IN THE HIGH COURT OF SINDH CIRCUIT COURT HYDERABAD

C.P. No. D — 321 of 2000.

BEFORE :
Mr. Justice Muhammad Shafi Siddiqui
Mr. Justice Muhammad Faisal Kamal Alam

Date of hearing : 18.02.2020
Date of decision : 10.03.2020

Petitioner — Grandiphar Pakistan through M/s. Rafiq Ahmed & Karim Bux Rind, Advocate.

Respondents: — Drugs Appellate Board and others through Mr. Aslam Pervaiz Khan, Asstt. Attorney General along with Dr. Affan Ali, Assistant Director, Central Drug Laboratory.

O R D E R

MUHAMMAD SHAFI SIDDIQUI, J:- This Petition impugns the two orders of the Drug Authority; the ultimate being of the Drug Appellate Board, Islamabad. Brief facts of the case are that the Petitioner was issued a license for Drug Manufacturing. Consequently, the petitioner got involved in the process of manufacturing of drugs. The two drugs came in consideration for the Drug Authority (Respondent No.1) and they procured samples of the medicines / drugs; one being Paracetamol Suspension and the other being Diphen Expectorant. Five samples were drawn of each drug and were sent to Central Drugs Laboratory, Karachi accordingly. The first report being of 25.5.1999 disclosed that the bottle contains 350 ml syrup instead of 450 ml as claimed in the label of the bottle / sample, hence it was declared as misbranded in terms of Drugs Act 1976. It was challenged by the petitioner in terms of letter dated 9.6.1999 and the samples were re-drawn and tested yet again and the analysis by the Drugs Control and Traditional Medicine Division, National Institute of Health, Islamabad, declared that the pink coloured suspension having suspended matter in a white plastic bottle contains 60.83% whose limit should have been 95 to 105%. Hence the percentage of the active ingredient in the subject drug did not comply with British Pharmacopoeia (B.P) 1993. This time the Petitioner was not aggrieved of the test result as no letter was issued, as it did earlier. As far as the other medicine is concerned, the report at page 67 dated 28.7.1999,

disclosed that the bottle contains 350 ml syrup instead of 450ml as claimed in the label of the bottle. This report was again challenged in terms of the letter of the petitioner dated 9.8.1999 and the contents were found short by 100 ml in terms of the report available at page 71 Annexure P/K hence the description was not in terms of the Manufacturers' specification as far as the volume was concerned.

2. Being aggrieved of these, the Petitioners preferred an Appeal before the Drug Appellate Board and were heard. While hearing the case, the Board concluded that the Appeal initially came-up for consideration on 8.4.2000 and was deferred for consideration along with the Appeal filed against the Central Licensing Board for cancelling their Drug Manufacturing License. It was the case of the Registration Board that under Section 22(5) of the Drugs Act, 1976 the report of NIH is considered as conclusive evidence for deciding the cases and also informed the Board that between 1993 to 1999 the Drug Testing Laboratory had declared 10 samples of Paracetamol Suspension of the Appellant's company as of substandard quality. As far as the report of the other samples of Diphen Expectorant Batch No. 1768 was concerned it was declared misbranded. Counsel for Petitioner submits that it was a belated report as it should have been obtained / issued within 60 days under the law. The sample was declared substandard by the Appellate Laboratory as it contained purplish mass sticking inside wall of the bottle with suspended substance. The volume was also reported to be 350ml instead of 450 ml and the reason disclosed was that it was tested in the month of November in a low temperature. The decision of the Central Licensing and Registration Board was upheld and the appeals were dismissed. The Central Licensing & Registration Board vide its order dated 30.3.2000 was pleased to cancel the Drug Manufacturing License of the Petitioner firm with immediate effect.

