

**CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL
BANGALORE**

REGIONAL BENCH - COURT NO. 2

Central Excise Appeal No. 20038 of 2016

(Arising out of Order-in-Original No. BLR-EXCUS-003-COM-10-15-16 dated 30.09.2015 passed by the Commissioner of Central Excise, Bangalore – III Commissionerate, Bangalore.)

M/s. Health Care Global Enterprises Ltd.

No. 8, P. Kalinga Rao Road,
Mission Road Cross,
Sampangirama Nagar,
Bangalore – 560 027.

.....**Appellant(s)**

VERSUS

**The Commissioner of Central Excise,
Bangalore – III Commissionerate,**

6th Floor, Central Revenue Building,
Post Box No. 5400, Queens Road,
Bangalore – 560 001.

.....**Respondent(s)**

WITH

Central Excise Appeal No. 20039 of 2016

(Arising out of Order-in-Original No. BLR-EXCUS-003-COM-10-15-16 dated 30.09.2015 passed by the Commissioner of Central Excise, Bangalore – III Commissionerate, Bangalore.)

B S Ajai Kumar,

Chairman & CEO,

M/s. Health Care Global Enterprises Ltd.

No. 8, P. Kalinga Rao Road,
Mission Road Cross,
Sampangirama Nagar,
Bangalore – 560 027.

.....**Appellant(s)**

VERSUS

**The Commissioner of Central Excise,
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6th Floor, Central Revenue Building,
Post Box No. 5400, Queens Road,
Bangalore – 560 001.

.....**Respondent(s)**

APPEARANCE:

Mr. S. Annamalai, Advocate for the Appellant.

Mr. Vinod Kumar Garhwal, Superintendent (AR) for the Respondent.

CORAM:

Hon'ble Mr. P.A. Augustian, Member (Judicial)

Hon'ble Mr. Pullela Nageswara Rao, Member (Technical)

Final Order Nos. 20561-20562 /2026

Date of Hearing: 15.10.2025

Date of Decision: 13.04.2026

PER: P.A. AUGUSTIAN

The issue in the present appeals is whether the activities carried out by the Appellant amounts to manufacture and whether the goods manufactured by the Appellant are classifiable under the Chapter Heading 28444000 as alleged by the Adjudication Authority.

2. The Appellant (formerly known as M/s. Health Care Global Advances Isotopes Pvt. Ltd.,) are engaged in manufacture and clearance of excisable goods viz., Radio Isotopes 'FDG F-18' (Fluoro-2-deoxy-D-Glucose) (FDG F-18' or 'FDG' for short), falling under Chapter 28444000 of CETA, 1985. M/s. Health Care Global Advances Isotopes Pvt. Ltd., which was incorporated on 30.05.2005, was amalgamated with the holding company M/s. Banashankari Medical and Oncology Research Centre Ltd., from 03.02.2011 vide Order OLR No.2/2011 in Company Petitions Nos.148 & 149 of 2010, of the Hon'ble High Court of Karnataka. Further, M/s. Banashankari Medical and Oncology Research Centre Ltd., was amalgamated with M/s. Health Care Global Enterprises Pvt. Ltd., on 16.03.2011 vide order in Company Petition Nos.148 & 149 of 2010.

3. The brief facts are alleging that the Appellant had evaded excise duty on the goods manufactured by them, proceedings were initiated and show cause notice dated 30.10.2014 was issued demanding excise duty for the period from 01.11.2009 to 31.03.2014 and thereafter Adjudication authority as per the impugned order confirmed the demand with interest and imposed penalty. The Adjudication authority also

confiscated the goods manufactured and cleared by the Appellant during the relevant period and imposed redemption fine of Rs. 6,00,000/- under Section 34 of the Central Excise Act, 1944. Aggrieved by said order, present appeal is filed.

