(2004) 03 KAR CK 0067

In the Karnataka High Court

Case No : Writ Petition No. 40227 of 2003

Medreich Sterilab Limited — APPELLANT

Vs

Union of India (UOI) and Others — RESPONDENT

Date of Decision : 30-03-2004

Acts Referred:

Constitution of India, 1950 — Article 14, 141, 19, 21
Drugs and Cosmetics Act, 1940 — Section 18 A, 23 (3), 23 (4), 25, 25 (2)
Drugs and Cosmetics Rules, 1945 — Rule 85
Evidence Act, 1872 — Section 4

Citation : AIR 2004 Kar 420 : (2004) ILR (Kar) 2545 : (2004) 3 KarLJ 404 : (2004) 3 KCCR 285 SN

Hon'ble Judges : H.L. Dattu, J

Bench : Single Bench

Advocate : B.V. Acharya, for Vishwanath Associates, for the Appellant; N. Devadas, for Respondents-1 and 4 and Satish M. Doddamani, A.G.A. for Respondents-2 and 3, for the Respondent

Judgement

H.L. Dattu, J.—Petitioner is a company incorporated under the provisions of the Companies Act, 1956 and is engaged in the manufacture of various pharmaceuticals preparations.

2. The second respondent-Drug Controller/Licensing Authority is the Competent Authority to issue licence under the provisions of the Drugs and Cosmetics Act, 1940 (''the Act'' for short) and the Rules framed thereunder. He has issued a licence to the petitioner-Company for manufacture of pharmaceutical preparations, apart from others, a drug formulation by trade name "Augmentin Duo Syrup" (Amoxycillin and Clavulanic Acid) and the said licence is renewed from time to time. It is the claim of the petitioner-Company that the Augmentin range of preparations manufactured by the petitioner-Company is sold all over the country.

3. The cause of action pleaded in the petition for the petitioner-Company to approach this Court is the show-cause notice issued by the second respondent to

the petitioner-Company dated 7-12-2002 under Rule 85(2) of the Drugs and Cosmetics Rules, 1945 (''Rules'' for short), inter alia directing it to show cause, why action as per law should not be taken against it, to cancel, suspend or revoke the licence granted, on the ground that "Augmentin Duo Syrup" batch No. 1017 date of manufacture -- June, 2001, date of expiry -- May, 2003 has been declared as ''not of standard quality'' by the Government Analyst, Drug Testing Laboratory, New Delhi, vide test report dated 24-10-2002 and along with the show-cause notice the report of the Government Analyst was also enclosed. The petitioner-Company was also directed to appear on 18-12-2002 and to produce the records of production, test and analysis in support of its defence and to adduce evidence, if any, controverting the report.

4. Petitioner-Company through its representative has appeared before the second respondent and has filed its preliminary objections on 18-12-2002 and has sought for some time to file its detailed reply. In the preliminary objections, apart from pointing out certain irregularities in the report, petitioner-Company has also brought to the notice of the second respondent, that, it has not been served with sealed portion of the sample and thereby it is prevented from contesting the correctness of the report of the Government Analyst and further to request the Competent Authority to send the sample to the Central Drugs Laboratory and so that the report obtained thereof would be conclusive evidence of the facts stated therein against the petitioner-Company also. Even before the second respondent could react to the preliminary objections filed, the petitioner-Company has rushed to this Court inter alia seeking the following reliefs. They are.--

"I. To declare Section 25 of the Drugs and Cosmetics Act, 1940 is illegal, void and opposed to certain provisions of Constitution of India and in particular to Articles 14, 19 and 21 of the Constitution.

II. To quash by issuing an appropriate writ, the report of the Government Analyst dated 24-10-2002 insofar as petitioner is concerned.

III. To quash by issuing an appropriate writ, the proceedings initiated by the second respondent for cancellation of licence granted in favour of the petitioner-Company by the impugned show-cause notice dated 7-12-2002".

