IN THE HIGH COURT OF SINDH, KARACHI

C.P.No.D-3049 OF 2023

Date Order with signature of Judge

Present:
Mr. Justice Aqeel Ahmed Abbasi.
Mr. Justice Abdul Mobeen Lakho.

Popular International (Pvt) Limited .....Petitioner

Versus

Pakistan & another .....Respondents

Date of hearing 06-11-2023

M/s.Makhdoom Ali Khan, Abdul Ghaffar Khan, Fahad Khan and Sami-ur-Rehman, Advocates for the Petitioner.
Mr.Muhabbat Hussain Awan, Advocate for Respondent No.1.
Mr.Khaleeq Ahmed, D.A.G.

O R D E R

Abdul Mobeen Lakho-J, Through instant petition, the petitioner firm who is engaged in the business of import and distribution of drugs, has expressed its grievance against issuance of the SRO 526 (1)/202, whereby, concessionary sales tax rate prescribed under Entry 81 of the Eighth Schedule to the Sales Tax Act, 1990 for imports of 'sutures' at the rate of 1% has been declined to the petitioner, following relief has been sought:-

(i) Declare that Notification SRO 526(1)2021 dated 30.04.2021 issued by DRAP under DRAP Act, 2012, cannot deny the benefits available to the Petitioner under Entry 81 of the Eighth Schedule to the Act, 1990

(ii) Declare that the benefits of the Act, 1990, available to the Petitioner can only be denied on the basis of the change in the Act, 1990, and not through subordinate legislation.

(iii) Declare that the Respondent No.1's denial of the benefits of Entry 81 of the Eighth Schedule of the Act-1990 for the Petitioner's import of sutures is without lawful authority.

(iv) Quash the online list created by the Respondent No.1 towards the recoverable amounts of sales tax and income tax Annex "K"

(v) Direct the Respondent No.1 to allow the Petitioner to clear its consignments under Entry 81 of the Eighth Schedule of the Act, 1990.

(vi) Prohibit the Respondents and the officers of customs, jointly and severally and directly as well as indirectly through their servants, officers and assign from taking any coercive/adverse action including but not limited to blocking of PSW ID of the Petitioner for the recovery of sales tax and income tax (Annex "K") on the consignments already cleared with the benefits of Entry 81 of the Eighth Schedule to the Act, 1990.

2. Pursuant to Court's notice comments have been filed on behalf of the respondent, wherein, it has been stated that after issuance of SRO under reference 'sutures' is categorized as 'Medical Device' and before issuance of the said SRO 'sutures' were declared as 'Drug' under Drugs Act, 1976, therefore, after categorization of 'sutures' as Medical Device @ chargeable Sales Tax on statutory rate of 17% or 18% as the case may be instead of concessionary rate of 1% in terms of Entry 81 of the Eighth Schedule to the Sales Tax Act, 1990, which is only meant for 'Drugs'. Thus, the benefit was rightly denied in conformity with SRO ibid since November, 2022. It has been further stated that the Federal Government is fully empowered to declare any item in "Medical Device' through notification in the official Gazette. It is further stated that since October, 2022 all the Collectorates of Customs are charging Sales Tax on statutory rates in respect of consignments of 'sutures', but the petitioner did not file any petition against charging on statutory rates, however, after display of Board's notice for recovery of short levied amount of Sales Tax and Income Tax in respect of consignments of 'sutures' cleared after issuance of SRO in question, therefore, the stance of the petitioner portrayed in this petition is untenable, thus, this petition is liable to be dismissed.

3. Learned counsel for the petitioner argued that the petitioner is importing sutures as a drug under PCT Heading 3006.1090 without any objections as to its classification and Section 3 (2)(aa) provides as under:-

> "3(2)(aa) 'goods specified in the Eighth Schedule shall be charged to tax at such rates and subject to such conditions and limitations as specified therein."

