IN THE HIGH COURT OF SINDH, AT KARACHI

C. P. No. D-4425 of 2021

Present:
Ahmed Ali M. Shaikh, CJ
and Yousuf Ali Sayeed, J

Petitioner	:	M/s. Medisure Laboratories Pakistan (Pvt.) Limited through Abdul Sattar Pirzada & Mamoon N. Chaudhry, Advocates.
Respondent No.1	:	Federation of Pakistan through Khaleeque Ahmed, DAG along with Mukhtiar Ali Junejo, Assistant Attorney General.
Respondent No.2	:	The Drug Regulatory Authority of Pakistan (DRAP) through Syed Muhammad Ghazanfar, Advocate, alongwith Hafiz Bilal and Shoaib Khan, A. D Legal Affairs.
Respondents No.8 & 9	:	M/s. Collector of Customs Model Customs Collectorate, Jinnah International Airport & Appraisement West, Karachi through Muhabbat Hussain Awan, Advocate.
Respondent No.10	:	M/s. Collector of Customs Model Customs Collectorate, Appraisement East, Customs House, Karachi through Javed Hussain, Advocate
Date of hearing	:	17.03.2022.

JUDGMENT

YOUSUF ALI SAYEED, J - The Petitioner is a manufacturer of pharmaceutical products, operating in the regulatory domain of the Drug Regulatory Authority of Pakistan (the "**Authority**") under the Drug Regulatory Authority of Pakistan Act 1997 (the "**DRAP Act**"), the Drugs Act, 1976 (the "**Drugs Act**") and the Drugs (Import & Export) Rules, 1976 (the "**Rules**").

2. As part of its product range, the Petitioner *inter alia* manufactures a painkiller containing the molecule Tramadol HCI ("**Tramadol**"), which is marketed in tablet form in varying degrees of dosage/strength under the name 'Tramaking', including Tramaking 225 mg ("**T-225**").

3. The Petitioner apparently transacted to export a consignment of 10,000 packs of T-225 having an invoice value of USD 1450/- to an importer in Nigeria (the "**Subject Consignment**"), and submitted an Application dated 23.06.2021 to the Authority for its permission in that regard, as necessarily required to be obtained in terms of the Rules.

4. However, instead of issuing the desired NOC, the Authority responded through its letter bearing No. F-01-04/2021-DRAP(K)-AD-V dated 30.06.2021 (the "**Impugned Letter**"), which reads as follows:

"NO. F-01-04/2021-DRAP (K)-AD-V
GOVERNMENT OF PAKISTAN
DRUG REGULATORY AUTHORITY OF PAKISTAN
2ND FLOOR US AID BUILDING No.4-BLOCK-B
SMCHS, KARACHI

Karachi, the 30th June, 2021

M/s Medisure Laboratories Pakistan (Pvt), Limited
A-115, S.I.T.E-II Super Highway,
Karachi.

SUBJECT:- **EXPORT OF TRAMAKING 225MG TABLET (TRAMADOL) TO NIGERIA.**

I am directed to refer to your application on subject cited above received on 29th June, 2021.

You are hereby directed to submit the copy of registration of your product Tramaking 225mg (Tramadol) Tablet in importing country, Nigeria and also submit the clearly signed copy of purchase order from buyer.

An early submission will help in early disposal of case.

(KIRSHAN)
Assistant Director-V
DRAP, KARACHI"

5. In the wake of that communique, the Petitioner invoked the Constitutional jurisdiction of this Court, praying that the issuance of the Impugned Letter and refusal of the Respondents No. 2 to 5 to issue the NOC in respect of the export of the Subject Consignment be declared illegal, unlawful and unconstitutional and of no legal effect, and that the Respondents be directed to issue the same forthwith.

6. Learned counsel for the Petitioner submitted that several consignments of T-225 had been exported by the Petitioner to Nigeria from time to time with the permission of the Authority, hence the transaction for the Subject Consignment had been entered into during the routine course of business, however, when the particular application was made to the Authority for grant of permission in that regard, the same was unwarrantedly withheld under the garb of the Impugned Letter. It was argued that through the Impugned Letter, the Authority had sought to impose and apply an extraneous and

