IN THE HIGH COURT OF SINDH, AT KARACHI

C. P. No. D-2150 of 2020

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

Petitioner	:	M/s. Heal the World, through Mahmood Anwar Balouch and Ali Asadullah Bullo, Advocates.
Respondent No.1	:	Federation of Pakistan through Khaleeque Ahmed, DAG.
Respondent No.5	:	M/s. Alpha Lab's through Aijaz Ahmed Khan, Advocate.
Dates of hearing	:	25.11.2021, 20.12.2021 & 24.01.2022

ORDER

YOUSUF ALI SAYEED, J. - The Petition stems from the competing claims of the Petitioner and Respondent No.5 to enlistment of a range of nutraceutical/health supplements bearing the brand-name "Vivioptal" under the Alternative Medicines and Health Product's (Enlistment) Rules, 2014 (the "**Rules**"), made by the Drug Regulatory Authority of Pakistan ("**DRAP**") vide S.R.O. 412 (I)/2014 dated 27.05.2014, in exercise of powers conferred by the Drug Regulatory Authority of Pakistan Act, 2012 (the "**DRAP Act**").

2. The Petitioner had applied for and was provisionally granted enlistment as an Importer for 'OTC/dietary supplements/Multi vitamins' by virtue of Form-6 Enlistment dated 18.4.2017 (the "**Form-6 Enlistment**"), followed by the enlistment of six such products, including (i) Vivioptal Protect Capsules, (ii) Vivioptal Active Capsules and (iii) Vivioptal Multi Capsules, by virtue of a Decision taken by the Appellate Board of DRAP at its 151st Meeting held on 16.1.2019, with Form-7 being issued accordingly on 08.02.2019 (the "**Form-7 Enlistment**") so as to allow for their import and sale.

3. However, both the Form-6 Enlistment and Form-7 Enlistment (collectively, the "**Enlistments**") were revoked through a Decision taken by the Enlistment Evaluation Committee ("**EEC**") of DRAP at its 72nd Meeting held on 11.01.2020, in the following terms:

> "The EEC, as per provisions of the Alternative Medicines and Health Products (Enlistment) Rules, 2014 notified vide S.R.O 412(1)/2014, dated 27th May, 2014, what has been discussed in above paras and in the light of the above mentioned documents & replies submitted from time to time by the company and observations & remarks by the Division of Health & OTC, DRAP and the enquiry made by EEC, DRAP. The committee decided, as per provisions of Rule 5 (j) & 7 (5) and sub-rule 9 of rule 8 of S.R.O 412(1)/2014 dated 27th May, 2014 read with the condition (g) of the Provisional Certificate for Enlistment as Manufacturer/Importer (Form-6) bearing E.No.444 issued vide letter No.F.10- 1/2017-DD (H&OTC) (19th Meeting) dated 18th April, 2017, to revoke the said Form-6 (E.No.444). EEC, further noted that since the Provisional Certificate for Enlistment as Importer is revoked, therefore, all the Provisional Certificates for Enlistment of products issued, on the basis of said Form-6 (E.No.444), stand invalid and thus automatically revoked.
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> EEC, further directed that the company (M/s. Heal The World) as per condition "g" of From-6 (E.No.444) should surrender the said **Form-6 in original, within 7 days** and as per condition "n" of the Provisional Certificate for Enlistment of products, surrender all Provisional Certificates for Enlistment of products **Form-7 in original within 7 days**. The EEC, furthermore, directed that the company, as per conditions "a, b, c & d of the above said From-6 (E.No.444), shall recall all the stocks from the market in this respect immediately."

4. Appeal No. 03/20202 preferred by the Petitioner against that decision before the Appellate Board also culminated in dismissal through a short order made on 10.03.2020, for the reasons that followed on 27.04.2020.

5. Being aggrieved, the Petitioner invoked the jurisdiction of this Court under Article 199 of the Constitution, initially impugning only the Decision of the ECC dated 11.01.2020 but later amending the Petition so as to extend the scope of challenge to the detailed Order of the Appellate Board dated 27.04.2020, which was forthcoming during the intervening period.