Whereas, Entry 81 of the Eight Schedule to the Act-1990 provides as under:-

Sr.No.	Description	Heading Nos. of the First Schedule to the Customs Act, 1969 (IV of 1969)	Rate of Tax	Condition
81.	Manufacture or import of substances registered as drugs under the Drugs Act, 1976 (XXXI of 1976)	Respective Heading	1%	(i) Tax charged and deposited by the manufacturer or importer, as the case may be, shall be final discharge of tax in the supply chain ii) No input tax shall be adjusted by the manufacturer or import

therefore, the petitioner is entitled to benefit of Entry 81 of the Eighth Schedule of the Act, 1990, which was accordingly extended to it on the import of sutures. Learned counsel for the petitioner further argued that to qualify under Entry 81, the petitioner's import i.e. sutures must be registered as drugs under the Drugs Act, 1976 and this condition confers the right to the concessionary rate of tax under Entry 81, which is enough to grant the relief to the petitioner. But in November, 2022, the benefit was denied and the petitioner was required to pay Sales Tax at the rate of 17% on the basis of SRO 526(1)2021 dated 30.04.2021 issued by DRAP treating the 'sutures' as medical Device under its Schedule "E". Learned counsel for the

petitioner argued that the said SRO does not change the status of the 'sutures' as drug under the Drugs Act, 1976 and even under the DRAP Act, 2012 'sutures' are not termed as medical device. Learned counsel further argued that SRO 526(1)2021 amends the Medical Devices Rules, 2017, with the title 'List of Medical Devices' and "Sutures" are found at Serial No.9 of Schedule E to deny the benefit of Entry 81, which reliance is completely without lawful authority. Learned counsel further argued that neither the Drugs Act nor the DRAP Act, 2012 state that the definition of "drugs" and "medical devices" are mutually exclusive of each other. He further argued that Schedule "E" has been issued under Rule 52 of Medical Devices Rules, 2017 which itself draws its power from Section 36 of the DRAP Act, which pertains to removal of difficulties that in case of any difficulty arises in giving effect to any of the provisions of the Act, the Federal Government may make such order by notification in the Gazette Official, but this clause can only be utilized for a limited purposes to introduce machinery where there is a genuine issue of implementation whereas, as per Section 3(g)(ii) of Drugs Act, 1976 "sutures" comes within the definition of "drug" and the petitioner can only be denied the concession on the basis of the change in the Act, 1990 and not through subordinate legislation. Learned counsel further argued that Section 32 of the DRAP Act states that its provisions are to be read in addition to and not in derogation of the provisions of the DRAP Act.

4. Learned counsel also argued that the Customs Department is acting discriminatorily against the petitioner by allowing the benefit of Entry 81 to other importers on the import of "sutures" but denying the same relief to the petitioner. Learned counsel also attached customs data along with written synopsis showing the clearance of various consignments of "sutures" with the benefit of Entry 81.

Summarily, learned counsel for the petitioner argued that 'sutures' is registered as drugs under the Drugs Act, 1976 and there is no dispute of classification. Per learned counsel, the issue involved in the petition is also issue of general public importance and the benefit available to the petitioner under Entry No.81 of the Eighth Schedule to the Act, 1990 to the extent of 'sutures' cannot be denied unless there is an amendment in Section 3(g) of the Drugs Act, 1976. In support of his arguments, learned counsel for the petitioner has placed reliance on the following case law:-

(1) 2023 PLD SC 609 (Government of Balouchistan……v……Shah Muhammad)

(2) 2022 SCMR 1787 (Farrukh Raza Sheikh…..v……The Appellate Tribunal, Inland Revenue & others)

(3) PLD 2021 Sindh 492. (Abbu Hashmi…….v…….Federation of Pakistan & others)

(4) 2019 SCMR 282. (Messrs PAKISTAN TELEVISION CORPORATION LIMITED…..v….COMMISSIONER INLAND REVENUE (LEGAL) LTU, ISLAMABAD and others.)

(5) 2017 SCMR 1136 (Messrs PAKISTAN TELEVISION CORPORATION LIMITED…..v…….COMMISSIONER INLAND REVENUE (LEGAL), LTU, ISLAMABAD and others.)

(6) 1997 PLD 582 (Elahi Cotton Ltd…..v……Federation of Pakistan.)

(7) PLD 1990 Lahore 121. (Ittefaq Foundry…..v…..Federation of Pakistan & others.)

