

\$~3

*

IN THE HIGH COURT OF DELHI AT NEW DELHI

Decided on: 13.03.2015

+

W.P.(C) 5470/2014, C.M. NO.10865/2014

M/S. THEON PHARMACEUTICALS LTD.....Petitioner

Through: Sh. Himanshu Gupta, Advocate.

Versus

DG, ESIC AND ORS.Respondents

Through: Ms. Rekha Palli, Ms. Ankita Patnaik and Ms. Garima Sachdeva, Advocates, for Respondent Nos. 1 and 2.

Sh. Aseem Chaturvedi and Sh. Abhijeet Swaroop, Advocates, for Respondent No.4.

CORAM:

HON'BLE MR. JUSTICE S. RAVINDRA BHAT

HON'BLE MR. JUSTICE R.K. GAUBA

MR. JUSTICE S. RAVINDRA BHAT (OPEN COURT)

%

1. The present Writ Petition challenges the award of Employees State Insurance Corporation ("ESIC") Rate Contract No. 138 for Product Code No. 534 by the first two Respondents to the fourth Respondent, despite the Petitioner allegedly being the lowest bidder. A direction to quash and set aside the said decision and a direction to the Respondents to accept the Petitioner's lowest bid, and cancel the fourth Respondent's bid in respect of supply of Drug Product Code No. 534 of ESIC is sought.

2. The Petitioner is a public limited company incorporated under the Companies Act, 1956. It was first granted permission for manufacturing and marketing fixed dose composition of the drug in question by the Drugs

Controller General of India (“DCGI”), the third Respondent herein, on 15.3.2010. Pursuant to certain objections raised by the fourth Respondent, this permission was amended on 30.7.2010.

3. The Director General, ESIC issued a Tender Notice on 12.9.2012 for Rate Contract No.138 for supply of Drugs & Dressings, which include product code No. 534 (Pre & Probiotic Capsules) against ESIC Rate Contract no. 138. The Tender Document specifically provided that price bid of only those tenderers would be opened who fulfil all the eligibility criteria (provided in Clause 3 of the Terms & Conditions of the Rate Contract). Paragraph IV of the Terms and Conditions provided that the bids (Technical Bid in Cover ‘A’ and Price Bid in Cover ‘B’) were to be submitted by 01.11.2012. The Petitioner & fourth Respondent participated in the bid for the drug in question. The Petitioner’s price bid for supply of the subject drug was ₹ 44.87 for 10 capsules, whereas the fourth Respondent’s price bid for the same was ₹ 56.05 (for 10 capsules). The final rate contract was issued on 22.11.2013, wherein the Petitioner’s bid for the subject drug was rejected in favour of fourth Respondent.

4. Consequently, the Petitioner filed RTI Applications on 07.12.2013 and 17.01.2014 with the ESIC seeking certain information with regard to the allotment of tender for the subject drug. Based on the information received upon filing of the RTI Applications, the Petitioner states that in the meeting in respect of Rate Contract No.138 held on 5/6.2.2013, the Committee had specifically recommended that the drug in question quoted by the Petitioner may be considered provisionally eligible subject to reply from DCGI. Thereafter, by Minutes of Meeting for finalization of Rate Contract No.138 held on 24.7.2013, the Committee after taking into consideration the

concerned facts and opinion of the representative of the DCGI recommended that both the Petitioner and fourth Respondent may be considered as eligible. However, after clearance of participation of the Petitioner for the drug in question, the tender was granted to the fourth Respondent.

5. The Petitioner submits that the acceptance of the bid of a higher tenderer, i.e. fourth Respondent, and the rejection of its bid is prejudicial to the financial interests of the ESIC as well as the end consumer. According to the Petitioner, it would entail additional cost for the exchequer, which is against the public policy. This selection is evidently arbitrary, *malafide*, high-handed and colourable exercise of power and tainted with ulterior motives.

6. The first, second and fourth Respondents submit, *inter alia*, that the tender was rightly granted in favour of the fourth Respondent as the Petitioner was not eligible to submit its bid for the drug in question as per the Terms and Conditions for the Rate Contract. The said Respondents highlight that the eligibility criteria required the Petitioner to furnish a certificate from the State Drug Controller showing three years' manufacturing and marketing experience, except if the drug for which tender was being submitted was not a 'new drug'. Since the drug in question was not a 'new drug' as per Explanation (ii) to Rule 122E of Drugs and Cosmetics Rules, 1945 and the Petitioner, admittedly, did not have three years' experience, its bid could not have been considered.