irrelevant consideration in the shape of the registration of T-225 in Nigeria. He argued that the application of the Petitioner had been complete in all respects as per the requirements prevailing at the time of its submission, which did not include any proof of registration in the importing country, thus the requisite NOC accordingly ought to have been issued as per established past practice. It was pointed out that the Petitioner had similarly applied for the issuance of NOCs in respect of certain batches of the aforementioned products, which were consistently and regularly issued by the relevant functionaries of Respondent No.2, without any let or hindrance, yet in the matter of the Subject Consignment a new requirement had additionally been imposed. It was argued that the Respondents were estopped by virtue of past practice and the principle of consistency from refusing to issue the NOC in favour of the Petitioner, and such act on the part of the Respondents was tantamount to placing an arbitrary, illegal and unreasonable restriction on the Subject Consignment. It was submitted that a vested right had been created in favour of the Petitioner by virtue of past practice and the Respondents could not arbitrarily resile therefrom. He placed reliance on the judgments of the Honourable Supreme Court in the cases reported as Manzoor Ali & others v. United Bank Limited, reported at 2005 SCMR 1785; M/s Radaka Corporations v. Collector of Customs and another 1989 SCMR 353; and Muhammad Tariq Badr & another v. National Bank of Pakistan & others 2013 SCMR 314. Attention was also drawn to a letter of the Respondent No.2 dated 02.08.2021, wherein it was *inter alia* mentioned that:

> "the Committee also decided that matters related to import and export of Tramadol shall be processed as per previous practice following the Drug Import and Export Rules, 1976 until Federal Government grants approval for their inclusion in the Schedule of Control of Narcotic Substances, Act 1997."

7. On the other hand, learned counsel for the Authority argued that the mere filing of an application for the grant of permission/NOC did not vest any right in the Petitioner, and a change in the relevant policy during the pendency of an application would not mean that the same was being applied retrospectively. It was pointed out that the particular change requiring the provision of additional information for the export of T-225 had been initiated by the Authority in its 112th Meeting held on 24.06.2021 and confirmed at its 115th Meeting held on 27.07.2021 (collectively, the "**Meetings**"). It was stated that this change had been made in view of it being brought to the attention of the Authority by the United Nations Office on Drugs and Crime ("**UNODC**") that there had been a sudden and sharp increase in the exports of T-225 to Nigeria by a commercial exporter, sourced from the Petitioner and another manufacturer, where the labelling and packing of consignments lacked certain necessary information on the packaging, which fit the pattern for the illicit trade in Tramadol for non-medical usage in that country.

8. Attention was drawn to the cautionary letters dated 21.05.2021, 15.06.2021 and 22.06.2021 addressed by the Assistant Director — V, DRAP Karachi to the concerned quarter within the Authority, as well as the Minutes of the Meetings, with it being argued that the additional information called for from the Petitioner, viz – the registration of T-225 in Nigeria and a signed copy of the importers purchase order, had a clear and direct nexus with the regulatory function to statutorily be served by the Authority and the requisition of those documents for purpose of processing the application for the requisite NOC was neither onerous nor unreasonable, and did not serve to place a clog on the Petitioner's right to carry on business.

9. It was argued that the Petitioner had not challenged the validity of the decisions taken by the Authority in either of the Meetings, whereby the requirement of additional documents has been imposed for issuance of an NOC to export T-225, and the Petition was even otherwise premature, as the application of the Petitioner for the issuance of a NOC had not yet been decided, and it had been wrongly claimed that the same had been refused by the Authority. Furthermore, as and when a final order was made, the Petitioner, if aggrieved, had an adequate remedy under Section 9 of the Drugs Act, 1976 before the Appellate Board. Reliance was placed on the judgment of the Honourable Supreme Court in the case reported as Government of Pakistan through Secretary, Ministry of Commerce v. Zami Ahmad Khan PLD 1975 SC 667 as well as a judgment of the Supreme Court of India reported as P.T.R. Exports (Madras) Pvt Ltd. & Ors v. The Union Of India & Ors (1996) SCR 268. As to the difference between 'substantive' and 'procedural' laws, reference was made to N.S. Bindra 'Interpretation of Statute', 12th Edition, where it was observed that:

> "There is a distinction between 'a right of action' and 'a right of action to be conducted in a particular way'. The former is a vested right while the latter is merely a matter of procedure."

10. We have heard the arguments advanced at the bar and examined the material on record relating to the shipments of T-225 exported by the Petitioner prior to its request for an NOC in respect the Consignment, as well as the documents preceding the proceedings of the Authority culminating in the decisions taken at the Meetings.

