

AUTHORITY FOR ADVANCE RULINGS
(Central Excise, Customs and Service Tax)
Hotel Samrat, 4th Floor, Kautilya Marg, Chanakyapuri
New Delhi

Present:

Justice V.S. Sirpurkar (Chairman)
Shri S.S.Rana (Member)
Shri R.S.Shukla (Member)

The 12th day of July, 2016

Ruling No. AAR/44/ST-I/ 27 /2016
in
Application No. AAR/44/ST-1/13/2015

Name & address of the applicant : M/s Steps Therapeutics Limited,
Hyderabad

Commissioner concerned : Commissioner of Customs,
Central Excise & Service Tax,
Hyderabad-IV, Ground & 6th Floor,
Posnett Bhavan, Tilak Road,
Ramkote, Hyderabad-500001

Present for the applicant : Sh. Tarun Gulati
Sh. Kishore Kunal
Sh. Manish Rastogi

Present for the Department : Shri Ranjan Khanna (AR)

Ruling

M/s Steps Therapeutics Limited (hereinafter also referred to as applicant) is in the process of setting up its business of Contract Research Organization whereby, the applicant will be establishing, developing and carrying on research in basic and applied sciences in relation to all kinds of drugs, pharmaceuticals and formulations, health care and bio—technology and also to provide services to its customers in this regard (“proposed research services”). In furtherance to its business objects, the applicant proposes to conduct clinical trial of drugs provided by its customers located outside

India on eligible volunteers within the applicant's facilities which are proposed to be in India. Applicant is in the process of negotiating contracts with various customers located outside India. The agreement for the proposed research services and clinical trials to be conducted by the applicant, provides that the following heads of service will be rendered by the applicant to its customers:-

- i. **Clinical Pharmacology:** The Service involves Bio-equivalence and Bio-availability clinical studies (studies carried out for generic drugs) which includes fasting and fed conditions, single and multiple dose in healthy subjects, drug-drug interaction, drug-food interaction, special/patient population studies. The study is proposed to be undertaken using formulations in the form of tablets, capsules, gels sprinkles, syrups, sprays, inhalers etc.;
- ii. **Clinical Research:** The service involves activities in nature of Project Management, Regulatory Affairs, Project Monitoring, Medical Writing, Bio-Statistics and Programming and Compliance. Each of these are discussed in detail as follows:-
 - a) **Project Management-** Planning and integration service which includes serving as the primary resources and point of communication for sponsor/project team, undertaking study/site feasibility assessment, updating the sponsor and participation in telecom;
 - b) **Regulatory Affairs:** Assistance in regulatory submissions at all phases of drug development and obtaining approvals from DCGI, DGFT and ICMR including approvals for conduct of clinical trials in India, for importing test drug and for exporting biological samples;
 - c) **Medical Writing:** Assistance in preparation of investigator brochure, protocol, case report form, patient information leaflets, informed consent form, safety data reports, medical translation and study related forms and logs;
 - d) **Project Monitoring:** 24/7 response line for medically related questions or report adverse events.

- e) **Compliance:** Audit of investigator sites as per protocol and other regulatory requirements like GCP compliance review, IRB/EC audits, on-site investigator audits, drug accountability reviews, database audit, study document reviews.

2. In terms of the sample Agreement, the applicant will be undertaking clinical trials of the drugs of the customers situated outside India on volunteers in India. The said volunteers will be given dosages of the drug as prescribed by the customers and medical professionals and thereafter, the applicant will be conducting screening of such volunteers wherein the volunteers are kept under observation and their blood samples are tested for identification of various parameters as required by the customers. Pursuant to the said clinical trials, the applicant will be required to report the test results through online medium to the customers. The applicant will be charging consideration from the customers on project to project basis. The above activities form part of the main activity of providing research assistance services to the customers and would not be provided in isolation. However, the activities of Bio-Statistics & Programming and Compliance services may be provided independently.

3. The present application is being filed for a definitive ruling on the following questions:

Whether the proposed activities of undertaking Clinical Research and Clinical Pharmacology by the Applicant are taxable under the Act in light of Rule 3 of the Place of Provision of services (POP) Rules, 2012 as the applicant renders the said services to its customers and the place of provision is located outside India?

4. Applicant inter-alia submits that since Rules 5 to 12 are not applicable to the applicant's case, the two rules which are to be considered are Rule 4 and Rule 3; that since the scope of proposed activities to be carried out by the applicant are research based advisory services and are neither related to (a) goods or, (b) requiring physical presence of the customers located outside India and therefore, Rule 4 is not applicable to the activities proposed by the applicant; that the advisory research activities of the applicant are not executionary or performance based service as envisaged in Rule 4 of POP Rules and therefore, the said services are not covered under Rule 4.

