



BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

DATED: 28.10.2020

CORAM:

THE HONOURABLE MR. JUSTICE **G.K.ILANTHIRAIYAN**

Crl.O.P.(MD)No.20982 of 2016

and

Crl.MP(MD).Nos.10693 & 10694 of 2016

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1.M/S.Zee Laboratories Ltd.,
Behind 47 Industrial Area,
Paonta Sahib 173 025,
Rep by its Managing Director,
Mr.Rajeev Mukul,
District Sirmour,
Himachal Pradesh.

2.Raheev Mukul
Managing Director of the Firm,
M/s Zee Laboratories Ltd.,
Behind 47 Industrial Area,
Paonta Sahib 173 025,
Director Sirmour,
Himachal Pradesh.

... Petitioners/ Accused Nos.1 & 2
Vs.

Tamil Nadu State rep by the
Drugs Inspector,
Tirunelveli-II Range,
Tirunelveli Zone.
O/o The Assistant Director of Drugs Control
C-36, 25th Cross Street,
Maharaja Nagar,
Palayamkottai,
Tirunelveli-11.

...Respondent/Complainant

Prayer:Criminal Original Petition filed under Section 482 Cr.P.C.,
to call for the records relating to S.T.C.No.516 of 2014 pending on
the file of the Judicial Magistrate Court, Valliyoor, Tirunelveli
and quash the same.

For Petitioners : Mr.P.Subramanian
For Respondent : Mr.K.Suyambulinga Bharathi
Government Advocate (Crl.Side)

ORDER

This petition has been filed to quash the proceedings in
S.T.C.No.516 of 2014 pending on the file of the Judicial Magistrate
Court, Valliyoor, Tirunelveli.

2.The respondent filed a complaint for the offences punishable
under Sections 18 (a) (i) and 18 (B) of the Drugs and Cosmetics Act

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1940 and punishable under Section 27 (d) and 28 (A) of the Drugs and Cosmetics Act 1940, alleging that the respondent had drawn the sample of ' Koldex DMR Soft Gelatin capsules' from M/s.Interest Traders, Valliyoor on 30.10.2013 and the samples were sent to the Government Analyst (Drugs), Chennai on 31.10.2013. The said sample was declared as Not of Standard Quality by the Government Analyst (Drugs) report dated 08.05.2014. Hence, the first respondent issued show cause notice to the proprietor of M/s Interest Traders, Valliyoor, dated 14.05.2014. A reply letter dated 14.05.2014 was given wherein they have stated that the said drug was procured from one M/s. Sano Pharma, Nagercoil and no stock was available with them. Therefore, the respondent issued a show cause notice to the M/s. Sano Pharma, Nagercoil dated 14.05.2014. In response to the above memo, M/s. Sano Pharma, Nagercoil, has disclosed that they have acquired the subject drug from M/s. Sai Medi World, Chennai. Again a show cause notice was sent to M/s. Sai Medi World, Chennai on 02.06.2014. In their reply, they disclosed that they have acquired the subject drug from the first accused herein / M/s.Zee Laboratories Ltd., Himachal Pradesh. Again a show cause notice dated 21.05.2014 was sent to the first accused to offer their explanation as to why action should not be taken on manufacture and sale and sold the subject drugs Not of Standard Quality Drugs. The first accused replied by the letter dated 05.06.2014, they have not received the Form-13. Therefore, a letter along with copy of Form-13 was sent to the first accused dated 16.06.2014. Another show cause notice was sent to the first accused dated 14.07.2014 to furnish the particulars and required to offer their explanation. The first accused replied by the letter dated 22.07.2014, again stated that they have not received the Form-13. Further, a show cause notice dated 20.08.2014 along with Form-13 issued to the first accused. After receipt of the same, the first accused did not reply. Further, alleged that another reply from M/s. Sai Medi World, Chennai dated 29.09.2014, they have produce the details about mode of transport and mode of payment for the subject drug purchased from the first accused. Since the sample does not confirm to label claim with respect to content of one drug Phenylphrine Hydrochloride out of three drugs combination. Therefore, the first accused have contravention under Section 18 (a) (i) of the Drugs and Cosmetics Act, 1940, for having an manufactured and distributed the Not of Standard Quality Drugs and it is punishable under Section 27 (d) of the said Act. They also have contravention under Section 18-B of the Drugs and Cosmetics Act, 1940, for not having to produce particulars/documents for the subject drug, which is punishable under Section 28-A of the said Act.

