IN THE HIGH COURT OF SINDH
AT KARACHI

C.P No. D-4260 of 2019

Petitioner	:	Martin Dow Limited, through Mr. Abdul Sattar Pirzada, Advocate
Respondent No.1	:	Federation of Pakistan, through Mr. Kafeel Abbasi, DAG.
Respondent No.2	:	Drug Regulatory Authority of Pakistan, through Mr. Amanullah, Director (Pricing).
Date of hearing	:	26.02.2020.
Present	:	Muhammad Ali Mazhar and Yousuf Ali Sayeed, JJ

JUDGMENT

YOUSUF ALI SAYEED, J - The Petitioner, a pharmaceutical concern, has invoked the jurisdiction of this Court under Article 199 of the Constitution of the Islamic Republic of Pakistan, impugning the Orders made by the Drugs Appellate Board of the Drug Regulatory Authority of Pakistan ("**DRAP**") in various Appeals filed by the Petitioner under Section 9 of the Drugs Act, 1976 (the "**1976 Act**"), assailing the fixation of prices for its products under the trade names "*Rivotril*" and "*Rocephin*", both of which are said to be originator brands imported in semi-finished form under license from F. Hoffmann-La Roche, Switzerland (the "**Licensor**"), and marketed in the form of Rivotril drops of 2.5 mg/m, Rocephin Vial 500 mg IM, Rocephin Vial 500 mg IV, Rocephin Vial 1 g IM and Rocephin Vial 1 g IV (hereinafter collectively referred to as the "**Products**").

2. Of the Products, *Rivotril* has been described in the Petition as containing the molecule Clonazepam - apparently a broad spectrum antiepileptic which selectively inhibits the activity of the epileptogenic focus while at the same time preventing the generalizing of convulsive activity, whereas *Rocephin* is said to contain the molecule Ceftriaxone - a sterile, semisynthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration, which is prescribed for treatment of development of drug-resistant bacteria and a wide variety of bacterial infections.

3. Succinctly stated, the backdrop to the matter, as best discernible from the pleadings, is that the Maximum Retail Price (the "**MRP**") of the Products had remained unrevised since the year 2002, however, following a sequence of litigation, the Petitioner's request for an upward revision came to be dealt with as hardship cases under Clause 9 of the Drug Pricing Policy 2018 (the "**2018 Policy**"), with the same being determined at the level of the Drug Pricing Committee (the "**DPC**") following hearings conducted on 09.10.2018 and 10.10.2018 and then fixed accordingly by the Federal Government vide Notification No. S.R.O. 1610(I)/2018 dated 31.12.2018 (the "**Notification**") in exercise of the powers conferred as per Section 7(a) read with Section 12 of the 1976 Act. Being aggrieved, the Petitioner then filed Appeal No. 52 of 2019 assailing the price fixation of *Rivotril*, and Appeal Nos. 50, 51, 53 and 54 of 2019 as against the price fixation of the aforementioned variants of *Rocephin*, all of which were dismissed by the Drugs Appellate Board vide two separate Orders, both dated 18.06.2019 (the "**Impugned Decisions**").

4. As it transpires, the earlier MRP approved in respect of a unit of Rivotril 2.5 mg/ml was apparently Rs.137/-, with a demand being made by the Petitioner for upward revision to Rs.198/-, in response to which a price of Rs.158/- had been determined by the DPC at its 36th Meeting and then fixed accordingly by the Federal Government in terms of the Notification, and in the wake of such a determination the Petitioner had appealed to the Drugs Appellate Board for fixation of an MRP of Rs.221.62, an amount even higher than earlier requested. As regards *Rocephin*, from the material available on record in respect of three of its variants, the MRP earlier approved, the enhancement in MRP initially sought, the MRP approved vide the Notification and the MRP then requested in appeal were as follows:

Product	**Old MRP**	**Initial Demand**	**MRP Notified**	**MRP IN Appeal**
Rocephin 1 gm IM	478/-	989/-	783/-	1109.27
Rocephin 500mg IM	243/-	587/-	376/-	659.73
Rocephin 500 mg IV	243/-	587/-	376/-	659.73

5. Learned counsel for the Petitioner submitted that this was so as in terms of an amendment to the Supply and License Agreement executed between the Petitioner and Licensor in relation to the Products on 27.09.2018 (the "**Amendment**"), the per unit prices thereof had been increased with effect from that date as follows:

Product Description	**Earlier Price Per Unit**	**Revised Price Per Unit**
Rivotril 2.5 mg/ml	US$ 0.5	US$ 0.74
Rocephin 1 gm IM	US$ 2.99	US$ 3.80
Rocephin 1 gm IV	US$ 2.99	US$ 3.80
Rocephin 500mg IM	US$1.43	US$ 2.24
Rocephin 500 mg IV	US$1.43	US$ 2.24

6. Learned counsel submitted further that in order to ensure the uninterrupted supply of the Products, the Petitioner had requested that the fixation of their MRPs be reconsidered in accordance with the revised supply prices as per the Amendment, however, whilst fixing the MRP of the Products, the DPC completely ignored this fact albeit that the revised prices had become applicable prior to the 36th DPC, and the Petitioner had since been importing the Products on such terms, with the relevant commercial invoices subsequently being provided for corroboration before the Drugs Appellate Board. Indeed, the crux of the Petitioners Appeals to the Drug Appellate Board revolved solely around the aspect of revision in prices pursuant to the Amendment, and for reference, the relevant excerpt from the Appeal in respect of Rivotril is reproduced herein below:

> "We import this product in semi-finished from from F. Hoffmann-LA Roche, Switzerland. Our supplier has increased the price of this product from **USD 0.59 per unit** to **USD 0.74 per unit** effective from **27th September 2018 (Copy of agreement attached as Annexure A)**. Hardship case was applied on the basis of proforma invoice, but the same was not entertained by DRAP who granted us MRP on the basis of supply rates as per import invoice/GD."