6. Advancing his submissions, learned counsel for the Petitioner traced the sequence of proceedings preceding the revocation of the Enlistments, and emphasised that the contest as between the Petitioner and Respondent No.5 before the EEC and Appellate Board of DRAP had been interspersed by certain Writ Petitions filed by the latter before the Lahore High Court, where directions had been issued for deciding certain representations made by the Respondent No.5 regarding the matter of the Enlistments, but which were all decided against the Respondent by the relevant fora. However, when the Petitioner applied to the EEC for enlistment of eight further products on the same basis as had earlier been accepted by the Appellate Board, the EEC rejected the application vide a decision taken in its 68th Meeting held on 19.9.2019, prompting the Petitioner to file for Review. It is while adjudicating on the Review Applications that the Enlistments were revoked by the EEC.

7. Learned counsel argued that the action taken by the EEC in respect of the Enlistments was not backed by any show-cause notice and had been taken without an opportunity of hearing being afforded to the Petitioner. Furthermore, it was contended that the EEC lacked the capacity to revoke the Form-7 Enlistment in as much as the same had been issued in pursuance of a decision of the Appellate Board. He sought that the Impugned Decisions thus be declared to be bad in law and set aside.

8. Opposing the Petition, learned counsel for the Respondent No.5 invited attention to the Impugned Decisions as well as the comments submitted on behalf of the DRAP so as to point out that the action taken by the EEC had ensued as the Enlistment had been predicated on the Petitioner being an agent of M/s. Alaska Spring Pharmaceuticals, New York, USA ("**Alaska Springs**") and a Certificate of Free Sale shown to have been issued to that concern by the Greater New York Chamber of Commerce. It was pointed out that when the Petitioner's application for enlistment of further

products had been resisted by the Respondent No.5, certain correspondence between the Respondent's principal in the United States and Alaska Springs was placed before the EEC so as to demonstrate that the latter was a bulk manufacturer which did not produce finished goods or label products, and lacked any proprietary right or marketing authorization in respect of the Vivioptal brand in that jurisdiction. It was submitted that it was thus evident that the Enlistments were not in consonance with the Rules and had been obtained on a false premise, hence the same were rightly revoked by the EEC after providing an opportunity of hearing, with the ensuing Appeal correctly being dismissed by the Appellate Board. It was contended that the Petition was misconceived and ought to be dismissed.

9. We have considered the arguments advanced by learned counsel in light of the documents on which they placed reliance in support of their contentions.

10. It is well established that in exercise of judicial review under Article 199 of the Constitution, the High Court does not act as an Appellate Authority. On the contrary, such jurisdiction is circumscribed and confined to correcting an error of law or a procedural error, if any, resulting in a manifest miscarriage of justice or violation of the principles of natural justice. As such, it has to be seen whether the 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 evidence so as to substitute its own finding.

11. In that very vein, the Honourable Supreme Court held in the case reported as Chairman, NAB v. Muhammad Usman and others PLD 2018 Supreme Court 28 that:

> 17. It is the bedrock principle of law that discretion once exercised by the Court vested in it by law, shall in no manner be disturbed or set aside by the courts superior, in rank. This principle shall apply more vigorously in constitutional jurisdiction of the High Court under Article 199 thereof, which shall be exercised sparingly and considerable restraints should be exercised in this regard.
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> 18. As held time and again that the powers of judicial review vested in High Court under Article 199 of the Constitution is no doubt a great weapon in the Judge's hands however, the same shall not be exercised in a case where discretion is exercised by the subordinate court/Tribunal in a fair and just manner without violating or disregarding statutory provision of law, likely to occasion the failure of justice. Ordinarily such extraordinary jurisdiction shall not be exercised at random and in routine manner.

