

THE HIGH COURT OF DELHI AT NEW DELHI

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Judgment delivered on: 06.12.2013

+ **W.P.(C) 5844/2013**

ALPA LABORATORIES LTD.

..... Petitioner

versus

ESI CORPORATION

..... Respondent

Advocates who appeared in this case:

For the Petitioner : Mr Adil Alvi.

For the Respondent : Ms Rekha Palli & Ms Punam Singh.

CORAM:-

HON'BLE MR JUSTICE BADAR DURREZ AHMED

HON'BLE MR JUSTICE VIBHU BAKHRU

JUDGMENT

BADAR DURREZ AHMED, J (ORAL)

1. By way of this petition, the petitioner has, *inter alia*, sought a writ order or direction for quashing the letter dated 17.06.2013 issued by the respondent, whereby the petitioner has been debarred from participating in future tenders for three years. The petitioner was, *inter alia*, supplying sterile water for injections under a Running Rate Contract. Clause 15(iii)(d) of that Running Rate Contract reads as under:-

“15.(iii)(d) If Category A (major) defect is found, the firm will be debarred for three years for one or more or all the products in the Rate Contract of ESI Corporation. The classification of defects into – A category (major) and B category (minor) defects will be as per the guidelines issued by the Drug Controller General of India.”

2. On 20.10.2011, a Show Cause Notice was issued to the petitioner by the Deputy Commissioner (Rate Contract). The said Show Cause Notice was as under:-

“No..U-25/12/NSQ/2010-Med.V

Dated 20.10.2011

To

M/s Alpha Laboratories Ltd.,
33/2, A.B. Road,
Pigdamber,
Madhya Pradesh.

SHOW CAUSE NOTICE

Subject: Purchase of drugs/medicines under ESI Rate
Contract- Declaration of drug as ‘Not of Standard
Quality’.

Sir,

I am directed to say that Dy. Med. Suptd. Kolkatta has reported to this office that the following drug/medicines supplied by your firm have been declared as “Not of Standard Quality” on analysis by Govt. approved lab.

NAME OF THE FIRM	ITEM NAME NO. RCNO.	BATCH NO DOM DOE	REPORT NO & DATE	NAME OF LAB
M/s Alpha Lab Ltd.	Sterile water for inj., 5ml Item no.277 RC133	AV1792 AV1778 AV1786 AV1787	D/12961/11 D/12958/11 D/12960/11 D/12959/11	M/s Acharya P.C. Ray R & D Drug Testing & Pollution Testing Laboratory

		12/2010 11/2013	dated 29.8.11	
		AV1771 11/2010 10/2013	D/12957/11 dated 29.8.11	

In this connection, I am to draw your attention to the terms & conditions of the Rate Contract under which you are required to replace the entire consignment or make full payment irrespective of the fact that the part of the goods may have been consumed by the time of the report received from the drug laboratory and to request you to replace/make payment for the entire consignment(s) of above batch (es) of above said drug(s) supplied to ESI Scheme institutions/hospital of Madhya Pradesh and other states immediately.

It is requested to explain as to why action should not be taken as per terms & conditions of ESI Rate Contract. You are hereby advised to submit your reply within 15 days on receipt of this letter failing which necessary action including debarring of firm will be taken without any intimation.

A line in confirmation to the action taken in this regard may be intimated urgently.

Copy of Test Report is enclosed.

Please acknowledge the receipt of this letter.

Your faithfully

Sd/-

(Dr. Kayam Singh)
Dy. Medical Commissioner RC

Copy to :- The Dy.Med.suptd. ESIH, Joka Kolkatta With ref. To their letter No. 412.U.25/1/Med. Policy/2005/vol.III/5759 dated 19.9.2011 with a request to take immediate action for recovery of the cost of supplies from the firm or replacement of the drug under intimation to this office.

Dy. Medical Commissioner (RC)”

3. From the above Show Cause Notice, it is apparent that five batches of sterile water for injections which had been supplied by the petitioner were found to be not of standard quality on an analysis by a Government approved laboratory namely M/s Acharya P.C. Ray R & D Drug Testing & Pollution Testing Laboratory, Kolkata.

4. The petitioner was required to show cause, as to why action should not be taken as per the terms and conditions of the ESI Rate Contract which included the above mentioned Clause 15(iii)(d). It is also to be noted that alongwith the Show Cause Notice a copy of test report was also enclosed.

