CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL
NEW DELHI.

PRINCIPAL BENCH - COURT NO. II

Customs Appeal No. 50976 of 2021-SM

(Arising out of order-in-appeal No. IND-EXCUS-000-APP-095-2020-21 dated 30.12.2020 passed by the Commissioner (Appeals), Customs, CGST & Central Excise, Indore (M.P.).

M/s Medista Overseas — **Appellant**
M-34, Yashwant Plaza
Indore.

VERSUS

Commissioner, Central Excise & Central Goods and Service Tax — **Respondent**
Manik Bagh Palace
Post Box No. 10, Indore (M.P.)

APPEARANCE:

Sh. Rajnish Kumar Verma, Advocate for the appellant
Ms. Tamanna Alam, Authorised Representative for the respondent

CORAM:

HON'BLE MR. ANIL CHOUDHARY, MEMBER (JUDICIAL)

FINAL ORDER NO. 50019/2023

DATE OF HEARING: 10.08.2022
DATE OF DECISION: 10.01.2023

ANIL CHOUDHARY:

The appellant, M/s Medista Overseas is holder of license to manufacture drugs with the help of supporting manufacturer who is named in the license. Pursuant to manufacture, the appellant sells the pharmaceutical /drugs and mainly exports the goods. The appellant filed shipping bill No. 7099329 dated 16.04.2016 through EDI system for export of six drugs to overseas consignee M/s Bunty Pharmaceuticals, Monrovia, Liberia (West Africa). The details are as follows:-

Sr. No.	Drugs name	Quantity	Amount (in USD)	Supporting manufacturer
1	Ferozin Syrup 200 ML (B. No. LE6022 & LE6023)	10620	4035.60	M/s Zest Pharma
2	Amox-125 Oral Dry Syrup (B. No. DBE6007)	20000	4800.00	M/s Zest Pharma
3	Cold Clear Syrup 100 ML (B. No. LE6024 & LE6025)	15000	3750.00	M/s Zest Pharma
4	E-Mycin Suspension 60 ML (B. No. L-820)	14700	3969.00	M/s Medista Overseas
5	B-Co Syrup 100 ML (B. No. L-821)	13600	2176.00	M/s Medista Overseas
6	Sabtron Suspension 60 ML (B. No. L-842)	13600	2584.00	M/s Medista Overseas

2. It appeared to Revenue that there is legal requirement on the exporter to submit 'No Objection Certificate' (NOC) from the Regulatory Authority i.e. Drug Controller. As directed, appellant submitted the details with the Drug Inspector, Assistant Drug Controller (ADC), ICD Pithampur for obtaining NOC with respect to the aforementioned six drugs. The ADC observed that on inspection, it is found that name of manufacturer is mentioned as M/s Medista Overseas, Indore under manufacturing license No.25A/16/2013 dt. 19.07.2013 and manufacturing license No. 28A/14/2013 dt. 19.07.2013. However, address of Principal unit – M/s McW Healthcare Pvt. Ltd., Indore was missing on the drug at Sl. No. 4, 5 and 6 above. On enquiry Sh. Abhijeet Motiwale, Director of M/s McW Healthcare Pvt. Ltd., had stated that these drugs have not been manufactured and supplied by them to M/s Medista Overseas. The details of which are as follows:-

Sr No	Drugs Name	Batch No.	Mfg. date	Expiry date	Mfg. Lic. No.	Mfg. by
1	E-Mycin Suspension 60 ML	L-820	03/2016	02/2019	28A/14/2013 dt. 19.07.2013	Medista overseas, 416, Shankar Colony, Sant Marg, Gandhi Nagar, Indore-
2	B-CO Syrup 100 ML	L-821	03/2016	02/2019		
3	Sbtron Suspension 60 ML	L-842	03/2016	02/2019		

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3. As the three drugs appeared to be spurious as per Section 17B of the Drugs and Cosmetic Act, 1940, the ADC did not issue NOC.

