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In the Karnataka High Court

Case No : Writ Petition No''s. 5245 and 12123 of 1986

Mahendra Labs Pvt. Ltd. — APPELLANT

Vs

State of Karnataka and Others — RESPONDENT

Date of Decision : 07-08-1986

Acts Referred:
Constitution of India, 1950 — Article 14
Drugs and Cosmetics Act, 1940 — Section 18, 3

Citation : AIR 1987 Kar 166

Hon'ble Judges : Muralidher Rao, J

Bench : Single Bench

Advocate : G.S. Visveswara, for the Appellant; U. Abdul Khader, High Court Govt. Pleader, for the Respondent

Judgement

1. The subject-matter and question of law arising in these cases is one and the same. However, since the factual circumstances and reliefs claimed are distinct and separate, I propose to deal them separately.

W. P. No. 5245/1986

Petitioner is a Private Limited Company. It manufactures drugs and claims to have supplied its products to various Government establishments, V.I.S.L. and Central Food Technological Research Institute. Established as Small Scale Industry in 1985, it has obtained licence from the competent Authorities.

2. On 29th Jan. 1986, Respondent-2 Director of Health and Family Welfare Services invited Tenders from Manufacturers and their Authorised Agents for the supply of drugs, specialities, chemicals, Tinctures and Surgical items. The last date for submission of Tender was 31-3-1986. Petitioner filed this petition on 21st March 1986. By an interim order did. 25th March, 1986, he was permitted to submit his Tender, and Cl. (9) of the Tender conditions was kept in abeyance. Petitioner has filed his Tender; though, in pursuance of the orders of the Court dtd. 17-4-1986 the Tenders are opened, results are not yet declared.

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Respondents are awaiting the decision of this Court.

3. Petitioner''s challenge is to Cl. 9 of the Tender Form; the said clause, as also, Cls. 10 and 10A read thus: -

"9. The manufacturers from within the State should have a minimum of three years manufacturing experience to quote their products directly/ through the dealer and hence has to enclose a certificate from the drug controller to that effect apart from the manufacturing licence.

10. The manufacturers from outside the State should have a minimum of five (5) years manufacturing experience to quote, their products directly/through the dealer and hence has to enclose a certificate from the drug controller of -that State to this effect apart from the manufacturing licence.

10A. Loan Licence manufacturing experience will be considered." (underlining is mine).

4. It is contended by the petitioner that "three years experience in manufacturing" was not in existence up to 1984-85 and it is introduced for the first time; the said condition is arbitrary, irrational and unreasonable; it has no nexus to the object, which is to secure effective and quality drugs and it is calculated ''to eliminate upcoming manufacturers and favour the big Units. Secondly, it is contended that policy of the State Government is to encourage and help Small Scale and tiny Industries, and give preference to these Units; the said clause is against the Policy of the State Government. In this context, reliance is placed on Proceedings of the Govt. of Karnataka, culminating in the Order No. CI 28 SPM 84 dtd. 20th Feb. 1986. Particular attention, in this regard, is invited to -the following paragraphs: -

"3. Government of India has reserved nearly 400 items for purchase exclusively from the Small Scale and tiny industries. In our State, just 40 items are reserved for purchase exclusively from the SSIS.

4. Government consider that there is an urgent need to ensure a strict implementation of the Government Policy of giving a price preference, compelling the Govt. Department, Public Undertakings etc., to purchase their requirements from the tiny and SSI Units of the State alone and to reserve all items as have been reserved by the Government of India for purchase exclusively from tiny and SSI Units."

5. Keeping in view the above Policy, Price preference is given to the products of tiny and Small Scale Industries of the State in all purchases as per direction (i) in the above Government Order. Of course the Annexure to the said Government Order does not deal with drugs and hospital requirements. But the argument constructed is that being a State Policy, it cannot discriminate between the products. So it is contended that the Policy decision has to be applied to all the purchases in the State and any attempt to eliminate the Small Scale and tiny Industries would be arbitrary and violative of Art. 14 of the Constitution of India.

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6. In the return filed by respondents, it is stated thus:

"2.....The condition has been imposed having due regard to the facts and circumstances of the case. The purpose of imposition of condition No. 9 is to see that quality drugs are secured by the Department concerned for consumption by the patients coming to the Government Hospitals. The purpose is to secure the best drugs available in the Market for proper treatment of the patients. An experienced Firm can certain

manufacture better drugs and quality of such drugs will be definitely better than that of the drugs manufactured by the other Units, which have no or less experience in the field. It is to be noticed that in case of Medicines, it, is not merely chemical contents, of the drugs - liquids, tablets or injections - that is important, but, it is the bio-availability of the drug that is most important. In other words, it is how much of bio-availability is available in a medicine and utilised by the body that is important and this can be known only by the Doctors when they use the drugs on their patients. It is for this reason that the Doctors prefer to use drugs manufactured by the reputed concerns, which with their large manufacturing experience will produce good quality drugs with standard bio-availability and required bio-assimilability.