5. Before I refer to the submissions of the learned Senior Counsel, let me first notice some more facts, which has prompted the petitioner-Company to approach this Court at a very preliminary State. I say preliminary stage, only because, we are still at the stage of show-cause notice issued by the second respondent, who intends to take certain action, based on the report of Government Analyst as provided under the provisions of Drugs and Cosmetics Rules against the petitioner-Company. The Drugs Inspector, Drugs Control Department, New Delhi, who has been arrayed as fifth respondent in the writ petition, it appears, on 29-4-2001 had taken six bottles of the preparations referred to earlier (Augmentin Duo Syrup) as samples from M/s. Friends Medical

Hall, New Delhi, for test and analysis under the provisions of the Drugs and Cosmetics Act, which in turn had purchased three bottles each, from two different sources, namely, British Medical Stores and M/s. Arya Medicos, New Delhi and thereafter had divided the sample taken into four portions by following the procedure prescribed under Sub-section (3) of Section 23 of the Act, and had restored one portion of the sample so divided to the person from whom he had purchased the drug and has disposed off the remaining three portions as envisaged under Sub-section (4) of Section 23 of the Act. At this stage itself, it is useful to state that the statutory provisions do not provide for sending of the samples so taken to the manufacturer of the drug by the Drugs Inspector.

After testing the sample of the drug received from the Drugs Inspector, the Government Analyst has sent his test report dated 24-10-2002 in triplicate in the prescribed form to the Drugs Inspector and in that, has observed, that the sample does not conform to the requirements of the United States Pharmacopoeia (USP) in respect of PH and assay (content) of Clavulanic Acid. The Drugs Inspector in turn, by his communication dated 30-3-2003, has sent one copy of the report of M/s. Arya Medicos, New Delhi, from whom he had purchased the drug for the purpose of test and analysis under the Act and also has endorsed a copy of the report to British Medical Stores, New, Delhi, whose name has been disclosed u/s 18A of the Act and further, has retained the third copy for use in any prosecution in respect of the sample as required under Sub-section (2) of Section 25 of the Act, inter alia calling upon them to notify in writing within twenty-eight days of the receipt of the copy of the report, if they wish to adduce evidence in controversion of the report. A copy of this communication is also furnished to the petitioner-Company but without calling upon them to notify in writing within twenty-eight days of receipt of the information to the Drugs Inspector that they intend to adduce evidence in controversion of the report and according to the petitioner-Company, non-supply of one portion of the sample collected by the Drugs Inspector and the copy of the report of the Government Analyst has resulted in depriving the petitioner-Company a valuable right to notify the Drugs Inspector within the time prescribed under the Act its intention to controvert the report. In the petition, it is also stated that, since the provisions of the Act envisage, that it is the manufacturer of a drug, which is found to be lacking in requisite standard of quality, is ultimately held responsible for supply of such drug and thus liable for prosecution. Alternatively, it is suggested, that, ultimately the liability for breach of Section 18 of the Act with regard to the quality of drug rests upon the manufacturer, and therefore, it is the manufacturer who should be furnished with the report of Government Analyst and also the samples that were taken and submitted by the Drugs Inspector to the Government Analyst.

6. The learned Senior Counsel Sri B.V. Acharya for the petitioner-Company would contend that the report of the Government Analyst under the Act shall be evidence of the facts stated therein and such evidence shall be conclusive even against the petitioner-Company, though it is not supplied with the portion of the

sample collected by the Drugs Inspector and a copy of the report of the Government Analyst, calling upon the manufacturer to notify in writing within the prescribed time, if it desires to adduce evidence in controversion of the report and therefore, a provision which deprives the right of fair hearing is not only arbitrary but also violative of Article 14 of the Constitution of India. The learned Senior Counsel adds that in the context of fair hearing and to meet the requirement of principles of natural justice, an opportunity should be given to the person accused to make effective representation and to make opportunity of representation effective, materials relied upon by the authority requires to be supplied to him, especially in a case where a person would be deprived of his liberty or property or be subjected to pains or penalties or be exposed to prosecution proceedings or deprived of remedies or redress or be affected by adverse consequences and since that is not provided u/s 25 of the Act, the said provision is ultra vires and opposed to constitutional provisions, which provides safeguards to the rights of a citizen.

