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In the Delhi High Court

Case No : Rev. Pet. 217/2014, C.M. No. 5895/2014 and 5896/2014 in W.P. (C) 4557/2013

Rhydburg Pharmaceuticals Ltd. APPELLANT

Vs

ESI Corporation RESPONDENT

Date of Decision : 25-07-2014

Acts Referred:

Citation : (2014) 7 AD 66 : (2015) 213 DLT 719

Hon'ble Judges : S. Ravindra Bhat, J;Najmi Waziri, J

Bench : Division Bench

Advocate : Rajat Aneja and Ishaan Chhaya, Advocate for the Appellant; Rekha Palli, Punam Singh and Ankita Patnaik, Advocate for the Respondent

Final Decision : Partly Allowed

Judgement

S. Ravindra Bhat, J.

C.M. No. 5895/2014 (for condonation of delay)

For the reasons mentioned in the application, C.M. No. 5895/2014 is allowed.

C.M. No. 5896/2014 (for exemption)

Allowed, subject to all just exceptions.

REV. PET. 217/2014

1. The review petitioner seeks recall of the judgment and order of this Court dated 22.07.2013. The petitioner had challenged an order of blacklisting issued by the respondent on 17.06.2013. The petitioner had entered into a contract with the respondent for supply of specific pharmaceutical products under the terms and conditions of the Rate Contract existing at that time. The respondent had intimated on 06.12.2012 that two categories of drugs supplied were sub-standard. Subsequently, a Show Cause Notice dated 21.02.2013 was received, proposing penal action, including the possibility of debarring. The petitioner

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replied to this, contending that under the terms and conditions of the Rate Contract, it had complied with the demand for the failed batches by replacing the entire quantity and also refunded the amounts received by it. In the light of these developments, the respondent issued the impugned order debarring the petitioner, for a period of three years, from entering into any contract with it. This Court had, by its judgment and order, (the review of which is sought for), held that there is no fault with the debarring order and had given an opportunity to the petitioner to approach the respondent authorities in the light of the decision of the Chief Judicial Magistrate with respect to the samples. The review petitioner urges that this Court fell into error in overlooking the terms of the contract between the parties, especially Clause 15(iii)(a) of the Rate Contract. It was urged that the Show Cause Notice dated 21.02.2013 failed to mention any condition, much less Clause 15 (iii)(d), or even to disclose to the petitioner that the alleged failed samples fell within the description of that condition as they were Category ''A'' major defects. Learned counsel for the respondent urged that no review is called for. She relied upon the report of the Technical Evaluation Committee (TEC) in respect of the petitioner''s Rate Contract dated 18.02.2013 which had indicated that the defects were classifiable properly in Category ''A''.

2. We have considered the submissions. As is evident from a plain reading of Show Cause Notice dated 21.02.2013, the respondent did not specify or spell-out as to the conditions that they were likely to invoke at the time they proposed the debarring order. Having regard to the fact that the petitioner had concededly complied with the previous demand for substitution of the faded batches/supplies and also refunded the amount, it could reasonably assume that the conditions spelt out in Clause 15(iii)(a) had been fulfilled, and rest content with the assurance that no debarring would take place. In these circumstances, we are of the opinion that the writ petition deserved to be allowed. It is accordingly allowed.

W.P.(C) 4557/2013

3. With consent, we have heard learned counsel for the parties The detailed narrative of the fact is unnecessary in view of the fact that the essential circumstances have been set-out in the order which has led to the review petition. The Show Cause Notice in the present case issued on 21.02.2013 reads as follows:

To,

M/s. Rhydburg pharmaceuticals Ltd.,

C-2&3, Sara Industrial Estate,

Rampur Village, Selaqui,

Dehradun, Uttarakhand,

Dehradun.

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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 Med. Supdt., ESIH Jammu 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.

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 Jammu 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.

4. Prior to the issue of Show Cause Notice dated 21.02.2013, the respondent had issued another letter pointing the defects in the specific samples provided by the petitioner. At this stage, before proceeding on the issue, it is essential to set-out the conditions in the Rates Contract which were invoked by the respondent while passing the impugned order.

15. (i) The stores offered should comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder as amended upto date and Drug Price Control Order.

(ii) While quoting against items with ISI Mark, it should be ensured that ISI code number is indicated on quotation and at the time of making the supplies, the firm should ensure that the items supplied has ISI Mark as well as Code Number, as is the statutory requirement of the Bureau of Indian Standards. The attested copy of the valid ISI Marking license issued by Bureau of Indian Standards should be enclosed alongwith the quotation.

