

T.N. DADHA PHARMACEUTICALS
v.
COLLECTOR OF CENTRAL EXCISE, MADRAS

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FEBRUARY 5, 2003

[SYED SHAH MOHAMMED QUADRI AND ASHOK BHAN, JJ.]

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Central Excise Act, 1944/Central Excise Rules, 1944:

S.11-A(1)/Rules 8(1)—Exemption Notification No. 116/69—Drug—Darzamol Injection I.V.—Containing Metronidazole—For assessment year 1982-83 classification list No. 7/82 filed claiming exemption—Exemption approved—However, later it transpired that Darzamol Injection I.V. also contained Dextrose, an item not eligible for exemption—Accordingly, show cause notice issued on 17.6.1987 that assessee suppressed the fact in classification list No. 7/82—Exemption sought to be withdrawn for the period 12.7.1982 to 11.10.1984 and demand raised under proviso to s.11-A(1)—Held, Dextrose in Darzamol Injection is not a pharmaceutical necessity, nor could it be considered as therapeutically inert, therefore, assessee cannot claim exemption—Withdrawal of exemption is upheld—However, as regards Revenue invoking provisions of proviso to s.11-A(1) for raising the demand within extended period of five years, since Revenue is alleging that there has been suppression of fact, burden is on it to show by producing the actual classification filed by assessee, to show that there is no mention of 'Dextrose' under column (4) and there has been suppression of fact—Revenue has failed to discharge the burden, therefore, it can not be said that proviso to s.11-A(1) is attracted—Demand relating to extended period set aside—Burden of proof.

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Exemption Notification No. 116/69—Drug—Darzamol Injection I.V.—Containing Metronidazole (IP) and Dextrose—Dextrose not eligible for exemption—Demand of excise duty raised withdrawing exemption—Appeal by assessee—Dismissed by Collector (Appeals) holding that he had no jurisdiction to entertain the appeal—Appeal by Assessee before CEGAT—CEGAT disposing of the appeal without deciding whether Collector (Appeals) had jurisdiction to entertain the appeal or not—Held, matter remitted to CEGAT for fresh disposal—Appeal—Jurisdiction of Collector (Appeals).

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CIVIL APPELLATE JURISDICTION : Civil Appeal Nos. 2123-

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A 2124 of 1994.

From the Judgment and Order dated 2/12/1993 of the Customs, Excise and Gold (Control) Appellate Tribunal. New Delhi passed in Appeal Numbers E-331/88-C and E/1329/89-C.

B S. Muralidhar, for the Appellant.

Jaideep Gupta and Mrs. Rekha Pandey for Mr. B.K. Prasad, for the Respondents.

C The following Order of the Court was delivered :

These two appeals, by the assessee, arise from the order of the Customs, Excise and Gold (Control) Appellate Tribunal (CEGAT), New Delhi in Appeal Nos.E/331/88-C and E/1329/89-C made on December 2, 1993.

D The assessee manufactures, among other pharmaceutical formulations, Darzamol Injection I.V. under a licence granted to it by the Drug Controller, Tamil Nadu. Each millilitre of Darzamol contains Metronidazole (IP) 50 mg. in water for injection, IP made isotonic with Dextrose. The assessment years in question are 1982-1983 to 1984-1985. In the Assessment Year 1982-83, E the assessee filed classification list 7/1982 claiming exemption under Notification No. 116/69, dated 3.5.1969, in respect of the said drug. The classification list was approved and exemption was allowed.

On the ground that during the course of verification it was noticed that Darzamol Injection I.V. contained Dextrose apart from Metronidazole and that the ingredient Dextrose was not a pharmaceutical necessity and also not therapeutically inert and, therefore, the assessee was not eligible for the benefit of exemption Notification 116/69, a show cause notice was issued to it on February 26, 1985. The notice, *inter alia*, stated that the assessee suppressed the fact that Darzamol Injection contained Dextrose and that it was not declared to the department with deliberate intention to evade the payment of duty by claiming exemption under Notification 116/69. The assessee was called upon to show cause why the exemption should not be withdrawn and the duty, particulars of which were given in the notice, should not be demanded; it was asked to produce along with the cause all evidence on which it intended to rely. The assessee replied to the said notice stating that Dextrose was a H nutrient and it had no therapeutic properties and that it was used in the

vehicle for injectables to make the solution isotonic; dextrose would not react with Metronidazole which was the only therapeutic agent in Darzamole Injection I.V. The assessee filed various documents in support of its contention. The Assistant Collector, having been satisfied with the reply given to the show cause notice, dropped the proceedings by order dated May 23, 1985.

