CUSTOMS, EXCISE AND SERVICE TAX APPELLATE TRIBUNAL REGIONAL BENCH AT HYDERABAD

Division Bench

Court – I

Service Tax Appeal No. 300 of 2012

(Arising out of Order-in-Original No.39/2011-Adjn. (Commr.) S.Tax dt.28.10.2011 passed by Commissioner of Customs, Central Excise & Service Tax, Hyderabad-IV)

Axis Clinicals Ltd.
Sy No.66 & 67, Miyapur,
Serlingampally, Hyderabad – 500 049 **......Appellant**

VERSUS

Commissioner of Customs, Central Excise & Service Tax, Hyderabad - IV
Tilak Road, Ramkoti,
Hyderabad, Telangana – 500 001 **......Respondent**

Appearance

Shri Nagraj Rao, Advocate for the Appellant.
Shri A. Rangadham, AR for the Respondent.

Coram:

HON'BLE MR. ANIL CHOUDHARY (JUDICIAL)
HON'BLE MR. P. VENKATA SUBBA RAO, MEMBER (TECHNICAL)

FINAL ORDER No. A/30099/2022

Date of Hearing: 13.09.2022
Date of Decision: 13.09.2022

[Order per: ANIL CHOUDHARY]

The issue relates to export of services of clinical research and performance of services under Export of Service Rules, 2005 and demand thereof. Appellants conducted clinical medical trials in India and the consequential analytical reports of the performance of the medicines in the human volunteers, is delivered to foreign sponsorers/Principal. This service rendered is disputed, that it did amount to export of service under Rule 3(1)(ii) of the Rules, and service tax is payable. Entire consideration was received in foreign convertible currency, and such reports are used by the foreign sponsorers situated outside India.

Periods and Demands:

a) First Show Cause Notice dt.28.02.2011: 2007-08 to 2009-10 – Rs.7,45,39,858/-
b) Second Show Cause Notice dt.13.10.2011: 2010-11 – Rs.2,19,61,879/-

2. Appellants had been conducting 'technical testing and analysis' of clinical service. This in short is the trial of invented and new medicines on the willing human volunteers, and conducting pathological and clinical tests of the individuals administered with the sponsored medicines. They started this service in 2006 and confined to domestic customers, from FY 2007-08 onwards it was provided to foreign clients also. This is a taxable service under Section 65 (105)(zzh) of the Finance Act, 1994 (Act), and defined under Section 65 (106) of the Act.

> *"**Section 65(106)**: "technical testing and analysis" means any service in relation to physical, chemical, biological or any other scientific testing or analysis of goods or material or information technology software or any immovable property, but does not include any testing or analysis service provided in relation to human beings or animals;*
>
> ***Explanation**.—For the removal of doubts, it is hereby declared that for the purposes of this clause, "technical testing and analysis" includes testing and analysis undertaken for the purpose of clinical testing of drugs and formulations; but does not include testing or analysis for the purpose of determination of the nature of diseased condition, identification of a disease, prevention of any disease or disorder in human beings or animals;*
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> **Explanation inserted by Finance Act, 2006 w.e.f. 01.05.2006.*

Taxable service is defined under Section 65(105)(zzh) is:"(zzh) to any person, by a technical testing and analysis agency, in relation to technical testing and analysis."

3. The service involves testing of the newly developed medicines. These medicines are sent by the pharmaceutical and biotechnology companies and medical device companies, for testing and analysis purpose. These clinical trials are to be conducted as per the ICH-GCP (WHO) standards. Appellants are recognized CRO and have approval from the NABL (National Accreditation Board for Testing and Calibration Laboratories) for conducting the clinical tests. These medicines sent by the sponsorers are administered to the human volunteers in the Hospital of the appellants, under Doctors' care, as advised by them or independently, periodical clinical analysis are

done of the patients; later the test and analysis reports are prepared with detailed pro-action and reactions observed pathologically and clinically, and are sent to the Principal abroad.