Secondly, the learned Senior Counsel would contend, that Section 25 of the Act provides for supplying of samples collected by the Drugs Inspector and furnishing of report of Government Analyst only to those persons from whom the samples are collected for test and analysis under the Act and to those persons who are named u/s 18 of the Act inter alia directing them to notify whether they intend to adduce any evidence in controversion of the report. The manufacturer of the drug is not even entitled for a portion of the sample of the drug collected by the Drugs Inspector nor is it entitled for a copy of the report of the Drug Analyst and thereby the manufacturer of the drug is deprived of his right to controvert the findings of the Government Analyst, though ultimately he would be the sufferer, if any action is initiated by the Drugs Inspector under the Act and the licensing authority under the Rules. A provision, which makes an invidious and hostile discrimination between persons who are identically placed, is violative of Article 14 of the Constitution.

7. Further, the learned Senior Counsel contends that Guarantee of Equal Protection is applied against the substantive as well as procedural laws and all litigants, who are similarly placed are entitled to avail themselves the same procedural rights for reliefs and defence without discrimination. It is further contended, that, if the intendment of the Act is to get hold of the manufacturer of the drug which is manufacturing drugs of "not standard quality", then the manufacturer should have effective opportunity for reference to the effect, that, the drug manufactured by them out of which the samples are drawn is not lacking in necessary standards of quality and for such defence, it is obvious that the petitioner-Company should have access to a portion of the sample drawn as well as to the report describing it as lacking in standards of quality within a reasonable period, to enable him to exercise its right of adducing evidence in controversion of the report of the Drug Analyst.

8. The learned Senior Counsel for the petitioner-Company would further contend

that the petitioner-Company being the manufacturer of a drug should have the first opportunity to controvert the report of the Government Analyst, who has found that one of the pharmaceutical preparation manufactured by the petitioner-Company was of substandard quality by not only furnishing his report but also portion of sample collected by the Drug Inspector either from a retailer or a distributor. Since an effective opportunity is denied to the manufacturer, Section 25 of the Act is not only arbitrary but also violative of Article 19(1)(g) of the Constitution of India.

9. Insofar as show-cause notice issued by the second respondent-Drug Controller, the learned Senior Counsel would further contend that since the report of the Government Analyst is a conclusive evidence of facts stated therein, unless it is not filed in writing to the Inspector or the Court that it intends to adduce evidence in controversion of the report and since that has not been done by the petitioner-Company in the absence of copy of the report of the Government Analyst, no useful purpose would be served, even if petitioner-Company files any objection to the show-cause notice issued by the second respondent. Therefore, the learned Senior Counsel would contend that, show-cause notice issued by the respondent-authority is arbitrary and illegal. Secondly, it is stated that the proceedings initiated by the second respondent by issuing the impugned show-cause notice for cancellation of petitioner-Company''s licence is illegal, erroneous and improper as the proceedings ought not to have been initiated on the basis of the report of the Government Analyst and lastly, the report of the Government Analyst and the action of the fifth respondent thereon is illegal, improper and erroneous inasmuch as the report is liable to be quashed on the ground of violative of principles of natural justice,

10. Per contra and in support of the proceedings taken, Sri Devadas, learned Counsel appearing for respondents 1 and 4 would submit that the legal issues raised by the learned Senior Counsel for petitioner-Company insofar as the constitutional validity or otherwise of Section 25 of the Act is concerned is no more debatable in view of the law declared by the Apex Court in the case of Amery Pharmaceuticals and Another Vs. State of Rajasthan, . Therefore, petitioner-Company in law is not entitled to either the copy of the test report or portion of the sample of the drug collected by the Drugs Inspector. Therefore, it cannot be said the provisions of Section 25 of the Act is violative of any constitutional provisions.