(iii) (a)If any store/stores supplied against this Rate Contract are found to be not of standard quality on test analysis from approved laboratory and/or on inspection by competent authority, the contractor will be liable to replace the

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entire quantity or make full payment of entire consignment against the particular invoice irrespective of fact that part or whole of the supplied stores may have been consumed.

(b) If the produce is found to be ''not of standard quality'', the cost of testing will be recovered from the supplier.

(c) If the firm fails to replace the batch declared to be ''not of standard quality'' or fails to make payment in lieu of that, the firm is liable to be debarred for two years in respect of the one or more or all the items in the Rate Contract of the Corporation.

(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.

5. The respondent today relies upon the decisions taken by the TEC in respect of the petitioner''s Rate Contract dated 18.02.2013. The said list contains the names and description of several suppliers, including the petitioner''s firm, which are part of an enclosure to the said minutes of the TEC. The minutes and the relevant extracts of the tabular statement, enclosed as Annexure-A are extracted below: Meeting of Technical Evaluation Committee in r/o Rate Contract No. 138, held on 18.02.2013 in the Committee Room, ESIC, Hqrs. Office

The Technical Evaluation Committee as approved by Director General met on 5th and 6th February, 2013 in Committee Room, ESIC Hqrs. Office, New Delhi to evaluate the technical bids received against the Tender Enquiry for Rate contract No. 138 and to make recommendations regarding eligibility of various firms and drug quoted by the participating tenderers.

The Meeting was attended by following officials:-

1. Dr. S.R. Chauhan, Medical Commissioner - Chairman.

2. Dr. Anil Malik, Civil Surgeon-on behalf of Director - ESIS, Haryana.

3. Dr. Shashi Avasthi, Manager, Central Stores-on behalf of D(M)D.

4. Shri Ashok Verma, Dy. Director, Finance, Hqrs. Office.

5. Dr. Kayam Singh, Dy. Med. Commissioner (RC).

Director-ESI Scheme, Karnataka, Gujarat and representative from DGCI did not attend the meeting.

As per Terms and conditions of DGESIC RC clause 19(f) & Tender Enquiry 15(iii) (d) in r/o Testing of drugs - Quality Control - 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

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- category A (Major) and category B (Minor) defects will be as per the guidelines issued by Drug Controller General of India (F/A).

Total items 28 (Twenty eight) which have been declared ''Not of standard quality by govt. approved labs during the July 2011 to Jan'' 2013 has been scrutinized into Category A (Major) or category ''B'' (Minor) defects as per DCGA guideline No. X-19013/6/92-D dated 13.5.93.

Accordingly, a drug/dressing material of a firm having Category ''A'' (Major) defect upto two different drugs/dressings material or two different batches of single drug/dressing material within last 03 years, i.e. January, 2010 to January, 2013 should be debarred for those particular items for 03 years for running Rate Contract and to participate in future DG-ESIC rate contracts. The recommendation of the committee are placed at Annexure ''A''.

Further the committee also reviewed the drugs/dressing materials declared ''NSQ'' during last 03 years and recommended that either three or more than three different drugs/dressing materials or if three or more than three batches of single drugs/dressing material w.r.t. a particular firm have been declared ''Not of Standard Quality'' having category ''A'' Defect (Major) within last 03 years, i.e. since January, 2010 to January, 2013, the firm should be debarred for a period of 3 years in running Rate contract and to participate in future ESIC rate contracts as per T&C No. 15(iii)(d) of Tender Enquiry and Clause 19(f) of DG-ESIC Rate Contracts. Accordingly, the recommendations of committee are as per Annexure ''B''.

Further w.r.t. Technical Evaluation of Tenders in TE-138, the Committee recommends that in all cases where a clarification has been sought from various agencies in r/o eligibility of the firm/item, the price-bid/bids of these firms/item may be opened provisionally and final decision will be taken by TEC at the time of finalization of Rate Contract based on the reply/clarification received from the concerned agency and in absence of such reply/clarification, decision will be taken by the Competent Authority of ESI Corporation.

Sd/-

Dr. S.R. Chauhan

Medical Commissioner

DETAILS OF DRUG DECLARED ''NOT OF STANDARD QUALITY''

(July 2011 to January 2013)''

SI. No. Name of Purchasing Authority Name of the firm and Address Name of the drug/item No. & RC No. Batch No.