4. Appellants had been paying service tax on these services/supplies made to the local customers, and did not pay service tax on the services exported. Export of services are under the then existing 'Export of Service Rules, 2005' as amended from time to time.

Service: There are two types of research test analysis undertaken of Bioavailability and Bioequivalence. These tests are to be conducted as per the Guidelines of Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, MOH. Drug Controller General of India (DCGI) grants the permission to conduct clinical trials of new drugs including Investigational New Drugs and appellants obtained the necessary permissions from the DCGI.

'Guidelines of Bioavailability and Bioequivalence studies' as published by the Directorate General of Health Services is as under:

> *"Bioavailability refers to relative amount of drug from an administered dosage from which enters the systematic circulation and the rate at which the drug appears in the systematic circulation.*
>
> *Bioequivalence of a drug product is achieved, if its extent and rate of absorption are not statistically and significantly different from those of the reference product when administered at the same molar dose."*

These tests on human volunteers require permission from the Independent Ethics Committee (IEC).

5. Appellants conducted clinical research study on the Bio-availability of drugs and Bio-equivalence drugs. BA is on the study of the newly developed drugs (Investigational New Drugs) and BE is study of the equivalent products (after expiry of the patented time). These studies are undertaken on human volunteers under constant medical-vigil with lab tests at regular intervals. Drug manufacturers have to conduct research on the BA and BE drugs to observe the bio absorbability and reactions, before they are released into market. It involves medical study and requires human volunteers; they do not have the necessary infrastructure to test the medicines and hence sponsor to other recognized clinical institutes like the appellants to undertake the tests. These clinical institutions require statutory

permissions and to follow guidelines, discussed supra. These trials of medicines and the clinical and pathological analyses are carried out in the Hospital and labs in the premises of the appellants or in other super labs.

6. After administering the BA/BE drugs on the human volunteers (as directed to be given), test results are recorded. These reports contain every minute detail of the action of the drug in the human system and reactions thereof. Based on the data given by the appellants-like clinical institutes, the manufacturers would seek permission from the statutory authorities for bulk manufacture to release into the market. It is obligatory to have the Test and Analysis Reports for the sponsorers. Appellants, like any other CRO, deliver the Test Results to the sponsorers and the service is completed only upon delivery of these analytical reports either to the local sponsorers or foreign sponsorers. Invoices are raised for the service rendered. Service tax is paid on the service to domestic sponsorers since the service is consumed within taxable territory. Service tax was not paid on the services rendered to overseas sponsorers during this period, since it is export of service and clinical test analyses charges were collected in 'foreign convertible currency'. Service tax is a destination-based tax and the services rendered are consumed abroad by the principal who are located outside India. There is no service tax payable, and if paid, is rebated under Export Rules (later under Rule 6A of STR). Present dispute related to the test results consumed abroad and Notice was issued alleging that they are leviable to service tax, even if such services are consumed abroad.

7. First Show Cause Notice dt.28.02.2011 (by DGCEI): 2007-08 to 2009-10 of Rs.7,45,39,858/- alleged that there were receipts from foreign clients located abroad during 2007-08 onwards; that sponsorers engage on Research Organisations (such as appellants) for conducting studies of the medicines; that process of administering the reference drugs to volunteers is performed at the test facility in India; that 'NOC' is taken from DCG (India) for such tests; that in the ST3 Returns those services were shown as export of service, which is alleged to be mis-declaration, that the services are classifiable under section 65(105)(zzh) of the Act; that under Rule 3(1)(ii) of Export of Service Rules, services are to be performed outside India (at least part); that Rule 3(2) ibid stated that such service is provided from India and used outside India and payment is received in convertible

foreign currency; that 'performance' and 'delivery' are independent and both to be satisfied for export; that mere delivery of report outside India after concluding the test process would not make if export of service; that at least part of service is to be performed outside India; that appellant/noticee performed the analysis activity totally within India, but mis-declared it as Export of Service; that they are liable to service tax for 2007-08 to 2009-10 of Rs.7,45,39,858/- on such export of services, that they had been discharging tax on the domestic services and not on the export services; that that approval was given by DCGI to the laboratory of the noticee and the noticee was aware that all the services were performed within India and wilfully mis-declared the services as export of services in the statutory ST3 returns with intent to evade payment of tax and hence proviso under Section 73(1) is applicable with penalty under Section 78 & 76, and interest under Section 75; that Rs.40,00,000/- paid during investigation is to be appropriated.