Secondly, the learned Counsel would contend, that as a matter of right, petitioner-Company though was not entitled for a copy of the report of the Drugs Inspector, to satisfy the requirement of principles of natural justice, along with the show-cause notice, the petitioner-Company was supplied with a copy of report of Government Analyst and the petitioner-Company could have questioned the correctness or otherwise of the same before the appropriate forum within the time prescribed under the Act. Having not utilised that opportunity, according to the learned Counsel, petitioner-Company is estopped from contending that it is

deprived of an opportunity to question the correctness of the report of the Government Analyst. In aid of this submission, the learned Counsel would rely on the observations made by the Apex Court in the case of State of Haryana Vs. Brij Lal Mittal and Others, .

11. Sri Satish M. Doddamani, learned Additional Government Advocate appearing for respondents 2 and 3 would contend that the petition filed by the petitioner-Company is wholly premature, in the sense, petitioner is merely questioning the show-cause notice issued by the respondents, to show cause why the petitioner-Company''s drug manufacturing licence should not be cancelled in view of the report of the Government Analyst, wherein he has opined that the drug manufactured by the petitioner-Company is not of standard quality. According to the learned Counsel, petitioner has ample opportunity to produce all its evidence before the respondents that the report of the Government Analyst need not be accepted and used against the petitioner by the second respondent.

Alternatively the learned Additional Government Advocate would contend that the petitioner having filed its preliminary objection to the show-cause notice before the second respondent, should have waited for the outcome of the proceedings and even before any action could be taken by the second respondent, petitioner should not be permitted to question the correctness or otherwise of mere show-cause notice issued by the second respondent, since it is not the case of the petitioner that the notice is issued by an incompetent authority or contrary to the provisions of the Act and the Rules framed thereunder or it is issued with mala fide intention without there being any material in the possession of second respondent.

The learned Additional Government Advocate would lastly contend that the petitioner has ample opportunity before the second respondent to demonstrate and prove that the drug manufactured by it is of a standard quality and it is because of the default committed by the retailer in not storing the drug according to the procedure prescribed, the Government Analyst might have come to the conclusion that the drug samples tested might have proved to be substandard quality.

12. Per contra, Sri B.S. Acharya, learned Senior Counsel appearing for the petitioner would contend that since the report of the Government Analyst is conclusive proof against the petitioner, since it is not questioned by the petitioner-Company within the time prescribed under Sub-section (3) of Section 25 of the Act and therefore, no useful purpose would be served even if petitioner is asked to show cause by filing its objections before the second respondent, Hearing once given must be genuine and not formal or empty public relations exercise, and in the instant case, according to the learned Senior Counsel, the audience allowed tantamounts to nothing.

13. Now the questions that requires to be considered and decided by this Court are, firstly, whether the provisions of Section 25 of the Act is in violation of any

of the constitutional provisions as contended by petitioner''s learned Senior Counsel? and secondly, whether the proceedings initiated by the second respondent for cancellation of licence is illegal, erroneous and improper as the proceedings have been initiated on the basis of the report, of the Government Analyst?

14. Insofar as the constitutional validity or otherwise of Section 25 of the Act is concerned, the said provision did come up for consideration before the Apex Court in the case of Amery Pharmaceuticals, supra. In the said decision, the arguments canvassed by the appellant''s learned Counsel was more or less similar to the arguments canvassed by the learned Senior Counsel before this Court.

In the said decision, it was contended by the learned Counsel for the appellant that the conclusiveness of the report of the Government Analyst as envisaged in Sub-section (3) of Section 25 of the Act would nail the manufacturer with the findings in the report as he would otherwise be disabled from controverting the said findings because he has no right to challenge such findings due to the absence of a portion of the sample with him. It was also contended that since the manufacturer is not entitled to get a copy of the report of the Government Analyst as of right, the manufacturer would be disabled from challenging the correctness of the facts stated in the report and such deprivation would visit him with hard civil consequences, as the facts stated in the report would become conclusive evidence against him and that such a provision which disables an accused from disproving the correctness of the facts contained in a document which would nail him down is unfair and unreasonable, besides being oppressive and that amounts to violation of fundamental right enshrined in Article 21 of the Constitution.

