

CWP-17437-2021

2023:PHHC:090087-DB

**IN THE HIGH COURT OF PUNJAB AND HARYANA AT
CHANDIGARH**

CWP-17437-2021

Date of Decision:-24.04.2023

M/s Fresenius Kabi Oncology Ltd.

....Petitioner

Vs.

Union of India and others

....Respondents

**CORAM:- HON'BLE MS. JUSTICE RITU BAHRI
HON'BLE MRS. JUSTICE MANISHA BATRA**

Present:- Mr. Sandeep Goyal, Advocate
for the petitioner.

Mr. Gurinderjit Singh, Sr. Standing counsel
For U.O.I

Mr. Sharan Sethi, Addl.A.G. Haryana

Ritu Bahri, J.

1. The petitioner has approached this Court seeking quashing of order dated 13.09.2019 (Annexure P-10) and order dated 04.03.2021 (Annexure P- 12) passed by Respondent Nos. 3 and 2 respectively, whereby the claim of the petitioner for refund for the period July 2017 to March 2019 for which separate applications for refund in Form RFD-01 have been filed, was rejected.

2. The petitioner is one of the leading pharmaceuticals companies engaged in manufacture of anti- cancer drugs as well as innovation and development in the field of oncology drugs, maintaining global standards. The petitioner is an entity constantly striving to grow to the Global level on the strength of its deep-rooted values and key strategic Investments in the field of Innovation and Development related to oncology drugs.

3. The petitioner develops, manufactures and makes specialty pharmaceutical products in the area of oncology and has also emerged as a

CWP-17437-2021

2023:PHHC:090087-DB

competing centre for development and production of Active Pharmaceuticals Ingredients (APIs) and) Finished Dosage Forms that are used in chemotherapy. Petitioner has its API manufacturing Plant at Kalyani, West Bengal and Finished Dosage manufacturing plant at Baddi, Himachal Pradesh. Petitioner's Innovation and Development Centre at Gurugram, Haryana, has also been recognized by Department of Scientific and Industrial Research (DSIR), Ministry of Science and Technology, Government of India. A true copy of the recognition certificate dated 27.04.2015 Issued by the DSIR is annexed as Annexure P-1. The petitioner is continuously enhancing the 1&D scale through investments in equipment capabilities and people. Scientists are engaged in developing innovative chemistry processes as well as formulations and discharge forms for treatment of cancer. The laboratories of the petitioners are equipped with modern equipment such as NMR Mass spectrometry, RD, DSC, EGA, GCS, HPLCS etc. to name a few thereby ensuring uncompromising standards of quality.

4. The petitioner had invested about 250 Crore on I&D alone in the past few years. Many of the products which are manufactured in Petitioner's plants were also scientifically researched and developed by the Innovation and Development Centre of the petitioner company.. The petitioner employs more than 200 scientists in various fields of research and development who are continuously working to find out Innovative products by way of 1&D for captive as well as export markets. In order to develop the business of Innovation and development, the petitioner has invested huge capital and resources, by way of skilled scientists, experts, buildings and machinery for the innovation and development centre of the company. Innovation and development are not a static process and it depends on amount of capital investment and R&D, which is made for the manufacturing of various products by the company. The petitioner is providing services for and sells

CWP-17437-2021

2023:PHHC:090087-DB

oncology products to number of entities throughout the world. The petitioner is having intellectual property rights in various drugs and their manufacturing processes which are manufactured in the country and are being exported also.

5. The petitioner had entered into agreements distribution of products as well as innovation & development services with various companies across the world including Fresenius Kabi Deutschland GmbH Germany ("hereinafter called FKDG") which is incorporated in Germany under German Laws. The petitioner had entered into various agreements with the FKDG, Germany for providing services. The copy of the Service Agreement dated 23.12.2011 is annexed as Annexure P-2. In the said Agreement, FKDG has appointed the petitioner for providing specific services specified in Appendix-A annexed with the said Agreement for an agreed compensation. As per said Agreement, the petitioner would be providing the following services:-

- (i) Preparation, coordination and completion of safety documents;
- (ii) Providing supports to Global Competence Centre of Pharmacovigilance for Oncology Products
- (iii) Providing support to Global Business Centre, (GBC), Generics; and
- (iv) Any other services as mutually agreed between petitioner and FKDG.

6. Another Agreement dated 01.07.2021 Annexure P-3 was entered into between the petitioner and FKDG, which is called Research and Development Service Contract. The Petitioner had also entered into Service Agreements with FKDG on 04.01.2013 and 01.01.2018. As per the said agreement, the Petitioner had to provide services only to FKDG and not to any other entity. The scope of the services as per the Agreement -reads *as under*:

"The support services to be rendered by the contractor includes:-

1) Clinical research and medical services includes but not limited to-

1. Bioequivalence studies -

CWP-17437-2021

2023:PHHC:090087-DB

Conduct and management of bioequivalence studies to support product registration in EU/US/PHM countries.

