

**IN THE CUSTOMS, EXCISE & SERVICE TAX
APPELLATE TRIBUNAL
West Block No. 2, R.K. Puram, New Delhi – 110 066.
Principal Bench, New Delhi**

COURT NO. IV

DATE OF HEARING/DECISION : 22/02/2018.

Service Tax Appeals No. 522-524 of 12 and 56440 of 2013

[Arising out of the Order-in-Original No. 12-14/GB/2012 dated 24/01/2012 and No. 08/GB/2013 dated 29/01/2013 both passed by The Commissioner (Appeals), Service Tax, Delhi – I.]

M/s MSD Pharmaceuticals Pvt. Ltd.

Appellant

Versus

CST, Delhi – I

Respondent

Appearance

S/Shri N. Venkataraman, Senior Advocate and Ms. Indu Amar, Advocate – for the appellant.

Shri R.K. Manjhi, Authorized Representative (DR) – for the Respondent.

CORAM: **Hon'ble Shri S.K. Mohanty, Member (Judicial)**
Hon'ble Shri B. Ravichandran, Member (Technical)

Final Order No. 50802-50805/2018 Dated : 22/02/2018

Per. B. Ravichandran :-

These 4 appeals are on common dispute and are accordingly taken up together for disposal. There are two impugned orders covering period 2006-2007 to 2011-2012.

2. The brief facts of the case are that the appellant entered into an agreement with their holding company, M/s Merck, USA

who is a pharmaceutical company engaged in, among other things, research, development and manufacture of medicines and vaccines. In the course of their business M/s Merck, USA intended to do certain clinical trials for newly developed drugs, in India. For this purpose, they have entered into two separate agreements, one with the appellant and other one with M/s SIRO, Thane. The common purpose of these agreements is to conduct clinical trial in India as per the requirement of M/s Merck, USA. The present dispute is with reference to service tax liability of the appellant for their activities connected to such clinical trials. The Revenue proceeded against the appellant to recover and demand service tax under business support service. The claims of the appellant are that these are clinical trial operations, exempted from service tax in terms of Notification 11/2007-ST dated 01/03/2007 as well as these services are in any case are availed by M/s Merck, USA, qualifying the export of service criteria. Both these grounds submitted by the appellant were rejected by the Original Authority who proceeded to confirm service tax liability under BSS alongwith penalties.

3. The learned Counsel appearing for the appellant submitted that agreements entered into by M/s Merck, USA with the appellant and SIRO are with a common goal of getting a new drug tested in India in clinical trial. Both the appellant as well as SIRO are recognized clinical research organization. Both applied to the Drug Controller General of India (DCGI) and obtained no objection to proceed with the clinical trial in pursuance of the said

agreement. In terms of these agreements with M/s Merck, USA appellant and SIRO had defined roles which complemented each other in the final conclusion of the clinical trial as per the standards and also in preparing and reporting to DCGI and coordinating with M/s Merck, USA.

4. The learned Counsel submitted that the Notification 11/2007 is clear to the effect that services provided in relation to testing and analysis of newly developed drugs on human participants so as to ascertain the safety and efficacy of such drugs are exempted. The nature of activities undertaken by the appellant are, admittedly, in connection with such testing and analysis of new drug on human participants. Accordingly, he submitted that the services are clearly exempted by the said notification.

5. Without prejudice to the submission on merit, as above, the learned Counsel submitted that the services of clinical trial are carried out for and on behalf of M/s Merck, USA, their holding company. The beneficiary of clinical trial is M/s Merck, USA. The payment in foreign exchange is received from M/s Merck, USA. All the ingredients to satisfy export of service have been fulfilled in this case. Relying on the decision of the Tribunal in **Paul Merchants Ltd. vs. CCE, Chandigarh – 2012 – TIOL – 1877 – CESTAT – DEL.** the learned Counsel submitted that the services are not liable to be taxed in India.

6. The learned AR drew our attention to specific findings recorded by the Original Authority. He submitted that SIRO was carrying out clinical trial. The appellant only provided support for such clinical trial. As such, the activities of the appellant are to be taxed as support service of business or commerce.

7. We have heard both the sides and perused the appeal record. The Original Authority clearly recorded that SIRO and the appellant have entered into an agreement with M/s Merck, USA. It is also recorded that the appellant, in terms of the said agreement, will coordinate clinical status in addition to conducting clinical studies. We have also perused the details of various activities undertaken by the appellant. The appellants were engaged in finalizing the testing protocol, training the staff for trial, applying and obtaining approval of DCGI, import of drug to be tested in India, monitoring the protocol, finance management, reporting adverse developments, documentation and archival of the said document of the final reporting to M/s Merck, USA and DCGI. SIRO were also involved in activities in the said clinical trial. These activities are initiation of trial sites, monitoring, trial monitoring, site management, query response and coordinate with M/s Merck, USA etc. Perusal of these details clearly reveal that the appellant are directly engaged in the activities of conducting clinical trial studies. They did obtain no objection approval from the concerned drug authorities in India. In the face of such factual details, we find that the findings recorded in the impugned order is neither factually nor legally

tenable. The appellants activities are clearly covered by the exemption under Notification 11/2007-ST dated 01/03/2007.

8. Considering also the alternate argument of the appellant, we note that these services are in fact provided in terms of agreement with M/s Merck, USA who paid the consideration in convertible foreign exchange. The beneficiary of service as per the terms of the agreement is M/s Merck, USA. Following the ratio of the decision of the Tribunal in **Paul Merchants Ltd.** (supra) it is clear that these services are for delivery and consumption of an entity located outside India. On this ground also, the appellant is having a case on merit.

9. In view of the above findings the impugned orders are set aside. The appeals are allowed.

(Order dictated and pronounced in open court.)

(S.K. Mohanty)
Member (Judicial)
PK

(B. Ravichandran)
Member (Technical)