8. The appellant contested the SCN and filed reply - That DG Health Services published the guidelines to be followed for the study of BA and BE, that scope of service in BE and BA is the clinical testing on human beings for the efficacy and performance of the medicines (before they are released into market); that appellant/CRO provided support to the pharmaceutical and biotechnology industries; that Notification 11/2007 ST dt.01.03.2007 exempted such services conducted on new drugs; that the services are exported and such services are export of services under Rule 3(1)(ii), even if part of services are performed outside India; that the service is complete only when the Report is delivered to the clients abroad; that delivery of report is performance or receipt of service abroad; that the issue of part performance is decided by this Tribunal in the case of BA Research India Ltd and is held to be part performance of service outside India; that Export Rules were amended in 2011 by Notifications 12/2001 dt.01.03.2011 and 22/2011 ST dt.31.03.2011 wherein (zzh) was omitted from the list; that after amendment it is export of services, if the recipient is located outside India and consideration is received in convertible foreign currency, that the demand is barred by time; that services rendered to domestic and foreign is clearly shown in the Returns and relied on the case laws on the subject; that the authorities were in the knowledge of the export of service from 2007 onwards, since ST3 Returns were filed with the details and hence there is no

suppression; that there was bonafide belief that the service to Principal located outside India would constitute export of services and there are not malafides; that penalty is not imposable; that penalty under Section 76 is not be imposed since section 78 proviso 5, excluded it; that Section 80 is applicable for waiver of penalty, there being no malafide, and the issue is wholly interpretational.

9. Learned Commissioner vide impugned Order-in-Original held that Section 65(105)(zzh) covers technical testing and analysis of drugs testing on human beings and fall under Section 65(105)(zzh); Export of Service Rules, 2005 applicable and scope is defined under Rule 3; 'zzh' is covered under Rule 3(1)(ii) and is said to be export if performed outside India even if partly performed outside India; that entire process of testing is carried out in India by the appellant/Noticee and only report is delivered outside India, and that the report delivery outside India cannot be treated as performance outside India under Rule 3(1)(ii); that periodical Returns contained the details of the exported services, but the details of performance and testing and analysis within India is not known and thus extended time is applicable; that under Rule 3(1)(ii) of Export Rules, part performance outside India is a precondition and Noticee did not fulfil the condition and proposed demands would sustain.

10. Thus, the learned Commissioner confirmed the demand of Rs.7,45,39,858/- against the First SCN and Rs.2,19,61,879/- against the second SCN, both under Section 73(2) with interest and equal amounts of penalty under Section 78 on the first SCN and under Section 76 for the second SCN.

11. Learned counsel assailing the impugned order, urges the issue is no more res integra. The only reason for holding that the subject services do not satisfy export is that entire process of testing and analyses are done in India (on human volunteers with the medicines of the sponsorers located outside India) and only the final result or Test Report (with all the clinical and pathological analyses) is sent abroad to the Principal, and such services (delivery of report) cannot be treated as part performance outside India. There are no further disputes, since the appellant have received consideration in convertible foreign currency. This very identical issue cropped up before the different Benches of the Tribunal – whether such

delivery of the reports abroad on the clinical services done in India, is export of service or not. In catena of decisions, it is held that such services are export of services.