- *Define bioequivalence study strategy to cater worldwide market.*
- *Guidance for designing bioequivalence studies.*

2. *Pre clinical Studies -*

- *Design and management of preclinical studies (In vitro & in vivo) to support product registration in Ph.D markets.*

3. *Generation of medical regulatory documents –*

Generate package inserts (PI), summary of product characteristics (SPC), patient information leaflet (PIL), non clinical/clinical overview and other scientific submission. Information for dossier submission.

4. *Response to medical queries -*

Provide scientific information to queries received by us and helped in answering medical queries from MU/PU and customers for products marketed in various countries.

5. *New product evaluation –*

Medical evaluation of new products as per business needs.

6. *Clinical trials -*

- *Design and conduct of clinical trials with various leading medical institutes to generate clinical data as per ICH GCP standard safety and efficacy of drug products.*

II) *Intellectual property management services includes but not limited to –*

Literature search

Preparation of patent landscapes

Patent equivalency searches internally as well as externally

Market launch assessment

Patent invalidity analysis and filing oppositions / third party observations

iii) *Project Management services includes but not limited to-*

Manages and executes and monitors all aspects of the new product development process from project initiation to product approval, to ensure delivery of projects deliverables within budget and in time.

7. The petitioner has placed on record various agreements entered in between the petitioner and FKDG (P-4). Under the Service Tax regime, a show cause notice was issued and adjudication was conducted by

CWP-17437-2021

2023:PHHC:090087-DB

the Assistant Commissioner, Service Tax, Division XVIII, GGN and one of the question posed in the said adjudication was whether the Assessee has exported the services as per provisions of Export of Service Rules 6A or not. While answering the question, the Assistant Commissioner considered the question of export of services and the agreements entered by the Petitioner with FKDG and categorically held that the petitioner fulfils all the conditions as per Section 6A of the Export of Service Rules. The question as to whether the petitioner is an exporter of services or not has reached finality and is binding on the respondent.

8. After the introduction of the GST Act, the petitioner had approached the respondents authorities for grant of refund under the GST regime for the period July, 2017, Aug-Sep, 2017, April-June, 2018, June-Sept, 2018 and Oct to Nov 2018 and Oct 2017 to Mar 2018, Dec 2018 to Jan, 2019 and Feb 2019 to Mar 2019, the details of which are as follows:-

Sr. No.	Period	Amount
1.	July, 2017	Rs.3,19,49,187/- (with payment of IGST)
2.	Aug-Sep, 2017	Rs.1,98,21,083/-
3.	Oct 2017 to Mar 2018	Rs.8,17,33,346/-
4.	April-June, 2018	Rs.3,88,77,621/-
5.	July 18 to Sept 2018	Rs.2,37,30,088/-
6.	Oct 2018 to Jan 19	Rs. 1,45,49,676/-
7.	Dec 18 to Jan 19	Rs.2,52,92,919/-
8.	Feb 19 to Mar 19	Rs.2,23,62,673/-

9. Thereafter, the authorities scrutinized documents and notified certain discrepancies by issuing the deficiency memo dated 28.09.2018 (P-6), in respect of claims for the period July, 2017, Aug, 2017 to Sep, 2017 and Oct 17 to March,

CWP-17437-2021

2023:PHHC:090087-DB

2018 and the petitioner cleared all the deficiencies by providing the required information (P-7). However, on 15.05.2019 (P-8), a show cause notice was issued to the petitioner with regard to refund of claims for the period April-June, 2018, July-Sep, 2018 and Nov, 2018 alleging therein that the services exported by the appellant did not fulfill the conditions of export under Section 2 (b) (v) of IGST Act, 2017. The petitioner gave his reply (P-9) to the show cause notice. Thereafter, the Deputy Commissioner Division I, East, Central Tax GST (Gurugram) vide letter dated 13.09.2019 (P-10) rejected all the eight refund claims submitted by the petitioner for a total amount of Rs.25,74,16,653/- despite the fact that no show cause notice was issued for five out of the eight claims of the period July, 2017 to Feb-Mar, 2019. The petitioner challenged the above order by filing an appeal (P-11), which was dismissed on 04.03.2021 (P-12) and hence the present writ petition.