Dt. of Mfg.

Dt. of Exp. Test report No., Date and Name of Laboratory Reports finding Date of Show Cause Reply received from firms Nature of defect Proposed Action1.Dir

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(ESIS)

Haryana M/s. Rhydburg

Pharma Ltd. Tab. Amlodepine

5 mg

Item No. 53

RC 133T10-4352

10/10

09/12 Vatsa Testing Laboratory, Sonepat

Haryana

F20110122026 dated 22.1.2011 Assay does not comply as per claim - 80.4% (40.2 mg) Limit 4.5 to 5.5 mg. 03/11/11 Firm challenged the test report. Vide letter Dt. 13.12.11 firm was advised to submit Test Report of ''SQ'' from appellate lab. No report has been furnished over the period of 03 months. ''A'' defect (Major) tablet (i)Item to be debarred for a period of 03 years from the date of approval, 2. M.S. Kerala M/s. Rhydburg

Pharma Ltd. Tab. Amlodepine Besylate 5mg

RC 133T5115320

05/11

04/13SGS India Pvt. Id. 2265008500

Dt. 6.1.12 Fails in uniformity of content ranging from 79.36% to 140% 18.4.12 Firm has requested to provide sample of said batch. ''A'' defect (Major) tablet (vi) & (i) Item to be debarred for a period of 03 years from the Date of Approval 3. Dy. M.S., Marol, Mumbai M/s. Rhydburg.

Pharma Ltd. Tab. Atorvastation 10 mg

Item, No. 368b

RC 135T5-11249

05/11

04/13 DCL Mumbai Maharashtra state

M 1886/2011 Dt. 21.11.11 Does not comply with IP requirement for dissolution test 01/02/12''A'' defect (Major) tablet (iii) Item to be debarred for a period of 03 years from the Date of Approval XXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXX XXXXXXXX XXXX

27. Med. Suptd. Jammu M/s. Rhydburg

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Pharma Ltd. Tab. Amlodepine & Atenolol tab.

Item No. 1373

RC 133T1-12075

01/2012

12/2013 Regional Drug Testing Laboratory, Chandigarh

ISZI-1 BB ACT 2

3 2012 dated

10.12.2012 Does not claim assay of Amlodepine, i.e. 51.60% Notice being issued ''A'' defect (Major) tablet (i)''-do-

The Show Cause Notice nowhere indicates or lists out that the respondent intended to take action under Clause 15(iii)(d). This circumstance was crucial because as on the date when the Show Cause notice was issued on 21.02.2013, the respondent was in possession of the report of the TEC, which had recommended the action of debarring the petitioner for three years, on the ground of defect of Category-A in respect of three items supplied. As these aspects were neither considered by the Court nor was such material available, the writ petition was restored to the file of the Court. Applying the ratio of the Supreme Court ruling in Erusian Equipment and Chemicals Ltd. Vs. State of West Bengal and Another, and Raghunath Thakur Vs. State of Bihar and Others, , it is evident that a fair reading would, in the circumstances of the case, mean citing of the relevant conditions or stipulations which the respondents sought to invoke for the purpose of debarring the petitioner. Furthermore, the respondent is under a duty to indicate at least the conclusions of the TEC, if not furnish the entire copy of the TEC Report to the petitioner, so as to afford it an effective and reasonable opportunity to represent against the proposed action. In these circumstances, ordinarily the Court would have to proceed to quash the impugned order. However, given the seriousness of the allegations that, on more than one occasion, Category A defects were found and the drugs are alleged to be have been of sub-standard quality, and having regard to the circumstances, we are not inclined to set aside or quash the impugned order. At the same time, the respondent is directed to issue a fresh Show Cause Notice outlining specifically the grounds upon which the proposed action of debarring action is proposed to be taken and setting-out the relevant conditions. As stated earlier, the respondent shall also enclose the relevant material, including copies of minutes and extracts thereof, to enable the petitioner to give an effective reply or representation against it. A fresh notice is directed to be issued within two weeks from today. Upon its receipt, the petitioner shall give its reply/response within four weeks thereafter. The respondent shall proceed to pass a reasoned order within eight weeks from today and directly communicate it to the petitioner. All rights and contentions of the parties are expressly reserved. The writ petition is allowed in the above terms to the above extent.

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