JUDGMENT SHEET

ISLAMABAD HIGH COURT, ISLAMABAD,
JUDICIAL DEPARTMENT

Writ Petition No.2303/09

M/s Shifa Laboratories Pvt. Ltd.
Versus
FOP through Secretary M/o Health, Islamabad, etc.

Petitioner by:	Mr. Ajmal Ghaffar Toor, Advocate, and Syed Ghazanfar Ali Shah, Advocate
Respondents by:	Ch. Abdul Khaliq Thind, Assistant Attorney General. Shoaib Ali Khan, Assistant Director (Legal), DRAP.
Date of Decision:	18.04.2017

AND

Writ Petition No.267/10

M/s Shifa Laboratories Pvt. Ltd.
Versus
FOP through Secretary M/o Health, Islamabad, etc.

Petitioner by:	Mr. Hamid Khan, Advocate
Respondents by:	Ch. Abdul Khaliq Thind, Assistant Attorney General. Shoaib Ali Khan, Assistant Director (Legal), DRAP.
Date of Decision:	18.04.2017

MOHSIN AKHTAR KAYANI, J:- Through this single judgment, I intend to decide both the aforementioned writ petitions as identical question of law and facts are involved in both these writ petitions.

2. The petitioner/Shifa Laboratories Pvt. Ltd. through WP No.2303/2009 has assailed the Test Reports No.82 to 84/2009 dated 27.04.2009, Test Reports No.FP-05 to 12/2009 dated 04.05.2009, Test Reports FP-24 to 41/2009 dated 15.05.2009 and Test Reports No.31 to 13-M/2009 dated 30.05.2009, issued by Central Drugs Laboratory Karachi as well as Certificate of Test of Analysis by the Drugs Control and Traditional Medicines Division, National Institute of Health, Islamabad. Whereas, the

petitioner/Shifa Laboratories Pvt. Ltd. Through WP No.267/2010 has assailed the order dated 06.11.2009 which was communicated through letter dated 25.11.2009 issued by Drugs Registration Board, Ministry of Health, Government of Pakistan, whereby the registration of drug (Paracetamol 500mg, Registration No.010449) of the petitioner company has been cancelled.

3. Brief facts as extracted from both the writ petitions are that the Shifa Laboratories Pvt Ltd., the petitioner company, deals with the manufacturing and sales of standard quality medicines in Pakistan for the last 50 years on the basis of valid drugs manufacturing license granted by Central Licensing Board, including the Paracetamol Tablet 500mg.

4. The petitioner company had participated in the tender for the supply of pharmaceutical tablet of 500mg, being successful bidder, a pre-award contract notification was issued on 17.12.2007 for the supply of Paracetamol Tablet 500mg to National Program for Family Planning and Family Healthcare and Reproductive Health Project, Ministry of Health for the year 2007-08. The contract was awarded to the petitioner company at the rate of Rs.47.37/- per pack for whole number of 1,522,899 packs against the total consideration of Rs.72,139,725.63 (rupees seventy two millions one hundred thirty nine thousand seven hundred twenty five paisa sixty three only).

5. Contract was executed on 07.02.2008 whereby the petitioner company had completed the consignment and supplied the product/medicines whereafter random samples from different batches were inspected on 17.03.2008, 05.05.2008, 05.08.2008 and 30.10.2008 by the Inspection Committee which were sent for test analysis to the Central Drugs Laboratory Karachi, whereupon the same were declared to be of standard quality vide Certificate of Test Analysis by Central Drugs Laboratory Karachi.

6. As per claim of the petitioner, they had only received 50% of the total sale considerations of Rs.72,139,725.63/- and upon claiming the entire consideration up till November 2008, they had received a show cause notice from the Federal Inspector of Drugs Hyderabad, Karachi and Federal Inspector of Drugs, Peshawar on the ground that samples of Paracetamol Tablet 500mg taken from Hyderabad and Peshawar have been declared of substandard quality by the Central Drugs Laboratory Karachi, whereby notice was issued from Federal Inspector of Drugs, Hyderabad dated 28.04.2009 which was duly replied. The petitioner received three show cause notices from the office of respondent No.2 Drugs Registration Board Ministry of Health, Government of Pakistan. In view of above background WP No.2303/09 was filed whereby the Test Reports have been assailed in which Paracetamol Tablet 500mg has been declared of "***sub-standard quality***" under the Drugs Act, 1976.