5. Revenue submits that in terms of Rule 4(a) of POP Rules, the essential ingredient to levy Service Tax on any service is the location, where the service is provided in respect of goods required to be made physically available by the recipient of service to the provider of service. Further, in terms of Rule 6A (1) (d) of the Service Tax Rules, 1994, any service can be termed as export of service where the place of provision of service is outside India. By synchronous reading of Rule 6A (1) (d) of Service Tax Rule and Rule 4(a) of POP Rules, any service to be termed a export of service, it should be performed in relation to the goods which are made physically available by the recipient of the service in the non taxable territory i.e. outside India to the provider of service located in India. In the instant case, the samples are made available to the applicant, the service provider, in India and location of actual performance of services is the premises of the applicant. Thereafter, only the report is being sent to the service recipient. As the said samples are entirely available in India either provided by the foreign customer or otherwise, the provisions of Rule 4(a) of POP Rules are aptly applicable to the instant case. Further the fact of location of actual performance of service also confirms the applicability of Rule 4 (a) of POP Rules.

6. In short, the issue involved is whether the services i.e. Clinical Pharmacology and Clinical Research proposed to be provided by the applicant shall be liable to Service Tax, as place of provision of service would be location of the recipient of service in terms of Rule 3 of POP Rules or the location where services are actually performed in terms of Rule 4 of POP Rules. It is noticed that as per Rule 14 of POP Rules, where as the provision of a service is prima facie, determinable in terms of more than one rule, it shall be determined in accordance with the rule that occurs later among the rules that merit equal consideration. Therefore, in the case before us, if proposed services are covered by Rule 4, then Rule 3 shall not be applicable.

7. Relevant portion of Rule 4 of POP Rules is reproduced as under:

“Rule 4- Performance based services: - The place of provision of following services shall be the location where the services are actually performed, namely:-

(a) services provided in respect of goods that are required to be made physically available by the service receiver to the service provider or to any person

acting on behalf of the service provider, in order to provide the service.....

(b) Services provided entirely or predominantly, in the ordinary course of business, in the physical presence of an individual, represented either as the service receiver or a person acting on behalf of the receiver.

8. Applicant submits that a reading of the provisions of Rule 4 provides that the conditions which are required to be fulfilled for the place of provision of services is the place where the services are performed, are as under:-

- i. Where the services are performed with respect to goods, the said goods should be physically made available to the service provider;
- ii. Where the services are performed in the ordinary course of business, the said service should require physical presence of the service recipient or his representative;

that the activities of the applicant are not with respect to any goods and are not provided in presence of the offshore customers and therefore, the activities of the applicant will not be covered under Rule 4.

9. It is observed from the above referred Rule 4(a) *ibid* with respect to this case that the place of provision shall be the location where services are actually performed, if

- a) services are provided in respect of goods and
- b) said goods are required to be made physically available by the recipient of service to the provider of service.

10. It is noticed that applicant's proposed service of Clinical Pharmacology is study carried out for generic drugs. Further, study is proposed to be undertaken using formulations in the form of tablets, capsules, gels, sprinkles, syrups, sprays, inhalers etc. provided by applicant's customers located outside India, on eligible volunteers in India. Therefore, it is clear that the formulations in various forms (goods) shall be provided by applicant's customers located outside India, who is recipient of service from the applicant - provider of service. Further, service of Clinical Pharmacology is in respect of said formulation, which is provided to the applicant by its customers from outside India. Therefore, said service of Clinical Pharmacology satisfies above referred 2 conditions and therefore would fall in the ambit of Rule 4(a) of POP Rules.

11. The contention of the applicant is that as per requirement of Rule 4(a) of POP Rules, it is mandatory that the services are provisioned qua the specific goods and not class thereof. It is observed that the language of said Rule 4 (a) do not state that services provided be in respect specific goods. Therefore, the contention of the applicant is not correct.

12. Further, applicant placed reliance on paragraph 5.4.1 of the Educational Guide published by TRU, which is one of the Wings under Central Board of Excise & Customs (CBEC). Said paragraph is reproduced as under:

5.4 Rule 4- Performance based services

5.4.1 What are the services that are provided “in respect of goods that are made physically available by the receiver to the service provider, in order to provide service”?- sub-rule (1)

Services that are related to goods, and which require such goods to be made available to the service provider or a person acting on behalf of the service provider so that the service can be rendered, are covered here. The essential characteristic of a service to be covered under this rule is that is goods temporarily come into the physical possession or control of the service provider, and without this happening, the service cannot be rendered. Thus, the service involves movable objects or things that can be touched, felt or possessed. Examples of such services are repair, reconditioning, or any other work on goods (not amounting to manufacture), storage and warehousing, courier service, cargo handling service (loading, unloading, packaging or unpacking of cargo), technical testing / inspection/certification/analysis of goods, dry cleaning etc. It will not cover services where the supply of goods by the receiver is not material to the rendering of the service e.g. where a consultancy report commissioned by a person is given on a pen drive belonging to the customer. Similarly, provision of a market research service to a manufacturing firm for a consumer product (say, a new detergent) will not fall in this category, even if the market research firm is given say, 1000 nos. of 1 kilogram packets of the product by the manufacturer, to carry for door-to-door surveys.

