CUSTOMS, EXCISE AND SERVICE TAX APPELLATE TRIBUNAL
CHANDIGARH

REGIONAL BENCH - COURT NO. I

Service Tax Appeal No. 60448 of 2021

[Arising out of Order-in-Original No. 13/ST/Pr.Commr./PKL/AKG/2021-22 dated - passed by the Commissioner of CGST, Panchkula, Haryana]

Commissioner of Central Goods & Service Tax, Gurugram ……**Appellant**
GST Bhavan, Plot No.36-37, Sector-32,
Gurugram, Haryana122001

VERSUS

M/s Eli Lilly Company India Pvt. Ltd. ……**Respondent**
Plot No.92, Sector-32, Gurugram,
Haryana-122001

APPEARANCE:

Ms. Amita Gupta, Authorized Representative for the Appellant

Shri Vivek Sharma and Ms. Saumya Mehrotra, Advocates for the Respondent

CORAM: HON'BLE MR. S. S. GARG, MEMBER (JUDICIAL)
HON'BLE MR. P. ANJANI KUMAR, MEMBER (TECHNICAL)

FINAL ORDER NO. 60265/2026

DATE OF HEARING/ DECISION: 17.03.2026

P. ANJANI KUMAR:

M/s Eli Lilly & Company (India) Pvt. Ltd. are registered with Service Tax and are engaged in the activity of trading and import of pharmaceuticals; the appellants also provide support services to their group companies abroad; on conduct of an audit of the records of the respondents for the years 2013-14 to 2016-17; it was noticed

that the respondents have entered into an agreement with M/s Eli Lilly Co. USA for getting clinical trials conducted on their behalf. On the basis of permission letter dated 06.07.2016 by the Drug Controller General of India to the respondents and the terms of the agreement, it appeared to the Revenue that the respondents have themselves conducted clinical trials as the same were conducted in India, the same did not qualify to be considered as export of services; accordingly, a show cause notice dated 21.05.2019, demanding service tax of Rs.2,69,77,242/- along with interest and penalty were issued to the respondents invoking extended period of limitation. Commissioner of CGST, Panchkula vide Order dated 07.06.2011 has dropped the proceeding initiated against the respondents. Being aggrieved by the order of the Commissioner, Revenue is in appeal.

2. Ms. Amita Gupta, learned Authorized Representative for the Revenue reiterates the grounds of appeal which are summarized as follows:

- The terms of the agreement give a clear understanding that the respondents have been appointed by M/s Eli Lilly USA to conduct clinical trials through third noticee providers; the noticee entered into various agreements with respective hospitals and doctors; the respondents received permission from Drug Controller General of India; the samples of drugs imported by the respondents was for further supply to respective hospitals; the hospitals/ doctors submitted the

report to the respondents; financial support to the hospitals/ doctors was given by the respondents.

- In terms of Rules 4 & 9 of Place of Provision Rules, in respect of performance based services, the place of provision of the service shall be the location of the service provider; the respondents satisfied two conditions under Rule 4(a) that (i) services are provided in respect of goods and (ii) that said goods are required to be made physically available by the recipient of service to the provider of service.

3. Shri Vivek Sharma assisted by Ms. Saumya Mehrotra, learned counsel for the respondents, submits that the respondents were providing Business Support Services to M/s Eli Lilly USA in consideration of foreign exchange; in terms of Rule 3 of POPS Rules, the same qualifies to be considered as export; even if it is assumed that the service provided by the respondents were clinical trial/ testing services, the same qualifies to be export service as the reports are sent to M/s Eli Lilly USA. He relies on the following cases:

- Veeda Clinical Research P Limited Versus Commissioner of Central Excise & ST, Ahmedabad - 2024 (8) TMI 1333 - CESTAT AHMEDABAD
- Veeda Clinical Research Ltd v. Pr. Comm CGST Ahmedabad 2024 (11) TMI 206 CESTAT AHMEDABAD
- CCE & ST v. Glaxo SmithKline Asia Pvt Ltd 2023 (10) TMI 998-CESTAT-Chandigarh
- Pr. CCE v. Advinus Therapeutics Ltd 2017 (51) S.T.R. 298 (Tri. - Mumbai)

- Roche Products (India) Pvt Ltd Versus Commissioner of CGST & Service Tax, Mumbai 2022 (10) TMI 515-CESTAT-MUM
- Apotex Research Pvt Ltd v. CCE & ST Bangalore-1 2022 (63) GSTL 99 (Tri-Bang)
- CCE v. SAI Life Sciences Ltd 2016 (42) S.T.R. 882 (Tri. - Mumbai)

4. Learned Counsel submits also that in terms of the agreement, the respondents were engaged to provide clinical trial related services; the respondents were required to appoint third-party service providers for carrying out clinical trials and that the respondent does not have capabilities in terms of human resources and infrastructure for performing clinical trials on their own. He submits that the agreements with the doctors clearly indicate that doctor will personally conduct and supervise the study at the hospitals; the certificate given by the Drug Controller General of India clearly indicated that the clinical trial must be supervised by doctors; the hospitals which were carrying clinical trials on their request were charging service tax and paid the same to the Government.

