(2000) 02 PAT CK 0093

In the Patna High Court

Case No : Civil Writ Jurn. Case No. 3553 of 1998

Core Healthcare Limited — APPELLANT

Vs

The State of Bihar and Others — RESPONDENT

Date of Decision : 03-02-2000

Acts Referred:
Drugs and Cosmetics Act, 1940 — Section 18, 22, 23, 23(3), 23(4)

Citation : (2000) 48 BLJR 950 : (2000) CriLJ 3150 : (2000) 2 PLJR 324 : (2000) 4 RCR(Criminal) 454

Hon'ble Judges : Asok Kumar Ganguly, J

Bench : Single Bench

Advocate : Tarakant Jha, A.B. Ojha and Vinay Kumar Tiwary, for the Appellant; Azfar Hassan, S.C. VII and Abha Verma, J.C. to S.C. VII, for the Respondent

Final Decision : Allowed

Judgement

Asok Kumar Ganguly, J.—The subject matter of challenge in this writ petition is memo No. 1499 dated 23-9-1996 by which some of the drugs manufactured by the petitioner Company has been declared to be banned and the petitioner Company has been black listed. The said order is to the effect that the drug Sodium Chloride and Dextrose Injection I. V. Batch No. F....l, 1641 and 6150 allegedly manufactured by the petitioner Company has been declared substandard by the Government analyst after examination at Central Drug Laboratory, Calcutta. It has been alleged that there is presence of foreign particles in this essential life saving drugs like I. V. Fluid and this can be fatal for life. There is also an allegation that the drugs have been supplied by the petitioner Company to different hospitals of the State at different rates. As such it was ordered to black list M/s. Core Parenteral Limited at present M/s. Core Health Care Limited, Ahmedabad, Gujarat.

2. Challenging the said order this writ petition was filed on 28-4-1998. Thereafter during the pendency of the writ petition another resolution was brought on record. The petitioner has also challenged the said resolution of the Government

of Bihar, Department of Health, Medical Education and Family Welfare dated 23-9-1996 by which ban is imposed on the sale and purchase of Sodium Chloride and Dextrose Injection I. V. manufactured by the petitioner Company as it was considered that the same was unsafe for human life.

3. It is averred in the writ petition that the petitioner Company, incorporated under the Indian Companies Act is having its registered office at Core Towers near Parimal Crossing, Ellisbridge, Ahmedabad. The petitioner Company manufactures vide range of health care products i.e. I V. Fluids, Irrigation Solutions, Total Parenteral nutrition, blood products, Renal care products and various other items. The name of the petitioner Company was changed in the year 1994 from Core Parenteral to Core Healthcare Limited. It has been also stated in the writ petition that the petitioner Company is one of the largest Companies manufacturing I V. Fluids in the world. The petitioner Company has appointed the Span Medicals Limited as its Clearing and Forwarding Agent which has its branches all over the country and it has also a branch at Patna situate at Suman Sadan near I.A.S. Colony, Kidwaipuri, Patna and also deals with its customers directly through its Patna Branch. It has been stated that the drugs in question manufactured by the petitioner Company are sold by the aforesaid clearing and forwarding agent through petitioner''s stockists in the State of Bihar.