12. If any further authority is required, one may also look to the judgment of the Supreme Court of India in the case of Jal Mahal Resorts (P) Ltd.-vs.-K. P. Sharma (2014) 8 SCC 804, where it was observed as follows:

> "140. At this juncture, we take note of two overriding considerations which combined, narrow the scope of review. The first is that of deference to the views of administrative experts and the other we take assistance from the words of Chief Justice Neely who expressed as follows:
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> "I have very few illusions about my own limitations as a judge and from those limitations I generalise to the inherent limitations of all appellate courts reviewing rare cases." The learned Chief Justice further observed as follows: "I am not an accountant, electrical engineer, financier, banker, stock broker, or systems management analyst. It is the height of folly to expect judges intelligently to review a 5000 page record addressing the intricacies of public utility operation.
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> It is not the function of a judge to act as a super board, or with the zeal of a pedantic schoolmaster substituting its judgment for that of the administrator. The result is a theory of review that limits the extent to which the discretion of the expert may be scrutinized by the non- expert judge. It was suggested that the alternative for the court is to desist itself from interference on technical matters, where all the advantages of expertise lie with the agencies. If the

> court were to review fully the decision of an expert body such as State Board of Medical Examiners, 'it would find itself wandering amid the maze of therapeutics or boggling at the mysteries of the pharmacopoeia'."

13. The jurisdiction to regulate the 'import' of drugs (as defined in terms of the Drugs Act, 1976) stand conferred upon DRAP under the Act, being the 'Authority', as defined under Section 2 (iv) and created under Section 3 of the DRAP Act, being empowered in terms of Section 7 to prescribe, regulate or implement measures and standards on matters related or connected to it.

14. The Rules provide *inter alia* for the enlistment of alternative medicine and health products as well as their manufacturers or importers, as the case may be. In that regard, Rule 3, Sub-Rules (1) and (2) provide that:

> "3. Procedure for Enlistment.- (1) The Authority shall enlist alternative medicine and health products, their manufacturers and importers subject to fulfillment of the criteria prescribed below.
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> (2) The following shall be eligible to apply for enlistment namely;--
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> (a) manufacturers having manufacturing and quality control facilities;
> (b) contract giver as prescribed in rule 6;
> (c) importers authorized by the overseas principal manufacturer; and
> (d) manufacturers holding manufacturing license under the Act may
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> also apply for approval of dedicated sections for manufacturing of alternative medicines or health products and probiotics or food supplements to the Authority and thereafter become eligible to apply for enlistment."

15. A perusal of the record reflects that whilst the Petitioner professes to be the owner/proprietor of the name Vivioptal in Australia, New Zealand and Pakistan, it had obtained the Enlistments as an importer and as an agent of Alaska Springs.

16. However, as it transpired, Alaska Springs was shown to have disclaimed any proprietary right to the Products or the name Vivioptal through the intervention of the Respondent No.5's foreign principal, namely M/s. Bomuca International Corporation ("**Bomuca**"), on whose behalf a legal notice dated 18.04.2019 was apparently addressed by its intellectual property counsel, with the reply forthcoming from counsel for Alaska Springs in terms of a letter dated 30.05.2019 disclaiming any right to the mark. That correspondence was placed before and considered by the EEC and Appellate Board, and formed the basis for the decisions made by those fora. Additionally, it is apparent from the Form-7 Enlistment that the same was in respect of the Products in a finished form; that is to say, in a specified pack size, whereas it was observed that the import documents submitted by the Petitioner reflected imports in bulk, which fell beyond the pale of the Rules.

17. The detailed decision of the Appellate Board dated 27.04.2020 covers these aspects, with the relevant excerpt therefrom disclosing the reasons for the short order dated 10.03.2020, reading as follows:

> "3. The Board noted that the following are key questions to decide the instant appeal:-
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> A. **Who has the ownership/marketing authorization rights of Vivioptal brand in the country of origin (USA)?**
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> 4. As per official website of the United States Patent and Trademark Office (USPTO), trademark VIVIOPTAL is registered in the name of M/s Bomuca International Corporation California since 30.11.2010 under registration number 3884076. This fact has also been conceded by the learned counsel for the appellant during hearing of the appeal. Since principal manufacturer of the appellant i.e. M/s Alaska Spring Pharmaceuticals, New York, USA is not the authorization of the Vivioptal brand in the country of origin, hence cannot claim marketing authorization of Vivioptal brand in the country of origin i.e. USA. Therefore, it cannot export products under the name of Vivioptal to Pakistan through the appellant when other party with sole proprietorship agreement is present in Pakistan.