7. This Court vide order dated 24.06.2009 entertained the instant writ petition (old WP No.1114/2009) and passed the restraining order on CM No.2804/2009 with the following terms:

> *"CM No.2804-09*
> *3. Notice. In the meanwhile, further proceedings in the matter shall remain stayed till next date of hearing."*

After the passing of order dated 24.06.2009, the respondents on 02.07.2009 had requested for time to file rejoinder, however, subsequently the Islamabad High Court, Islamabad was declared unconstitutional by the Apex Court in case titled *Sindh High Court Bar Association v/s FOP*. Nevertheless, Drugs Registration Board issued another show cause notice to the petitioner vide office letter dated 05.11.2009 to appear before the board in its 221st meeting held on 06.11.2009 at Pak Secretariat, Islamabad which the petitioner company replied through letter dated 05.11.2009 and requested the Drugs Registration Board that the matter is pending before the High Court and interim injunction has been granted in this regard but

the Drugs Registration Board in utter disregard of all norms of natural justice cancelled the registration of (Paracetamol Tablet 500mg, Registration No.010449) manufactured by the petitioner through letter dated 25.11.2009 issued by the Drugs Registration Board, Islamabad.

8. The Learned counsel for petitioner, in WP No.2303/09, started his arguments by putting in plain words that Article 4 of the Constitution provides equal protection of law and any act done, order passed or proceedings initiated in violation of status quo order are against the rights given under Article 4. The learned counsel for petitioner further argued that the test reports of Central Drugs Laboratory No.SC 82 to 84/2009 dated 27.04.2009 Annexure-U/1 to U/3, Test reports Nos.FP.05 to 12/2009 dated 04.05.2009 Annexure-W/1 to W/8, and Test Report Nos.FP 24 to 41/2009 dated 15.05.2009 Annexure-Y/1 to Y/18, are in clear violation of the mandatory requirements of Rule 16 of the Drugs (Federal Inspectors, Federal Drugs Laboratory and Federal Government Analyst) Rules 1976 as the Government Analyst failed to give the details and full protocols of the test applied.

9. The learned counsel for petitioner also borrowed the opinion of Hon'ble Division Bench of the Lahore High Court, Lahore laid down in cases, i.e., ICA Nos.127 and 128 of 1989 titled *Provincial Quality Control Board and other Vs. Irza Pharma and others*, that:-

> *"…. When the basic test report does not conform with the provision of law, it is wholly without jurisdiction and incapable to be acted upon. Hence, asking the respondent to choose the aforesaid remedy is nothing but to perpetuate the tyranny. Hence, we repel the contention and we also disapprove the action taken otherwise than law which is nothing but amounts to tyranny of law, and the citizens are to be saved therefrom."*

The learned counsel for petitioner claimed that after the above referred judgments, sending the samples for re-test to National Institute of Health is also without jurisdiction.

10. The learned counsel for petitioner further argued and raised a question that Dr. Farnaz Malik, Chief National Institute of Health Drugs Control and Traditional Medicines Division was on long leave till 08.06.2009, so how she had signed the reports on 30.05.2009 and under what authority? Learned counsel for petitioner by referring Section 16 of the Drugs Act, 1976 argued that Government Analysis CDL Karachi and Chief NIH Dr. Farnaz Malik are not legally authorized to perform the test of the petitioner's product (Paracetamol Tablet 500mg) being not appointed as Government Analyst. Carrying the same notion, the learned counsel for petitioner further raised a question that competent committee for test purposes had chosen random samples from different 76 Batches of Paracetamol Tablet 500mg that were delivered to Central Drugs Laboratory Karachi and found it of standard quality, so how the committee after conducting re-sampling/re-testing found the same product as of sub-standard quality? Learned counsel for petitioner further argued that if the same product proved to be of a sub-standard quality, the same might be due to maltreatment of the product on the part of respondents or respondent No.4 in connivance with rivals of petitioner who are trying to cause irreparable loss to the petitioner.

11. Learned counsel for petitioner while concluding his arguments stated that acts of the respondents for taking samples under the control of respondent No.4 or his superiors, test reports for CDL Karachi and show cause notices etc. are unlawful and without lawful authority.