5. Conversely, learned counsel for the Respondent No.1 as well as learned D.A.G. vehemently opposed such contention of the learned counsel for the petitioner and argued that in exercise of powers conferred under Section 23 of the DRAP Act, 2012, the Drug Regulatory Authority with the approval of Federal Government can make amendment in the Medical Devices Rules, 2017 and the SRO in question was issued in the light of aforesaid provisions of DRAP Act, 2012. They argued that under the DRAP Act, 2012 sutures are regulated as 'medical devices' and not 'drugs' as defined under the Drugs Act, 1976 and this definition has over riding effect over the

definition of 'drugs' as contained in the Drugs Act, 1976. Per learned counsel for the respondents as well as D.A.G. the DRAP's regulatory influence extends over 'Therapeutic Goods' which under Section 2 (xxxvi) includes within its ambit 'drugs' and 'medical devices' and it emphasized here that under Section 32(2) of the DRAP Act, 2012, it shall have an over-riding effect in case it is in conflict with the Drugs Act, 1976 (or any other law). Per learned counsel for the Respondents as well as learned D.A.G. Medical Devices Rules, 2017 defines and regulates the 'sutures' as medical devices, which are different and distinct from 'drug' as defined under the Drugs Act, 1976. They further argued that Schedule "E" was specifically inserted in the Medical Devices Rules, 2017, which clarifies that the 'sutures' were previously defined or declared as drugs but now fall within the regulatory regime of Medical Devices under the DRAP Act, 2012, therefore, the benefit of Entry 81 of the Eighth Schedule to the Sales Tax Act, 1990 was rightly denied in conformity with SRO in question and the custom department wants recovery, but the petitioner has paid the short levied amount of sales tax after filing the instant petition. In support of their arguments, learned DAG and learned counsel for the Respondent No.1 have placed reliance on the following case law:-

(1) PLD 2021 Lahore 314 (Johnson & Johson Pakistan (Pvt.) Limited v. Federation of Pakistan).
(2) 2019 CLC 1761 (PMDC v. Shahida Islam Medical Complex (Pvt.) Limited

6. Heard learned counsel for the parties and perused the material zooming out of the situation, it appears that the petitioner was availing relaxation in tax rate, but the Respondent while exercising powers under Section 23 of the Drug Regulatory Authority of Pakistan Act, 2012, which provides that "*The Authority may, with the approval of the Federal Government by notification in the official Gazette make rules for carrying out the purposes of this Act.*" issued

S.R.O.526/(1)2021 made amendment in Rule 52 of the Medical Devices Rules, 2017, to change the status of 'sutures' as 'Medical Device' in terms of Section 36 of the DRAP Act, 2012. The DRAP Act, 2012 was promulgated "*to establish a Drug Regulatory Authority of Pakistan to provide for effective co-ordination and enforcement of The Drugs Act, 1976 and to bring harmony in inter-provincial trade and commerce of therapeutic goods*." Whereas, under Section 3(g)(ii) of the Drugs Act, 1976, which reads as under:-

> **"3 (g)(ii) abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatin capsules and antiseptic solution."**

The 'sutures' falls within the definition of 'drug', therefore, Entry 81 of the Eight Schedule to the Sales Tax Act, 1990 'sutures' were treated as drug. The impugned S.R.O.526/(1)2021 is reproduced as under:-

"GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 30th April, 2021

NOTIFICATION

S.R.O. 526(1)2021:- In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with approval of the Federal Government, is pleased to make the following amendments in the Medical Devices Rules, 2017, namely:-

In the aforesaid Rules:-

(1) for rule 52, the following shall be substituted, namely:-

"**52. Exemption from operation of the rules:**- (1) The medical devices specified in column (2) of the Table below shall, in terms of section 36 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and from commencement of these rules, be exempted from the operation of these rules for a period as specified in column (3) thereof, namely:-

TABLE

Sr.	Class of medical device	Exemption period
(1)	(2)	(3)
1	Class D medical devices	Till the 31st day of March, 2022
2	Class C medical devices	Till the 30th day of June, 2022
3	Class B medical devices	Till the 30th day of September, 2022
4	Class A medical devices	Till the 31st day of December, 2022

Provided that the exemption shall be applicable only to the establishment license holders either as importer or local manufacturer under these rule.