4. When the appeal came up for hearing, the Learned Counsel for the Appellant submits that the impugned order is prima facie unsustainable, since there is no provision of law to issue notice in respect of the activities carried out by the amalgamating company, similar to that of Section 170(2) of the Income Tax, 1961. In this regard the Learned Counsel relied on the following decisions: -

(i) *United Telecom Ltd Vs. CCE., Hyderabad - 2011 (21) STR 234 (Tri-Bang)*

(ii) *CIT Vs. Manjunatha Cotton and Ginning Factory - (2013) 359 ITR 565 (Kar).*

(iii) *State of Punjab Vs. Jullundur Vegetables Syndicate - 1966 (17) STC 326 (SC),*

(iv) *Additional Tahsildar, Raipur and Others Vs. Gendalal - (1968) 21 STC 263 (SC)*

(v) *D. Matai Vs. CCE, Mumbai - 2000 (126) ELT 1264 (Tri)*

5. Learned Counsel further submits that the activity carried out by the Appellant is not amounting to manufacture as per Rule 2(f) of the Central Excise Act, 1944 and thus there is no need for them to obtain registration from the Department and to pay duty. Appellant is engaged in the business of diagnosis and treatment of all type of Cancers which is carried out through CT-Scan, MRI and PET CT-scan. For carrying out the said activity, the appellant uses a product called 'FDG F-18' (Fluoro-2-deoxy-D-Glucose), which is administered primarily to cancer patients before they undergo PET-CT scanning. The process undertaken by the appellant in production of FDG F-18 is, proton bombardment of Heavy Water (Deuterium Oxide) and mixing the same with glucose using an equipment called 'Cyclotron'. The appellant had installed this equipment 'Cyclotron' in their premises during 2007. This process of production of FDG F-18, which involves a series of process, takes about 2 hours to

complete. To examine whether the above said activity amounts to manufacture in terms of Central Excise Law, Learned Counsel drew our attention to Section 2(f) of the Act, which defines 'manufacture' as :-

"manufacture" includes any process,

(i) incidental or ancillary to the completion of a manufactured product; and

(ii) which is specified in relation to any goods in the Section or Chapter notes of the Schedule to the Central Excise Tariff Act, 1985 (5 of 1986) as amounting to, manufacture, and the word "manufacturer" shall be construed accordingly and shall include not only a person who employs hired labor in the production or manufacture of excisable goods, but also any person who engages in their production or manufacture on his own account;

6. Learned Counsel to substantiate the contention that the activity does not amount to manufacture, draws our attention to the activities where it is explained, while submitting reply to show cause notice which includes:-

a. The FDG is highly instable and starts decaying the moment it comes into existence. There is decrease in radio activity by 50% in 110 minutes (half-life period). Usually, one batch processing around 2000 Mcl of FDG is produced which is subject to quality check that takes 15-20 minutes. FDG starts decaying once dispensed from Cyclotron. FDG is taken in vial and administered to patients under a radio-active container. For dispatch of FDG to third party to be delivered at client's doorstep, the time required for transportation is crucial.

b. The important aspect is that life of FDG is only the time gap between production of the FDG and the time of administering to patient at appointed time. It can neither be administered before appointed time as radioactive strength would be higher than that required nor can it be administered after the appointed time as the radioactive strength would fall below minimum

level. Therefore, FDG is transient and unstable in nature as it breaks down-decays and may not be considered as goods at all. When there is an unstable product and not capable of being bought and sold in the market it is not goods. To that extent it may not be deemed to be marketable. As test of marketability is essential, when that fails, the levy would also consequently fail. The noticee rely on the decision of the Apex Court in the case of Union of India and Anr. Vs. Delhi Cloth & General Mills Co. Ltd. (DCM) reported in 1977 (1) ELT (J199) (SC).

- c. Goods with unstable character and not marketability goods are not dutiable. The noticee place reliance on the case CCE vs. Ambalal Sarabhal Enterprises Ltd. 1989 (4) SCC 112*
- d. The obvious rationale for levying excise duty linking it with production or manufacture is that goods so produced must be distinct commodity known as such in common parlance or to the commercial community for purpose of buying and selling. The article which is unstable product and not capable of being bought and sold in the market in some cases it has been held that it is not goods. The noticee have relied on the case of Moti Laminates Pvt. Ltd. Vs. CCE, Ahmedabad, reported in 1995 (76) ELT 241 (SC), wherein the Hon'ble Court held that, where a shelf life of upto 15 days was held not enough to make the product marketable.*
- e. The production having short life is not goods, if not marketable. The noticee has relied on the case of CCE, Chandigarh-II Vs. Jagatajit Industries Ltd., reported in 2002 (141) ELT 306 (SC), wherein it was held that, yeast obtained by propagating the same by mixing it with molasses and water for manufacture of potable alcohol, having shelf-life of 6-8 hours, is not 'goods' when there is no proof about its marketability.*
- f. The life of FDG is short shelf life, from time gap between production till the time of administering to patient at appointed*

time, therefore, to that extent it may not be deemed to marketable. As test of marketability is essential, when that fails, the levy would also consequently fail. They place reliance on the following cases, in support of their contention:

- i. CCE, Boroda Vs. United Phosphorus Ltd., (2004) 4 SCC 18;*
 - ii. UOI Vs. Delhi Cloth & General Mills Co. Ltd., (1997) 5 SCC 767;*
 - iii. Bhor Industries Ltd., Vs. CCE, Bombay - (1989) 1 SCC 602,*
- g. FDG is reducing by 50% every 110 minutes, thus it is not marketable. Further, an unstable intermediate product which is not marketable is not goods even if there is a specific entry in the Central Excise tariff Act, 1985. In this connection, they rely on the following decisions, wherein it was held that the product is unstable having short life and not marketable or not capable of being marketed, no excise duty can be levied and therefore the noticee have argued that FDG is not goods and consequently production of FDG is not leviable to duty:*
- i. CCE Vs. Satia Paper Mills - 2004(173) ELT 178 (Tri-Del);*
 - ii. Viral Laminates Pvt. Ltd. Vs. CCE - 1996 (85) ELT 191 (CEGAT-LB)*
- h. The noticee have placed reliance on the judgment of Shri Ramakrishna Industries Ltd. vs CCE, Madras, - 1996 (82) 575 (Tribunal Larger Bench), wherein it was held that, Revenue has not produced any material to show marketability, not to regarded as marketable goods or excisable goods.*
- i. Merely because a certain article falls within the schedule, it would not be dutiable under excise law if the said article is not "goods" known to the market. Marketability, therefore, is an essential ingredient in order to be dutiable as held in the case of Bhor Industries v. CCE, (1989) 1 SCC 602. The fact that an article answers the description of a tariff entry would not make*

it dutiable. It should be known in the market as an independent product as was held in the case of the B.M.F. Belting Ltd. vs 001-1990 (50) ELT 10 (AP).

j. The article which have no shelf life and are not marketable, hence, they are not excisable goods. They have relied on the following decisions:

- i. CCE v. Apurva Containers Pvt. Ltd. (1998 (102) ELT 86 (T))Held - Products namely, Cepol D.V. (Special) and Movicol T used captively in paper finishing are products which have very short shelf life and are not marketable. Their adhesive characteristics change within 24 hours. Therefore, durability is not established.*
- ii. Everest Rubber Works vs CCE [1999 (107) ELT 41 (T-EB)) - Held - The fact that vulcanization solution arising during manufacture of rubberized textile sheet has 48 hours shelf life is not a proof of its marketability.*
- iii. CCE v. Famous Cine Laboratory [1993 (66) ELT 253 (T-C)), Held - Hypo Solution is a product meant for instant use in film processing laboratories and has a short shelf life. Its marketability not having been established by the department, Hypo solution cannot be treated as excisable goods.*
- iv. CCE v. Charishma Cosmetics Pvt. Ltd. (2003 (156) ELT 427(T-Mumbai)] Denatured Ethyle alcohol was produced by cooling neutral alcohol to a very low temperature and adding DEP and other ingredients to it. This product has a short life of less than 10 minutes and that too at a very low, artificially created temperature, it was held to be non-marketable.*

v. *CC & CE v. Shivaji Works [2002 (139) ELT 717 (T-Mum)]*
Absence of shelf life or short shelf life of goods proves non-marketability.

7. As regarding classification, Learned Counsel submits that as per impugned order, the Adjudication authority confirmed the classification of the goods under Chapter sub-heading 28444 000 which is reproduced below:-

2844 40 00	Radioactive elements and isotopes and compounds other than those of subheading 2844 10, 2844 20 or 2844 30; alloys, dispersions (including cermets), ceramic products and mixtures containing these elements, isotopes or compounds; radioactive residues	Kg.	12.5%
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8. Learned Counsel further submits that the process undertaken by the Appellant is for preparation of pharmaceutical products and even if it is held that the process undertaken by the Appellant amounts to manufacture, it can be classifiable Chapter sub-heading 3006 30 00 under the pharmaceutical goods specified in Note 4 to this Chapter:-