12. On the other hand, the learned counsel for petitioner, in WP No.267/2010, while endorsing aforesaid arguments evoked the interim order dated 24.06.2009 passed by this Court in the instant case and stated that the respondents being aware of the restraining order conducted random test/re-test, issued show cause notice dated 05.11.2009 and cancelled the drug manufacturing license (Paracetamol Tablet 500mg), respondents No.2

and 3 had violated orders of the Court and therefore the actions taken by the respondents are illegal, perverse, *void ab initio* and of no legal effect.

13. Conversely the learned AAG as well as Drugs Inspector contend that petitioner is not entitled for any equitable relief as alternate remedy is available against the final order of cancellation of Paracetamol Tablet 500mg. They further contend that petitioner has not filed WP No.2303/09 against any final order, therefore, writ petition is not maintainable and final order impugned in WP No.267/10 can be assailed before the hierarchy/authority provided under Drugs Act 1976, therefore, the second writ petition is also not competent.

14. Arguments heard, record perused.

15. From the perusal of record it has been observed that petitioner Shifa Laboratory Pvt Ltd. deals with manufacturing and sales of medicines/pharma products for the last 50 years through a valid license issued under Drugs Act, 1976. The petitioner had participated in the tender for supply of Paracetamol Tablet 500mg and being a successful bidder, received pre-award notification for supply of Paracetamol Tablet 500mg to National Programme for Family Planning and Primary Healthcare and Reproductive Health Project, Ministry of Health for year 2007/08 vide letter dated 17.12.2007 issued by National Coordinator of National Programme for Family Planning and Primary Healthcare, Islamabad respondent No. 3.

16. The contract was executed on 07.07.2008 for supply of Paracetamol Tablet 500mg @47.37/pack, total 1,522,890 packs against total consideration of Rs.72,139,725.63/-, whereby purchase order on behalf of respondent No.3 was issued on 07.07.2008 with a schedule of supply of Paracetamol Tablet 500mg with a condition that the packing shall contain phrase on each strip, i.e., "*NOT FOR SALE, FOR USE ONLY BY THE NATIONAL PROGRAMME FOR FAMILY PLANNING AND PRIMARY HEALTHCARE*".

17. As per terms and conditions of contract, random samples were to be taken from all batches for the purposes of test analysis by Central Drugs Laboratory CDL Karachi, however, after few samples which were of standard quality it was observed that the samples taken from Hyderabad and Peshawar have been found sub-standard by CDL Karachi, whereupon three (03) show cause notices were issued by respondent No.2, the Drugs Registration Board, Ministry of Health, Government of Pakistan, Islamabad on the basis of test analysis certificate dated 30.05.2009 wherein it was observed that the samples do not comply with B.P. 2007 and the samples have been found of sub-standard quality on the basis of test performed whereupon show cause notices dated 04.06.2009 were issued and the petitioner was directed to appear before the 219th Meeting held on 08.06.2009 in C-Block Pak Secretariat, Islamabad before the Drugs Registration Board. The petitioner had raised certain objections in the sampling of the said Paracetamol Tablet 500mg. But there is no final order in the field nor even referred in WP No.2303/09 whereby the petitioner has assailed the Test Reports No.82 to 84/2009 dated 27.04.2009, Test Reports No.FP-05 to 12/2009 dated 04.05.2009, Test Reports FP-24 to 41/2009 dated 15.05.2009 and Test Reports No.31 to 13-M/2009 dated 30.05.2009. However, when petitioner did not participate in the proceedings, the respondents had finally passed an order dated 06.11.2009 of Cancellation of Registration of Paracetamol Tablet 500mg which was communicated through letter dated 25.11.2009 by the Drugs Registration Board, Ministry of Health, Government of Pakistan.

18. The petitioner assailed the cancellation of registration of Paracetamol Tablet 500mg in second WP No.267/10 on the ground that the High Court has already passed restraining order vide order dated 24.06.2009 but the respondents have cancelled the registration of the product in violation of restraining order.