7. In response to the aforesaid contention, the Petitioner submits that the third Respondent granted permission to the Petitioner to manufacture the

subject drug as a new drug and therefore, no certificate from the State Drug Controller proving three years' experience was required.

8. Having considered the submissions made by the parties, this Court is inclined to accept the Respondents' contention. Clause 3(iii) of the Terms and Conditions of the Rate Contract provided one of the eligibility criteria as “[a] certificate from the State Drug Controller concerned that the firm has been manufacturing and marketing the product/products for which the firm has quoted the price for the last three years except for new drugs. Firm should have three complete years experience of marketing and manufacturing as on date of opening of the tender”. Therefore, the two issues that arise for consideration herein are: (i) whether the Petitioner had three years' manufacturing and marketing experience for the subject drug; and (ii) in the event that it did not have such experience, whether the subject drug is a new drug.

9. As regards the first issue, the Petitioner was admittedly granted permission by the third Respondent for manufacturing and marketing the drug in question on 15.03.2010 (modified on 30.07.2010). The date of opening (the relevant date on which the three years' experience had to be assessed) of Cover 'A' (Technical bid) was 01.11.2012. Therefore, the Petitioner was not eligible for submitting Cover 'A' (Technical bid) as it did not have three years' experience on this date. Petitioner has submitted that since there was no date specified for opening of Cover 'B' (Price bid), it was to be opened on 22.11.2013 (the date on which the Rate Contract was granted). However, this contention does not assist the Petitioner's case in any manner, as the Tender Notice stipulated that “Cover 'B' i.e. Price Bid of only those tenderers who fulfil all the Eligibility criteria as laid down on the

basis of details furnished by the tenderer in cover 'A' will be opened". Since the Petitioner did not satisfy the eligibility criterion of three years' experience for Cover 'A' (Technical bid), it could not succeed in Cover 'B' (Price Bid) as well. Therefore, this Court holds that the Petitioner did not have the requisite experience to participate in the tender for the subject drug, except if it were to be proven that it is a new drug.

10. Explanation (ii) to Rule 122E of the Drugs and Cosmetics Rules, 1945 forms the basis of contention between the parties. It reads as follows:

"a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia whichever is earlier."

11. The Petitioner submits that on 15.03.2010, it was granted permission by the third Respondent to manufacture and market the subject drug as a 'new drug' and therefore, it continues to be a new drug as defined in Rule 122E. As such, the Petitioner submits, no certificate from the State Drug Controller furnishing proof of three years' experience was required. However, the Respondents submit that at the relevant time, the said drug was being manufactured for a period of more than four years by the fourth Respondent and was being duly supplied in various ESIC hospitals pursuant to Rate Contract Nos. 120, 128, 131 and 135 since February 2004. Although the said Respondents have not produced on record material to support this specific contention, the fourth Respondent has produced licences obtained by it for manufacturing the subject drug from the concerned State Licencing Authority. One of the licences was granted (by the Director of Drugs Control, Chennai, Tamil Nadu) on 25.06.2002. Subsequently, licences were granted by the concerned authorities in Pondicherry and Himachal Pradesh

on 01.03.2004 and 12.07.2005 respectively. Therefore, this Court holds that the subject drug had been in use for more than four years at the relevant time and consequently, it does not qualify as a new drug as per Explanation (ii) to Rule 122E of the Drugs and Cosmetics Rules, 1945.

12. Accordingly, as per Clause 3(iii) of the Terms and Conditions of the Rate Contract, the Petitioner was required to submit a certificate establishing three years' experience in the manufacturing and marketing of the subject drug. Since the Petitioner did not have three years' experience, it could not have done so. It, therefore, does not fulfill the eligibility criteria to be considered for Rate Contract No. 138 insofar as Product Code No. 534 is concerned. The Petitioner's plea fails.

13. This Court is also of the opinion that given that the Rate Contract was for two years, the present Petition is hit by laches. Having learnt that its bid was rejected, and the Petitioner became aware of this on, at the latest, 17.01.2014, the Petition was filed on 08.08.2014. Considering that the contract was for two years, effective from November 2013, this constituted serious delay which disentitled the Petitioner to any relief.

14. The writ petition is, therefore, dismissed.

S. RAVINDRA BHAT
(JUDGE)

R.K. GAUBA
(JUDGE)

MARCH 13, 2015