4. The main grievance of the petitioner Company is that the respondent authorities have purportedly seized some bottles allegedly showing the label of the Petitioner Company and without any information to the petitioner Company, sent it for laboratory test to respondent No. 3. It has also been stated that without following the procedure prescribed by the Drugs and Cosmetics Act and Rules framed there under and without affording any reasonable opportunity to the petitioner Company in the matter, the decision has been arrived at by the respondents. It is further alleged that no notice was ever given by the respondent No. 3, the Central Drug Laboratory, Calcutta to ascertain whether the specimen in question was actually manufactured by the petitioner Company or whether the same was sent to the market for sale and human consumption through its clearing and forwarding agent, the Span Medicals Limited. Therefore, the report submitted by respondent No. 3, the Central Drug Laboratory, Calcutta cannot be in respect of any thing manufactured by the petitioner Company. Therefore, the grievances of the petitioner Company boils down to this that without any opportunity being given to it to defend its case the two notifications were issued black listing the petitioner Company and banning its products. It is asserted by the petitioner Company that it is the first I. V. fluid manufacturing Company in India to receive the ISO 9002 certificate by Bureau Veritas Quality International, London. During 1993-94 the Company was awarded the IDMA quality excellence Certificate of Merit which is the highest recognition of quality and excellence in the Indian Pharmaceutical Industry. The Company was awarded with the same excellence certificate in 1991 also and is the only intravenous fluid company to be felicitated with this award amongst all the Indian Pharmaceutical Companies. It has also been stated that the petitioner Company was awarded

the GMP (Good Manufacturing Practices) Award by WHO in the years 1994 and 1996 and many other certificates.

5. It has also been stated that the petitioner Company exports I. V. Fluids to over 63 countries all over the world. It has also been stated that the petitioner Company''s large manufacturing capacity and advanced technology is comparable to the world''s best and largest Company manufacturing I. V. Fluids. It has been stated that the petitioner Company employs the world class "Asceptic Form-Fill-Seal" (AFFS) technology. This technology is imported from Rommelag Switzerland to manufacture I. V. Fluids. This technology involves forming, filling, sealing and coding of the intravenous fluids in one single stage operation within a closed sterile chamber, absolutely free from human or atmospheric contamination. This technology involves extrusion process of melted plastic granules at 185 degrees Celsius, to manufacture sterile containers. A bottle pack machine is used which forms-fills-seals five bottles in a time cycle of just 15 seconds. There is a custom built filtration system incorporating 02 micron (size of particles 1 micron =1/1,000 mm) filters to ensure that even the air used for blowing the bottle is sterile and filtered. In addition, this system also incorporates 0.2 micron filters to filter the solution before it gets filled into the bottle. The petitioner Company has given details of its manufacturing process in various paragraphs of the writ petition.

6. In this matter a counter-affidavit has been filed on behalf of respondent No. 2. The expertise and the excellence claimed by the petitioner in its field was not been disputed. In the said counter-affidavit the case which has been made out is that a complaint was received from one Sri Rajendra Prasad resident of Patliputra Colony along with the sample of Sodium Chloride and Dextrose I.V. fluids of two different batches. The complaint was enquired into and the sample of Sodium Chloride and Dextrose I.V. of two different batches were seized and sent to Central Drug Laboratory, Calcutta. The test report of those batches has been disclosed as Annexure-A to the counter-affidavit. It has also been alleged that a team from Drug Controller''s Office inspected the drug store of Patna Medical College and Hospital, Patna wherein a number of bottles of the said drug were found full of fungus indicating that the above drug is contaminated and non-sterile and it is injurious to the ailing patient and also pose a risk to their life. It has also been stated that tenders were invited by different hospitals of the Bihar Government and it was found that the drugs supplied by the petitioner-Company through his stockists charged different prices. It has also been alleged that high profit is charged from the hospitals and it appears that the petitioner-Company did not comply with the conditions in the tender. The case of the respondents is that under the tender the petitioner-Company has accepted in writing that the Central Sales Tax will not be charged and if the goods would have been supplied directly from the petitioner-Company, no sales tax was applicable. But the allegation is that: by supplying the drugs through its local stockists, local sales tax of 7% was charged which costs extra burden on the hospitals to purchase certain drugs. Under this circumstance the petitioner-Company was black listed

by the Government. It has been also stated in paragraph 7 of the counter-affidavit that before black listing of the Company asking for an explanation is not mandatory. The stand taken in the counter-affidavit is that the black listing of the Company means to debar the company from supplying drugs to the Government Institution. Therefore, this does not call for any explanation. About the drawing of sample, the stand taken in the counter-affidavit is that, as a matter of fact, the samples were drawn by the appropriate authorities i.e. Drug Inspector following the procedure prescribed in Section 23 of the Drugs and Cosmetic Act, 1940 and at the time of drawing sample it is not necessary to intimate or inform the petitioner-Company as the petitioner-Company is located in the State of Gujarat. The matter was referred to the Food and Drugs Authority. It has also further stated that the petitioner-Company has been black listed in public interest. In so far as the question of hearing is concerned, it has been stated that the petitioner-Company made a representation which was duly considered and ultimately the same was rejected as would appear from Annexure-E to the counter-affidavit.