12. In Commissioner of Service Tax, Ahmedabad vs B.A. Research India Ltd. [*2010 (18) STR 439 (Tri-Ahm)*] filed by the Revenue, it is held that delivery of reports to clients outside India amounted to part performance of taxable service outside India. Clinical trials are conducted in India and the test results are delivered to foreign clients outside India. Revenue contended that service is performed wholly in India and did not qualify to be export under Export of Services Rules, 2005. It was held that performance of service is not complete until testing and analysis report is delivered to client. Relevant para is as under:

> *"10. From the above provisions it is clear that the said services came under Rule 3(1)(2) (sic) of the Rules. It is very much clear that the performance of the service is not complete until the testing and analysis report is delivered to its client. In the present case, when such reports were delivered to the clients outside India it amounts to taxable service partly performed outside India. The performance of testing and analysing has no value unless and until it is delivered to its clients and the service is to be complete when such report is delivered to its client. Thus, delivery of report to its client is an essential part of the service, report was delivered outside India and same was used outside India. This is not the disputed fact. We hold that the respondent satisfied the conditions of Rule 3(2) and accordingly the respondents are eligible for the exemption under Notification No.11/2007-ST dt.1-3-2007. We do not find any force in the argument made by the learned DR. With this observation, the impugned order is also disposed off accordingly."*

The ruling in B.A. Research have been confirmed by Hon'ble Gujarat High Court dismissing the Revenue appeal as reported at 2013 (31) STR 663 (Guj.).

13. It was held to be export of service in similar facts in Lotus Pvt Lab Ltd. vs CCEx Bangalore [*2020-TIOL-508-CESTAT-BANG*];

> *"5.2 We find that it is an admitted fact that the services have been performed from India. Further the principal or the service receiver is located outside India. Thus the 'technical testing and analysis service' (reports by the appellant), have been delivered by the appellant outside India and have been used by the service receiver outside India. The contention of the Revenue is rejected that as the clinical tests were performed on persons in India, the services are performed in India. Further the appellant also has undisputedly satisfied the other conditions by receiving the service charges in convertible foreign exchange."*

14. Learned counsel also relies on the following judgments in support of their contention.

i. Syngene International Ltd vs CST, Bangalore [2020-TIOL-508-CETAT-BANG]
ii. CCEx, Ludhiana vs Nestle India Ltd [2014 (36) STR 563 (Tri-Del)]
iii. MSD Pharmaceuticals P Ltd vs CST, Delhi [2019 (20) GSTL 566 (Tri-Del.)]
iv. CC,CE & ST, Hyderabad-II vs Price Waterhouse [2019 (22) GSTL 358 (Tri-Hyd)] = {2019-TIOL-398-CESTAT-HYD]
v. SGS India Pvt Ltd vs CST, Mumbai [2011 (24) STR 60 (Tri-Mumbai)]
vi. CST, Mumbai-II vs SGS India Pvt Ltd [2014 (34) STR 554 (Bom.)]
vii. CUE, Pune-I vs Sai Life Sciences Ltd [2016 (42) STR 882 (Tri-Mumbai)]

Learned counsel also relies on the Board Circular No. 111/05/2009-ST dt.24.02.2009. Accordingly, prays for allowing the appeal with consequential benefits.

15. Opposing the appeal learned AR for Revenue relies on the impugned order. He further relies on the ruling by Advance Authority under GST provisions in the case of Cliantha Research Ltd. [2019 (26) GSTL 417 (AAR-GST)].

16. Having considered the rival contentions, I hold that in the facts of the present case, wherein the principal/receiver of service is located outside India and the essence of service is delivery of report pursuant to the clinical trial for use of the principal, located outside India. Thus, it is a clear cut case of service provided from India and received outside India and further the service is undoubtedly, used by the principal outside India. Further, I find that the appellant have admittedly received the consideration for service in convertible foreign currency. Under the circumstances, part of the service is definitely rendered outside India as the service is not complete until the report generated is received outside India by the principal for their use and reference. Accordingly, following the precedent decisions relied upon by the appellant, I hold that the appellant have definitely exported the service under dispute and are entitled to exemption from service tax. Accordingly,

this appeal is allowed and the impugned order is set aside. The appellant shall be entitled to consequential benefits, in accordance with law.

17. Appeal is allowed.

(Operative part of the order was pronounced in the Open Court)

(ANIL CHOUDHARY)
MEMBER (JUDICIAL)

(P.VENKATA SUBBA RAO)
MEMBER (TECHNICAL)

Veda