Suffice it to say that the very same ground is to be found, *mutatis mutandis*, in the Appeals filed in relation to the variants of Rocephin.

7. He averred that the aspect of the Amendment and the corroborative material shared in that regard was neither properly considered at the level of the DPC nor the Drugs Appellate Board, it being argued that the Impugned Decisions were therefore mala fide, capricious, arbitrary, illegal, without any lawful jurisdiction and in violation of the fundamental rights of the Petitioner.

8. Attention was invited to the post Amendment commercial invoices submitted to DRAP, with the receiving stamps reflecting the relevant dates as being 16.10.2018 onwards, and it was contended that upon being apprised of the Amendment, the DPC in relation to the products ought to have been held in abeyance so as to enable the Petitioner to place the corresponding commercial invoices on record, however, on query posed as to whether any request had been made to DRAP to defer its consideration of the matter for such reasons, he was unable to point to any application or other relevant material on record indicating that such a representation had in fact been made. Be that as it may, he pointed out that the commercial invoices had been in place by the time the matter had come up consideration before the Drugs Appellate Board.

9. Conversely, the Director (Pricing), DRAP, submitted that the Impugned Decisions were in accordance with law and had been made in conformity with procedure. He pointed out that whilst Clause 9(3) of the 2018 Policy required that "*In case of imported raw and packaging materials and finished drug, evidence of value as determined on bill of entry under the Customs Act, 1969 along with commercial invoice and import documents will be submitted*", at the relevant time that the case of the Petitioner had come up for consideration before the DPC, the only commercial invoices on record were those that reflected the pre-Amendment prices, and only certain Pro-forma invoices had been submitted by the Petitioner in relation to the revised prices pursuant to the Amendment, whereas the commercial invoices reflecting the revised prices were submitted only after the determination by the DPC. He submitted that no request for withdrawal of the hardship application for purpose of its resubmission along with updated transactional/shipping documents or any request for the decision on the pending application to be deferred so as to allow for production of supplementary material had been made on behalf of the Petitioner, and it was pointed out by him and the learned DAG that as per the

directives of the Honourable Supreme Court in the Order made on 03.08.2018 in Human Rights Case No. 2858 of 2006, all pending hardship cases were to be decided in accordance with law within a period of 10 weeks from that date, hence there was even otherwise no scope for the decision to be put off. He submitted that, as such, the DPC had correctly decided the matter on the basis of the admissible material available for consideration and the Drugs Appellate Board had considered the matter accordingly. He and the learned DAG contended that this being so, the Impugned Decisions did not suffer from any infirmity.

10. Having heard the submissions advanced, it appears that the crux of the Petitioner's case for judicial review is that the Amendment had been necessitated so as to ensure continued uninterrupted supply of the Products, but was ignored by the DPC whilst determining the MRPs and the commercial invoices submitted by way of evidence thereafter were also not considered by the Drugs Appellate Board, therefore the Impugned Decisions suffer from a misreading and/or non-reading of relevant material and the ensuing price-fixations are arbitrary and mala fide, having been made in bad faith. However, from an examination of the Impugned Decisions as well as the material on record, it is manifest that the only material available before the DPC within the scope of Clause 9(3) of the 2018 Policy at the relevant time were the commercial invoices reflecting the pre-Amendment prices of the Products, which did not in any manner serve to bolster the Petitioner's claim for enhancement of MRPs. The Pro-Forma invoices submitted by the Petitioner were beyond the pale of Clause 9(3), hence rightly excluded from consideration, and in the absence of corroborative material of imports at post-Amendment prices, the bare agreement reflecting the Amendment could not of itself be pressed before the DPC so as to form the basis for a revision of MRPs, as rightly observed by the Drugs Appellate Board. Ergo, the very construct of the Petitioner's case on such a basis appears to be a *non-sequiter*.

11. Needless to say, it is well settled that the scope of judicial review by the Court under Article 199 is not to inquire into the merits of the decision being challenged so as to dissect and reconstruct the same, but to conduct a review of the process by which the decision was reached in order to assess whether the same was flawed in the sense of being illegal, irrational or suffering from some element of procedural impropriety that requires that the decision should be set aside. A case in point is the judgment of a learned Division Bench of this Court (of which one us, namely Muhammad Ali Mazhar, J, was a member) in the case reported as Hajj Organizers Association of Pakistan through Authorised Officer and 11 others v, Federation of Pakistan through Secretary Ministry of Religious Affairs and Interfaith Harmony, Islamabad and 2 others PLD 2020 Sindh 42, held as follows:

> "One of the principal aims of a system of judicial review must be to maintain a high level of public confidence in the administrative decision making process and this must also be borne in mind in assessing the level of judicial intervention which is desirable. With reference to the case of Dr. Akhtar Hassan Khan, the apex court reiterated the parameters of judicial review with another reference of Tata Cellular v. Union of India (36(1994) 6 SCC 651) in which the Supreme Court of India while dilating the parameters of judicial review in matters of awarding of contract by the Government candidly laid down that the duty of the court is to confine itself to the question of legality. Its concern should be, whether a decision-making authority exceeded its powers; committed an error of law; committed a breach of the rules of natural justice; reached a decision which no reasonable tribunal would have reached or abused its powers. The grounds upon which an administrative action is subject to control by judicial review can be classified as illegality, this means the decision-maker must understand correctly the law that regulates his decision-making power and must give effect to it; irrationality, namely, Wednesbury unreasonableness and procedural impropriety."

12. That being so, are of the view that the Petition is without merit, hence the same is dismissed accordingly, but with no order as to costs.

JUDGE

JUDGE

TariqAli/PA