10. Learned counsel for the petitioner is challenging the above orders on the ground that the petitioner fulfills all the conditions enumerated under Section 2 (6) of IGST Act, 2017 which reads as under:-

Section 2 (6) "Export of Services" means the supply of any service when:-

- (i) the supplier of service is located in India;
- (ii) the recipient of service is located outside India;
- (iii) the place of supply of service is outside India;
- (iv) The payment for such service has been received by the supplier of service in convertible foreign exchange; (or in Indian rupees wherever permitted by the Reserve Bank of India); and
- (v) The supplier of service and the recipient of service are not merely establishments of a distinct person in accordance with Explanation I in Section 8

11. The petitioner-company is a company organized and existing under the laws of India, having its registered office at New Delhi and entered into

CWP-17437-2021

2023:PHHC:090087-DB

agreement with FKDG, having its place of business at Germany (P-4). FKDG, headquartered in Bad Homburg, Germany, which is a multinational group of companies engaged in the research, development, manufacturing, sale and distribution of pharmaceutical products for the therapy and care of critically and chronically ill persons in hospital and outpatient care. The services provided by the petitioner are without involvement of any third party and invoices are being raised by the petitioner directly to FKDG without any reference of sub-contractor/third party. Payments are made by FKDG directly to FKOL in foreign currency. Similar issue was considered by CESTAT, Delhi in the case of *M/s Verizon India Pvt. Ltd vs. Commissioner of Service Tax, 2019 SCC Online CESTAT 8066* wherein it has been held that the appellant therein has provided output services and raised invoice on principal to principal basis and further held that the appellant had provided services at cost plus 11% mark up and had received remittance in convertible foreign exchange and the appellant satisfied all the conditions.

12. In the present case, no show cause notice has been issued for the claim for five invoices i.e for the period July, 2017, Aug-Sept, 2017, Oct to Mar, 2018, Dec, 2018 to Jan 2018 and Feb 2019 to Mar, 2019. The petitioner had submitted eight refund claims. Out of those 08 claims, show cause notice was issued only in respect of three claims and for the remaining five claims, show cause notice was never issued. This fact is not disputed in the reply filed by the respondents. It is not in dispute that issuance of show cause notice and granting of opportunity of hearing before rejecting of any refund claim, is a statutory requirement.

13. The petitioner has been exporting services under an agreement with FKDG for a long time i.e from 2011 onwards. The Assistant Commissioner in its order dated 29.07.2016 has held that the service provided by the petitioner is an export of service and this order was binding on the respondents and it could not be

CWP-17437-2021

2023:PHHC:090087-DB

re-considered when no appeal has been preferred against the earlier assessment. The revenue cannot be permitted to adopt an inconsistent stand in a subsequent assessment where the facts and position of law is identical. Reliance can be placed in the case of **BSNL vs. Union of India, 2006 (3) SCC 1** wherein while relying upon case of **Radhasoami Satsang vs. CIT, 1992 (1) SCC 659**, it was held as under:-

"15. The question in Radhasoami Satsang v. CIT [(1992) 1 SCC 659] (also cited by the State of U.P.) was whether the Tribunal was bound by an earlier decision in respect of an earlier assessment year that the income derived by the Radhasoami Satsang, a religious institution, was entitled to exemption under Sections 11 and 12 of the Income Tax Act, 1961. The Court said: (SCC p. 666, paras 16-17)

"We are aware of the fact that strictly speaking res judicata does not apply to income tax proceedings. Again, each assessment year being a unit, what is decided in one year may not apply in the following year but where a fundamental aspect permeating through the different assessment years has been found as a fact one way or the other and parties have allowed that position to be sustained by not challenging the order, it would not be at all appropriate to allow the position to be changed in a subsequent year, [unless there was] any material change justifying the Revenue to take a different view of the matter."

14. It is not in dispute that the petitioner is a public limited company incorporated in India, in consonance with the Indian Companies Act, 1956. The petitioner is also registered with the department under GST vide Registration No. 06AABCD7720L1ZM dated 01.07.2017 whereas FKDG is a company incorporated in Germany. The petitioner does not carry out any marketing of the products of FKDG nor any product is delivered by FKDG to it. The activities performed by the petitioner are original activities and for doing the same, it has been charging costs from FKDG. Therefore, it cannot be stated to be intermediary

CWP-17437-2021

2023:PHHC:090087-DB

of FKDG and the services provided by it to FKDG cannot be stated to be intermediary services. In our opinion, a wrong observation has been made by the respondents in this regard.

15. In view of the discussion as made above, the instant petition is allowed. The orders dated 13.09.2019 (Annexure P-10) dated 04.03.2021 (Annexure P-12) are set aside and the writ petitioner is entitled to seek refund for the period from July 2017 to March 2019 from the respondents. The respondents are accordingly directed to release the refund amount to the petitioner within a period of four weeks.

(RITU BAHRI)
JUDGE

(MANISHA BATRA)
JUDGE

24.04.2023
G Arora

Whether speaking/reasoned : Yes/No
Whether reportable : Yes/No