3. We have heard learned counsel(s) and perused the material available on record.

4. With reference to two reports relating to Paracetamol Suspension is concerned, it is explained by Dr. Affan Ali Assistant Director, Central Drug Laboratory that they have an outdated mixing and filling mechanical / machine units in their factory. Invariably it was noticed when different samples were drawn and tested that the bottles did not contain the declared contents in terms of its volume. It happens only when the rotary machines, where these bottles are being filled, have a faulty mechanism as a delay of even a second may cause fault in the filling mechanism. Secondly, since in the subsequent report where the "active ingredient" of Paracetamol

Suspension was found much less than the required or desired contents, hence the registration of the drug was lawfully cancelled. Similar is the case with other drug i.e. Diphen Expectorant. Since it has been consistently noticed that they have a faulty filling units which include filling of the bottles and mixing of the ingredients properly, the contents of the medicine tends to vary. In some bottles the active ingredient may be up to the mark as required but in some bottles it may be less than as required. Petitioner's faulty unit or testing of samples during winter season is not an excuse as far as manufacturing of drug is concerned. This explanation or excuse does not legitimize the negligence and faults unearthed by the Drug Inspectors. The child suffering from fever may not be relieved even if a proper dose of medicine such as Paracetamol Suspension having less than the desired percentage of active ingredients is given. There seems to be no anomaly as far as suspension of registration of these two drugs are concerned.

5. Insofar as the requisite time of 60 days is concerned, the benefit of doubt may be extended to an accused in response to a criminal charge but as far as the civil liabilities are concerned, on these doubts a licensee cannot be allowed to continue to manufacture such drugs which in terms of the Report does not contain the active ingredients required to cure the illness; hence the case of Muhammad Amin Khan v. Muhammad Siddiq reported in 1984 P.Cr.L.J 1580, is not applicable.

7. The question was then ultimately raised by the petitioner counsel that the entire license of the Petitioner, as far as other medicines are concerned has also been cancelled. The Petitioner besides these two drugs are also manufacturing 32 more drugs as alleged. The two orders, that is, one passed by the Central Licensing and Registration Board and the other by the Drugs Appellate Board, Islamabad, do not talk about any other drugs being taken into consideration while cancelling the Drug Manufacturing License of the firm. The two orders discussed only above mentioned two drugs whose samples were drawn and were sent to the laboratory. It is also not verified as to whether they have just one filling unit where these fault occurs or they have other units as well. At the most the manufacturing of the two drugs could have been restricted by cancelling their registration and not the entire license as there were no grievances of the respondents as far as manufacturing of other drugs are concerned.

8. This petition however remained pending for two decades while the Drug Manufacturing License remained cancelled. If at all the petitioner is inclined to involve themselves in manufacturing of other drugs/medicines,

they shall undergo a process as provided under Drugs (Licensing, Registering & Advertizing) Rules of 1976.

9. In terms of Rule 6 the duration of a license to manufacture drug is for a specified period. If a license, if not otherwise suspended or cancelled, shall remain in force for a period of five years from the date of issue and be renewed for a period of five years at a time. Provided that an application for renewal is made before the expiry of period of validity of a license, the license shall continue in force until orders are passed thereon. It further provides that if the application for renewal is made after the expiry of period of validity of a license but within sixty days of its expiry, the license shall continue to be in force on payment of additional surcharge unless such orders are passed on the application. The Rule further provides that the duration of a license issued under Rule 21 shall be two years unless earlier suspended or cancelled. Rule 21 of the ibid Rules however, is to manufacture drugs for experimental purposes. In terms of Rule 10 the Central Licensing Board, before issuing a license, cause the premises, in which the manufacturing is proposed to be conducted, to be inspected by itself or by its sub-committee or by a panel of Inspectors or experts appointed by it for the purpose which may examine all portions of the premises and plants and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardizing, if necessary, and testing and analyzing substances to be manufactured and enquire into the professional qualification of its technical staff employed. In so far as the renewal of license is concerned Rule 13 provides that on application being made for the renewal, the Central Licensing Board may cause an inspection to be made and if satisfied that the conditions of the license and the Rules are and will continue to be observed, shall issue a certificate of a renewal. Provided that if the directions of the Central Licensing Board shall be followed by licensee strictly in terms of the time specified therein. The renewal also require implementation of Rules 15, 16, 17, 18, 19 & 20 of the ibid Rules as far as their applicability is concerned in an appropriate case. Thus in case the petitioner intend to manufacture other registered drugs as claimed, it has to undergo a process of issuance or renewal of a license as required under the ibid Rules and unless such Rules are implemented by the Central Licensing Board such license can neither be issued or renewed.

We therefore in view of the above, dismissed this petition.

JUDGE

JUDGE

Arif.