CUSTOMS, EXCISE AND SERVICE TAX APPELLATE TRIBUNAL MUMBAI

WEST ZONAL BENCH

SERVICE TAX APPEAL NO: 85644 OF 2015

[Arising out of Order-in-Original No: PUN-STC-001-COM-001-002-14-15 dated 19th December 2014 passed by the of Commissioner of Central Excise & Customs, Pune-III.]

Deenanath Mangeshkar Hospital & Research Centre
S No. 1+ 13, Near Himali Society
Erandwane, Pune – 411 004 … ***Appellant***

versus

Commissioner of Central Excise & Customs
Pune – III
ICE House, 41A Sassoon Road, Opp: Wadia College
Pune - 411001 ***…Respondent***

APPEARANCE:

Shri Bharat Raichandani, Advocate for the appellant

Shri Dilip Shinde, Assistant Commissioner (AR) for the respondent

CORAM:

HON'BLE MR C J MATHEW, MEMBER (TECHNICAL)
HON'BLE DR SUVENDU KUMAR PATI, MEMBER (JUDICIAL)

FINAL ORDER NO: A/87643 / 2019

DATE OF HEARING:	29/11/2019
DATE OF DECISION:	29/11/2019

PER: C J MATHEW

Proceedings initiated against M/s Deenanath Mangeshkar Hospital & Research Centre, culminating in order in-original no. PUN-

STC-001-COM-001-002-14-15 dated 19th December 2014 of Commissioner of Central Excise & Customs, Pune–III that is now impugned before us, in notice dated 24th April 2014 comprised enhancement of taxable value to the extent of ₹ 4,03,59,754 and recovery of ₹ 12,51,61,661 as provider of 'support services of business or commerce', 'business auxiliary service' and 'technical testing and analysis agency service' and as person liable to pay tax for availing 'goods transport agency service' between April 2008 and March 2012 and statement of demand of ₹ 5,42,37,994 for the period from April 2012 to June 2012. The impugned order has, however, restricted the demand to ₹ 1,18,50,780 leviable on providing of 'technical testing and analysis agency service' and ₹ 2,96,387 on providing of 'renting of immovable property service', 'commercial coaching service' and 'mandap keeper service' while dropping the proposed recovery as provider of other services.

2. Learned Counsel for the appellant submits that they are eligible for exemption, afforded by notification no. 11/2007-ST dated 1st March 2007, as a duly approved 'clinical research organization' which had been wrongly discarded by adjudicating authority with the finding that the Drug Controller General of India had not granted them approval and, thereby, not being in conformity with the definition in rule 122 DAB of Drugs and Cosmetics Rules, 1945. Learned Counsel refers to the tripartite clinical trial agreement, with the principal investigator and

the pharmaceutical company concerned, which carries the 'protocol number' approved by Drug Controller General of India. It is contended that all the trials had been conducted in the hospital after registering with the Clinical Trial Registry of Indian Council of Medical Research.

3. We have heard Learned Authorized Representative who contends that the hospital is not a 'clinical research organization' and that mandates of rule 122 DAB of Drugs and Cosmetics Rules, 1945 have not been complied with.

4. On perusal of the impugned order which cites the relevant rule in Drugs and Cosmetics Rules, 1945 for determination of 'clinical research organization' as

> *'..an individual or an organisation (commercial, academic or other) to which the sponsor may transfer or delegate some or all of the task, duties and/or obligations regarding a clinical trial provided that all such contractual transfers or obligations are defined in writing'*

and the exemption notification *supra* as applying to

> *'taxable service provided or to be provided by a Clinical Research Organisation approved to conduct clinical trials by the Drugs Controller General of India, in relation to testing and analysis of newly developed drugs, including vaccines and herbal remedies, on human participants so as to ascertain the safety and efficacy of such drugs on human participants'*

it would appear that the denial of exemption is founded on this.

5. The adjudicating authority has inferred that the approval of the institution by the Drugs Controller General of India is not substitutable with specific approval for each trial. It is seen from

> *'(zzh) to any person, by a technical testing and analysis agency, in relation to technical testing and analysis;'*,

describing the scope of the taxable service, that exemption applies to such 'technical testing and analysis agency' which is a 'clinical research organization' that has been approved by the Drugs Controller General of India for conducting clinical trials in relation to testing and analysis of newly developed drugs on human participants. On perusal of the Drugs and Cosmetics Rules, 1945, it is seen that clinical trials are to be conducted only under permission accorded by the 'Licensing Authority', as defined in rule 21(b) of those Rules, under authority of rule 122 DAC of Drugs and Cosmetics Rules, 1945 and subject to the conditions specified therein which, *inter alia*, require registration with 'Clinical Trial Registry of India' and the application for permission to conduct clinical trials is provided for in rule 122DA of Drugs and Cosmetics Rules, 1945. Nonetheless, we take note that the expression 'clinical research organization' does not find definition within these Rules.

6. It would therefore appear that the 'clinical research organization' is a generic description for agencies that undertake clinical trial of new drugs. We also find nothing on record that a general permission of the

Drugs Controller General of India is mandated for eligibility to benefit from the exemption notification. It is admitted in the impugned order that the appellant herein has demonstrated that each tripartite agreement contains the approval granted for clinical trial and it is also contended by Learned Counsel that appropriate entries have been made in the Clinical Trial Registry of India. There is no evidence to controvert either of these claims.

7. In view of the above, it would appear that the clinical trials conducted by the appellant are in conformity with the conditions prescribed in the exemption notification and, hence, eligible for exclusion from tax under section 65(105)(zzh) of Finance Act, 1994. The appellant has discharged tax liability under the other heads confirmed in the notice. It is contended by Learned Counsel that the appellant is entitled to the threshold exemption as permitted in notification no. 6/2005-ST dated 1st March 2005. Accordingly, the penalty imposed under section 78 of Finance Act, 1994 will not sustain.

8. Appeal is, accordingly, allowed.

(Pronounced in open court)

(Dr. Suvendu Kumar Pati)
Member (Judicial)

(C J Mathew)
Member (Technical)

**/as*