CUSTOMS, EXCISE AND SERVICE TAX APPELLATE TRIBUNAL MUMBAI

WEST ZONAL BENCH

CUSTOMS APPEAL NO: 86798 OF 2013

[Arising out of Order-in-Appeal No: RPS/56/NSK/2013 dated 25th February 2013 passed by the Commissioner of Central Excise & Customs (Appeals), Nashik.]

Commissioner of Central Excise & Customs
Kendriya Rajaswa Bhavan, Gadkari Chowk
Nashik - 442002 … ***Appellant***

versus

Mylan Laboratories Ltd
F-4 & F-12 MIDC Malegaon
Sinnar, Dist: Nashik ***…Respondent***

APPEARANCE:

Shri Ramesh Kumar, Assistant Commissioner (AR) for the appellant

Ms Y Siri Reddy, Advocate for the respondent

CORAM:

HON'BLE MR C J MATHEW, MEMBER (TECHNICAL)
HON'BLE DR SUVENDU KUMAR PATI, MEMBER (JUDICIAL)

FINAL ORDER NO: A/85876 / 2020

DATE OF HEARING:	24/02/2020
DATE OF DECISION:	24/02/2020

PER: C J MATHEW

For a chronicler of judicial decisions, from time to time, some few are, by giving cause to pause for return to the straight and narrow boundaries of legality, evocative of the natural instinct for rule of law. Notwithstanding the restricted remit of a departmental appellate authority - restricted not by law but by incumbency that, only for a time, is freed from executive authority - the first appellate authority has brought to focus the question of applicability of the framework of Customs Act, 1962 for determination of compliance with conditions imposed under other laws. Though an answer to the dispute may also be found within the facts and circumstances of the case laid before us, the appeal of Revenue against the impugned order, seeking resolution of legal aspects that the first appellate authority has relied upon to grant relief to the importer, requires us to exercise our minds in that direction too.

2. It is inevitable that any authority, principally concerned with specific aspects of enforcement, would, over a period of time, internalise that framework as inevitable in each and every situation. The respondent herein had imported goods that the original authority opined to be 'drugs' within the meaning of Drugs and Cosmetics Act, 1940 requiring compliance with certain conditions of import prescribed in Drugs and Cosmetics Rules, 1945 and, taking note of alleged breach, proceeded to invoke empowerment for confiscation under section 111(d) of Customs Act, 1962 with option to pay fine of ₹ 2,29,83,185 in *lieu* and for imposition of penalty of ₹ 4,59,66,370 under section 112 of Customs Act, 1962.

3. Customs Act, 1962, enacted particularly for assessment and collection of duties of customs on cross-border trade in goods, does enable imposing of prohibitions under section 11 besides providing for an elaborate structure of statutory and physical control for enforcement. Just as the exigencies of administration has devolved this authority upon officers appointed under the erstwhile Central Excise Act, 1944 owing to significant presence at several places, the border control establishment of customs had been found convenient for devolving authority under several other enactments that mandate control at source or from source to destination within the country. Such restrictions may be quantitative in character or may have been erected as 'non-tariff barrier' in pursuance of trade policy or for promotion of public safety. The detriment visited upon the importer by the original authority had its genesis in the law for control over imported 'drugs' and 'cosmetics' which, *inter alia*, was to be channelled only through locations specified in rule 43A of Drugs and Cosmetics Rules, 1945. Allegedly, the presentation of 'plasdone S-630' at CFS Ampad, Nashik was in breach of the said restriction warranting penal consequences.

4. On appeal, the impugned order, reflecting upon the classification of the goods under heading that did not, by any stretch, comprise 'drugs' in the pharmaceutical sense, held that the rigours prescribed in Drugs and Cosmetics Rules, 1945 would not apply and that, even if it did, substantive compliance, evidenced by certification on the part of