5. Learned Counsel further submits that the show cause notice was issued on an incorrect understanding of the Drugs and Cosmetics Laws, the guidelines of which clearly define the terms "investigator" and "sponsor"; the sponsor is the company responsible for initiation, management, financing of the clinical trials done by the doctors/ hospital i.e. the investigator. He submits that Rule 4 of POPS Rules does not apply to the impugned issue as it is

the doctors/ hospitals who conduct the clinical trials and not the respondents; the respondent merely initiates and finance the same; the hospitals pay applicable service tax and charge the same to the respondents; even if it is assumed that the clinical trials are conducted by the respondents, as the reports are sent to overseas company who is the beneficiary of the trials, the service constitutes export of service; this was correctly appreciated by the impugned order. He relies on Sai Life Sciences Ltd. – 2016 (42) STR 882 (Tri. Mumbai)

6. Learned Counsel submits that extended period cannot be invoked and interest and penalties cannot be invoked as the issue is of interpretation of provisions of statute at the most and there is no positive act of commission or omission on the part of the respondents with intent to evade payment of duty; Revenue has not established any mis-declaration, suppression, collusion etc. with evidence. He relies on the following cases:

- Uniworth Textiles Ltd v. CCE 2013 (288) ELT 161 (SC),
- Compark E Services Pvt. Ltd. vs. CCE & ST, Ghaziabad 2019 (24) GSTL 634 (Tri - All.)
- Reliance Infratel Ltd. vs. CCE, Thane 2016 (42) STR 452 (Tri. - Mumbai)
- Pushpam Pharmaceuticals Co.-1995 (78) ELT 401 (SC)
- Sarabhai M. Chemicals – 2005 (179) ELT 3 (SC)

7. Heard both sides and perused the records of the case. We find that the respondents have entered into the agreement with their masters i.e. M/s Eli Lilly USA for providing support in respect of clinical trials. Revenue contends that the respondents have obtained

necessary permission from DCGI for conducting clinical trials; such clinical trials being conducted in India cannot be treated as export of services in terms of Rule 4 & Rule 9 of POPS Rules. The respondents, on the other hand, contend that they are not conducting any clinical trials but are outsourcing the same to different hospitals/ doctors and provided finance and other support to them; the hospitals have discharged the applicable service tax on the clinical trials initiated by the respondents and undertaken by hospitals/ doctors. In terms of the permission given by the DCGI, it is only the doctors or hospitals who conduct clinical trials. The respondents also submit that even if it is assumed for the sake of argument that they are providing the service of clinical trials, they are submitting the reports to their parent company i.e M/s Eli Lilly USA and therefore, in terms of Rule 3, they have exported the service.

8. On going through the various clauses of the agreement, we find that the agreements do not indicate that the respondents shall conduct the clinical trials. The indication in the agreement is to the extent that the respondents have no human/ infrastructural facilities to conduct clinical trials and such, they shall identify the hospitals/ doctors and would enter into suitable agreements with them. Therefore, the agreements give a clear understanding that the respondent is only rendering support services to their masters in USA in getting the clinical trials/ tests conducted. We find that the Revenue wrongly raises the issue of intermediary and submits that the services rendered by the respondents are intermediary in

nature. As we find that there is no tripartite agreement between the respondents, their masters in USA and third-party service providers and therefore, the services cannot be called intermediary services. We find that the services rendered by the respondents are nothing but support services to their masters in USA, in connection with getting clinical trials/ tests conducted in India. Therefore, the allegation of the Department that the respondents are rendering clinical trials service has no substance. At the same time, the arguments of the respondents that even if it is assumed that they have conducted clinical trials, the same should be considered as export of service in terms of Rule 3 of POPS Rules, is stretching the law beyond certain limits. This argument could be valid in the cases like Glaxo SmithKline Asia Pvt Ltd and Advinus Therapeutics Ltd (both supra) wherein the appellants themselves conducted the clinical tests.

9. We find that learned Commissioner has correctly analysed the issue and held as under:

> 4.3 NATURE OF SERVICE PROVIDED BY THE NOTICEE
>
> I observe that M/s Eli Lily, USA has been engaged in research and development, manufacture and sale of Pharmaceuticals, medical instruments, devices and diagnostic products. In course of business, they develop and acquire valuable secret technical know-how for manufacturing, formulation, testing, quality control and sale of its products. They entered into agreement with the Noticee to render Clinical Trials related services in India and for doing so, the noticee can appoint third party service providers for carrying out clinical trials in India subjected to terms and conditions between the Noticee and such third party service providers. Annexure to this agreement

provided the scope of services provided by the Noticee and the same is reproduced here for reference:

(g) Initiate selection of sites/ centres (Hospitals) for Clinical Trial study based on protocols received from Lilly US.

(h) Suggesting and appointing sites/ centres for conducting the Clinical Trial:

(i) Submit the application with the Drug Controller General of India (DCGI) or any specified authority to ensure compliance of all regulatory obligations in this regard before initiation of Clinical Trial:

(j) Notify the centre/ sites for initiating Clinical Trial, post approval from DCGI.