The Apex Court while answering this specific legal issue was pleased to point out that:

"24. The extent of the implication of the words "such evidence shall be conclusive" as employed in Section 25(3) of the Act has to be understood now. Section 4 of the Indian Evidence Act says that when one fact is declared by the said Act to be conclusive proof of another "the Court shall, on proof of one fact, regard the other as proved, and shall not allow evidence to be given for the purpose of disproving it". The expression "conclusive evidence" employed in Section 25(3) of the Act cannot have a different implication as the legislative intention cannot be different. Such an import as for the word "conclusive" in the interpretation of statutory provisions has now come to stay. If so, what would happen if the manufacturer is disabled from challenging the facts contained in the document, which would visit him with drastic consequences when he is arraigned in a trial. Any legal provision which snarls an indicated person without affording any remedy to him to disprove an item of evidence, which could nail him down cannot be approved as consistent with the philosophy enshrined in Article 21 of the Constitution. The first effort which Courts should embark upon

in such a situation is to use the power of interpretation to dilute it to make the provision amenable to Article 21.

25. In our view, the Court should lean to an interpretation as would avert the consequences of depriving an accused of any remedy against such evidence. He must have the right to disprove or controvert the facts stated in such a document at least at the first tier. It is possible to interpret the provisions in such a way as to make a remedy available to him. When so interpreted the position is thus: The conclusiveness meant in Section 25(3) of the Act need be read in juxtaposition with the persons referred to in the sub-section. In other words, if any of the persons who receives a copy of the report of the Government Analyst fails to notify his intention to adduce evidence in controversion of the facts stated in the report within a period of 28 days of the receipt of the report, then such report of the Government Analyst could become conclusive evidence regarding the facts stated therein as against such persons. But, as for an accused, like the manufacturer in the present case, who is not entitled to be supplied with a copy of the report of the Government Analyst, he must have the liberty to challenge the correctness of the facts stated in the report by resorting to any other modes by which such facts can be disproved. He can also avail himself of the remedy indicated in Sub-section (4) of Section 25 of the Act by requesting the Court to send the other portion of the sample remaining in the Court to be tested at the Central Drugs Laboratory. Of course, no Court is under a compulsion to cause the said sample to be so tested if the request is made after a long delay. It is for that purpose that a discretion has been conferred on the Court to decide whether such sample should be sent to the Central Drugs Laboratory on the strength of such request. However, once the sample is tested at the Central Drugs Laboratory and a report as envisaged in Section 25(4) of the Act is produced in Court the conclusiveness mentioned in that sub-section would become incontrovertible".

(emphasis supplied)

15. In my view, the observations made by the Apex Court in Amery Pharmaceuticals case, supra, is a complete answer to the submissions made by learned Senior Counsel Sri B.V. Acharya, for the petitioner-Company. However, the learned Senior Counsel would contend before me, that the observations made by the Apex Court in the aforesaid decision was with reference to proceedings before a Criminal Court, where a manufacturer of a drug was arrayed as one of the accused and that accused could request the Criminal Court to cause the sample of the drug or cosmetic produced before the Magistrate under Sub-section (4) of Section 25 to be sent for test or analysis to the Central Drugs Laboratory. Since such an opportunity was/is available to the accused/ manufacturer, according to the learned Senior Counsel, the Apex Court has observed that the provisions of Section 25 of the Act does not violate Article 21 of the Constitution of India and further mere non- supply of the test samples cannot be said has deprived the manufacturer of the drug an opportunity to