It appears that the Superintendent, Central Excise, Madras sent a sample of Darzamol Injection I.V. to the Chief Chemist, Central Revenue Control Laboratory, New Delhi for examination and for technical opinion whether Dextrose in the formulation is pharmaceutical necessity and whether it is therapeutically inert. While the matter stood thus, the Principle Collector of Customs and Central Excise *suo motu* initiated proceedings and passed an order under Section 35-E (2) of the Central Excise Act. The proceedings noted that the statutory audit report which pointed out that from the label to the Darzamol Injection, in addition to Metronidazole listed in the Schedule, Dextrose had also been used which was not one of the ingredients specified in the Notification No. 116/69 and, therefore, grant of exemption was not in order. The said Collector directed the Assistant Collector, to apply to the Collector, Central Excise (Appeals) for determination of the issue involved in granting exemption to Darzamol Injection I.V. under Notification No.116/69, dated 3.5.1969. On an appeal filed pursuant to the said direction, the Collector of Central Excise (Appeals), Madras, by his order dated October 23, 1986, set aside the order of the Assistant Collector, dated May 23, 1985, and directed that adjudication be made afresh after receipt of necessary report from the Chief Chemist, C.H.C.L., New Delhi of Central Drug Laboratory.

It is stated that, in the meanwhile, there was re-allocation of jurisdiction of work Thereupon, the Collector, Central Excise, issued a fresh show-cause notice on June 17, 1987 to the assessee in regard to: (i) Darzamol Injection has the ingredient Dextrose, in addition to Metronidazole; the ingredient Dextrose contained in the product was not a pharmaceutical necessity and also not therapeutically inert; and in view of the report of the State Drug Controller, the assessee was not entitled to the benefit of exemption under Notification No. 116/69; (ii) that the assessee suppressed the fact in classification list no. 7/82 that the Darzamol Injection contained Dextrose as an ingredient which was not specified in the Schedule to the Notification No. 116/69, with deliberate intention to avert payment of duty by claiming exemption under Notification No. 116/69, dated 3.5.1969, in their classification list no. 7/82. The assessee was called upon to show cause why exemption granted under Notification No. 116/69 should not be withdrawn for the period

A from 12.7.82 to 11.10.84 and why the duty amount of Rs. 4, 84, 191.40 should not be demanded under proviso to sub-section (1) of Section 11-A of the Central Excise Act, 1944.

B The assessee filed its reply to the said show-cause notice stating, *inter alia*, that the product Darzamol Injection I.V. had the following composition:

“Each ml, contains Metronidazole I.P. 5 m.g. in water for injection I.P. made isotonic with Dextrose, Metronidazole I.P. is covered under Notification No. 116/69 and the product Darzamol Injection I.V. was cleared without payment of excise duty.”

C It was denied that there was suppression of fact in regard to Dextrose; it was also denied that Dextrose was not declared to the department with deliberate intention to evade the payment of duty. The Collector however, by his order dated October 28, 1987, withdrew the exemption granted to the assessee and upheld the demand. That order was challenged by the assessee in Appeal No. E./331/88-C before the CEGAT.

D It may also be noted here that in respect of the period from 1985 to 1988, demand of excise duty was raised, withdrawing the exemption, on March 7, 1988. The assessee preferred an appeal against the said demand before the Collector (Appeals) who, by his order dated November 30, 1988, dismissed the appeal taking the view that he had no jurisdiction to entertain the appeal. Dissatisfied with the said order of the Collector (Appeals), the assessee filed Appeal No. E/1329/89-C before the CEGAT. This appeal and the appeal arising out of the show-cause proceedings, being Appeal No. E/331/88-C, were disposed of by common order dated December 2, 1993, which is the subject matter of these appeals.

E Insofar as the appeal arising out of the order of the CEGAT passed in Appeal No. 1329/89 is concerned, it must be pointed out that there has been no adjudication of the grievance of the appellant-assessee. The CEGAT did not advert to the question whether the Collector (Appeals) had jurisdiction to entertain the appeal or not. We are, therefore, of the view that the order of the CEGAT under challenge, insofar as it relates to Appeal No. 1329/89 is concerned, is liable to be set aside and, we, accordingly, do so. We remit that appeal (No. E/1329/89-C) to the CEGAT for fresh disposal in accordance with law, after giving opportunity to the parties of being heard.

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Insofar as the appeal arising out of the show cause proceedings is concerned, the main thrust of the argument of the appellant has been with regard to invoking of proviso to section 11-A (1) of the Central Excise Act. But before we deal with that contention, we deem it necessary to dispose of the contention that the withdrawal of exemption was unjustified. To appreciate this contention, it would be necessary to quote Notification No. 116/69, dated 3.5.1969.

“Partial exemption to medicines containing specified ingredients.-
-- In exercise of the powers conferred by sub-rule (1) of rule 8 of the Central Excise Rules, 1944, and in supersession of the notification of the Government of India in M.F.(D.R.&I.) No. 160/66-C.E., dated 8th October, 1966, the Central Government hereby exempts patent or proprietary medicines falling under Item No.14E of the First Schedule to the Central Excise and Salt Act, 1944 (1 of 1944), and containing one or more of the ingredients specified in the Schedule hereto annexed, from the whole of the duty of excise leviable thereon:--

Nothing contained in paragraph 1 shall apply to any medicine which contains any ingredient not specified in the said Schedule unless the ingredients in the medicine are pharmaceutical necessities such as diluents, disintegrating agents, moistening agents, lubricants, buffering agents, stabilisers and preservatives:

Provided that such pharmaceutical necessities are therapeutically inert and do not interfere with therapeutic or prophylactic activity of the ingredient or ingredients specified in the schedule.

SCHEDULE

1 to 20 xxxxxxxxx

21. Metronidazole

22 to 30 xxxxxxxxx

From a perusal of the notification, extracted above, it is clear that the exemption granted under the notification is in respect of patent or proprietary medicines falling under item no.14E of the First Schedule to the Central Excise Act and containing one or more ingredients specified in the Schedule

A to the notification.

B There can be no dispute that without any further drug Metronidazole is one of the ingredients of the drug which is entitled to the exemption under the said notification. But the notification qualifies the exemption by adding that if any medicine contains any ingredient not specified in the Schedule then the exemption will not apply unless the ingredients in the medicine are pharmaceutical necessities such as diluents, disintegrating agents, moistening agents, etc. The proviso to the notification says that such pharmaceutical necessity must be therapeutically inert and they should not interfere with the therapeutic or prophylactic activity of the ingredient or ingredients specified in the Schedule. The effect of this notification with regard to the drug in question, namely, Dextrose which is not specified in the Schedule, would be that if as an ingredient it is pharmaceutical necessity and therapeutically inert, it would satisfy the requirement of the exemption and, consequently, Metronidazole, which is one of the schedule drugs, would be entitled to exemption. But, if dextrose does not have any of those properties above stated, then it being one of the ingredients of Metronidazole the exemption under the notification will not be available.

E In view of the technical report of the Drugs Controller of India confirming the view of the Drugs Controller, Tamil Nadu that "Dextrose in Darzamole Injection is not a pharmaceutical necessity and Dextrose cannot be considered as therapeutically inert, we do not think that the assessee has any case to place before us in support of the claim for exemption. In this view of the matter, withdrawal of exemption by the Collector as confirmed by the CEGAT deserves to be confirmed and we, accordingly, do so.

F The main point that remains to be considered is whether the CEGAT erred in confirming the order of the Collector, Central Excise invoking the proviso to sub-section (1) of Section 11-A of the Central Excise Act.