Provided further that the imported consignment of the devices and raw materials of above mentioned licensed importers and manufacturers may be released by Pakistan Custom till the validity of exemption period after ensuring the submission of following documents, namely:-

(i) for clearance of class A medical device from Pakistan Customs, it is mandatory for importer to submit notarized ISO 13485 and notarized letter of authorization from manufacturer abroad along with any of the following documents, namely:-

(a) notarized free sale certificate from country of origin; or
(b) notarized declaration of conformity from manufacturer abroad; or
(c) notarized production or full quality assurance certificate (CE-marking certificate) from conformity assessment body CAB);

(ii) for clearance of class B, C or D medical device from Pakistan Customs, it is mandatory for importer to submit notarized ISO 13485 and notarized letter of authorization from manufacturer abroad along with any of the following documents, namely:-

(a) notarized free sale certificate from country of origin along with declaration of conformity, full quality assurance certificate (CE-marking certificate) from CAB. However, for class D medical device, design examination certificate shall be mandatory; or
(b) notarized free sale certificate from any of the reference countries i.e., USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom; or
(c) notarized free sale certificate from country or origin along with WHO prequalification status; and

(iii) for clearance of raw materials for local manufacturing of medical device from Pakistan Customs, a valid establishment license to manufacture medical devices locally issued under these rules.

(2) The exemption in sub-rule (1) shall not be applicable to the life-saving or life-sustaining medical devices specified in Schedule-D and Schedule-E.”; and

(II) after Schedule-D, the following new Schedule shall be inserted, namely;-

“SCHEDULE E

[see rule 52]

LIST OF MEDICAL DEVICES WHICH WERE PREVIOUSLY DEFINED OR DECLARED AS DRUGS UNDER THE DRUGS ACT, 1976

1. **Auto-disable and disposable syringe;**
2. **Cannula;**
3. **Disposable sets of collection or transfusion of blood or giving any infusion;**
4. **Catheter;**
5. **Butterfly needle;**
6. **Stent;**
7. **Abortive and contraceptive device;**
8. **Surgical ligature;**
9. **Suture;**
10. **Bandage; and**
11. **Absorbent cotton.”.**

[No. F.10-1/2020-MD]

Sd./-
AAMAR LATIF,
Deputy Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad."

Having a glance on Section 36 of the DRAP Act, 2012, which provides as under:-

> "**36. Removal of difficulties.** If any difficulty arises in giving effect to any of the provisions of this Act, the Federal Government may make such order by notification in the Official Gazette, not inconsistent with provisions of this Act, for the purpose of removing the difficulty."

It is settled law that 'removal of difficulties' clause can only be utilized for a restricted purpose and such provision cannot be used to alter the scope of parent law. The answer to the arguments advanced by learned counsel for the respondents with regard to over-riding effect of DRAP Act, 2012 in case it is in conflict with Drugs Act, 1976 (or any other law), the Section 32 of DRAP Act, 2012 itself provides that its provisions to be read ***"in addition to and not in derogation of the provision of Drugs Act, 1976",*** meaning thereby that Section 32 completely restricts from and or making amendment to change the nature and outlook of the provisions of Drugs Act, 1976 including the terms and definitions already given under such law, therefore, pursuant to aforesaid S.R.O. concessionary tax rate prescribed under Entry 81 of the Eight Schedule to the Sales Tax Act, 1990 for its imports of 'sutures' to pay sales tax at the rate of 1% has been denied, which raises the following question to be examined:-

> "Whether an authority can strike down the statutory provisions by notifying rules in disharmony of the said provisions? OR Can rules have an overriding effect over the Act/statutory law?

7. Rules are considered subordinate and delegated legislation deriving authority and legal cover from the provisions of the main statute and cannot override the provisions of the Statute. To determine the vires of delegated legislation, the Court has to examine as to whether, such delegated legislation was beyond

the power granted by the enabling legislation and whether such delegated legislation was consistent and in furtherance with the parent statute. It is settled rule of interpretation that the delegated legislation can be struck down if it was repugnant to general purpose of the statute which authorized it or was in conflict with the main statute.