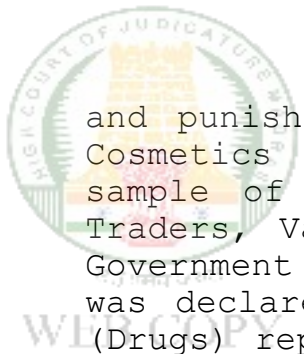
3.The learned counsel appearing for the petitioner would submit that the first accused is a Public Limited Company incorporated under the Companies Act, 1956, assisted by the Board of Directors and the second accused is the Founder and the Managing Director of the first accused Company. Therefore, the 2nd accused never involved in the day to day affairs of the first accused manufacturing units.

He further submitted that neither the alleged report dated 08.05.2014 of the Government Analysts, Chennai, nor the copy of the said report was furnished to the petitioners Company at the earliest point of time and the respondent has not afforded the reasonable opportunity to the petitioners at the earliest point of time immediately upon the alleged sampling enabling the petitioners Company to conduct the independent test at the registered independent testing centre of Central Drugs Laboratory, Calcutta so as to establish that the said sample is only Standard quality as per the label claim. The petitioner has received the Form-13 test report from the respondent on 28.08.2014. He further submitted that the present complaint has been filed before the Trial Court only on 11.11.2014 just few days prior to the expiry of the self life of the Drug in question namely expires November 2014. Therefore, the petitioners have been deprived of their valuable right to controvert the test report under Section 25 (3) and 25 (4) of the Drugs and Cosmetics Act. In this regard, he also relied upon the following judgments.

- 1) **Medicamen Bio Tech Limited and another Vs Rubina Bose, Drug Inspector Case** reported in 2008 (7) SCC P.No.196.
- 2) **M/s North Bihar Agency and others Vs State of Bihar and others** reported in 1981 (3) SCC P.No.131.
- 3) **The Drugs Inspector, Central Drugs Standard Control Organisation (South) Zone Madras - 600 006 Vs M/s.Modern Drugs and another** reported in 1982 Criminal Law Journal P.No.2285.
- 4) **State of Haryana Vs Unique Farmaid (P) Ltd.,** reported in 1999 (8) SCC P.No.190.
- 5) **Amery Pharmaceuticals Vs State of Rajasthan** reported in 2001 (4) SCC P.No.382.
- 6) **M/s.Northern Minerals Ltd., and others Vs State of Rajasthan and another** reported in CDJ 2016 SC 446.

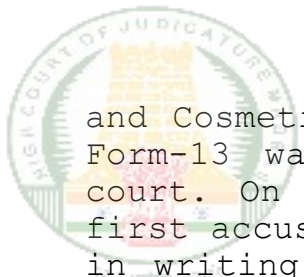
4.Further, he would submit that as far as the second accused is concerned he is the Founder and the Managing Director of the first accused company and he involves only in the policy affairs of the first accused Company and he has not at all involved in the day-to-day affairs of the Plant/Manufacturing units level. Therefore, the second accused has not participated at any liability as alleged by the respondent herein. The Section 34 of the Drugs and Cosmetics Act, 1940, provides that when the person is not responsible for the day-to-day activities and conduct of the business activities, he will not be liable for the offence under the Drugs and Cosmetics Act, 1940. In this regard, he also relied upon the decision of the judgment in **Rahul Sehgal Vs State of Kerala & others** reported in 2014 **Crl.L.J P.No.2399.**

5.Per contra, the learned Government Advocate (Crl.Side) appearing for the respondent would submit that the respondent filed a complaint before the Trial Court for the offences punishable under