It will be apt to read the proviso which runs as follows :

G "11-A. Recovery of duties not levied or not paid or short-levies or short-paid or erroneously refunded.-----

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H Provided that where any duty of excise has not been levied or

paid or has been short-levied or short-paid or erroneously refunded by reason of fraud, collusion or any wilful mis-statement or suppression of facts, or contravention of any of the provisions of this Act or of the rules made thereunder with intent to evade payment of duty, by such person or his agent, the provisions of this sub-section shall have effect, as if for the words "one year", the words "five years" were substituted." A
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A perusal of the proviso, extracted above, makes it clear that where duty of excise has not been levied or paid or has been short-levied or short-paid or erroneously refunded by reason of fraud, collusion or any wilful mis-statement or suppression of facts, or contravention of any of the provisions of the Central Excise Act or of the rules made thereunder with intent to evade payment of duty by such person or agent, the period of limitation of one year in the main section is substituted by the words "five years". In other words, where the said proviso is attracted the duty etc. can be claimed even after expiry of one year for an extended period of five years from the date of the demand. To invoke the proviso three requirements have to be satisfied, namely, (1) that any duty of excise has not been levied or paid or has been short-levied or short-paid or erroneously refunded; (2) that such a short-levy or short-payment or erroneous refund is by reason of fraud, collusion or wilful mis-statement or suppression of facts or contravention of any provisions of the Central Excise Act or the rules made thereunder; and (3) that the same has been done with intent to evade payment of duty by such person or agent. These requirements are cumulative and not alternative. To make out a case under the proviso, all the three essentials must exist. C
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In the instant case, in regard to the first requirement, we have held above that the assessee is not entitled to the exemption under the said notification and, therefore, the duty of excise was not paid. On the second essential, the demand of duty for an extended period of five years is sought to be justified on the ground of suppression of fact in the classification list 7/82 on the allegation that Dextrose as one of the ingredients was not disclosed. F

The assessee has placed before us copies of the classification lists, not of 1982 but of a subsequent period, to show that in column (3) under the heading "Name of specified ingredients(s) used" Metronidazole is mentioned, and under columns (4) and (5) under the heading of "other ingredients used", dextrose, water for injection and water for washing were indicated as pharmaceutical necessity for adjustment of isotonicity, diluent and washing G
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A of bottles respectively. Inasmuch as the material placed by the assessee before us does not relate to the classification list in question, namely 7/82, and as the Revenue is alleging that there has been suppression of fact, the burden is on the Revenue to show, by producing the actual classification list filed by the assessee, that there is no mention of 'dextrose' under column (4) and there has been suppression of fact. The original records received from the

B authorities which were placed before us did not contain the said classification list. We, therefore, passed an order on September 11, 2002 directing the Commissioner, Central excise, Nungambakkam High Court, Madras to send, by special messenger, all the original records relating to these appeals, including the classification lists from 1982-83 to 1985 and the audit report

C which formed the basis for issuing the show cause notice within two weeks from that day.

When the case was taken up on 23.1.2003, records were received in part from the Additional Commissioner (Legal), Chennai III, Commissionerate which did contain the documents called for. It was brought to our notice that

D the other records were sent to CEGAT and they had to be received from the CEGAT. The case was again adjourned, when the matter is taken up today, some records are received but the classification lists and the audit report, which were specifically called for, were not sent. In a matter like the one under consideration, it was the duty of the concerned authorities, particularly,

E the Commissioner/Collector, Central Excise, Madras to have pursued the matter diligently and place the record before us to support the allegation in the show cause notice that there has been suppression of the fact and that dextrose was not mentioned in the classification list 7/82. In the absence of production of such record, the burden cast on the Revenue to establish suppression of fact is not discharged. Consequently, it will not only be unfair

F and unsafe but also illegal to infer that there was suppression of fact. For these reasons, we are unable to approve the view taken by the Collector as well as the CEGAT that there has been such a suppression of material fact.

However, we asked the learned counsel appearing for the Revenue to point out from the record any finding by any authority that on verification of

G the original classification list, in column 4 thereof dextrose is not mentioned. He was unable to do so and, in deed, he could not have done so. Our perusal of the records also did not yield any fruitful result.

In this view of the matter, we are unable to uphold the finding that

H proviso to Section 11-A(1) of the Central Excise Act is attracted. The order

under challenge is set aside. The demand, insofar as it relates to the extended period, is also set aside. However, the authorities will be at liberty to raise a fresh demand of excise duty falling within the period of limitation under Section 11-A of the Act. A

The Appeals are accordingly allowed. B

There shall be no order as to costs.

R.P.

Appeals allowed.