(k) Engage third party organizations for monitoring Clinical Trial in the hospitals.

(l) Keep Eli Lilly US informed about the progress of the Clinical Trial study (finding data, specification, report, document material etc).

The above work does not include:

a) Conducting CT for any third party

b) Establishing new protocols in India or amending existing protocols of Lilly US for the CT Program

LILLY India does not have capabilities in terms of physical or human infrastructure for performing a CT on its own record.

4.3.1 I observe that in terms of Rule 122-A of the Drugs and Cosmetics Rules, 1945, prior permission of the DCGI is required to import new drug for clinical trial or marketing and application for conducting clinical trial of new drugs shall be filed under Rule 122DA of the Rules ibid. The licensing authority grants permission to conduct clinical trials of new drugs under Rule 122DAC of the Rule, ibid. The noticee had applied to Directorate General of Health Services Contral Drugs Standard Control Organization (Global Clinical Trial Division), Govt. of India for conducting clinical trial who, vide their letter dated 12.02.2018, granted permission to conduct such clinical trials under supervision of investigators mentioned therein who conduct such clinical trial as per provisions of Drugs & Cosmetics Rules. I observe that Schedule Y to the Drugs and Cosmetics Rules, 1945 provided

requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials. Para 2 of the said Schedule Y pertains to clinical trial wherein it is mentioned that all trial Investigator(s) should possess appropriate qualifications, training and experience and should have access to such investigational and treatment facilities as are relevant to the proposed trial protocol. A qualified physician (or dentist, when appropriate) who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions. Laboratories used for generating data for clinical trials should be compliant with Good Laboratory Practices Roles and Responsibilities of the sponsor and investigators are clearly defined in the Schedule Y of the Rules, ibid. On going through these roles and responsibilities of the sponsor and investigators land in the light of judgment of the Tribunal in the case of Commissioner of CGST Indore vs Diabetes Thyorid Hormone Research Institute Pvt. Ltd. (Supra), it can be seen that in the present case, the noticee is acting as the sponsor of the clinical trials and the doctors/ hospitals appointed by the Noticee are acting as investigators and both are separate entities. The noticee has submitted copy of correspondence dated 19.12.2017 regarding appointment of Investigator. The noticee has also submitted sample invoices in respect of such clinical trials raised by designated Hospitals and duly signed by Principal Investigators. They have also submitted copies of Investigator Site Evaluation Checklist. The noticee has also submitted copies of Debit Notes raised in the name of Eli Lilly, US showing fee in relation to Clinical Trial Assistance Service and 17% mark-up fee as per agreement.

4.3.2 On perusal of the Agreement, I observe that Eli Lilly. US has appointed the Noticee to render Clinical Trials related services in India, not to conduct clinical trial as alleged in the impugned SCN Further, the Annexure to the agreement between the Noticee and Eli Lilly US clearly states that the Noticee does not have capability to perform clinical trial on their own Letter dated 12.02.2018 of Directorate General of

Health Services. Central Drugs Standard Control Organization (Global Clinical Trial Division), Govt. of India vide which permission was granted to conduct clinical trials in India clearly mentioned the names of the investigators who supervise the clinical trial and Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees. All these investigators are not employees of the noticee, rather they are doctors empanelled in different hospitals. The said letter dated 12.02.2018 extend support to the argument of the Noticee that they are not engaged in conducting clinical trials but they are merely providing support service to Eli Lilly. US in conducting such trial. The noticee has submitted copy of Bill of Entry vide which drugs were imported by the Noticee in India. NOC for conducting clinical trial in India is also issued in the name of Noticee Considering all these facts, I observe that the Noticee is not engaged in conducting clinical trials on their own. On scrutiny of the agreements between the Noticee and ELI LILLY US, the Noticee and Doctors/Hospital Establishment, import documents and invoices, it seems that the noticee is providing support services to their parent company. I find force in the contention of the Noticee that they did not provide clinical trial/testing services as they neither had neither human resource nor infrastructure facility to conduct clinical trial in India.

4.3.3 Further. I. on perusal of copies of invoices, find that the Hospital/Doctors have charged service tax on the applicable rate from the Noticee for providing clinical trials/testing in India. I observe that in the present case, service tax is being demanded from the service recipient (the Noticee) on same services on which the service tax had already been charged by the service provider (Hospitals/doctors). I find that the ratio of the judgments in the case of Mahaveer Kumar Jain vs. CIT, Jaipur (2018) 404 ITR 738 (SC)] and Laxmipat Singhania vs. CIT [1969 (72) ITR 291] are squarely applicable in the present case.

> 4.3.4 In view of the foregoing paras, I hold that the Noticee are engaged in providing support service to M/s Eli Lilly. US by providing administrative and finance support to the Hospitals/Doctors who actually performed the clinical trials/testing in India.

10. In view of the above, we find that there is no merit in the appeal filed by the Revenue and therefore, we dismiss the same.

(Operative part of the order pronounced in the open court)

(S. S. GARG)
MEMBER (JUDICIAL)

(P. ANJANI KUMAR)
MEMBER (TECHNICAL)

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