and punishable under Section 27 (d) and 28 (A) of the Drugs and Cosmetics Act 1940, alleging that the respondent had drawn the sample of ' Koldex DMR Soft Gelatin capsules' from M/s.Interest Traders, Valliyoor on 30.10.2013 and the samples were sent to the Government Analyst (Drugs), Chennai on 31.10.2013. The said sample was declared as Not of Standard Quality by the Government Analyst (Drugs) report dated 08.05.2014. Hence, the first respondent issued show cause notice to the proprietor of M/s Interest Traders, Valliyoor, dated 14.05.2014. A reply letter dated 14.05.2014 was given wherein they have stated that the said drug was procured from one M/s. Sano Pharma, Nagercoil and no stock was available with them. Therefore, the respondent issued a show cause notice to the M/s. Sano Pharma, Nagercoil dated 14.05.2014. In response to the above memo, M/s. Sano Pharma, Nagercoil, has disclosed that they have acquired the subject drug from M/s. Sai Medi World, Chennai. Again a show cause notice was sent to M/s. Sai Medi World, Chennai on 02.06.2014. In their reply, they disclosed that they have acquired the subject drug from the first accused herein / M/s.Zee Laboratories Ltd., Himachal Pradesh. Again a show cause notice dated 21.05.2014 was sent to the first accused to offer their explanation as to why action should not be taken on manufactured and sale and sole the subject Not of Standard Quality Drugs. The first accused replied by the letter dated 05.06.2014, they have not received the Form-13. Therefore, a letter along with copy of Form-13 was sent to the first accused dated 16.06.2014. Another show cause notice was sent to the first accused dated 14.07.2014 to furnish the particulars and required to offer their explanation. The first accused replied by the letter dated 22.07.2014, again stated that they have not received the Form-13. Further, a show cause notice dated 20.08.2014 along with Form-13 issued to the first accused. After receipt of the same, the first accused did not reply. Further, alleged that another reply from M/s. Sai Medi World, Chennai dated 29.09.2014, they have produced the details about mode of transport and mode of payment for the subject drug purchased from the first accused. Since the sample does not confirm to label claim with respect to content of one drug Phenylphrine Hydrochloride out of three drugs combination. Therefore, the first accused have contravention under Section 18 (a) (i) of the Drugs and Cosmetics Act, 1940, for having manufactured and distributed the Not of Standard Quality Drugs and it is punishable under Section 27 (d) of the said Act. They also have contravention under Section 18-B of the Drugs and Cosmetics Act, 1940, for not having produced particulars/documents for the subject drug, which is punishable under Section 28-A of the said Act.

6.He further submitted that as per Section 18 (a) (i) of the Drugs and Cosmetics Act, 1940, one copy of the report in Form-13 along with the protocols of analysis received from the Government Analyst, Drugs Testing Laboratory, Chennai, was sent to the first accused whose name, address and other particulars were disclosed by M/s. Sai Medi World, Chennai and as per Section 25 (2) of the Drugs



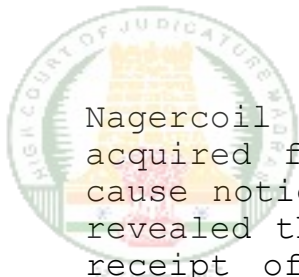
and Cosmetics Act, 1940, another copy of the report of analysis in Form-13 was filed along with the charge sheet before the Trial court. On receipt of the show cause notice dated 21.05.2014, the first accused by their reply dated 05.06.2014, had not been notified in writing by the Inspector that he intends to adduce evidence in contravention of the report. The first accused repeatedly stated that in their replies, they have not received the Form-13 by hiding the fact. Infact, Form-13 was duly received by the first accused and it was confirmed by the acknowledgment card.

7.Further, he relied upon the decision of the Hon'ble Supreme Court reported in **AIR 1998 P.No.2327**, in which it has been held that *'It must therefore be said that consequent upon their failure to notify the Inspector that they intended to adduce evidence in contravention of the report within 28 days not only the right of the manufacturers to get the sample tested by the Central Drugs Laboratory though the Court stood extinguished but the report of the Government Analyst also became conclusive evidence under Sub Section 3 of 25 of the Drugs and Cosmetics Act'*. Further, he would submit that in respect of second accused is concerned, he is the Founder and Managing Director of the Company. As per Section 34 (2) where an offence under this Act has been committed by the Company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any Director, Manager, Secretary or other Officer of the Company, such Director, Manager, Secretary or other and shall be liable to be proceeded against and punished accordingly. Therefore, the second accused is also liable to be proceeded and prayed for dismissal of the quash petition.

8.Heard the learned counsel appearing for the petitioners and the learned Government Advocate (Crl.Side) appearing for the respondent.

9.There are two accused, in which, the petitioners are arrayed as A1 & A2. The respondent has filed the complaint before the Trial Court against the petitioners under Section 18 (a) (i) and 18 (B) of the Drugs and Cosmetics Act, 1940, and punishable under Section 27 (d), 28 (A) of the Drugs and Cosmetics Act.

10.The crux of the allegation is that the respondent took the sample of 'Koldex DMR Soft Gelatin capsules' from M/s. Interest Traders, Valliyoor. The sample of the said drug was sent to the Government Analysts, Chennai on 31.10.2013 and it was declared as Not of Standard Quality by the report dated 08.05.2014. On receipt of the same, the respondent issued show cause notice to the proprietor of M/s. Interest Traders, Valliyoor and in their reply dated 14.05.2014, they stated that the said drug was procured from M/s. Sano Pharma, Nagercoil. On receipt of the same, again a show cause notice dated 14.05.2014 was issued to M/s. Sano Pharma,



Nagercoil and their reply disclosed that the subject drug was acquired from M/s. Sai Medi World, Chennai. Once again, a show cause notice issued to M/s. Sai Medi World, Chennai and their reply revealed that the said drug was acquired from the first accused. On receipt of the same, a show cause notice was sent to the first accused dated 21.05.2014. The first accused by the reply dated 05.06.2014 stated that they have not received the Form-13.