defend himself in the proceedings filed before the Magistrate. No doubt it is true that the matter which was before the Apex Court is out of an order made in criminal proceedings, but the matter which was substantially argued and discussed was with regard to the submissions made whether the conclusiveness of the report of the Government Analyst would prejudice the defence of the manufacturer since it has no right to challenge the report and the findings of the Government Analyst due to non-supply of the portion of the sample along with the report of the Drug Analyst. While answering this issue, the Apex Court has specifically observed that in view of the language employed in Section 25 of the Act, the manufacturer is not entitled to a copy of the report of the Drug Analyst and also the test samples collected by the Drug Inspector, but that would not prevent him from challenging the correctness of the facts stated in the report by resorting to any other mode by which facts can be disproved. The Court has also observed that the report of the Government Analyst is conclusive proof against those persons mentioned in Sub-section (3) of Section 25 of the Act unless they notify the Drugs Inspector or the Court before which any proceedings are pending that they intend to adduce evidence in controversion of the report and that cannot be conclusive proof against the manufacturer since the statute expressly excludes furnishing of either a portion of the sample of the drug or the report of the Government Analyst. By saying so, the Apex Court has negatived the stand of the manufacturer that the provisions of Section 25 of the Act violates Article 21 of the Constitution and thereby the constitutional validity or otherwise of Section 25 of the Act has been sustained by the Apex Court. It is no doubt true that the Apex Court has not noticed that whether the provision of Section 25 of the Act would violate the mandate of Article 14 of the Constitution, but that aspect of the matter cannot be looked into by this Court, in view of Article 141 of the Constitution of India. It is now well-settled that the law enunciated by the Supreme Court is binding and absolute. Its correctness cannot be doubted on the grounds, inter alia, of (a) there being another view which was not considered; or (b) was never urged and considered; or (c) the Supreme Court''s view being not in tune with "the mores of the day or change of events requiring a change in outlook of the law". The laws declared by the Supreme Court are not merely matters of individual opinion; they are products of judicial functioning arrived at on the basis of objective tests, not chances (The Collector of Kamrup v. Smt. Anandi Debi, AIR 1987 Gau. 13 (DB)). The Apex Court in the case of Delhi Cloth and General Mills Ltd. Vs. Shambhu Nath Mukherji and Others, was pleased to observe that when the Supreme Court has held that Section 10 of the Industrial Disputes Act, 1947, is intra vires, and not violative of Article 14, it is not permissible to raise the objection again on a new ground. It is certainly easy to discover fresh grounds of attack, but that cannot be permitted once the Supreme Court had laid down the law that Section 10 of the Industrial Disputes Act, 1947, does not violate Article 14 of the Constitution.

In a case decided by the Bombay High Court in the case of Mohandas Issardas and Others Vs. A.N. Sattanathan and Others, it is stated that once the Supreme

Court makes a declaration of law, that is binding on all the subordinate Courts. Principles of ''obiter'', ''per incuriam'' and ''distinguishable on facts'' which may perhaps apply to the decisions of Courts of co-ordinate jurisdiction cannot be applied to a declaration of law made by the Supreme Court and such principles cannot restrict the scope of Article 141 of the Constitution. If a declaration of law has been made by the Supreme Court, it is also not open to the subordinate Courts to hold that the declaration of law is not binding, because on facts, the case decided by the Supreme Court is distinguishable from the case before the subordinate Court.

16. In view of the above, it cannot be said that the provisions of Section 25 of the Act is discriminatory and thereby violates Article 14 of the Constitution. Therefore, the first prayer in the petition requires to be rejected.

17. In the present case, one more aspect which requires to be kept in view is that the 5th respondent-Drugs Inspector while communicating the report of the Government Analyst to the person from whom he had purchased the Drug, and to the person whose name and address is disclosed u/s 18A of the Act, had also sent a copy of the communication so addressed to the petitioner/manufacturer, though under law it was not required to do so. The petitioner could have utilised that opportunity by informing the Drugs Inspector within the time prescribed that it intends to adduce evidence in controvers ion of the report of the Government Analyst. But, that opportunity petitioner-Company has not utilised for the reason best known to it alone. Having failed to utilise an opportunity provided, petitioner-Company at this belated stage cannot contend that the provisions of the Act are in violation of principles of natural justice.