5. In response to the Show Cause Notice, the petitioner sent a reply on 01.11.2011 which is to the following effect:-

“Dated : 01.11.2011

To,

**Dr. Kayam Singh,
Dy. Medical Commissioner R.C.
Employees State Insurance Corporation,
Panchdeep Bhavan, C.I.G. Road,
New Delhi – 110 002.**

**Subject: Purchase of Drugs / Medicines under ESI Rate
Contract Declaration of drug as not of standard quality.**

**Reference: Your Show Cause Notice No. U-25/12/NSQ/2010
– Med. Dated 20.10.2010 received by us on 01.11.2011.**

Sir,

Apropos to above, we have to submit as under:-

1. As stated by you that the Dy. Med. Suptd. Kolkatta has reported medicines supplied by us to be not of Standard Quality on analysis by Govt. Approved Lab.
2. In this respect we have to submit that we are testing each and every batch of drug / medicines from our laboratory which is a Govt. Approved Laboratory, before selling the same in market.
3. Reasons for declaring the above batches of drugs / medicines to be not of Standard Quality are not given in the above said letter under reference.
4. However as per the terms and conditions of the Rate Contract we are ready to replace the entire consignment as desired by you with fresh lot of drugs / medicines.

In view of the above we request your honour to kindly refrain from any action against our company till the time of final report is received from CDL, Kolkatta.

Assuring of our best services.

Thanking you,
With regards
Your's sincerely
For Alpa Laboratories Ltd.

Sd/-

Mahendra Singh Chawla
Director”

6. It is apparent from the above, that the petitioner had stated that the reasons for declaring the five batches of drug/medicine to be of not standard quality were not given in the Show Cause Notice. It was also indicated by the petitioner that as per the terms and conditions of the Rate Contract, the petitioner was ready to replace the entire consignment as desired by the respondent with a fresh lot of drug/medicine. Finally, it was requested that the respondent should refrain from taking any action against the petitioner till the time the final report is received from CDL, Kolkata. In view of the request made by the petitioner to await the test report from CDL, Kolkata, the respondents did not take any action for some time. However, for more than a year, the petitioner did not communicate any test report of CDL, Kolkata to the respondent. Infact, till date no test report has been submitted by the petitioner with regard to the said batches of sterile water for injections. Left with no alternative, the respondents issued the impugned letter dated 17.06.2013, *inter alia*, debarring the petitioner company from supplying their products for a period of three years w.e.f. 10.05.2013 in Running Rate Contracts and also debarring the petitioner from participating in future Rate Contracts with ESI Corporation.

7. The learned counsel for the petitioner submitted that the testing at CDL, Kolkata could not be conducted because the samples were not provided by the respondent to the petitioner. The learned counsel for the petitioner drew our attention to Section 23 of the Drugs and Cosmetics Act, 1940 to submit that whenever a sample is taken by an Inspector, it has to be divided into four portions. One portion is to be sent to the Government for testing. The second portion is to be sent for production before a Court. The

third portion is to be given to the manufacturer and the fourth portion is to be retained by the Inspector. He submits that the portion which was to be given to the manufacturer has not been given and, therefore, for that reason, no testing could be conducted at petitioner's end.

8. We may agree with the learned counsel for the respondent that the reference made under Section 23 of the Drugs and Cosmetics Act, 1940 is entirely misplaced. That provision will come into play only if a prosecution is launched under the Drugs and Cosmetics Act, 1940. The present case is not a case of prosecution under the said Act but one of action in terms of the tender conditions of the Running Rate Contract by the customer (ESI Corporation).

9. The learned counsel also drew our attention to Clause 40 of the terms and conditions of the running contract which reads as under:-

“40. Testing of drugs

- a) Regular and random testing of drugs will be undertaken from Govt./Govt. approved laboratories at the time of supply and at any time during the shelf life or whenever any defect is noticed.
- b) The report of the Govt./Govt. approved laboratory shall be accepted by the firm. In case the same is disputed by the firm giving reasons, the report of the Appellate Laboratory only will be accepted as final and the same should be submitted with in three months, from the date, the disputed test report is communicated to the firm. For this, the firm should approach the concerned Drug Control Authorities for getting the drugs tested as per procedure from the Appellate Laboratory.”

10. She specifically drew our attention to the provisions that, in case the manufacturer did not accept the report of the Government approved laboratories, it was incumbent upon the manufacturer to approach the concerned Drug Control Authority for getting the drugs tested as per procedure from the Appellate Laboratory. She submitted that this was not done within the period of three months stipulated therein. Infact, it was not done at all. It is in this backdrop that the debarring order was issued on 17.06.2013. We may also point out that throughout this period of time, i.e. between reply dated 01.11.2011 and the debarring order dated 17.06.2013, there is no communication from the petitioner to the respondent requesting for samples. Therefore, the petitioner cannot be heard to make a grievance of the fact that no samples were provided to it for conducting the test at CDL, Kolkata.

11. In view of the foregoing, we do not see any reason to quash or set aside the impugned debarring order/letter dated 17.06.2013. Consequently, the writ petition is dismissed. There shall be no order as to costs.

BADAR DURREZ AHMED, J

VIBHU BAKHRU, J

DECEMBER 06, 2013
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