13. Based on above, applicant submits that Rule 4 only contemplates a situation where the goods are temporarily handed over to service provider for servicing and returned after servicing; that their interpretation is supported by the example of detergent packets distributed and feedback by such prospective customers are not said to be covered by Rule 4. It is to be observed that the Education Guide gives example of some services covered under Rule 4 *ibid* and technical testing/analysis of goods, which are akin to clinical testing, are also included in the example. This example is similar to the proposed service, as compared to the example of detergent packets. The said paragraph of Education Guide also mentions that *“it will not cover services where the supply of goods by the receiver is not material to the rendering of the service”*. In the instant case, there is no doubt that receipt of formulation by the applicant for the purpose of clinical trials is crucial to rendering of services. Therefore, service relating to Clinical Pharmacology will be covered under Rule 4(a) *ibid*, even as per Education Guide relied upon by the applicant. It is noticed that paragraph 1.2 of Education Guide clarifies that it is neither a Departmental Circular nor a manual of instructions issued by CBEC. Further, it states that it does not command the required legal backing to be binding on either side in any manner. In any case, contents of Education Guide cannot be substitute for POP Rules. As provisions of Rule 4 of POP Rules are clear, Education Guide cannot take precedence over it.

14. Applicant submits that the other service provided by him to the customers located outside India would be Clinical Research, which involves Project Management, Regulatory Affairs, Medical Writing, Project Monitoring, Bio-Statistics & Programming and Compliance. During hearing on 22.07.2016, applicant submitted that 2 services proposed to be provided by him i.e. Clinical Pharmacology and Clinical Research, would be on stand-alone services, for which separate invoices would be issued and Clinical Research service cannot be considered as service under Rule 4(b) *ibid*, as same is not provided in the presence of service receiver or a person acting on behalf of service receiver.

15. It is observed from the application submitted by the applicant that he would be charging consideration from the customers on project to project basis. It is apparent that list of such services to be provided by the applicant will not be uniform and will

vary as per the requirements of project / customer. In case, said Agreement is examined in light of Rule 4 of POP Rules, there shall be two types of situations;

a) Service provided in respect of goods - Applicant has admitted that all above activities would not be provided in isolation. Therefore, when Clinical Research i.e. Project Management, Regulatory Affairs, Medical Writing, Project Monitoring, Bio-Statistics and Programming and Compliance is carried out in respect of formulations that are required to be made physically available to the applicant (i.e. service provider) by the service receiver located outside India, such service shall be covered under Rule 4 (a) *ibid*. Clinical Research carried out in respect of formulations received from the service receiver, that are consumed in the process or clinical testing, which are necessary for carrying-out other processes of Clinical Research, would also be covered under this category, as these services will be provided in respect of formulation.

(b) Service relating to Clinical Research provided on stand-alone basis - During personal hearing on 22.07.2016, applicant submitted that services relating to Clinical Pharmacology and Clinical Research would be provided on stand-alone basis and separate invoices would be issued for each service. Applicant submits that the Clinical Research service proposed to be undertaken by the applicant can also not be considered to be service provided in the physical presence of an individual, represented either as the service receiver or a person acting on behalf of the receiver in terms of Rule 4 (b) *ibid*; that the volunteers which are identified, selected and gathered by the applicant are in India and such volunteers having nothing to do with the Drug Company i.e. the service recipient, and therefore the said volunteers cannot be said to be acting on behalf of the receiver; that the activities of the applicant essentially involves provision of expert opinion on test results and as such are advisory services as opposed to executionary services and therefore, are not covered under Rule 4 of the POPS Rules for the place of provision to be in India. It is observed that where service of Clinical Pharmacology (which is provided in respect of formulations received from service receiver located outside India) is not provided by the applicant and only service of Clinical Research is provided, then this service would not be in relation to formulation. Further, there will not be physical presence of an individual, represented either as the

service receiver or a person acting on behalf of the receiver, in terms of Rule 4 (b) of POP Rules. Therefore, such service will not fall in the ambit of Rule 4 ibid.

18. In view of above, we rule as under;

The proposed activities of undertaking Clinical Pharmacology by the applicant are taxable under the Act in light of Rule 4 of the Place of Provision of Services (POP) Rules, 2012, as the services are proposed to be provided in respect of goods that are required to be made physically available by the service receiver to the service provider (applicant). Further, Clinical Research service provided in respect of goods that are required to be made physically available by the service receiver to the service provider (applicant) are also taxable under the Act in light of Rule 4 of the Place of Provision of Services (POP) Rules, 2012. However, where service of Clinical Pharmacology is not provided by the applicant and only service of Clinical Research is provided, then such service would not be in relation to formulation provided by the service receiver located outside India, to the applicant. Hence, it would be not taxable under the Act in light of Rule 3 of the Place of Provision of Services (POP) Rules, 2012 as the applicant renders said services to its customers and the place of provision is located outside India.

Sd/-
(S.S. Rana)
Member(R)

Sd/-
(V.S.Sirpurkar)
Chairman

Sd/-
(R.S.Shukla)
Member (L)