11. Succinctly stated, the case advanced by the Petitioner proceeds on the assertion that it had a legal right to export T-225, and having done so from time to time pursuant to NOC's forthcoming from the Authority, it thus had a legitimate expectation that an NOC would similarly be issued in respect of the Consignment on the same terms, since the applicable policy remained unchanged on the date when the Application had been presented in that regard. As to the change in policy then brought about through the decisions taken by the Authority at the Meetings, the Petitioner's stance is that the same would not apply 'retrospectively' to an existing Application, and the requirement of additional documents could not be imposed in the particular case. However, on query posed, learned counsel for the Petitioner conceded that in the wake of the decisions taken at the Meetings, future NOCs would be subject to the amended policy and the determination to be made in the present Petition was thus confined to the Consignment alone.

12. In that context, it is discernible that the subject of tightening control over the exports of T-225 had been under scrutiny and consideration and was not a sudden measure introduced without nexus to the regulatory function. Indeed, in the wake of the UNODC warning, the increase in the volume of exports was raised as a point of concern in the letters dated 21.05.2021, 15.06.2021 and 22.06.2021 addressed by the Assistant Director — V, DRAP Karachi to the QA&LT Division, with the last correspondence ending with the following recommendation:

> "It is to submit that during routine working, it is observed that export of Tramadol has been increased significantly in last few months. Since Tramadol is an opeid analgesic and huge quantity of these medicines is being exported to single country i.e. Nigeria. It is therefore requested that the matter may be discussed in agenda of DRAP, Authority meeting at the earliest please, as such cases are increasing on day to day basis."

13. The issue then came to be considered at the 112th Meeting of the Authority held on 24.06.2021, with the ensuing Decision reading as follows:

> "**Decision:**
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> I. The Authority observed that Tramadol, an opioid analgesic, has misuse potential and is now a controlled item in number of countries including India. The substantial increase in export of Tramadol containing products to a specific country in last few months is unprecedented. Therefore, the Authority advised QA&LT Division to verify following from the relevant regulatory authority and embassy of Nigeria in Pakistan:
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> i. Registration status of following Tramadol containing products in Nigeria:
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> a. Tramaking Tablets 200mg, 225mg of M/s. Medisure Laboratories.
>
> b. Tramaking Capsules 100mg of M/s. Avensis Pharma.
>
> ii. Legal status of Tramadol in Nigeria whether controlled under INCB convention or otherwise.
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> II. QA&LT Division was also advised to review trends in export of Tramadol containing products to Nigeria for last one year and to verify the legitimate import of raw material i.e. Tramadol imported by the manufacturers

14. Thereafter, upon further review of the trend in export of T-225 to Nigeria, as envisaged, it was decided at the 115th Meeting of the Authority convened subsequent to the filing of the instant Petition that:

> "**Decision:**
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> I. The Authority, keeping in view of steep increase in trend in exports of Tramadol containing products in recent years and numerous pending requests for issuance of NOC for export of Tramadol containing products to African countries particularly Nigeria also considering report of National Bureau of Statistics of Nigeria regarding misuse of Tramadol and INTERPOL's intimation regarding diversion of Tramadol containing products, advised QA&LT Division to assure that following additional prerequisites are also verified before issuance of NOC for export of Tramadol containing products:

i. Registration of Tramadol containing product(s) of exporter in importing country.

ii. Legal status of Tramadol in importing country whether controlled under INCB convention or otherwise.

iii. In case of any already exported consignment, clearance document of Customs and regulatory authority of the importing country.

II. QA&LT Division was also advised:

a. to request Ministry of Narcotics Control and Anti-Narcotics Force to take up the matter with their relevant counterpart in Nigeria regarding recent trends for, for information and liaison to check illegality, if any.

b. to verify the legitimate import of raw material i.e. Tramadol imported by the manufacturers intending to export their Tramadol containing products. Complete facts and figures along with decision of the Authority be incorporated in the parawise comments of Constitutional Petition No. D-4425 of 2021 before Honorable Sindh High Court."

15. When the matter is weighed in its proper perspective, it transpires that the authorities relied upon by the Petitioner are distinguishable and its case as to an entitlement to an NOC in respect of the Consignment on the terms prevailing at the time of submission of its Application for issuance thereof is not well founded. Nor can a legitimate expectation be claimed for issuance of such NOC on the basis of past practice. The cited judgments pertained to cases where a vested right had crystalised or, as in the case of Radaka Corporation (Supra), an interpretation had been consistently followed by the department in the context of the PCT classification of certain imported items. Quite differently, in the instant case a decision on the Petitioner's application remained in abeyance pending submission of further documents, and the requisite NOC had yet to be issued. Furthermore, it is not a case where the Authority has deviated from past practice as to how the prevailing rules/policy are to be interpreted and applied in as much as the requisition

of further documents in respect of the Consignment proceeds on the basis of a change in policy rather than a different interpretation or approach being adopted in respect thereof.