11.The learned counsel for the petitioner raised two grounds that the respondent did not afford reasonable opportunity to the petitioners at the earliest point of time immediately upon the alleged sampling enabling the petitioners' Company to conduct the independent testing centre. So as to establish that the sample also only of Standard Quality as per the label claim. Further, the second accused is Founder and Managing Director of the first accused Company and he did not involve in the day-to-day affairs of the Company and as such, he cannot be fastened with the liability of the prosecution. The first accused received Form-13 test report on 28.08.2014 from the respondent and challenged the said report. It is revealed that the control sample lying in Company's possession is complying with the test of 'Assay for Phenylephrine Hydrochloride'. It shows the contradictory results. Accordingly, informed the respondent that the first accused Company did not agree with the test report to adduce evidence in controversion of the test report by re-analysing the sample from the Appellate Authority namely, the Central Drugs Laboratory, Calcutta. In this regard, it is relevant to extract provision under Section 25 (3) of the Drugs and cosmetics Act is as follows:-

" Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken (or the person whose name, address and other particulars have been disclosed under Section 18 A) has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report"

12.The impugned complaint lodged on 11.11.2014 just few days prior to the expiry of self life of the drugs in question namely expires in November 2014. It revealed that the petitioners have been deprived of their valuable right to controvert the test report under Section 25 (3) and 25 (4) of the Drugs and Cosmetics Act. In this regard, the learned counsel for the petitioners relied upon the decision of the judgment in **Medicamen Bio Tech Limited and another Vs Rubina Bose, Drug Inspector Case (cited supra)**, in which, the Hon'ble Supreme Court of India has held as follows:-

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" 16. It is, therefore, evident that the appellant had not once but on at least two occasions and within 28 days of the receipt of the show-cause notice clarified that it intended to adduce evidence to show that the test report of the Government Analyst was not correct. The judgments cited by the learned counsel for the respondent, therefore, do not apply to the facts of the case as they were given in the context where the dealer/manufacturer had not expressed its desire to challenge the veracity of the report of the Drugs Analyst.

18. In Unique Farmaid Case which was a case under the Insecticides Act which has provisions analogous to Section 25 (34) of the Act, the Court found that the accused had indeed made a request to the Inspector for sending the sample for retesting within the prescribed time-limit and as this request had not been accepted an important right given to an accused had been rendered ineffective on which the proceedings could be quashed. This is what the Court had to say: (SCC P197, paras 12-13)

' 12. It cannot be gainsaid, therefore, that the respondents in these appeals have been deprived of their valuable right to have the sample tested from the Central Insecticides Laboratory under Sub-Section (4) of Section 24 of the Act. Under Sub-Section (3) of Section 24 report signed by the Insecticide Analyst shall be evidence of the facts stated therein and shall be conclusive evidence against the accused only if the accused do not, within 28 days of the receipt of the report, notify in writing to the Insecticides Inspector or the Court before which proceedings are pending that they intend to adduce evidence to controvert the report. In the present cases the Insecticides Inspector was notified that the accused intended to adduce evidence to controvert the report. By the time the matter reached the Court, the shelf life of the sample had already expired and no purpose would have been served informing the Court of such and intention. The report of the Insecticide Analyst was, therefore, not conclusive. A valuable right had been conferred on the accused to have the sample tested from the Central Insecticides



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Laboratory and in the circumstances of the case the accused have been deprived of that right, thus, prejudicing them in their defence.

13. In these circumstance, the High Court was right in concluding that it will be an abuse of process of Court if the prosecution is continued against the respondent, the accused persons. The High Court rightly quashed the criminal complaint. We uphold the order of the High Court and would dismiss the appeals.'