7. In the counter-affidavit it has been alleged in paragraph 15 that it is not mandatory to draw a sample or to seize the drugs and to seal and pack it in presence of manufacturer and it is not possible to do so.

8. In this case a rejoinder has also been filed by the petitioner-Company and the objection which has been taken in it, this Court finds, to be quite a valid one. The objection is that the deponent to the counter-affidavit was a Drug Inspector in Ayurved whereas the drugs in question are certainly allopathic drugs. Therefore, it is expected that the said affidavit should have been affirmed by a person who is conversant with the allopathic drugs. Apart from that, it is has been stated in the rejoinder that no sample has been taken or purchased from the petitioner manufacturing-Company whereas the Inspector was required u/s 18A read with Section 23 of the Act to collect the details of the manufacture from the petitioner and it is mandatory under the Act to send one of its sample to the petitioner-Company which admittedly, in the instant case, has not been done.

9. In this matter a supplementary counter-affidavit has also been filed. It has been stated in paragraph 4 of the said supplementary counter-affidavit that the sample of Sodium Chloride and Dextrose Injection I.P. Batch No. F-11 -1641 were drawn for test and analysis on 31 -5-1995 from M/s. Metro Agencies Commercial House, Kankarbagh Road, Patna and it has been stated that the said Agency is an authorised Agent for distribution of the aforesaid drugs manufactured by the petitioner-Company. It is further stated that the sample was drawn jointly by Sri Y.K. Saiswal, R.L.A., Patna and Sri Ramesh Kumar, Inspector of Drug, Patna under the order of the State Drug Controller, Bihar, Patna. It is further stated that the second sample of Sodium Chloride and Dextrose Injection were drawn for test and analysis on 27-9-1994 from the Store of Lok Narayan Jai Prakash Sadan Hospital, Bhagalpur. It is alleged that those medicines were supplied by M/s. Shree Balaji Enterprises who is the authorised

stockist/agent of the petitioner-Company. It is further stated in the counter-affidavit that after testing and analysis of the sample the Government analyst found the same to be of substandard quality.

10. To the said supplementary counter-affidavit a rejoinder has also been filed by the petitioner-Company. In the said supplementary counter-affidavit in paragraph 4 it has been denied that M/s. Metro Agencies, Commercial House, Kankarbagh, Patna was ever the authorised agent of the petitioner-Company. It has been also stated that the respondents-authorities never sent any notice to the petitioner to find out whether the aforesaid M/s. Metro Agencies, Commercial House, Kankarbagh Road, Patna was ever appointed by the petitioner- Company as an authorised agent or Distributor within the meaning of the Drugs Act/Rules. It has also been specifically denied in paragraph 5 of the said rejoinder that M/s. Shree Balaji Enterprises is not an agent for distribution of the drugs of the petitioner-Company. It has also been denied that any drug was collected from the said M/s. Balaji Enterprises or any specimen was sent to the petitioner-Company. In the said rejoinder it has been repeated that the only agent of the petitioner-Company is Span Medicals Limited and there is no other agent of the petitioner-Company. It has been stated categorically in the said rejoinder affidavit that no specimen or sample was ever served on the petitioner-Company nor was it served with any notice.

11. It is common ground that while carrying on the aforesaid search and seizure and inspection in respect of the drugs, the respondents are governed by the provisions of the Drugs and Cosmetics Act, 1940 (here-inafter called the said ''Act''). Under the said Act, Section 23 lays down the procedure which are to be followed in cases of such inspection. The detailed provisions made in Section 23 of the said Act are set out below :-

23. Procedure of Inspectors.-

(1) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price thereof and may acquire a written acknowledgment therefor.