4. Statement of Sh. Ajay Raisinghania, Prop. of the appellant was recorded on 27.04.2016. He stated that the export goods were as per the order placed by the overseas buyer. Further stated that the drugs under dispute namely E-Mycin Suspension, B-CO Syrup and Sabtron Suspension have been got manufactured by them under manufacturing license No. 28A/14/2013 dt. 19.07.2013 on the basis of loan license from M/s McW Healthcare, Indore. He further assured to produce the supporting documents like invoice, delivery challan, contract/ agreement and copy of manufacturing license.

5. The export consignment was seized under panchnama dt. 23.04.2016, it appeared to Revenue that the goods are liable to confiscation. The representative samples were drawn vide Test Memo No. 01/2016-17/Export dt. 23.04.2016 and handed over to the Drug Inspector vide letter dt. 30.04.2016 for testing purpose. The Drug Inspector submitted test report dt. 27.12.2016, forwarded the certificate of analysis & test report done by CDSCO, Mumbai. As per the report of the Government analyst E-Mycin (Erythomycin Estolate Oral Suspension USP, batch No. L-820) was found not of standard quality, while the other drugs namely B-CO Syrup and Sabtron Suspension were found of standard quality.

6. Subsequently, on request of Revenue the Dy. Drug Controller, Indore vide letter dt. 10.03.2017 informed that drugs

manufactured by the appellant which was meant for export vide Invoice No. 09-2016-BABA-BUNTY-LIB dt. 14.04.2016 are considered to be spurious drugs under Section 17B(e) of the Drugs and Cosmetic Act, as these drugs purport to be the product of manufacturer of whom it is not truly a product. Further correspondence with M/s McW Healthcare was also enclosed.

7. Thus, it appeared to Revenue that appellant have attempted to export spurious drugs as per report of the Drug Inspector valued at Rs.5,74,368/-, are liable for confiscation under Section 111 of the Customs Act. Accordingly, show cause notice dated 20.04.2017 was issued proposing to confiscate the goods valued at Rs. 5,74,368/- under Section 113(d) of the Customs Act with further proposal to impose penalty under Section 114 and 117 of the Act. It further appeared to Revenue that appellant have attempted to wrongly availed the benefit of duty drawback.

8. This is the second round of litigation. In the first round, the matter was remanded to the Commissioner (Appeals) with direction to hear the appellant and pass reasoned order. The appellant had filed reply to the show cause notice on 19.03.2019 inter-alia stating that the drugs meant for export have been treated spurious not on account of the drugs being unfit for human consumption, but on account of the fact that the supporting manufacturer whose name have been printed on the products refused to have manufactured the said product. The Drug Inspector have nowhere suggested that the product was unfit for human consumption and there was no such laboratory report. The Drug Inspector declared the export goods as spurious only on the ground that

the supporting manufacturer M/s McW Healthcare refused to have manufactured them. Further, for the purpose of export the drugs are required to meet the standards laid-down by the importing country. As per the Public Notice dated 11.12.2015 issued by the Drugs Controller General (India), Central Drugs Standards Control Organisation, New Delhi from F. No. DCGI/MISC/2015(199), the Government have decided that the requirement of "NOC" with respect to Shipping Bills from the Port offices of CDSCO for the export consignments shall not be insisted with effect from 01.01.2016. This was issued in pursuit to bring ease in the drug regulatory practices in India related to export of drugs, medical devices and cosmetics. Further provided that all the stakeholders are however required to comply with the regulatory requirements of the importing countries as per their specific need. A copy of the Public Notice was marked to various authorities including the Customs offices at the port/seasport/ airport. The appellant also produced copy of invoice wherein they have purchased drugs from supporting manufacturer M/s McW Healthcare. The appellant also produced copy of drug manufacturing license as mentioned hereinabove wherein M/s McW Healthcare have been shown as supporting manufacturer. The appellant also demonstrated from letter/ instructions issued by Joint Drugs Controller (India), CDSCO, West Zone, Mumbai, Ref. No. 198/WZ-2014/Medista Overseas/3681 dated 31.01.2014 where in the subject, name of certain drugs have been mentioned. By this letter "NOC" was issued to the appellant to manufacture the drugs formulations for export only against export order, subject to the condition that the drug will be manufactured by M/s McW Healthcare, Indore and shall test the drugs in the laboratory to be exported. Thus,

the appellant was a recognized manufacturer and exporter of pharmaceuticals/ drugs. Appellant annexed documents to this letter issued by the Joint Drugs Controller (India), inter-alia the name of the drugs presented for export as aforementioned. The appellant also produced certificate of pharmaceutical products issued by the licensing authority, Food and Drugs Administration, Madhya Pradesh, mentioning that the drugs meant for export to Liberia namely Sabron, certifying that the appellant is entitled to export the goods under dispute. The certificates are dated 21.09.2014. The appellant also produced free sale certificate dt. 30.11.2013 issued by the Licensing Authority, Food and Drugs Administration, M.P., certifying that appellant is holding valid manufacturing license which is valid upto 18.07.2018 to manufacture for sale and distribution of drugs for export freely, subject to the law and regulation of the importing country.

9. It was also contended by the appellant that as per Section 23 of the Drugs and Cosmetic Act, the prescribed procedure for declaring a product as spurious has not been carried out by the Drug Inspector and thus the findings are not conclusive and hence unreliable. Further, the report of the Government analyst was not brought on record and hence such opinion was fit to be rejected. Further, the Drug Controller has not taken steps to declare the goods spurious and initiate confiscation proceedings. Thus, the whole allegation is based on assumption and presumption. Further, no case is made out of claiming false product as the goods have been made in India for the purpose of export. The Joint Commissioner had adjudicated the show cause notice who vide Order-in-original dt. 22.06.2020 holding the goods to be

spurious based on the opinion of the Drugs Inspector and ordered absolute confiscation of the export goods and further imposed three times penalty of Rs.17,23,104/- under Section 114(i) of the Customs Act. Further, penalty of Rs. 10,000/- was imposed under Section 117 of the Customs Act.

10. Being aggrieved, the appellant preferred appeal before the ld. Commissioner (Appeals) reiterating the grounds taken before the Adjudicating Authority and also emphasizing, that in view of the aforementioned submissions, and admittedly no "NOC" was required to be obtained from the Drug Inspector. Admittedly, the appellant was entitled to freely export the goods, subject to meeting the standard of the importing country. However, the appeal was rejected.

11. Assailing the impugned order, ld. Counsel for the appellant Sh. Rajnish Kumar Verma inter-alia urges that it is evident from the Public Notice dt. 11.12.2015 issued by the Drug Controller General (India), that in the case of export by the appellant under the shipping bill dt. 16.04.2016, customs was not required to call for "NOC" from the Drug Inspector. The appellant was only required to comply with the regulatory requirement of all the importing country. Further, appellant have led sufficient evidence that they are licensed manufacturer, wherein M/s McW Healthcare are the supporting manufacturer, duly manufactured the drugs under manufacturing (loan) license. Further, the appellant have led evidence that they were regularly manufacturing for the purpose of export. Further, appellants are regular exporters and not fly by night operator. Further, the whole proceedings are vitiated

and there was no requirement for obtaining "NOC" from the Drug Controller. Accordingly, he prays for allowing the appeal.

12. Learned Authorised Representative Ms. Tamanna Alam appearing for the Revenue relies on the impugned order.

13. Having considered the rival contentions and on perusal of records and evidence led at the time of hearing, it is evident that there was no requirement of "NOC" from the Drug Controller in respect of export consignment vide Shipping Bill No. 7099329 dt. 16.04.2016 filed by the appellant for export of drugs to Liberia. Further, I am satisfied from the evidence led that the appellant was a genuine manufacturer duly licensed to manufacture and export of drugs. Further, even from the test report of CDSCO, Mumbai, out of the three drugs, two drugs namely B-CO syrup and Sabtron have been found to be of standard quality. Thus, I find that the whole proceedings by the Customs Authority for confiscation are vitiated. Accordingly, I set aside the impugned order and allow the appeal. The appellant is entitled to consequential benefits, in accordance with law.

(Order pronounced on 10.01.2023).

(Anil Choudhary)
Member (Judicial)

Pant