We find that this judgment helps the case of the appellant rather than that of the respondent because in spite of two communications from the appellant that it intended to adduce evidence to controvert the facts given in the report of the Government Analyst, the fourth sample with the Magistrate had not been sent for reanalysis. The observations in Amery Pharmaceuticals case are also to the same effect. We find that the aforesaid interpretation supports have the fourth sample tested from the Central Drugs Laboratory. IT is also short of the expiry date of the drug and as such had the appellant-accused appeared before the Magistrate even on 02.07.2002 it would have been well-high impossible to get the sample tested before its expiry. "

13.In the case on hand, the petitioners were not given an opportunity to controvert the test report by the Government Analyst. Therefore, the above judgment relied upon by the petitioners is squarely applicable to the case on hand. He also relied upon the judgment reported in **2015 (4) MLJ (Cr1) 56** in the case of **Embiotic Laboratories (P) Ltd., rep by its Director, Thiru Harish K.Jain and another Vs State of Tamil Nadu, rep by Drugs Inspector, George Town II Range, Teynampet, Chennai - 600 006**, which held as follows:-

" 8.Though in the instant case, some explanation is sought to be made in the counter filed by the respondent for not filing the complaint within reasonable time, the same is not sufficient and satisfactory enough to explain the delay either in filing the complaint or in issuing summons to the petitioners, which has as in the case decided by the Apex Court, deprived the petitioners herein of the valuable right available to them under Sections 25 (3) and 25 (4) of the Act. That being the factual and legal position, this Court by applying the observation of the Hon'ble Supreme Court, is of the



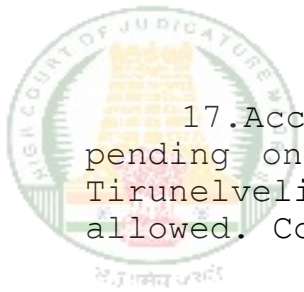
view that the proceedings initiated against the petitioners is contrary to relevant provisions of the Act and against the principles of natural justice and in the event of such prosecution being allowed to go on, it would amount to abuse of process of law and serious prejudice would be caused to the petitioners. As such, the proceedings initiated against the petitioners is liable to be quashed"

14. In view of the above, the impugned complaint is nothing, but, clearly an abuse of process of law and it cannot be sustained as against the petitioners. Apart from that the second petitioner is the Founder and Managing Director of the first accused Company. On perusal of the complaint, there is no specific allegation as against the second petitioner and admittedly he did not participate in the day-to-day affairs of the first accused Company. It is administered by the Board of Directors. In this regard, the learned counsel for the petitioner relied upon the judgment in **Rahul Sehgal Vs State of Kerala & others (cited supra)**, which is held as follows:-

" 7. From the plain reading of the Section it is clear that when an offence has been committed by a Company, every person who at the time the offence was committed was in charge of and was responsible to the Company as well as the Company shall be deemed to be guilty of the offence. In that context one question arises, will it be necessary to distinctively narrate in the complaint that the person accused was in charge of and responsible for the conduct of the business of the Company. In my opinion, in case of offence by Company to bring its responsible person in charge of the Company, it shall be necessary to allege that they were in-charge of and responsible for the conduct of the Company. I cannot read more than what has mentioned in Sections 34 of the Act"

15. In the case on hand, the second accused is the Managing Director of the first accused Company and he is conversant only with the policy affairs of the Company at the highest Board level and was not at all conversant with the day-to-day affairs of the Company. Therefore, the second accused cannot be fastened with the liability of the prosecution. As per Section 34 of Drugs and Cosmetics Act, 1940, the second accused is not held responsible for the prosecution initiated by the respondent herein.

16. In view of the above discussion, the complaint lodged by the respondent cannot be sustained as against the petitioners herein and the same has to be quashed.



17. Accordingly, the proceedings in S.T.C.No.516 of 2014 pending on the file of the Judicial Magistrate Court, Valliyoor, Tirunelveli, is hereby quashed and the Criminal Original Petition is allowed. Consequently, connected miscellaneous petitions are closed.

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Sd/-

Assistant Registrar (crl.side)

// True Copy //

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Sub Assistant Registrar(CS)

Note: In view of the present lock down owing to COVID-19 pandemic, a web copy of the order may be utilized for official purposes, but, ensuring that the copy of the order that is presented is the correct copy, shall be the responsibility of the advocate/litigant concerned.

To

- 1.The Judicial Magistrate Court,
Valliyoor, Tirunelveli,
- 2.The Drugs Inspector,
Tirunelveli-II Range,
Tirunelveli Zone.
O/o The Assistant Director of Drugs Control
C-36, 25th Cross Street,
Maharaja Nagar,
Palayamkottai,
Tirunelveli-11.
- 3.The Additional Public Prosecutor,
Madurai Bench of Madras High Court,
Madurai.

+1 CC to M/s.V.SASI KUMAR, Advocate (SR-20747[F] dated 29/10/2020)

Crl.O.P.(MD)No.20982 of 2016
and

Crl.MP(MD).Nos.10693 & 10694 of 2016
28.10.2020

PE (CO)

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