3006 30 00	Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient	Kg.	6%
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8.1. In support the above contention, Learned Counsel draws our attention to the following documents:-

- a. Copy of the Paper named "Fludeoxyglucose F 18 Injection" (1981). In NDA 21-870: FDG F 18 Injection.
- b. Copy of the Article named What is Fludeoxyglucose F-18 used for? (n.d.).<https://synapse.patsnap.com/article/what-is-fludeoxyglucose-f-18-used-for>

- c. Copy of the Paper named Kilicoglu, O., Sepay, N., Ozgenc, E., Gundogdu, E., Kara, U., Alomairy, S., & Al-Buriah. (2022). Evaluation of F-18 FDG radio pharmaceuticals through Molecular Docking and radiation effects. Applied Radiation and Isotopes, 191 110553. <https://doi.org/10.1016/j.apradiso.2022.110553>
- d. Copy of the What are radioisotopes? (n.d.). <https://www.ansto.gov.au/education/nuclear-facts/what-are-radioisotopes>
- e. Copy of the Ashraf, M; Goyal, A. (2023, August 28). Fludeoxyglucose(18F). StatPearls NCBI Bookshelf. <https://www.ncbi.nlm.nih.gov/books/NBK557653/>
- f. Copy of the Public Assessment Report Fludeoxyglucose (¹⁸F) solution for injection. <https://www.geneesmiddeleninformatiebank.nl/pars/h115336.pdf>

9. As regards classification, Learned Counsel draws our attention to the license issued by the Atomic Energy Regulatory Board on 07.11.2016 where the license is issued for operation of Medical Cyclotron facility with strict condition to comply with the provisions of Atomic Energy Act and other related Rules.

- a. Fludeoxyglucose F 18 Injection is indicated in positron emission tomography (PET) imaging for assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with an existing diagnosis of cancer.
- b. Fludeoxyglucose F 18 Injection is indicated in positron emission tomography (PET) imaging in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function.

- c. Fludeoxyglucose F 18 Injection is indicated in positron emission tomography (PET) imaging in patients for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

10. Learned Counsel also submits that the Appellant is also eligible for claiming the benefit of SSI exemption. In this regard, Learned Counsel draws our attention to the reply to show cause notice submitted by them where it is categorically stated that:-

- a. The SCN is issued for the period from 01.11.2009 to 31.03.2014. But the amount considered for levy of excise duty is the clearances made from 01.04.2009 to 31.03.2014. The clearances made from 01.04.2009 to 31.10.2009 are beyond the SCN period. The appellant wish to place the quantification for the period in the written submission to be filed by the noticee. The value mentioned in the notice is at Rs.10,06,59,210/- which is not correct and contrary to the value adopted by the appellant.
- b. The allegation that the noticee is not entitled for the benefit of Notification No.8/2003-CE dated 01.03.2008 is not correct. As per notification No.8/2003- CE, SSI units whose turnover is less than Rs. 4 Crore are eligible for the concessions. If SSI unit does not avail CENVAT on inputs, turnover up to Rs.150 lakhs is fully exempt. The correct value of clearance for the purpose of SSI Exemption is as follows:

Sl. No.	Year	Value of FDG Clearance to in patients	Value of FDG Clearance to third parties	Total Value
1	2009-10	21,04,500	1,03,57,625	1,24,62,125
2	2010-11	14,94,500	1,33,73,924	1,48,68,424
3	2011-12	12,13,000	72,11,650	84,24,650

4	2012-13	24,19,500	69,55,701	93,75,201
5	2013-14	21,96,000	25,52,129	47,48,129

10.1 Learned Counsel also submits as seen from the above, in none of the year total amount has crossed Rs.150 lakhs and consequently the appellant is entitled for SSI exemption as per Notification No. 8/2003-CE dated 01.03.2008 and as per the show cause notice (SCN) also in none of the years a sum of Rs. 4 Crores is crossed. This is without prejudice to the contention that the goods are not excisable.

