to the petitioner, while he had no responsibility towards the drugs being of sub-standard quality, those being procured from the

licensed manufacturer, the respondent No. 2 passed an order holding that the petitioner was responsible for violation of Section 18(a)(i) of the

Act, as he had failed to take due diligence as required u/s 34 of the said Act and the explanation given by the petitioner was not satisfactory.

Respondent No. 2, therefore, ordered suspension of licence for three months.

6. Petitioner herein feeling aggrieved thereby preferred an appeal before the respondent No. 1. In the appeal he raised ground namely - whenever

the licensed Chemist and Druggist procures the medicines from the licensed manufacturer and stocks them for sale as per rules, they are properly

stored and maintained in the same state as they were acquired, he cannot be held liable for the drugs being found sub-standard, when they were

not either tampered with or were not found stored in any objectionable manner. The petitioner claimed exemption from any action u/s 19(3) of the

said Act.

7. Petitioner's appeal was heard by respondent No. 1, and decision i.e. the impugned order is communicated to the petitioner under

communication dated 28-2-1996 which is part of Annexure "E".

8. On perusal of the impugned order passed by the Hon'ble Minister/respondent No. 1, it is seen that the Minister has recorded the background

of the case in paragraph Nos. 1 to 4 including that since the manufacturers were found to be responsible for introducing and selling to the Chemist

sub-standard drugs, one amongst them was prosecuted and prosecution as to the rest was in process. Without recording the findings as to whether

the petitioner is guilty for any dereliction or violation of law, rules etc. the respondent No. 1 simply proceeded to pass operative order and reduced

the period of suspension from 90 days to 10 days.

9. Consequent upon the order of the respondent No. 1, the respondent No. 2 has modified the order dated 4-4-1996 thereby reducing the

suspension to 10 days.

10. The order passed by the Minister (Exh.E) communicated under intimation dated 28-2-1996 is subject-matter of challenge of this petition.

11. Since it was seen from the record, though this Court admitted the petition, the interim relief was declined. On enquiry learned Advocate for the

appellant has stated that though stay was refused the suspension was not acted upon or enforcement thereof was not insisted by the Authorities,

therefore, the challenge survives, and as the impugned order attaches stigma to the petitioner, he would like to pursue the petition.

12. Heard learned Advocate Mr. Kulkarni for the petitioner and learned Assistant Government Pleader Smt. Jog for the respondents.

13. Learned Advocate Mr. Kulkarni has drawn attention of the Court to Section 18(a)(i) of the Act. As per Section 18(a)(i) of the Act, the

failures attributable are mainly to the drugs not being of standard quality or is misbranded, adulterated or spurious. Section 18(a)(i) reads as below

-

18. Prohibition of manufacture and sale of certain drugs and cosmetics.

- From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any

other person on his behalf -

(a) [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute -

(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious...

14. Learned Advocate Mr. Kulkarni then pointed out Section 19 Sub-section (3), which pertains to plea available for any dereliction in relation to

Section 18. It covers the cases of such person who have acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer

thereof and he could not know with reasonable diligence that the drugs so acquired do not in any way contravened the provisions of Section 18 of

the Act and that the drugs were properly stored and remained in same condition as were when he acquired those. Section 19 Sub-section (3)

reads as below -

19...

(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof shall not be liable for a contravention of

Section 18 if he proves -

(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the

provisions of that section; and

(c) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as when he acquired it.

15. According to learned Advocate Mr. Kulkarni, it is very clear from Clauses (a), (b) and (c) of Sub-section (3) of Section 19 that if a chemist

satisfies the condition referred to therein, he cannot be held responsible for any dereliction or failure due to which Section 18 of the Act is alleged

to have been violated.

16. On the facts of the case, learned Advocate Mr. Kulkarni has pointed from the notice that what has been alleged is that six preparations

containing batch Number, name of manufacturer were found to be sub-standard and what was alleged is that the samples which were drawn from

the petitioner's shop being found sub-standard, petitioner's conduct was in violation of Section 18(a)(i) of the Act. It was further alleged that the

petitioner has failed to take "due diligence" in maintaining the quality of the medicines.

17. Mr. Kulkarni then pointed out that reading of the text of the show cause notice at verbatim, does not reveal as to what was the exact

imputation which constituted the dereliction i.e. what was the failure which led to the inference of "lack of due diligence.

Learned Advocate Mr. Kulkarni placed reliance on the text of imputation in show cause notice which in vernacular is seen at page 17 of paper

book and its translation is at Page 17-B, both are quoted below -

ojhy izek.ks dk;nĀĀ;Ā½kps rjrqnhps mYya?ku Vkg.;klkBh vki.k vKS""k/kkaph xq.koRrk fVdowu Bsd.;kps n`f""Vus fo""k;kafdr dk;n;kps dye 34

vuqlkj ;ksX; rh [kcjnkjh o n{krk [due diligence] ?ksr ukgh- vls fnlwu vkys vkgs-

It is also revealed that in order to avoid the violation of the provisions of the Act as aforesaid, you have not taken precaution and due diligence as

per Section 34 of the said Act for maintaining the standard of the medicines.

18. Learned Advocate Mr. Kulkarni then pointed out that as it is clear that it was stated before the Hon"ble Minister by the respondent No. 2 that

the manufacturers were also found guilty for manufacturing the drugs of substandard quality and in relation to whom the process of prosecution was

in progress, goes to suggest that in absence of specific imputation as to the lacunae in relation to the method of preservation and storing of

medicines, the fault in relation to the drugs being found sub-standard that too only 20 to 40% volume, thereof, is not supported by any set of facts

directly attributable against the petitioner.

19. According to Mr. Kulkarni, therefore, the allegation of lack of due diligence is without any factual foundation and details thereof could not have

been effectively replied by the petitioner, save and except by bare denial, the charge being devoid of factual narration to be basis thereof. Mr.

Kulkarni further pointed out that due diligence is a relative term and could be attributed, proved and denied or defended only on availability of all

factual details being put to the person accused of failure thereof.

20. Thus, the defence available to the petitioner under Clause (c) of Sub-section (3) of Section 19 of the Act was thus sufficiently raised, as will

have to be held in absence of details of lack of diligence in proper storing thereof. It is also clear that it has not been alleged against the petitioner

that the sales thereof or packing thereof were tampered with.

21. In the circumstances, this Court finds that the charge of non-compliance or failure to take required care u/s 34 of the Act on account of

violation of Section 18 of the Act is not properly made out and the action of suspension based on inadequately worded notice was wholly un-

justified.

22. It is also seen that the Appellate Authority failed in its jurisdiction to apply mind while rendering its judgment. Appellate Authority by the very

fact of its nature of appellate jurisdiction was exercising quasi-judicial function and was duty bound to record its agreement or disagreement with

the order of respondent No. 2 and reasons therefor. In absence of the reasons, the order of respondent No. 1 is unsustainable.

23. While this Court finds that the judgment of Appellate Court is rendered without following judicial principles, this Court finds that no practical

purpose will be served in remitting the case back to the Appellate Authority for hearing and disposal as per law. In view of the fact that now the

petition is about nine years" old and no fruitful purpose will be served thereby when on facts this Court has found that the very notice initiating the

action was devoid of actual foundation.

24. The Court is, therefore, of the view that the issue can be concluded right here, and it will be proper to quash and set aside the judgment and

order passed by the respondent No. 1 i.e. Exh.E and consequently set aside the order passed by the respondent No. 2 dated 6-12-1995 against

which the appeal was filed on dated 4-4-1996 passed by the respondent No. 2, as order consequential to the judgment by the respondent No. 1.

In the result, the petition is allowed.

25. Rule is made absolute in above terms. There shall be no order as to costs.