19. I have gone through every document on record and it has been observed that the petitioner has assailed the test results of Paracetamol Tablet 500mg whereas through the certificate of test analysis by Central Drugs Laboratory, it has been declared that the samples are of sub-standard quality as they do not comply with the determined quantity of the product in the tablet as required under the quality control. The samples taken by Federal Inspector of Drugs Hyderabad and Peshawar were further sent for test to the Drugs Control and Traditional Medicines Division, National Institute of Health, Islamabad. However, Drugs and Traditional Medicines Division, NIH confirmed that the samples do not contain the required percentage substances in each tablet and the samples are of sub-standard quality. On the basis of said results, different show cause notices have been issued initially on 04.06.2009 whereas the proceedings were under process but the petitioner filed WP No.2303/09 while challenging the results of Paracetamol Tablet 500mg issued by Central Drugs Laboratory, Karachi.

20. In the second writ petition the petitioner assailed the final order of cancellation of registration of Paracetamol Tablet 500mg vide registration No.010449 dated 25.11.2009.

21. It is a settled law that show cause notice cannot be considered as a final result to settle any issue rather it is an opportunity to the individual to reply the same and justify his stance in order to clear himself from the allegations referred in the show cause notice. However, in present case the petitioner has not replied the show cause notice rather adopted the approach to delay the proceedings on the basis of lame excuses. Even otherwise, the petitioner has been granted with sufficient time to appear before the Drugs Registration Board in 219th Meeting held on 08.06.2009 at Islamabad through a show cause notice dated 04.06.2009 but petitioner did not adopt the due course and failed to appear before the

Board, however the proceedings remained pending and finally the petitioner was called to appear before the Drugs Registration Board in its 221st meeting held on 06.11.2009 in the Committee Room, Block-C, Pak Secretariat, Ministry of Health, Islamabad but the petitioner through his letter dated 05.11.2009 never opted to appear before the Board rather mentioned in their reply that matter is subjudice before the High Court, therefore, the Drugs Registration Board has issued the Cancellation of the Registration of the Product (Paracetamol Tablet 500mg) registration No.010449 vide letter dated 25.11.2009. In such like eventuality, when proceedings have not been concluded and show cause notice is pending, constitutional remedy could not be invoked, reliance is placed upon ***2011 PLC(CS) 914 Lahore (Zulfiqar Cheema v/s Technical Education and Vocational Training Authority)*** wherein it is held that:-

> *11. There is another aspect of the matter. Issuance of show-cause notice does not mean that the case will invariably be decided against the petitioner and there is always a possibility that the same may be decided in favour of the petitioner. Laying challenge to a show-cause-notice is, therefore, no different that filing a petition on the basis of an apprehension or a speculation. Such a petition is premature and not ripe for adjudication. "Just as a case can be brought too late; ... it can be brought too early, and not yet be ripe for adjudication ... until the controversy has become concrete and focused, it is difficult for the Court to evaluate the practical merits of the position of each party." The basic rational behind the ripeness doctrine is "to prevent the courts through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.*

Similar view has also been taken by Division Bench of Lahore High Court in ***2011 PLC (CS) 1551 (Abdul Raheem Khan v/s MD PEPCO, WAPDA House Lahore)*** holding therein that:-

> *"This Court in Muhammad Akhtar Sherani and 35 others v. The Punjab Textbook Board, Lahore and 4 others 2001 PLC (C.S.) 939 has held that a petition under Article 199 of the Constitution*

> *of Islamic Republic of Pakistan 1973 would not be maintainable against mere issuance of a show cause notice since the appellant has been simply called upon to show cause as to why he should not be proceeded against. The august Supreme Court of Pakistan in Virasat Ullah v. Bashir Ahmad, Settlement Commissioner (Industries) and another (1969 SCMR 154) has also held that mere issuance of a notice by the settlement Commissioner calling upon the transferee to justify his transfer could not furnish the basis for filing a constitutional petition."*

22. The basic stance taken by the petitioner in WP No.2303/09 is that the proceedings were already pending before the High Court and a restraining order was well in field.

23. But despite that respondents cancelled their registration. I have gone through the restraining order dated 24.06.2009 passed in CM No.2804/09 in WP 2303/09 (old number WP 1114/09), and reached to a conclusion that this Court passed the restraining order only "***till next date of hearing***" whereas on the next date of hearing i.e., 02.07.2009 the restraining order was not extended and thereafter instant case got fixed before this Court on 17.01.2017 for the first time. Similarly, the record of the second WP No.267/10 which was initially filed before the Lahore High Court, Rawalpindi Bench, Rawalpindi, clearly demonstrates that the final order dated 06.11.2009 communicated vide letter dated 25.11.2009 was suspended vide order dated 25.01.2010 and the same was in field till 13.05.2010 and thereafter the second writ petition has also been fixed before this Court for the first time on 17.01.2017 after the elapse of almost seven and a half years.