11. As regards invoking the extended period of limitation, Learned Counsel for the Appellant submits that the Appellant were under bonafide believe that Fludeoxyglucose F-18 (FDG- F 18) processed by the Appellant is not liable to excise duty and there was no intention to evade payment of duty. The Appellant has not suppressed the fact and not contravened the provisions of the Act for invoking the extended period of limitation and penalty. In this regard, Learned Counsel draws our attention to the decision of the Tribunal in the matter of **M/s. Johnson & Johnson Ltd Vs. CC-1995 (781) E.L.T 193** wherein it was held that when the assessee is under bonafide belief that the product is not liable to duty and intention to evade payment of duty is not established, extended period of limitation cannot be invoked. Learned Counsel also relied on the decision of **M/s. PB Pharmaceuticals Pvt. Ltd Vs. CC -2003 (153) E.L.T 14 (SC), M/s. Electronics Kelvinator Pvt. Ltd. Vs. CC -2004 (163) E.L.T 234 (Tri. Bang).**

12. As regards Valuation, Learned Counsel also draws our attention to the statement of sale to third parties for the period from 2009-2010, 2014-2015 and also cost of production as per CAS under Rule 8 of Central Excise Rules, 2002. Learned Counsel further submits that the Adjudication authority has valued the goods for captive consumption higher than the value adopted by the Appellant that is Rs. 50 per MCI. As regards valuation of goods sold to own branch hospitals /patients, Adjudication Authority adopted residuary Rule 11 of Central Excise

Valuation (Determination of Price of Excisable goods) Rules, 2000 whereas Adjudication Authority has not considered the price in terms of Section 4(1)(a) of the Act, that is the price at which the goods are sold to independent buyers at the same time and place, for the goods cleared to the appellant own branches /hospitals /patients. Thus, adopting such method for valuation is also unsustainable.

13. Learned Authorized Representative (AR) for Revenue reiterated the finding in the impugned order.

14. Heard both sides and perused the records.

15. As regards marketability of the product to demand excise duty, we find that the Appellant admits there was third party supply of goods and facts being so the product manufactured by the Appellant is marketable and even if the shelf life is limited, it cannot be held that the goods are not marketable, specifically when evidences are available on record to show that the Appellant had sold the goods to third party entities. Even if it is admitted that the 'FDG F-18' manufactured by the Appellant is reduced by 50% every 110 minutes (half-life period), it is marketable and the activity amounts to manufacture.

16. As regards classification of the goods under Chapter Heading 2844 4000 of the Central Excise Tariff Act, 1985, considering the documents relied by the appellant, we find that the product 'FDG F-18' is a 'radioactive pharmaceutical' used in medical imaging in Positron Emission Tomography (PET), 'FDG F-18' does not find a place in goods classifiable under Chapter Heading 2844 4000 of the Central Excise Tariff Act, 1985. Pharmaceutical products are classifiable under Chapter 30 of the Central Excise Tariff Act, 1985. Chapter sub-Heading 30063000 covers 'opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient'. Since product 'FDG F-18' is a radiopharmaceutical, it is rightly classifiable under Chapter Heading 3006 3000 of the Central Excise Tariff Act, 1985. Consequently, the classification under Chapter Heading 2844 4000 is incorrect, hence the demand confirmed by the Adjudication Authority classifying the

impugned goods under Chapter sub-Heading 2844 4000 is unsustainable.

17. Further as regards invoking the extended period of limitation, we find that the Appellant had bonafide belief that the goods are not subject to excise duty. Moreover, Appellant has not suppressed the facts, further it being an amalgamated entity, invoking the extended period of limitation is also unsustainable. As regards valuation, we find that when goods are sold to independent buyers at the same time and place, the goods are also cleared to the appellant's own branches /hospitals /patients, the Adjudication Authority has valued the impugned goods captive consumed at a rate higher than the value adopted by the Appellant that is Rs. 50 per MCI. Further, the valuation of goods sold to own branches/ hospitals /patients, Adjudication Authority adopted residuary Rule 11 of Central Excise Valuation (Determination of Price of Excisable goods) Rules, 2000 whereas Adjudication Authority ought to have considered the price in terms of Section 4(1)(a) of the Act, that is the price at which the goods are sold to other independent buyers. Thus, the method adopted for valuation is also unsustainable.

18. In view of the above discussion the impugned order is unsustainable and is liable to be set aside.

19. Accordingly, the impugned order is set aside, and the appeals are allowed with consequential relief, if any, in accordance with law.

(Order was pronounced in Open Court on 13.04.2026)

(P. A. AUGUSTIAN)
MEMBER (JUDICIAL)

(PULLELA NAGESWARA RAO)
MEMBER (TECHNICAL)

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