18. Provisions of Section 25 of the Act mandates the Drugs Inspector to furnish the copy of the report of the Drugs Inspector only to a person from whom samples of the drug taken and persons whose name and addresses is furnished u/s 18A of the Act. The section also deems that the contents of the report is conclusive of the facts and such evidence shall be conclusive against those persons alone, if they do not notify the Drugs Inspector in writing within twenty-eight days of the receipt of the copy of the report that they intend to adduce evidence in controversion of the report. The Statute excludes furnishing of the report of the Government Analyst to the manufacturer and the Statute also expressly states that the contents of the report shall be evidence of facts therein only against those persons who are expected to be supplied with the report of the Government Analyst, unless they make a request to adduce evidence of controversion of the report. If the Statute had expressly provided that the report of the Government Analyst is also conclusive evidence of facts against the manufacturer, then it could have been said that the provisions are discriminatory, since equals are treated unequally and thereby the provisions are violative of Article 14 of the Constitution. At the cost of repetition, the conclusiveness of the report of the Government Analyst is only against the persons mentioned in Sub-section (3) of Section 25 of the Act and that conclusiveness of the facts stated

therein cannot be conclusive evidence against the petitioner-Company.

19. The other aspect of the matter which requires to be noticed is that the Assistant Drugs Controller, Delhi, while informing the Drugs Controller at Bangalore in whose jurisdiction the manufacturer/ petitioner is located to take necessary action in the matter had enclosed a copy of the report of the Government Analyst and that intimation dated 21-11-2002 was also sent to the petitioner-Company and the records produced by learned Counsel Sri Devadas would disclose that along with the copy of the intimation, the report of the Government Analyst was enclosed and it appears, petitioner has not responded to this intimation within the time prescribed u/s 25(3) of the Act, notifying the Drugs Inspector, that it intends to adduce evidence in controversion of the report. Whether this lapse on the part of the petitioner could be used against the petitioner while considering its defence to the proposed action under the show-cause notice by the Drugs Controller need not be considered by this Court at this stage.

20. Now, what remains to be considered and decided by this Court is the proceedings initiated by the authorities under the Act in exercise of their powers under Rule 85 of the Drugs and Cosmetics Rules, 1945. The authorities, based on the report of the Drug Inspector have initiated the aforesaid proceedings. The petitioner-Company can resort to any other mode by which such facts can be disproved. At the risk of repetition, the observations made by the Apex Court can be once again noticed.

"But as far as accused, like the manufacturer in the present case, who is not entitled to be supplied with a copy of the report of the Government Analyst, he must have the liberty to challenge the correctness of the facts stated in the report by resorting to any other mode by which such facts can be disproved".

21. Sri Satish M. Doddamani, learned Additional Government Advocate appearing for the respondents would submit that the respondents would consider the preliminary objection and any other additional objections that may be filed by the petitioner to the show-cause notice issued by them in accordance with law. This statement of the learned Additional Government Advocate should ally any apprehension that the petitioner may be entertaining.

22. In view of the above, the following:

ORDER

I. Insofar as the first prayer sought for by the petitioner is concerned, the same is rejected.

II. Insofar as the second prayer sought for by the petitioner is concerned, petitioner is granted a month''s time from today to file their additional objections, if any, to the show-cause notice issued by the second respondent.

III. If such objections are filed by the petitioner within the time granted by this

Court, the second respondent is directed to consider the preliminary objections that is already filed and also additional objections that may be filed to the impugned show-cause notice in accordance with law and with an open mind as expeditiously as possible and at any rate within 30 days from the date of filing of the additional objections.

IV. All the other contentions of both the parties are left open.

V. In the facts and circumstances of the case, parties are directed to bear their own costs. Ordered accordingly.