24. From the perusal of record it has been observed that show cause notice has not been settled till date even otherwise it is settled proposition of law that status of show cause notice is not conclusive as nothing has been finalized till date in WP No.2303/09, the petitioner has assailed the test reports in the said writ petition which could be assailed as per remedy available under the law whereas Sec.7 of Drugs Acts, 1976 provides the

registration of drugs whereas Federal Government has setup a registration board for the said purposes. Sec.22(4) of the Drugs Act, 1976 provides the mechanism for test and analysis by the Government Analyst regarding any sample of drug which has been delivered to the Government Analyst by the Inspector. Adding more, the concept of appellate board is also available under the said law, however any person aggrieved with any order of central licensing board or the registration board or the licensing authority, can assail the said order before the appellate board and even otherwise the appellate board can entertain the revision of any said decision on its own motion, similarly Sec.9(a) provides appeal to appellate authority, hence it can safely be concluded that alternate remedies are in field but the petitioner has not availed any such remedy and directly approached this Court without availing statutory remedies. In such eventuality writ petition is not competent, reliance is placed upon ***2001 SCMR 1493 (Mst. Kaniz Fatima vs. Muhammad Salim)*** wherein it has been held that:-

> *"By now it is well-settled that "where a particular statute provides a self-contained machinery for the determination of questions arising under the Act as and where law provides a remedy by appeal or revision to another Tribunal fully competent to give any relief, any indulgence to the contrary by the High Court is bound to produce a sense of distrust in statutory Tribunals. Where, therefore, a petitioner without exhausting his remedy provided by the statute under which h complained had files a writ petition, it was held that the application in the circumstances would not lie."*

25. Similarly, petitioner has raised question of disputed facts. Firstly, when petitioner contends that Federal Inspector Drugs, Peshawar has issued a letter/corrigendum regarding correction of batch number mentioned on the test reports, secondly, the petitioner has referred in his petition and offered for re-sampling of drugs as petitioner did not accept the results and thirdly, the petitioner has claimed that full protocols of the test applied have not been provided. The above referred position of record

clearly demonstrates that the disputed question of facts have been raised which could not be adjudicated upon in the constitutional petition, reliance is placed upon ***PLD 2001 SC 415 (Secretary to the Government of Punjab, Forest Department, Punjab vs. Ghulam Nabi, etc.)*** wherein it is held that:-

> *"It hardly needs any elaboration that "the superior Courts should not involve themselves into investigations of disputed question of fact which necessitate taking of evidence. This can more appropriately be done in the ordinary Civil Procedure for litigation by a suit. This extraordinary jurisdiction is intended primarily, for providing an expeditious remedy in a case where the illegibility of the impugned action of an executive or other authority can be established without any elaborate enquiry into complicated or disputed facts."*

26. The net result which flows from above discussion is that:-

(i) In W.P. No.2303/09, as disputed questions of facts are involved, which cannot be decided without recording of evidence, therefore, instant writ petition stands dismissed.

(ii) As far as W.P. No.267/10 is concerned, in view of above discussion the petitioner has alternate remedy available to them under the law, therefore, said writ petition is not maintainable, resultantly, the same stands dismissed.

(MOHSIN AKHTAR KAYANI)
JUDGE

Khalid Z.

ORDER SHEET.

IN THE ISLAMABAD HIGH COURT, ISLAMABAD.
JUDICIAL DEPARTMENT.

W.P. No. 267/10

M/s Shifa Laboratories Pvt. Ltd.
Versus
FOP through Secretary M/o Health, Islamabad, etc.

S. No. of order/ proceedings	Date of order/ Proceedings	Order with signature of Judge and that of parties or counsel where necessary.
(09)	18.04.2017	Mr. Hamid Khan, Advocate for petitioner. Ch. Abdul Khaliq Thind, Assistant Attorney General Shoaib Ali Khan, Assistant Director (Legal) DRAP. Vide my detailed judgment of even date passed in W.P. No.2303/09, the instant writ petition stands dismissed. **(MOHSIN AKHTAR KAYANI)** **JUDGE**

Khalid Z.