(2) Where the price tendered under Sub-section (1) is refused, or where the Inspector seizes the stock of any drug or cosmetic under Clause (c) of Section 22, he shall tender as receipt therefore in the prescribed form.

(3) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked :

Provided that where the sample is taken from premises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into

three portions only :

Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it and shall retain the remainder and dispose of the same as follows-

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic; and

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed u/s 18A.

(5) Where an Inspector takes any action under Clause (c) of Section 22,-

(a) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of Section 18 and, if it is ascertained that the drug or cosmetic does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized.

(b) if he seizes the stock of the drug or cosmetic, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug or cosmetic, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an Inspector seizes any record, register, document or any other material object under Clause (cc) of Sub-section (1) of Section 22, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

12. The attention of this Court has been drawn to Section 23(3) of the said Act. In the said provision it is made clear that when an Inspector takes a sample of drugs or cosmetics for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and in the presence of such person shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked. But if the said sample is taken from the premises whereon the drugs or cosmetics are

being manufactured, it is necessary to divide the sample in three portions only. It is an admitted position here that the sample of drug was not taken from the premises whereon it was manufactured. Therefore, in the instant case for the purpose of test or analysis, the sample should be divided into four portionsection Under Clause (iii) of Sub-section (4) of Section 23 of the said act, it is made clear that the third portion shall be sent to the person, if any, whose name, address and other particulars have been disclosed u/s 18A of the said Act.

13. Section 18A of the said Act provides that every person, who is not a manufacturer of a drug or cosmetic or not the agent for distribution of such drugs shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

14. In the instant case it is an admitted position that the drugs which were seized for test and analysis were not seized from the petitioner-Company who is the manufacturer nor has it been seized from its Agent whose name has been disclosed in the writ petition. Therefore, it has been seized from persons other than either the manufacturer or the agent of the manufacturer. Therefore, in such a situation, while acting u/s 18A of the said Act, the person from whom it was seized must disclose to the Inspector the name and address and other particulars of the person from whom the drug was acquired and u/s 23(3) read with Section 23(4)(iii), the sample of such drugs taken for analysis shall be sent to the persons whose names are so declared u/s 18A of the said Act.

15. It is nowhere stated in the counter-affidavit or in course of argument that the aforesaid procedures were followed while sending the drugs in question for analysis.

16. There are also certain safeguards in the matters of reports of Government analyst. u/s 25(2) of the said Act, it is provided that the Inspector on receipt of a copy of the report shall deliver a copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed u/s 18A and shall retain the third copy of the report for prosecution. In the instant case no copy of the report has been given to the petitioner or its authorised agent mentioned in the writ petition.

17. It has been clearly stated in paragraph 5 of the writ petition that M/s. SPAN Medicals Limited is its Clearing and Forwarding Agent which has branches all over the country, inter alia, one at Patna situate at Suman Sadan near I.A.S. Colony, Kidwaipuri, Patna and it deals with the customers directly through its Patna Branch and the said drug was sold by the aforesaid Clearing and Forwarding Agent of the petitioner''s stockists in the State of Bihar. These facts stated in paragraphs 5 and 6 of the writ petition have not been even dealt with far less denied in the counter-affidavit filed by the State.

18. Therefore, it is incumbent upon the Inspector while purporting to carry on inspection, test and analysis of the drug in question, to send a notice either to the petitioner-Company or to its agent mentioned in paragraph 5 and also to

send a sample of the same. A report has also to be sent to either the petitioner-Company or its Agent mentioned in paragraph 5 of the writ petition. Admittedly the said procedure has not been followed. Therefore, the entire procedure relating to seizure and analysis and test of the drugs in question have been made in a manner which is not contemplated in law.