authority concerned, precluded resort to the detriment of confiscation and penalties under Customs Act, 1962. Objecting to this line of reasoning, the competent reviewing authority has sought the reversal of the decision for the restoration of the benchmark adopted by the original authority. Essentially, the grounds of appeal urge approval of resort to the familiar framework for implementation of that, which, with unabashed acknowledgement of primacy, are bundled together as ‘allied acts’, entrusted, for convenience of administration, to customs authorities. Without any intent of trivialising the plea, we may, nevertheless, perceive the similitude with the blanket of Linus Van Pelt that other characters, in the comic creation of Charles Schulz, led by the irrepressible Lucy, attempt to deprive him of without ever attaining final success as it tends to find its way back to its owner; so much so that another major perpetrator of such temporary abstractions, Snoopy, actuated by remorse on witnessing the palpable gratitude of Linus on restoration, remarks ‘Every now and then I feel that my existence is justified’. The appellant, apparently, expects us to be their Snoopy for penalising the imports effected against bills of entry no. 5561700/24.12.2011, no. 5648554/04.01.2012, no. 5946289/08.02.2012, no. 6167219/05.03.2012, no. 6530511/22.04.2012, no. 4434697/23.08.2011, no. 5561528/24.12.2011 and no. 6586333/09.01.2012 by setting aside order-in-in appeal no. RPS/56/NSK/2013 dated 25th February 2013 of Commissioner of Central Excise &

Customs (Appeals), Nashik.

5. The respondent, M/s Mylan Laboratories Ltd, is a unit approved under the '100% export oriented unit' scheme notified in the Foreign Trade Policy and the impugned consignments had been off-loaded at Nhava Sheva, the 'port of discharge' designated in the bills of lading, for onward transhipment to ICD/CFS Nashik, the designated 'place of delivery' in the bills of lading. On arrival at Nashik, the importer filed 'into bond' bills of entry as stipulated in section 46 of Customs Act, 1962 with no further record of clearance for home consumption in accordance with section 47 of Customs Act, 1962. However, from the submission of Learned Counsel for respondent that the goods are beyond confiscation owing to non-availability and their operation as 'export-oriented unit', it can be inferred that they had taken custody of the goods for deployment in production. At this stage, we take note of the operation of the scheme which will be relevant, in due course, to a finding on the factual matrix. The scheme envisages the units under the scheme to be accorded privilege of exemption from duties of central excise and duties of customs through appropriate notifications which, incidentally, require the manufacturing operations to be carried out under bond in accordance with section 65 of Customs Act, 1962. Not unnaturally, the units are licensed as 'private bonded warehouse' and imported goods are transferred to the warehouse on filing of 'into bond' bill of entry. The imported goods, once having undergone conversion,

are not required to be moved, even nominally, out of bond for home consumption and the finished products are cleared for export against shipping bill or, in the event of dispatch to the domestic market, on payment of duties under section 3 of Central Excise Act, 1944. It is only upon clearance of the imported goods as such, an improbable contingency, to the domestic market that an ‘ex-bond’ bill of entry for home consumption, as envisaged in section 47 of Customs Act, 1962, is filed and assessed. Hence, in the present instance, we are concerned with the detriment consequent upon filing of ‘into bond’ bill of entry that is not brought to a closure.

6. The first divergence between the first appellate authority and the reviewing authority is the ambit of Drugs and Cosmetics Rules, 1945 with the former holding that the classification under the appropriate tariff item for assessment has no connection with ‘drugs’ while the latter asserts that this is unacceptable by reason of the definition in section 3 of Drugs and Cosmetics Act, 1940 intended for wider inclusion than the headings in First Schedule to Customs Tariff Act, 1975 and which the impugned order, taking note of the certification by Assistant Drugs Controller, has itself taken cognizance thereof. Learned Authorised Representative submits that the impugned goods are branded products of the manufacturer and, citing catalogue material, draws attention to the use as ‘tablet binder’ in ‘denture cleanser tablets’ which is squarely covered by the definition of

> *'(b) "drugs" includes –*
>
> *(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on the human body for the purpose of repelling insects like mosquitoes;.....'*

in section 3 of Drugs and Cosmetics Act, 1940. Referring to circular no. 450/08/2007-Cus.IV dated 22nd January 2007 of Central Board of Excise & Customs, he further submits that the contents therein to the effect that

> *'the Central Drug Standard Control Organisation (CDSCO) is responsible for monitoring the quality of medicines manufactured, distributed, sold and imported into the country as per the provisions of the Drugs and Cosmetics (D & C) Act and Rules made thereunder. Chapter 3 of the Drugs and Cosmetics Act, 1940 deals with the control over drugs and cosmetics imported into the country....'*

not only highlights the criticality of such regulation but also accords recognition of the definition of 'drugs' in Drugs and Cosmetics Act, 1940. Learned Counsel for respondent has no specific counter-submission on this aspect.

7. The objectives of Drugs and Cosmetics Act, 1940 clearly includes control over standards of 'drugs' imported into India and containing, as it does, its own definition of 'drugs', the first appellate

authority was in error for attempting to benchmark the goods against a classification system intended for stipulating rates of duty for assessment under Customs Act, 1962. It is the definition in the regulatory statute should determine applicability of the regulatory regime. As to the coverage of the impugned goods within the meaning of section 3(b) of Drugs and Cosmetics Act, 1940 we desist from any speculation in the absence of any submission from either side on this aspect. The breadth of the definition compels such determination only by the competent authority under Drugs and Cosmetics Act, 1940 in the absence of specific devolution of such authority to customs officials coupled with ostensible want of domain knowledge. In the event of any doubt, it would be incumbent on the customs officials to defer to the expertise of the officers authorised under Drugs and Cosmetics Act, 1940. However, in the bills of entry filed for import of the impugned goods, we noticed that the description is followed by 'USP' which, we presume, is acknowledgement of its pharmacological provenance.

8. It is common ground that chapter III of Drugs and Cosmetics Act, 1940 has been legislated for regulating the standards of 'drugs' imported into India. To operationalise such regulation, it is, at times, administratively convenient to channelise imports through specified conduits which are in the nature of 'check post' and rule 43 A of Drugs and Cosmetics Rules, 1945 has enumerated such locations. As all goods and conveyances within the territorial waters of India are under the

supervisory and statutory control of the customs administration, it is incumbent on officers of customs to ensure that this is not deviated from. While the impugned order has held that landing of shipment at Nhava Sheva is sufficient compliance of this requirement, the reviewing authority contends that the intention of clearance at Nashik, which is not an enumerated place in rule 43 A of Drugs and Cosmetics Rules, 1945, suffices for confiscation under section 111 (d) of Customs Act, 1962. According to Learned Authorised Representative, the circular referred to *supra* has extracted the permissible list of locations from Drugs and Cosmetics Rules, 1945 and does not include the place at which the goods were sought to be cleared by the respondent. He argues that the positioning of competent authorities under Drugs and Cosmetics Act, 1940, as well as the risk of non-registration articulated in communication of Drugs Controller General of India, in no. 16/6-06-DC dated 15th June 2007, does not permit any latitude for leniency in this matter. He places reliance on the decision of the Tribunal in *Sadanam Personal Products v. Commissioner of Customs, New Delhi [2013 (287) ELT 455 (Tri-Del)]*. Learned Counsel for respondent contends that, while the circular referred to *supra* restricts import of ‘drugs’ through the places enumerated therein, the subsequent circular no. 8/2010-Cus dated 26th March 2010 clarifies the strict application thereof to ‘cosmetics’ in view of rule 133 of Drugs and Cosmetics Rules, 1945 while conceding that some flexibility is available for 'drugs' in view of schedule D of the said Rules read with rule 43 of Drugs and Cosmetics Rules, 1945 which has been further elaborated in the communication of Drugs Controller General of India referred *supra* thus

> *'….it was decided that at places where CDSCO offices already exist and clearances are being given at one place, the same officer of CDSCO can give NOC to other customers facilities at the same place. Other ICDs can also be administratively allocated to existing office of CDSCO for giving NOC to imported drugs consignments and customs would permit clearances only on the basis of NOC issued by ADC.'*

Reliance is also placed by her on the decision of the Tribunal in *Gaurav Pharma Pvt Ltd v. Commissioner of Customs, Ghaziabad [2013 (292) ELT 121 (Tri-Del)]*.

9. While the decision in *re Sadanam Personal Products* has been handed down in the context of import of 'cosmetics' which, as we have seen, does not admit of any flexibility in place of import, the decision in *re Gaurav Pharma Pvt Ltd* pertains to clearance of 'drugs' through ICD, Loni in which the assigning of other locations by the communication of Drugs Controller General of India referred *supra* was taken note of along with the approval issued by Assistant Drugs Controller to accord legitimacy to such imports. Furthermore, the decision in *re Sadanam Personal Products* did not take into cognizance the entire scheme of regulation of imports contemplated in chapter III

of Drugs and Cosmetics Act, 1940 as well as rule 38, rule 39, rule 40 and rule 41 of Drugs and Cosmetics Act, 1945 which elaborate upon the role of customs officials in the matter of import of ‘drugs’ into India. Likewise, section 11 of Drugs and Cosmetics Act, 1940 specified the powers of officers of customs for the enforcement of the statute. In section 3 of Drugs and Cosmetics Act, 1940, we find that

> *‘(g) “to import”, with its magical variations and cognate expressions means to bring into India;’*

A comprehensive enactment that carries its own meaning of ‘import’ does not have to take recourse to the definition of ‘import’ in the principal statute of customs officers while discharging statutory authority in relation to import of ‘drugs’ under Drugs and Cosmetics Rules, 1945. The closure accorded to ‘imports by ‘clearance of goods’ for the purpose of assessment is not relevant for propping up ‘to import’ in the regulation of imported ‘drugs’ within the country. Moreover, the scope and extent of restricting import through the locations specified in the rule 43 A of Drugs and Cosmetics Rules, 1945 has been adequately elaborated in the communications of the competent authority under those Rules. That the concerned officials at the locations specified in rule 43 A of Drugs and Cosmetics Rules, 1945 are empowered to allow movement thereon to other locations for clearances under Customs Act, 1962 is unambiguously clarified. It is, therefore, not within the competence of customs authorities to exercise monitorial oversight over the enforcement of Drugs and Cosmetics Act, 1940, and the Rules framed thereunder, by designated officials nor to deny legitimacy of approvals granted by such competent authorities merely for the dubious satisfaction of visiting detriments on importers. Consequently, unless any breach thereof is brought to the knowledge of the proper officer of customs by competent authorities under Drugs and Cosmetics Act, 1940, the invoking of section 111 of Customs Act, 1962 is without authority of law. Reliance on the framework of Customs Act, 1962 for determination of breach of Drugs and Cosmetics Act, 1940 and the Rules framed thereunder is not correct in law. The entry of the impugned goods into the country through Nhava Sheva, a permitted location, has been duly acknowledged by the Assistant Drugs Controller before allowing it to be moved to place of delivery which is not restricted, by the Rules, to one of the enumerated locations. This finding suffices to dismiss the appeal of Revenue.

10. It has been brought to our notice by Learned Counsel, as also noted in the impugned order, that the goods had been transferred to CFS Nashik only upon the specific 'no objection certificate' granted by the Assistant Drugs Controller in charge of Nhava Sheva. There cannot be any doubt that the prescriptions in Drugs and Cosmetics Rules, 1945 are intended for registration to ensure regulatory supervision by the authorities empowered therein; with the competent authority under those Rules having approved the transhipment, and subsequent

utilization, at a place other than that enumerated in rule 43 A of Drugs and Cosmetics Rules, 1945, the need for further monitorial supervision by customs authorities under Drugs and Cosmetics Act, 1940 is obviated.

11. The goods are, admittedly, intended for use in manufacture by '100% export oriented unit' and, for such units, imported goods are procured against 'into bond' bill of entry which are then subject to processing in accordance with the Rules framed, and for supervision of facilities licenced, under section 65 of Customs Act, 1962. Therefore, unlike other warehousing procedures, clearance against 'ex bond' bill of entry for home consumption is restricted only for removal as such with clearances undergoing the procedure prescribed under Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. Consequently, the pre-requisites for clearance of goods for home consumption, *viz.*, ascertainment of payment of duties and ascertainment of any prohibition on import, prescribed in section 47 of Customs Act, 1962, are not intended to impact the goods procured from abroad by units operating under the scheme. Therefore, the invoking of section 111 of Customs Act, 1962 on such goods brought into the bonded premises of '100% export oriented units', such as that of the respondent, is not within the scope of legislative intent. The initiation of proceedings against the respondents herein, therefore, does not have the sanction of law.

12. The impugned order cannot be faulted for setting aside the confiscation and penalty ordered by the original authority. Accordingly, we find no merit in the appeal of Revenue which is dismissed.

(Pronounced in open court)

(Dr. Suvendu Kumar Pati)
Member (Judicial)

(C J Mathew)
Member (Technical)

**/as*