5. The appellant claimed to have ownership of Vivioptal brand in Pakistan but could not substantiate it with documentary evidence i.e. Registration Certificate issued by the Trade Marks Registry of the Intellectual Property Organization of Pakistan. Mere submission of an application does not establish right of holding ownership of Vivioptal brand in Pakistan.

6. Learned counsel of the appellant contended that M/s Alaska Spring Pharmaceuticals, USA manufactures products under brand name Vivioptal for the appellant for sale in Pakistan on the basis of appellant's trademark registrations in Australia and New Zealand. However, trademark registrations in Australia and New Zealand are irrelevant for the purposes of the 2014 rules. The principal manufacturer's market authorization or product registration status in the country of origin is relevant factor under the 2014 rules.

7. As per record, M/s Heal The World, Karachi vide its application for grant of enlistment of products dated 21.01.2017 submitted copies of Bill of Entry/Goods Declaration under Airway Bill No.17620931706 which shows the import of Vivioptal Capsules is of M/s Bomuca Origin which is contrary to the facts as Vivioptal capsules are imported by M/s Alaska Spring.

B. Whether principal manufacturer of the appellant i.e. M/s Alaska Spring Pharmaceuticals is a finished good manufacturer or otherwise?

8. As per duly notarized documents presented by the learned counsel of M/s Alpha Labs Lahore, when the controversy of ownership and marketing of the Vivioptal brand came in the knowledge of M/s Bomuca International Corporation, they sought clarification regarding possible trademark infringement of Vivioptal in USA by M/s Alaska Spring Pharmaceuticals through their attorney. In reply, the attorney of M/s Alaska Spring Pharmaceuticals submitted the following:-

> "I am writing in response to your correspondence, dated April 18, 2019.
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> My client, Alaska Spring Pharmaceuticals ("Alaska Spring"), disputes your claims as set forth in that correspondence. Alaska Spring is a contract manufacturer of among other things Vitamins. As such, Alaska Spring does not sell directly to the public, nor does it package or distribute Vivioptal product. Therefore, Alaska Spring not packaging or distributing any offending goods as you claim.
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> Further, Alaska Spring is not packaging or distributing any vitamins in the United States which uses the Vivioptal mark. Alaska Spring is aware of a customer in Pakistan that uses a Vivioptal mark, but that customer has trademark rights to the mark in Pakistan. Alaska Spring has no control over any customer that may be taking the vitamins manufactured by Alaska Spring and then labeling and selling that product in a way which may violate your client's rights.
>
> That being said, my client would be willing to agree to limitations that it has control over

The foregoing is without prejudice to any of Alaska Spring's rights, none of which are waived."

(Underline added for emphasis.)

9. The above correspondence reveals that Alaska Spring is a contract manufacturer. It does not sell directly to the public, nor does it package or distribute Vivioptal product. It is, in fact, a bulk manufacturer and does not produce finished goods nor label the products. The Bill of Entry No.17620931706 submitted by M/s Heal The World, Karachi also shows the import of these products in bulk packing (not in finished pack) for which there is no provision in the 2014 rules.

C. Manufacturing License and Last Inspection Report of the overseas manufacturer.

10. Provision of Manufacturing License and Last Inspection Report of the overseas manufacturer are mandatory requirements under the 2014 rules. The appellant did not provide attested copies of these mandatory documents issued by the regulatory authority of the country of origin (i.e USA). The appellant instead submitted the document on the subject "173 GMP- Dietary Supplements GMP Registration Audit Corrective Action Report" issued by NSF international, Michigan, USA for M/s Alaska Spring Pharmaceuticals, New York, USA wherein the status of inspection is mentioned as pending on the following actions.

i. Corrective and preventive action (CAPA).
ii. Supplier qualification

11. Further, the document which is purported to be a Certificate of Registration to M/s Alaska Spring Pharmaceuticals, USA was issued by Registrar Corporation Virginia USA. This organization "**Registrar Corporation Virginia USA**" has been found as an organization which provides assistance to companies and itself is not a **Regulatory body.**"

18. The relationship between Alaska Springs and the Petitioner was thus revealed to be that of a "contract acceptor" and "contract giver" rather than that of an importer and overseas principal manufacturer, as had been professed. While registration under the Rules is envisaged in both cases, different criteria, procedures and forms are laid down for enlistment between the two categories, with an importer apparently operating on the basis of the proprietary rights of the overseas principal manufacturer, whereas the terms "contract giver" and "contract acceptor" are defined as per Rules 2(xvii) and (xv) to mean "the person who awards the

contract of particular products under his brand" and "a manufacturer who manufactures the finished product under the label and brand of contract giver" respectively.