8. The Honourable Supreme Court of Pakistan in its numerous judgments has held that, it is axiomatic that Rules being subordinate or delegated legislation, are framed under the authority of the parent statute, and are therefore subservient to the primary legislation. Rules cannot contradict or add to the clear provisions of the parent statute. The Honourable Court also held that it is trite law that Rules cannot override the specific provisions of the parent statute. The Rules are to carry out the purposes of the Ordinance and cannot offend, oppose or be inconsistent with the provisions of the parent statute (Ordinance in this case). Any rule, to the extent of any inconsistency with the parent statute is, therefore, ultra vires of the parent statute. In two different Suo Moto Cases reported as ***PLD 2014 SC 389, & PLD 2011 SC 619*** the Supreme Court of Pakistan discussed this point in detail as under:-

> "25. It must be kept in view that "when the legislature confers power on Government to frame rules it is expected that such powers will be used only bona fide, in a responsible spirit and in the true interest of the public and in furtherance of the object for the attainment of which such powers, were conferred". (Land Realization Co. Ltd. v. Postmaster-General (1950) 66 TLR (Pt. 1) 985, 991, per Romer, J. (1950) Ch. 435. It is to be noted that rule-making authority which falls within the ambit of subordinate legislation as conferred upon the Government by virtue of section 191 of the Ordinance is neither unlimited nor unbridled and the limitations as mentioned in section 191 of the Ordinance must be adhered to in letter and spirit.
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> 29. It is a well-recognized principle of interpretation of statutes that if the rules framed under the statute are in excess of the provisions of the statute or are in contravention

of or inconsistent with such provisions then those provisions must be regarded as ultra vires of the statute and cannot be given effect to. (Barisal Cooperative Central Bank v. Benoy Bhusan AIR 1934 Cal.537; Municipal Corporation v. Saw Willie, AIR 1942 Rang 70, 74)".

30. In the case of statutory rules the Court can always examine the question as to whether the same are inconsistent with the statute under which they are made. In this regard we are fortified by the dictum laid down in Hazrat Syed Shah Mustarshid Ali Al-Quadari v. Commissioner of Wakfs AIR 1954 Cal. 436.

31. A rule-making body cannot frame rules in conflict with or derogating from the substantive provisions of the law or statute, under which the rules are framed. No doubt that the rules-making authority has been conferred upon the Government but "a rule, which the rule-making authority has power to make will normally be declared invalid only on the following, grounds:

(1) Bad faith, that is to say, that powers entrusted for one purpose are deliberately used with the design of achieving another, itself unauthorized or actually forbidden;
(2) that it shows on its face a misconstruction of the enabling Act or a failure to comply with the conditions prescribed under the Act for the exercise of the powers; and
(3) that it is not capable of being related to any of the purposes mentioned in the Act. (Shankar Lal Laxmi Narayan Rathi v. Authority under Minimum Wages Act), 1979 MPLJ 15 (DB).

Rules cannot go beyond the scope of the Act M.P. Kumaraswami Raja AIR 1955 Mad. 326 nor can they, by themselves, enlarge the scope of statutory provisions. K. Mathuvadivelu v. RT Officer, AIR 1956 Mad. 143. They cannot also militate against the provision under which they were made. (Kashi Prasad Saksena ro. State of U. P. AIR 1967 All. 173.

32. There is no cavil with the proposition that "the power of rule making is an incidental power" that must follow and not run parallel to the present Act. These are meant to deal with details and can neither be a substitute for the fundamentals of the Act nor can add to them. PLD 1975 Azad J&K 81. There are two main checks in this country on the power of the Legislature to delegate, these being its good sense and the principle that it should not cross the line beyond which delegation amounts to abdication and self-effacement. The only requirement of law in such situations is to insist that the subordinate body charged with the duty of making rules must strictly confine itself within the sphere of its authority for the exercise of its subordinate legislative power and in each case it is the duty of the Courts in appropriate proceedings to be satisfied that the rules and regulations so made are:-

(a) by the authority mentioned in the Act, and
(b) that they are within the scope of the power delegated therein. (PLD 1966 Lah. 287).

9. It is well settled legal position that Rules which are merely subordinate legislation, cannot override or prevail upon the provisions of the parent Statute, and whenever there is any inconsistency between a Rule and the Statute, the latter must prevail. This, however, envisages that all efforts to reconcile the inconsistency be made and the provisions of the parent Statute shall prevail, if the conflict is incapable of being resolved.

10. In view of the dictum laid down in case law cited above, instant petition was allowed vide short order dated 06.11.2023 and above are the reasons.

Judge

Chief Justice

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