

Wyeth Laboratories Vs. Collector of Central Excise

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Court : Customs Excise and Service Tax Appellate Tribunal CESTAT Delhi

Decided On : Jun-12-1998

Reported in : (1999)(105)ELT691TriDel

Appellant : Wyeth Laboratories

Respondent : Collector of Central Excise

Judgement :

1. This is an appeal against the order of Collector of Central Excise, Bombay, dated 25-4-1991.

2. Ld. Counsel for the appellants stated that the assessee are holder of Central Excise licence for the manufacture of goods falling under Tariff Item 14E and 68. The assessee classified 11 products, as drug intermediates under TI 68, and claimed exemption under Notification No.55/75, super ceded by Notification 234/82, dated 1-11-1982. It appeared to the department that the products in r/o which the assessee claimed the exemption under the aforesaid notification, were not drug intermediates and hence it appeared to the officers that the exemption claimed was not admissible to them. Therefore, the said products were held as liable to duty under TI-68. The assessee were manufacturing products mentioned hereinafter claiming classification under TI-68 and exemption under Notification 55/75 (as amended), superceded by Notification No. 234/82.

The officers drew the samples of the aforesaid product on 22-3-1983.

The Dy. Chief Chemist vide letter dated 5-5-1984 had opined that the products in question do not come under the purview of the definition of drug intermediates. Superintendent on 16-5-1984 communicated the opinion of Dy. Chief Chemist to the assessee. The impugned goods are Organic Compounds and the dispute relates to whether the same are drug intermediates or otherwise. They manufactured drugs and pharmaceuticals in terms of Industries Development and Regulation Act, 1951 and were licenced under Maharashtra Food and Drug Administration. Further the goods in question were exempted from payment of duty by virtue of Notification 172/83 and therefore their products remained drug intermediates prior to the issue of notification.

3. They had specifically requested that the Dy. Chief Chemist on whose opinion the department was relying may be produced for cross-examination. Despite this, the Dy. Chief Chemist and/or the Chemical Examiner has not been produced for the same. The department was bound to furnish the so-called report to the appellants which has not been done to date. Strangely, the show cause notice dated 30-10-1985 was not adjudicated on until 1991 viz. for a period of six years. The show cause notice is dated 30-10-1985. It refers to the period from August, 1981 to June, 1983. There is absolutely not a single word or allegation of fraud, suppression or mis-statement.

Therefore, the proviso to Section 11-A of the Act would not apply. In that event the entire show cause notice is beyond the period of six months limitation.

4. Coming to the merits the appellants submit that pharmacopoeial monographs mention about those chemicals that are active drugs (e.g.

prednisolone, hydrocortisone etc.) or those chemicals that are used as excipients (eg. starch, lactose etc.) in the manufacture of unit dose pharmaceutical preparations and finished formulations (eg. prednisolone tablets, dexamethasone injection etc.). Drug intermediates are those chemicals that are used in the manufacture of drugs and the appellants have in their letter of November 28, 1993 clearly shown the products for which these eleven chemicals are drug intermediates.

5. At the department's instance samples of these eleven intermediates were sent to Dy. Chief Chemist for ascertaining whether they were drug/drug intermediates. At no stage did the appellants claim that these eleven chemicals are drugs. What they claim and for which they have given evidence is that all these eleven chemicals are drug intermediates. The appellants refer to and rely upon the reference from :- (i) 'Diosgenin and other steroid drug precursors,' by L.V. Asolkar and Y.R. Chadha, Publications and Information Directorate, DSIR, New Delhi (1979) incidentally, a Govt. of India publication.

(ii) 'Merck Index', Ninth Edition, to show that the eleven chemicals under discussion were all drug intermediates.

6. Ld. DR reiterated the department's view as contained in the order-in-original and stated that the Collector's order is based on the report of the Dy. Chief Chemist and as he had opined that the organic compounds in question were not intermediate products for drugs therefore his order was justified and the appellants were not eligible for exemption Notification No. 55/75.

7. We have considered the above submissions. We observe that the Collector's order is based merely on the Dy. Chief Chemist's opinion/report but a copy of the same has not been produced before us.

The appellants have stated that in respect of their request neither a copy of the report has been supplied to them nor he has been allowed to be cross examined in spite of request. We find that in our record there are a number of reports by the Chemical Examiners but all these reports merely indicate that the sample is organic compound. They do not indicate at all as to whether the items were or were not drug intermediates. The appellants have produced a lot of technical literature including the 'Diosgenin and other steroid drug precursors' by L.V. Asolkar and Y.R. Chadha published by the CSIR, New Delhi and also a copy of the extracts from the Merck's Index. They have also mentioned that they had drawn attention of the Collector to this technical literature but we find no discussion or finding with reference thereto in the Collector's order. We consider that once the samples have been drawn and tested it was necessary to supply to the appellants a copy of the report on the basis of which the department has

issued this show cause notice and the Collector has passed the order. Further, since this was the only material on which the department's case is based and the appellants had challenged that opinion and filed technical literature it was necessary on the part of the department to have not only furnished a copy of the report but also allowed the appellants to cross examine the Dy. Chief Chemist.

8. In this connection, we also note that the CSIR publication mentioned above indicates, inter alia, the manufacturing process titled 'Conversions' and a diagrammatic representation thereof as well. Further it is indicated, inter alia, at page 95 as follows : On the basis of chemical structures, the steroid drugs, being commercially manufactured in very high purities, can be classified into four groups (7): To obtain these chemically related steroid drugs, 16-DPA has to go through a series of intermediate steps as shown in molecular flow-sheet of some steroid processes using diosgenin. A manufacturer may terminate the steroid reaction at the intermediate level, sell the intermediate to the manufacturer or convert the same to desired drug as and when the demand arises. It may be mentioned here that a steroid drug may become an intermediate for other steroid drugs, e.g. progesterone for cortisone or estrone for 19-Nor compounds. The following steroids which are not drugs but are pure intermediates or 'midgets' for the above group of compounds, are obtained from 16-DPA.9. The appellant has also filed as annexure I a table indicating the name of the drug/drug intermediate, CSIR page number and Merck Index page wherever applicable.

10. Prima-facie this material appears to be relevant for decision of the case but the Collector has not taken cognizance thereof and not recorded any discussion or finding and he has not met squarely the points raised by the appellants. Therefore, it is evident that there was a violation of principles of natural justice. Further more we find that the appellant had duly declared the manufacturing process and the department was fully aware of it all through and in the show cause notice there is no allegation whatsoever of either suppression or mis-statement of facts with intention to evade Central Excise duty and the SCN has been issued on 30th October, 1985 in respect of the period August, 1981 to June, 1983. Therefore, it was time barred as the extended period of limitation was not available to the department in the above circumstances. We therefore, set aside the impugned

order and accept the appeal.

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