16. Indeed, as it transpires, the decision relied upon by learned counsel for the Authority better addresses the point involved, in as much as Zami Ahmad Khan's case (Supra) pertained to an alteration in governmental policy during pendency of an application for a license to import, with the Honourable Supreme Court having granted leave to consider inter alia whether an application for grant of license to import cinematographic films created a legal right which could be sustained in a superior Court in writ jurisdiction, and whether a writ of mandamus could be issued to the Controller or Imports and Exports to do that which at the time when the writ was issued he was not required by law to do. In that framework, it was held that the mere filing of an application did not create any vested rights in favour of the applicant, with it being observed that:

> "Thus it becomes clear that it is wrong to suggest that the respondent had acquired any legal right for the grant of license by merely applying for the same and deposit of the necessary fee. Grant of license remains a privilege until it is actually granted and is accompanied by a grant."
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> "The argument proceeds on the assumption that the respondent by applying for the license and complying with conditions for the grant of license had become entitled to it as a matter of right. The fallacy of this assumption had been sufficiently demonstrated."

17. The Apex Court went on to observe that it was fallacious to assume that a vested right in the grant of license had accrued merely by filing an application and, on the point of the change in policy arising during pendency of the application, held as follows:

> "On the above analysis, there is no substance in the further argument of learned counsel for the respondent that the amendment of item 49 in the Policy Order on 10.08.1972, could not impinge upon the respondent's entitlement on the basis of his application earlier on 4.8.1972."

18. Furthermore, it was concluded that no writ of mandamus could be issued under the given circumstances, with it being found that:

> "On the second question, as explained already, lair is well settled that in the generality of cases, licence (simpliciter) is a privilege and not a leaf right; much less there is a legal duty for its grant. Therefore, exceptional cases apart, Mandamus would clot issue in such cases. Speaking generally in such cases tae emphasis is on policy, and any discretion vesting in the authorities is directed towards attaining the policy objective." [sic]

19. In the case of P.T.R. Exports (Supra), a somewhat analogous matter came up before before the Supreme Court of India, pertaining to issuance of an import license, with it being laid down that:

> "4. An applicant has no vested right to have export or import licences in terms of the policies in force at the date of his making application. For obvious reasons, granting of licences depends upon the policy prevailing on the date of the grant of the licence or permit.
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> 5. It would, therefore, be clear that grant of licence depends upon the policy prevailing as on the date of the grant of the licence. The Court, therefore, would not bind the Government with a policy which was existing on the date of application as per previous policy...The High Court, therefore, was right in its conclusion that the Government are not barred by the promises or legitimate expectations from evolving new policy in the impugned notification."

20. In the matter at hand, it is manifest that the change in policy for the grant of permission to export T-225 did not affect any past and closed transaction or any vested rights of the Petitioner, and the decision of the Authority to demand additional documents was a procedural step that did not take away or affect the substantive right of the Petitioner to seek the issuance of permission/NOC. Even otherwise, the Check List for Export NOC that had remained in the field unaltered from an earlier period confers reasonable flexibility for the Authority to call for the submission of 'any other document(s) particularly required', and the requisitioned documents are not of such a nature as would be beyond the reach of the Petitioner, hence their requirement is neither onerous nor constitute an 'unreasonable restriction' on the Petitioner. On the contrary, it can reasonably be said, as indeed claimed by the Authority, that those documents have a direct nexus with the statutory purpose of regulating the export of drugs in the larger public interest.

21. It is well established that in exercise of judicial review under Article 199 of the Constitution, it has to be seen whether an authority has acted within the scope of its powers and that the discretion conferred on the authority has been exercised in a reasonable manner, keeping in view the object which the statute seeks to achieve. The scope of judicial review is thus confined to examining the decision making process in order to assess whether the same was flawed in the sense of being illegal, irrational or suffering from some element of procedural impropriety requiring the decision to be set aside. However, where the finding of a regulatory authority reflects a properly reasoned approach, the Court ought not to re-appreciate the matter so as to substitute its own finding.

22. Moreover, it falls to be considered that the Impugned Letter merely calls for additional documents for purpose of processing a pending application and does not amount to a final Order in the matter of the Subject Consignment.

23. In view of the foregoing the Petition appears to be misconceived and devoid of force, hence stands dismissed along with all pending miscellaneous applications.

JUDGE

CHIEF JUSTICE

Karachi.
Dated: