HON'BLE SRI JUSTICE U.DURGA PRASAD RAO

CRIMINAL PETITION No.5719 OF 2012

ORDER:

In this petition filed under Section 482 Cr.P.C., the petitioners/A-1 to A-4 seek to quash the order, dated 30-01-2012, in C.R.P. No.80 of 2011 passed by the learned II Additional District Judge (E.G. District) at Amalapuram, dismissing the Revision filed by the petitioners and confirming the order, dated 23.08.2011, in Crl.M.P. No.766 of 2011 in C.C. No.73 of 2010 passed by the Additional Judicial Magistrate of First Class at Amalapuram, dismissing the discharge application filed by the petitioners.

2) The factual matrix of the case is thus:

(a) On 17.11.2005, the Drugs Inspector, Amalapuram, lifted sample of PD Flam tablets from M/s.Subrahmanya Medicals, Amalapuram, under Form-17, by following the procedure prescribed under the Drugs and Cosmetics Act, 1940 (for short, 'the D.C. Act') and its Rules. Immediately after lifting the sample, he entered particulars in Form-18 and sent one out of four samples to the Government Analyst, Drugs Control Laboratory, Hyderabad. On 24.11.2006, the Drugs Inspector received report in Form-13 stating that '*NOT OF STANDARD QUALITY*' with the remarks that the sample does not meet the I.P. specifications in respect of Disintegration Test (Not more than 15 minutes for uncoated tablets, but it took 50 minutes). The drug, with Batch No.PD-4002;M/D:04/2004;E/D:03/2007, was manufactured by

M/s.Parenteral Drugs (India) Limited, Asarwad Village, Dudhia Post, Indore District – 453331 (M.P).

(b) While so, after receiving analyst report, the Drugs Inspector, Amalapuram, addressed letter on 28-11-2006 to M/s.Subrahmanya Medicals, Amalapuram, with instructions to disclose the source of supply of the said drug. On 01-05-2007, M/s.Subrahmanya Medicals, replied that they purchased the PD Flam tablets from M/s.Sarada Enterprises, 46-11-25A, Danavaipeta, Rajahmundry.

(c) On 24.05.2007, the Drugs Inspector addressed letter to M/s.Sarada Enterprises with instructions to disclose the source of supply of the subject drug, and sent a sealed sample portion of the subject drug by registered parcel along with copy of Form-13, under Section 23(4)(iii) of the D.C. Act. On 04.06.2007, the Drugs Inspector received reply from M/s.Sarada Enterprises, stating that they purchased the drug from M/s.Sri Sai Venkata Parameswari Medical Agencies, Anakapalle.

(d) On 29.06.2007, the Drugs Inspector addressed letter to M/s.Sri Sai Venkata Parameswari Medical Agencies, under Section 18A and under Section 22(i)(cca) with instructions to disclose the source of supply of said drug and a copy of Form-13 was also forwarded on 02.07.2007. On 05.07.2007, the said Agency sent reply stating that they purchased the drug from M/s.Parenteral Drugs (India) Limited, 6-1-118/25, Abhinav Nagar Colony, Padmaraonagar, Secunderabad.

(e) Therefore, on 23.07.2007, the Drugs Inspector addressed registered letter to M/s.Parenteral Drugs (India) Limited, with instructions to furnish the manufacturing and analytical records, distribution particulars etc., but said Agency has not sent the information as asked by the Drugs Inspector. So, again on 23.07.2008, he sent a letter instructing to furnish the particulars sought for; thereafter, he again sent a remainder on 16.07.2009. Besides on 16.07.2009, he also addressed letter to M/s.Parenteral Drugs (India) Limited, Asarwad village, Dudhia Post, Indore District (M.P.) with instructions to furnish the manufacturing and analytical records, distribution particulars etc., On 29.08.2009, the Drugs Inspector received reply from M/s.Parenteral Drugs (India) Limited, Asarwad village, Dudhia Post, Indore District, enclosing a copy of invoice No.90035890, dated 14.05.2004, to M/s.Parenteral Drugs (India) Limited, Padmaraonagar, Secunderabad. Basing on the analyst report, the complaint on 20.11.2009 filed C.C. No.73 of 2010 before Additional Judicial Magistrate of First Class at Amalapuram.

(f) Aggrieved, the Petitioners/A-1 to A-4 filed Crl.M.P. No.766 of 2011 under Section 255 of Cr.P.C. to discharge them. It was contended by the petitioners that the expiry date of the subject drug is March, 2007 *i.e.,* 31.03.2007 and notice about the analyst report was sent by the Drugs Inspector to the accused only on 23.07.2007 and the accused in their reply dated 27.07.2007 challenged the finding of the Government Analyst. Since the expiry date of the drug was over long back, the

petitioners lost the valuable right under Section 25(4) of the D.C. Act, to request the trial Court to send another sample for analysis to the Central Drugs Laboratory and therefore prosecution is not maintainable against them. However, the said contention was not found favour with the trial Court, as it observed that the Drugs Inspector fulfilled the requirements of the D.C. Act by remitting the sample to M/s.Sumrahmanya Medicals, Amalapuram and also to M/s.Sarada Enterprises but they have not filed any Petition before the Drugs Inspector or before the Court expressing their intention to adduce evidence in contravention of analyst report. The trial Court further observed that, even though the lifetime of drug was expired, the petitioners have every opportunity to prove their case and to send the second sample for retesting.

(g) Aggrieved, the petitioners filed Criminal Revision Petition No.80 of 2011 and the learned II Additional District Judge, Amalapuram, dismissed the Criminal Revision Petition on the observation that the Drugs Inspector was engaged in addressing letters to concerned agencies to find out the source of supply of drug and hence he could not make available the analyst report dated 14.11.2006 to the accused to enable them to challenge the report by seeking the opinion from the Central Drugs Laboratory, Kolkata. Hence the delay occurred in tracing out the source of PD Flam tablets cannot be taken advantage by the petitioners/accused to avoid trial. The petitioner/accused ought to have made available their address with the agents but they did not do so.

Hence, the instant Criminal Petition.

3. Heard arguments of Sri S.Ganesh, learned counsel for petitioners and learned Assistant Public Prosecutor (A.P.).

4. Severely fulminating the order of the learned II Additional District Judge, Amalapuram, learned counsel for the petitioners would submit that the expiry date of the PD Flam tablets was March, 2007, which was clearly mentioned on the tablet strips. The Drugs Inspector visited the shop of M/s.Subrahmanya Medicals, Amalapuram, on 17.11.2005 and collected the samples of the aforesaid medicines, sent the same for analysis to analyst on the same day and obtained the test report on 24.11.2006. As the expiry date of the drug *i.e.,* 31.03.2007 was fast approaching, the Drugs Inspector ought to have filed complaint immediately without any delay. Learned counsel, taking the attention of this Court to the copy of Form-17 notice, would submit that the address particulars of the manufacturer of PD Flam tablets was printed on the tablet strips and the same was mentioned in Form-17 notice also which indicate that the Drugs Inspector was well aware about the particulars of the manufacturer on 17.11.2005, when he obtained samples from M/s.Subrahmanya Medicals, Amalapuram. Therefore, when the particulars of the manufacturer and retailer were readily available with him, and as the lifetime of drug was going to expiry by 31.03.2007, the Drugs Inspector without wasting time for getting the particulars of the distributors, ought to have filed complaint in the Court and also sent a copy of the Analyst Report to the petitioners or the manufacturers of the drug so as to enable them to refer another sample of the Drug available

in the Court to the Central Drugs Laboratory, under Section 25(4) of the D.C. Act. However, without following this course, the Drugs Inspector belatedly filed the complaint on 20.11.2009 by which time, the lifetime of the drug was expired and thereby the petitioners have lost their valuable right under Section 25(4) of the D.C. Act. Learned counsel would further argue that without appreciating these facts in correct perspective, learned II Additional District Judge, observed as if the delay was not on the part of the Drugs Inspector and much time was taken to make correspondence with the agents of the accused to know the source of the manufacturer and distributor. Reiterating his arguments, learned counsel would submit when the particulars of the manufacturer were readily available on the tablet strips and clearly mentioned in Form-17 itself, there was no point in Drugs Inspector letting the time wither away so as to deprive the petitioners of their valuable right conferred under Section 25(4) of the D.C. Act.

5. In oppugnation, learned Assistant Public Prosecutor would argue that, under law, a manufacturer is not entitled to the sample of the drug and the Drugs Inspector, in compliance of Section 23(4), issued one sample to M/s.Subrahmanya Medicals, from whom he obtained samples and sent another sample to M/s.Sarada Enterprises, in compliance of Section 18(a) of the D.C. Act, and both of them have not expressed their intention to refer the samples available with them to the Central Drugs Laboratory. The complainant in the meanwhile tried to secure particulars of the distributors by making correspondence with the

successive agencies and since the complaint was filed by following the due process, the accused cannot ventilate any grievance.

6. The point for consideration is:

"Whether there are merits in this petition to allow?

7. **POINT**: A scrutiny of certain provisions of the Drugs and Cosmetics Act, 1940 is essential to know whether a manufacturer is, indeed, entitled to one sample out of those obtained by the Drugs Inspector, not directly from the manufacturer but from a retailer or agent or distributor, and if the manufacturer is not entitled to such sample, the method in which he can challenge the report of the Government Analyst.

8. Section 22 speaks of Powers of Inspectors. Section 23 lays down the procedure for taking sample. It reads thus:

*"**23. Procedure of Inspectors**—*

(1) Where an Inspector takes any sample of a drug [or cosmetic] under this Chapter, he shall tender the fair price thereof and may require a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused or where the Inspector seizes the stock of any drug [or cosmetic] under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he

willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked: Provided that where the sample is taken from premises whereon the drug [or cosmetic] is being manufactured, it shall be necessary to divide the sample into three portions only: Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug [or cosmetic]; and [(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.]

(5) Where an Inspector takes any action under clause (c) of section 22,—

(a) he shall use all dispatch in ascertaining whether or not the drug [or cosmetic] contravenes any of the provisions of section 18 and, if it is ascertained that the drug [or cosmetic] does not so contravene forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(b) if he seizes the stock of the drug [or cosmetic], he shall as soon as may be, inform [a Judicial Magistrate] and take his orders as to the custody thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug [or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause. [(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform [a Judicial Magistrate] and take his orders as to the custody thereof.] Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform [a Judicial Magistrate] and take his orders as to the custody thereof.]"

9. Thus, Section 23 lays down that if the sample is obtained by the Drugs Inspector other than from a manufacturer, he shall divide the said sample into four portions and tender one sample to the person from whom he takes it; remit one sample to the Government Analyst for analysis; produce one sample into the Court before which the proceedings are initiated; and the last sample he shall send to the person, if any, whose name, address and other particulars have been disclosed under Section 18(a) of the D.C. Act.

10. If on the other hand, the sample is taken from the premises, where drug or cosmetic is manufactured, the Drugs Inspector shall necessarily divide the sample into three portions only and give the first sample to the manufacturer and forward the second sample to the Government

Analyst for analysis and produce the third sample before the Court where Criminal Proceedings are initiated. In this regard, Section 18-A lays down thus:

> *"**18-A. Disclosure of the name of the manufacturer, etc**.— Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic."*

11. The above provision obviously refers to the retailer from whom the sample is obtained. If he discloses the particulars of the person from whom he purchased the drugs whose samples are obtained by the Drugs Inspector, then the Inspector shall in compliance of Section 23(4)(iii) send the fourth sample to the said addressee.

12. So a conjunctive study of Sections 18-A and 23 of the D.C. Act would disclose that there was no procedure contemplated for sending a sample to the manufacturer when the samples were not obtained directly from the manufacturer. Therefore, in such situations, a manufacturer cannot claim procedural violation for not remitting a sample to him.

13. Be that it may, Section 25 of the D.C. Act deals with the reports of Government Analysts and their presumptive conclusiveness in evidence and the remedy available to the accused against such reports. Section 25 reads thus:

*"**25. Reports of Government Analysts —***

(1) The Government Analyst to whom a sample of any drug [or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken [and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.

(3) 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 18A] 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.

(4) Unless the sample has already been tested or analyzed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct."

14. In the light of Section 25 of the D.C. Act, the remedy to a manufacturer as against the conclusiveness of Government Analyst report is an important aspect. The Apex Court in ***Amery Pharmaceuticals and others v. State of Rajasthan***[1] dealt with the question, "*when a manufacturer in a given situation is not entitled to get a copy of the report of the Government Analyst as of right, as happened in this case, what can he do for the purpose of challenging the report?*"

15. In that case, the manufacturer contended that non supply of one portion of the sample has resulted in depriving him of the valuable right under Section 25(4) of the D.C. Act to test the correctness of the report of the Government Analyst.

16. Repelling the said argument, the Apex Court held that the conclusiveness meant in Section 25(3) of the D.C. Act need be read in juxtaposition with the persons referred to in the Sub-section. In other words, if any of the persons who received a copy of the report of the Government Analyst failed to notify his intention to adduce evidence in contravention of the facts stated in the report within 28 days of receipt of the report, then such report of the Government Analyst would become a conclusive evidence regarding the facts stated therein as against such persons. But for a manufacturer who is not entitled to be

[1] AIR 2001 SC 1303

supplied with a copy of the report, 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. He can also avail the remedy indicated in Sub-section (4) of Section 25 of the D.C. 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, the Court was not under compulsion to cause the said sample to be so tested, if the request is made after a long delay.

17. Thus, the Apex Court in the above decision held that the conclusiveness of the report of the Government Analyst is confined only to those persons who received the report under Section 25(2) of the D.C. Act and not the manufacturer, who is not entitled to a report under law. In such a case, the Apex Court observed, he can challenge the report of Government Analyst by other mode and also by requesting the Court under Section 25(4) of the D.C. Act to send the sample available with the Court to the Central Drugs Laboratory whose report will be conclusive evidence of the facts stated therein.

18. When the above ratio is applied to the instant case, the procedure adopted by the Drugs Inspector, Amalapuram, cannot be approved. He lifted samples from M/s.Subrahmanya Medicals, Amalapuram, on 17.11.2005 under Form-17. A perusal of the copy of Form-17, wherein the particulars of the manufacturer of PD Flam tablets were clearly mentioned as M/s.Parenteral Drugs (India) Limited, Asarwad Village, Dudhia Post, Indore – 453 331 (M.P.). It is further mentioned that the

manufacturing date of the drug was 04/04 and expiry date 03/07. From this it can be inferred that the Drugs Inspector on the very date of lifting samples knew well about the particulars of the manufacturer and the date of expiry of the drug. In such event, after receiving the Analyst Report on 24.11.2006, without wasting further time in searching for the particulars of the distributor, he should have filed complaint immediately against the manufacturer and retailer to save precious time, as by then, only four months were left for the expiry of the drug. Had he adopted this course, the petitioners/ accused being the manufacturer of the drug would have got sufficient time to request the trial Court to send the sample available with the Court to the Central Drugs Laboratory, under Section 25(4) of the D.C. Act. However, the Drugs Inspector did not follow that course and instead, he tried to probe the particulars of distributors and in that process, valuable time was lost. It was only when the Drugs Inspector sent letter dated 23.07.2007 to M/s.Parenteral Drugs (India) Limited, who in turn send the same to his manufacturing unit at Indore, the accused came to know about the details and sent the reply letter, dated 27.07.2007, expressing that they were not agreeing with the finding of the Government Analyst. Even by that time, the shelf life of the drug was expired and thereby the valuable right of the petitioners to refer another sample available with the Court to the Central Drugs Laboratory was lost. So, the precious right of the petitioners/accused was perished due to the delayed acts of the Drugs

Inspector. Unfortunately, the Courts below have not considered this aspect in right perspective.

19. In the result, this Criminal Petition is allowed by setting aside the order dated 30.01.2012, in C.R.P. No.80 of 2011 on the file of II Additional District Judge, Amalapuram, and consequently, Crl.M.P.No.766 of 2011 in C.C.No.73 of 2010 on the file of Additional Judicial Magistrate of First Class, Amalapuram, is allowed and the petitioners/A-1 to A-4 are discharged from the criminal proceedings in C.C. No.73 of 2010.

As a sequel, the miscellaneous petitions, if any pending, shall stand closed.

U.DURGA PRASAD RAO, J

Date: 23.10.2018.
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