19. As such, in the wake of the correspondence ensuing between Bomuca and Alaska Springs it is manifest that the very foundation of the Enlistments, that of the Petitioner being an importer, stood shorn away. In fact, that foundation was itself dubious at the outset in as much as the very import documents that had been submitted by the Petitioner at the time of applying for the Enlistments had apparently shown the Vivioptal Capsules to be of Bomuca Origin, and for purpose of the Enlistments the principal manufacturer's market authorization or status of product registration in the country of origin is the relevant factor. As such, the stance taken by the Petitioner that it was the holder of the trademark in Australia, New Zealand and Pakistan was irrelevant and while certain documents with regard to Trade Mark "V" Logo purportedly issued by the IPO office, Karachi in the name of the Petitioner were placed on record, those have no effect over the name Vivioptal or its registration in the country of origin from the standpoint of the Enlistments. The revocation of the Enlistments thus followed as a logical consequence.

20. Whilst the decisions of the DRAP fora have been assailed on the ground of incapacity and natural justice, learned counsel for the Petitioner did not point to any material on record to demonstrate that there was any substantive error in that regard. Suffice it to say that the EEC is the relevant forum for deciding matters of enlistment at the forefront of the regulatory hierarchy and to say that it could not act so as to revoke an enlistment found to have been obtained through false pretences would yield an anomalous and absurd result so as to undermine the regulatory objective of maintaining control in the general interests of the public, which ought to be borne in mind when assessing the level of judicial intervention desirable in a particular case.

21. The mere fact that the Form-7 Enlistment ensued through the order of the Appellate Board does not preclude the EEC from acting so as to take remedial action in an appropriate case, especially when the facts underpinning such action emerged subsequent to the determination of the appellate forum. Even otherwise, the action has subsequently been upheld by that very body.

22. Turning then to the argument that the Petitioner was condemned unheard by the EEC, suffice it to say that as per the decision of the EEC in its 71st meeting held on 11.12.2019, the Petitioner was issued a notice vide letter F.No.10-19/2019-DDC (Health and OTC) dated 30.12.2019 to appear before the EEC in its 72nd meeting, where an opportunity of personal hearing was evidently given to the Petitioner, with the Health & OTC Division having also been directed to present a comprehensive report with regard to the vires of the Enlistments for consideration. A perusal of the decision made by that forum at its 72nd Meeting held on 11.01.2020 also reflects such participation, reading as follows:

> "2. … On behalf of the company, Mr. Karim Pardhan, Managing Director, Mr. Hassan Sardar, Marketing/Admn Director and Mr. Amjad Ali, Regulatory Manager appeared before the committee and presented their case. They did not present any new document or information despite the committee repeatedly asked for, rather they restricted to the information and documents which were already provide by their company. The committee asked them to comment about the letter (duly notarized) (copy placed at Annex A) dated May 30, 2019 of M/s. Alaska Spring Pharmaceuticals, titled "Re: Bomuca International Corporation/Alaska Spring Pharmaceuticals, your Ref: C118706586" through their attorney namely; MARKOTSIS & LIEBERMAN, P.C. Attorneys and Counsellors at law, 115B BROADWAY, SUITE, 2, HICHSVILLE, NEW YORK 11801 TELEPHONE (516) 935-2330, FACSIMILE (516) 935-2260, e-mail:info@mlesq.com signed by Mr. Douglas M. Lieberman which has been brought on the record and considered by the committee. The representatives of M/s. Heal The World, Karachi refused to comment on the said letter."

23. In view of the foregoing, the Petition is found to be bereft of merit, and stands dismissed accordingly.

JUDGE

CHIEF JUSTICE

Karachi
Dated _____