3. The State Government is duty bound to see that the quality drugs are secured for the purpose of treatment of the patients. Therefore, it cannot be said that the experience prescribed by the respondents is un-reasonable ..... (underlining is mine).

Again at the end of Para 3, it is asserted thus:

"The condition No. 9 is imposed to make fool-proof of the quality of drugs and to have better quality drugs, even though it was not so previously, and even though tested by Drug Control Department."

Regarding the Policy decision of the Government, to encourage and give preference to the Small Scale and Tiny Industries, it is stated thus:

"4. The reliance placed by the petitioner on the Government Orders dtd. 30-10-1982 and 20-2-1986 is of no assistance to them, as the same do not prescribe any qualification, as contended by the petitioner."

7. The averments in the Statement of Objections make it clear that the Department intends to secure the best quality drugs, it is said that the manufacturer''s experience has relevance, since such experience has direct bearing on the bio-availability and bio-assimilability of the drug. In other words, the greater the experience, the richer is the quality and greater is the bio-availability and bio-assimilability of the drug or medicine.

8. In the light of these rival contentions the question to be decided is whether the quality of the drug or medicine and its bio-availability and bio-assimilability depends on the manufacturer''s experience or does it depend on its components?

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Secondly, whether the Tender Notification violates the Policy decision of the State Government?

Taking the first of these questions, it has to be noted that what is required by the Department is the best quality drug or medicine. The commodity i.e. drug or medicine is on trial. It is the best quality product which is the requirement of the Department. Along with the Tender Notification, conditions of Enquiry are stipulated. To test the quality of the product, following conditions are mentioned.

"(a) All quotations should conform to the standards of I.P., B.P., B.P.C., U.S.P., or N.F.L (1)

(b) All Drugs which deteriorate should be replaced. (3)

(c) The supplies should accompany analytical report of each batch from the manufacturer. (6)

(d) The supplies should be from the latest batch. Items having dates of expiry should be replaced with new stock, if returned by the indenters before three months from the expiry date. (8)

(e) As regards supply of capsules, the capsules supplied (Gelatin) must be in sealed condition. (14)

(f) Tenders shall clearly specify whether the goods are offered from the indigenous! sources, from imported stocks in India or from Foreign sources to be imported under a licence. Department reserves the right to reject offers for import of goods in the Import Trade Control Policy in force at the time of award of the contract-prohibits such imports. (15)

(g) The drugs reported not of standard quality should be replaced. The sub-standard drugs will not be permitted to be removed from the stores without the written permission from Drugs Controller, without prejudice to the above, the Director of Health and Family Welfare, Services, reserves the right to impose fine not exceeding the value of the consignment, if Drugs are reported to be not of standard quality (16)

(h) The drugs having date of expiry should be replaced with fresh stocks from the latest batch if returned three months before the date of expiry (19)."

9. Having provided these terms and conditions of enquiry, which has a direct bearing to the quality, efficacy and potency, of drug or medicine, how far prescription of "manufacturer''s experience", as a test of eligibility, can be justified? Has it any nexus to the object sought to be achieved?

10. The expressions "Manufacturer" and "Loan Licence manufacturing" employed in conditions 9, 10 and 10A of the Tender Form have to be understood as defined in the Drugs and Cosmetics Act, 1940 and with reference to certain provisions in the Drug and Cosmetics Rules, 1945.

Section 3(f) of the Act defines, Manufacturer as follows:

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"manufacture" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting Any drug or cosmetic with a view to its sale and 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;"

(Underlining is mine)

Part-VII of the Rules provides for the procedure to obtain licence. Explanation to R. 69-A describes Loan - Licensed manufacturer, as one who does not have his own arrangement for manufacture but who, intends to avail himself of manufacturing, facilities owned by licensee, who has secured a licence of manufacturing drugs. The manufacturer has to obtain licence as per Form 25 under R. 70; the Loan Licence Manufacturer has to obtain licence as per Form 25-A. Rule 71 of these rules prescribes conditions for the grant or renewal of licence to the manufacturer. Though several conditions are stipulated in this rule, one such rule, which deals with qualification and experiences is as follows:

"71 (1) The manufacture shall be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person, who is a whole-time employee and who is -

(a) a graduate in Pharmacy or Pharmaceutical Chemistry of a University recognised by the Central Government for the purpose of this rule and has had at least eighteen months practical experience after the graduation in the manufacture of drugs. This period of experience may, however, be reduced by six months if the person has undergone training in manufacture of drugs for a period of six months during his University course; or

(b) a graduate in Science of a University recognised by the Central Government who for the purpose of his degree has studied chemistry as a principal subject and has had at least three years practical experience in the manufacture of drugs after his graduation; or

(c) a graduate in Chemical Engineering or Chemical Technology or Medicine of a University recognised by the Central Government with general training and practical experience, extending over a period of not less than three years in the manufacture of drugs, after his graduation; or

(d) holding any foreign qualification the quality and content of training of which are comparable with those prescribed in cl. (a), cl. (b) or cl. (c) and is permitted to work as competent technical staff under this rule by the Central Govt."

(Underlining is mine)

11. It will be seen that to obtain a licence, it has to be established that the "manufacture" is conducted, under the active direction and personal supervision of competent technical staff, one of whom shall be a whole-time employee.

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The said employee apart from academic qualification has to have practical experience in the manufacture of drugs, as stipulated above. The condition mentioned in R. 71 is applicable to the licensee, who has his own manufacturing Unit. The license-granted to "Loan License manufacturing" co-exists with the licence granted to manufacturer under R. 71. Rule 74B provides thus:

"74-B. Conditions of licence in Form 25-A. (1) The licence in Form 25-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25, whose manufacturing facilities have been availed of by the licensee is cancelled or suspended as the case may be, under these rules."

These being the relevant Statutory Provisions, which makes it compulsory to have experience, academic qualifications and several other requirement, is there any justification to impose a further condition of three year''s experience as per R. 9 or Five years experience as per R. 10 and further discard the experience in case of Loan Licence Manufacturing under R. 10-A. The definition of the word "manufacturer" in relation to drug includes the process of making, altering, ornamenting, finishing, packing labelling etc., with a view to its sale and distribution. Section 18 of the Act prohibits sale or distribution of any drug which is not of standard quality (as per S. 16) which is the misbranded (as per S. 17-A) or which is adulterated (see S. 17-13). Section 18 imposes certain other restrictions for sale, but there is no provision which prescribes additional experience to a licensed manufacturer or Loan Licence manufacturer to market his products.

The Act is a Central Act and the Rules, which are Statutory, are framed by Central Government. The Act and Rules having made adequate provisions for manufacture and sale of Drugs, is there any justification to impose further restriction on the sale of drug and is there any rational or nexus for such restriction? Is the Director competent to impose such restrictions?

12. Manufacturer may be an individual, as in the case Proprietary concern, may be a Partnership firm or may be a Company. In any event of the matter, it cannot be a one man activity. In the very nature of things, the manufacturing process, needs Pharmacologists, lab-Technicians, machine operators, men with requisite Scientific knowledge several other Technicians, who are to test the quality potency, the finish, the packaging, etc. The machinery used for the plant has to be sophisticated to suit the modern requirement. The industry in short calls for adequate finance, organisational ability, managerial talents, technical know-how etc. In this enterprise the manufacturer, may be a young qualified man, who taking assistance of experienced and skilled hands may be able to produce a good product. A highly qualified Pharmacologist, who has enough resources, may float a Company and produce a drug or medicine which, due to its quality, potency and efficacy may out beat all other similar products; will there be any justification to debar the product of this young entrepreneur, only on the ground that he does not have three years'' experience, after being a licenced manufacturer.

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13. In the light of the Statutory Provisions referred to above, a person having obtained licence for manufacture, can be prohibited to sell the drug only in accordance with S. 18 and on no other account, I am of the view that no other restriction can be imposed on him. Therefore, prima facie, the restriction imposed is without authority. The Department is a Purchaser; Purchaser has to purchase the commodity, if it is in accordance with Act and Rules. to prescribe ''experience'' for the supplies is to impose further conditions which the Act and Rules do not authorise; hence the imposition is clearly ultra vires and is beyond the powers of the Authority.

14. Mr. Abdul Khader, H.C.G.P. placed strong reliance of Ramana Dayaram Shetty Vs. International Airport Authority of India and Others, ; he relied on the following observations:

"7..... The test of eligibility laid down was an objective test and not a subjective one. What the condition of eligibility required was that the person submitting a tender must have 5 years'' experience of running a IInd Class hotel, as this would ensure by an objective test that he was capable of running a IInd Class restaurant'' and it should not be left to the Ist respondent, to decide in its subjective discretion that the person tendering was capable of running such a restaurant. If, therefore, a person submitting a tender did not have at least 5 years experience of running a IInd Class hotel, he was not eligible to submit the tender and it would not avail him to say that though he did not satisfy this condition, he was otherwise capable of running a IInd Class restaurant and should, therefore, be considered. This was in fact how the Ist respondent itself understood this condition of eligibility, when the 4th respondents submitted their tender along with their letter dt. 24th Jan., 1977 and it appeared from the documents submitted by the 4th respondents, that they did not have 5 years'' experience of running a IInd Class restaurant. The Ist respondent by its letter dtd. 15th Feb., 1977 required the 4th respondents to produce documentary evidence to show that they were "registered IInd Class hotelier having at least 5 years'' experience." The Ist respondent did not regard this requirement of eligibility as meaningless or unnecessary and wanted to be satisfied that the 4th respondents did fulfil this requirement. Now, unfortunately for the 4th respondents, they had over 10 years'' experience of running canteens but at the date when they submitted their tender, they were not running a 11 grade hotel or restaurant nor did they have 5 years'' experience of running such a hotel or restaurant. Even if the experience of the 4th respondents in the catering line were taken into account from 1962 onwards, it w6uld not cover 6 total period of more than 4 years 2 months so far as catering experience concerned. The 4th respondents thus did not satisfy the condition of eligibility laid down in para (1) of the notice and in fact this was impliedly conceded by the 4th respondents in their letter dtd. 26th Feb. 1977 where they stated that they had "experience equivalent to that of a IInd Class or even lst Class hotelier." The 4th respondents were, accordingly, not eligible for submitting a tender and the action of the Ist respondent in accepting their tender was in contravention of para (1) of the

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notice."

15. The experience that was required in Ramana''s case was "experience of running a Hotel or Canteen"; in other words, experience in catering, which again is a personal ability to cater to the needs of Tourists. The Air Port Authorities called tenders for running a IInd Class Restaurant and two Snack Bars at the Bombay Airport. The enterprise necessarily requires personal experience of catering to meet the demands of Foreign Tourists; involving knowledge of variety of dishes, of a very high standard, service in good crockery with napkins, etc. Apart from cleanliness, personal attention is required to maintain quality of eatables, with special attention to hygiene. The servers are required to be clean well dressed and maintain good behaviour and observe decent manners. The servers would be required to know English language. These minor details of management, preparation of eatables, proper service, demand personal attention in all Branches; in this view, the experience of caterer would certainly have relevance. These considerations will not be applicable to manufacturer, who has to supply the approved drugs and medicines. While the credibility of a caterer. depends on the art of catering, the credibility of drug manufacturer depends on the quality, potency and efficacy of his drug.

Tender by Authorised Agents and Dealers:

As per the Tender Notification, the authorised agents and dealers are also eligible to submit tenders. For the authorised agent or dealers, there is no requirement to state their experience. They are to produce the following documents:

"DOCUMENTS PRODUCED SAY YES/NO

(b) Income Tax Clearance Certificate for the year 1985-86 by Dealer.

(c) Sales Tax Clearance Certificate for 198586 by Dealer.

(d) Authority letter from the Manufacturer in case of Dealer.

(e) Manufacturing Licence

(f) Income Tax Clearance Certificate for 198586 of the Manufacturer

(g) Sales Tax Clearance Certificate for 198586 of the Manufacturer

(h) Drugs Licence

(as the pro forma)."

They are required to produce letter of Authority from the Manufacturers (Cl. 13 of other terms and conditions of Enquiry).

Further, Cl. 17 of the Terms and Conditions requires him to submit Photostat copies of the Drugs Licence of the Manufacturer and a certificate from the Drugs Controller to state where the manufacturer is located on whose behalf he is quoting, to the effect that the said manufacturer has not been prosecuted, his

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licence suspended or cancelled under the provisions of the Drugs and Cosmetics Act, 1940 and Rules there under.

Clause 28 requires him to specify the name of the manufacturer.

In the pro forma, the Manufacturer when he quotes directly has to fill up Columns (i)(j)(k)(l)(m)(n)(o) and (p) and Column (p) requires him to mention his experience and number of years. A manufacturer who does not have three years'' experience may supply his product through the authorised dealer or agent, who is not required to give that information. This may be beneficial to the authorised dealer. But, in doing so, he can eliminate his manufacturer and other manufacturers, who directly offer tender but stand to be rejected on the ground of lack of three years'' experience. Examined from this angle, the condition would eliminate manufacturer and give preference to authorised agents and dealers. Much more so, in the case of authorised dealers or Agents, whose manufacturer is outside the State of Karnataka, in those case the requirement is Five years'' experience.

16. It was next contended that insistence of experience is for assuring the normal and regular supply of drugs or medicine. If that be so, there is no reason why it should not be insisted for authorised dealers or Agents. Further, it is ''manufacturing'' experience, which is to be supported by Certificate of

Drug Controller apart from producing the manufacturer''s licence. The "Loan licence manufacturing experience" is excluded in reckoning the period of experience. In fact ''Loan Licence'' is granted to a manufacturer, who manufactures in a premises, not of his own and in all other respects his case is similar to that of ''Manufacturer'' except that he has no arrangements of his own but avails facilities owned by a licensee-manufacturer.

Preference to Small Scale Industries

As regards to Small Scale Industries, para 22 of the Terms and Conditions of the Enquiry reads thus: -

"22. If your firm of Industry is registered with Industries and Commerce Bangalore as S.S.I. a copy of the Certificate attested by a Gazetted Officer may be submitted along with the quotations for consideration of price preference."

This policy of price preference is to compel the Government Departments, Public undertakings to purchase their requirement from Tiny and Small Scale Industries alone. The policy having been reflected in the above condition, there is no substance in this contention of Sri Visveswara. Tiny and Small Scale Industries cannot, as of right, claim any higher rights; all things remaining same, after the acceptance of Tender, they are entitled for "price preference". Hence, it is not possible to accept this contention; hence it is rejected.

17. In the light of my discussion, my conclusion-, are as follows:

(i) Clauses 9, 10 and 10A of the Tender Form are ultra vires, the provisions of

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the Drugs Act and Rules, the Director of Health and Family Welfare Services had no competence to impose such restrictions;

(ii) The restriction contained in these clauses is artificial and has no nexus to the object. Hence, violative of Art. 14 of the Constitution of India.

18. With this conclusion, I take up W. P. 12123/1986.

FACTS:

Petitioner is a Proprietary concern, who has obtained licence under the Act. He contends that in view of Cl. 9 i.e. three years experience, he has not filed his tender; W.P. is filed on Ist July, 1986. He submits that if this Court finds Cl. 9 as illegal and unsustainable, he should be permitted to submit his tender, as that was the only hurdle in his way to submit the Tender. Reliance is placed on the following observation in Ramana Dayaram Shetty Vs. International Airport Authority of India and Others, -

"9..... A person whose tender was rejected might very well complain that the tender of someone else was wrongly accepted, but, it was submitted, how could a person, who never tendered and who was at no time in the field, put forward such a complaint? This argument, in our opinion, is misconceived and cannot be sustained for a moment. The grievance of the appellant, it may be noted, was not that his tender was rejected as a result of improper acceptance of the tender of the 4th respondents, but that he was differentially treated and denied equality of opportunity with the 4th respondents in submitting a tender. His

complaint was that if it were known that non-fulfillment of the condition of eligibility would be no bar to consideration of a tender, he also would have submitted a tender and competed for obtaining a contract. But he was precluded from submitting a tender and entering the field of consideration by reason of the condition of eligibility, while so far as the 4th respondents were concerned, their tender was entertained and accepted even though they did not satisfy the condition of eligibility and this resulted in inequality of treatment which was constitutionally impermissible. This was the grievance made by the appellant in the writ petition and there can be no doubt that if this grievance were well founded, the appellant would be entitled to maintain the writ petition ....."

(underlining is mine)

19. Despite permitting, respondents have not finalised the ''Tender, though they have opened them. Whatever may be their intention in doing so, since the tender, offer has not materialised and no right has been created in favour of any of the Tenderers, stage has not reached for invoking equitable consideration. As at present, every one is a competitor, there can be no justifiable reason to restrict the competition only to those, who have offered Tenders. Since the arbitrary rule has unjustly eliminated several other eligible persons, it would be proper that this petitioner and those similarly situated should be provided with

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opportunity.

20. Hence I make the following order, to cover both the cases:

(i) Both writ petitions are allowed;

(ii) Conditions 9, 10 and 10-A are struck down, as being violative of Art. 14 of the Constitution of India and the imposition was beyond the powers of Director of Health and Family Welfare Service.

(iii) A writ in the nature of mandamus is issued to call for fresh tenders (it is represented that the tenders already invited have since been opened) from all eligible applicants, including those, who have already submitted.

(iv) Time for compliance two months.

(v) No costs.

21. Petitions allowed.

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