19. These detailed procedures have been made under the provisions of the said Act with a purpose. The purpose is to give certain safeguards to the manufacturer of the drug: in question from frivolous complaints. The other purpose is to fix the responsibility upon persons who are engaged in spurious manufacture of drugs and it is expected that when those provisions have been made they should be followed by the authorities of the Stab before taking any punitive action against an; offender who is alleged to be manufacturispurious drugs. But in the instant case. those provisions have been completely vidlated. Having done so, the State cannot fasten on the petitioner-Company the allegation of manufacturing spurious drugs.

20. It is no body''s case that those provisions are not mandatory. In fact those provisions have been enacted with scrupulous care to see that a spurious manufacturer of drugs cannot elude the reach of the law. The consequences of such spurious manufacture of drugs are severe. Therefore, those provisions must be strictly complied with.

21. Apart from that, it is a well known position in law, that when Statute provides for doing something in a certain manner, it must be done in that manner only and all other modes of performance are necessarily forbidden. So going by this time honoured principle, this Court finds itself totally unable to affirm the orders impugned in this case.

22. In the instant case, the order of black listing the petitioner-Company is equally an instance of reckless exercise of power.

23. It is not in dispute that at no stage of the proceedings the petitioner was given any notice to show cause. On the other hand the arrogant stand taken in paragraph 7 of the counter-affidavit is that it is not required to ask for an explanation before black listing a Company. This stand is totally contrary to the law laid down on the subject by the Apex Court.

24. Reference in this connection may be made to the decision of the Supreme Court in the case of Erusian Equipment and Chemicals Ltd. Vs. State of West Bengal and Another, . In delivering the judgment of the Supreme Court, Chief Justice A. N. Ray, as his Lordship then was, observed that the order of black listing has the effect of depriving a person of equality of opportunity in matters of public contract. It has been further observed that in absence of an order of black listing, person or Company concerned would have been entitled to participate in commercial transaction with the Government. Therefore, the persons who are deprived of the same opportunity must be given an opportunity before the order is passed. The law on the subject has been very succinctly stated by the learned

Chief Justice in paragraph 20, which I quote below :

Blacklisting has the effect of preventing a person from the privilege and advantage of entering into lawful relationship with the Government for purposes of gains. The fact that a disability is created by the order of blacklisting indicates that the relevant authority is to have an objective satisfaction. Fundamentals of fair play require that the person concerned should be given an opportunity to represent his case before he is put on the blacklist.

25. The concept of blacklisting has also been elaborated by the learned Chief Justice in paragraph 15 of the said report which is quoted below :-

The blacklisting order does not pertain to any particular contract. The blacklisting order involves civil consequences. It casts a slur. It creates a barrier between the persons blacklisted and the Government in the matter of transactions. The blacklists are "instruments of coercion.

26. The stand in paragraph 7 of the counter-affidavit is just contrary to the said law. Therefore, the stand of the State Government in this case cannot be affirmed.

27. Apart from that from the materials disclosed in the pleading between the parties, this Court finds that the petitioner had an explanation to offer in answer to the charge of blacklisting. The Court need not go into the correctness of the explanation. But one thing is clear that blacklisting a company/organisation without calling for an explanation from it is something which offends the fundamentals of fair play in action. This Court strongly condemns the casual manner in which the order of blacklisting has been passed.

28. In that view of the matter, this Court quashes the impugned order, namely, memo No. 1499 dated 23-9-1996 and also the resolution of the Government of Bihar, Department of Health, Medical Education and Family Welfare dated 23-9-1996 on which ban has been imposed on the petitioner-Company. This writ petition thus succeeds.

29. But this Court makes it clear that this order will not stand in the way, if the Government is advised to initiate further proceedings under the provisions of the aforesaid Act for the purpose of carrying on any test of the drugs manufactured by the petitioner-Company, but this Court makes it clear that in that event they must follow the mandate of law in doing so.

30. For the reasons stated above, this writ petition is allowed. There will be no order as to costs.

