

AMERY PHARMACEUTICALS AND ANR.

A

v.  
STATE OF RAJASTHAN

MARCH 16, 2001

[K.T. THOMAS AND R.P. SETHI, JJ.]

B

*Drugs and Cosmetics Act, 1940—Sections 18A, 23(4)(iii), 25, 27, 32A—Drug sample obtained from retailer found to be adulterated, misbranded and spurious—Manufacturer sold the drug through a distributor to retailer—Prosecution proceedings against the manufacturer—Right of manufacturer to get a sample of the drug and report of Government Analyst—Held, manufacturer not entitled to obtain sample and report of Government Analyst—Manufacturer has alternative remedy to direct Court to give sample to Central Drugs Laboratory—Acquitting offending manufacturer on legislative lacuna would be hazardous to public health—Constitution of India, 1950—Article 21.*

C

D

Drug Inspector purchased a drug formulation from a medical retail shop for the purpose of sampling it under the provisions of Drugs and Cosmetics Act, 1940. The sample was found to be a misbranded, adulterated and spurious drug after testing by a Government Analyst. Appellant-concern was found to be manufacturer of the drug, who through a distributor, sold it to the retailer. A complaint was filed by the Inspector against the appellant-concern and its proprietor, distributor and retailer, for offences under Section 27(b), (c) and (d) of the Act. The Magistrate framed charges against the appellants and discharged the remaining accused. The Appellate Court dismissed the revision petition of the appellants but deleted the charge under section 27(c) of the Act. The High Court dismissed the appeal of the appellants.

E

F

In appeal to this Court, the appellants contended that the Inspector did not give a portion of the sample to the appellants on which charges were framed thereby depriving a valuable right to test the correctness of the report of the Government Analyst; that the provisions contained in Section 23(4)(iii) of the Act were not complied with; that the report of the Government Analyst would not be binding on the ground of non-supplying the sample; that the provision in the Act which disables an accused from disproving the correctness of the facts contained in a document is unfair, unreasonable and oppressive; and that it amounts to violation of the fun-

G

H

**A** **damental right under Article 21 of the Constitution.**

The respondent-State contended that it is open to the manufacturer in prosecution cases against him to adduce evidence for controverting the facts stated in the reports of the Government Analyst under the provisions of the Act.

**B** **Dismissing the appeal, the Court**

**C** **HELD : 1.** The obligation of the Inspector under Section 23(4) read with Section 18A of the Drugs and Cosmetics Act, 1940 is to give one portion of the sample to the person from whom he took the sample, the second portion to the Government Analyst, the third portion to the Court and the fourth portion to the person whose name and address, etc. were disclosed by the vendor. Thus, in a case where the drug or medicine has passed from the manufacturer to a distributor and then to the retailer, the obligation of the Inspector as for giving portions of the sample would end up by giving it to the retailer and also to the distributor from whom the retailer bought the drug. [455-E; F]

*State of Haryana v. Brij Lal Mittal*, [1998] 5 SCC 343, referred to.

**E** *Drugs Inspector v. M/s Modern Drugs & Anr.*, (1982) Drugs Cases 26 (Madras); *Kiran Dev Singh v. State of Himachal Pradesh*, (1990) Drugs Cases 324 (HP) and *Vetcha Venkata Raju v. State of Andhra Pradesh*, (1994) Drugs Cases 94 (AP), referred to.

**F** **2.** Any legal provision which snarls an indicted 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 of India, 1950. [459-D]

**G** **3.** 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. 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

**H**

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. [459-E-H; 460-A-B]

4. When the provision can be interpreted in such a way as to avert absurd consequences it is not congenial to the interest of criminal justice to acquit the manufacturers of forbidden medicines or drugs on a technical ground that there is a lacuna in the legislation by not supplying copy of the report of the Government Analyst to the manufacturer in certain situations. To adopt the course of acquitting such offending manufacturers only on the legislative lacuna (if at all it is lacuna) would be hazardous to public health and the lives of the patients to whom drugs are prescribed by medical practitioners would be in jeopardy. Hence, when the legislative provision is capable of being interpreted, the courts need not feel helpless in administering criminal justice in accordance with the objects sought to be achieved by the statute. [461-A-C]

CRIMINAL APPELLATE JURISDICTION : Criminal Appeal No. 300 of 2001.

From the Judgment and Order dated 25.10.99 of the Rajasthan High Court in S.B. CrI. Misc. P. No. 1034 of 1998.

R.N. Trivedi, Additional Solicitor General, Alok Singh, V.B. Joshi, Sushil Kumar Jain, Hemant Sharma and D.S. Mahra for the appearing parties.

A The Judgment of the Court was delivered by

THOMAS, J. Leave granted.

B Appellant, a pharmaceutical concern, succeeded in stalling prosecution proceedings launched against it by a Drug Inspector for a long period of well over a decade by now, and the trial remains where it started at. In the meanwhile the appellant concern and its proprietor sauntered through all the tiers of the judicial hierarchy and reached the apex Court and at all these forums they have one technical objection about the maintainability of the prosecution launched against them.

C The events started on 30-4-1998 when a Drugs Inspector visited a medical retail shop at Kota (Rajasthan) and purchased a drug formulation by the trade name "Ashoka Liquid Extract". The said purchase was made for the purpose of sampling it under the provisions of the Drugs and Cosmetics Act, 1940 (for short "the Act"). When one of the portions of sample was tested by the Government Analyst (Jaipur) he reported that the sample was "mis-branded, adulterated and spurious drug". The retailer disclosed the address of M/s. Chetan Medical Stores, Kota (as the distributor or wholesaler) from whom the drug was obtained. On being contacted the said distributor disclosed the name of the appellant concern and its proprietor as the manufacturers of the drug.

E A complaint was filed by the Inspector on 5.12.1990 against all the persons for the offences under Section 27(b), (c) and (d) of the Act. After hearing the arguments at the preliminary stage the trial magistrate framed a charge for the aforesaid offences against the appellants alone and the remaining accused were discharged. Appellants thereupon filed a revision petition before the Sessions Court contending that no charge could have been framed against them because the Inspector did not send or give one portion of the sample to the appellants and thereby the mandatory provision contained in Section 23(4)(iii) of the Act was not complied with. The Sessions Judge repelled the said contention as well as certain other contentions (which are not relevant as they were not followed up by the appellants later). Nonetheless, the Sessions Judge expressed the view that there is no material on record to show that the drug is spurious. Hence the count under Section 27(c) of the Act was deleted from the charge while the remaining counts were upheld as per the order passed by the Sessions Judge on 23.11.1995.

H

Appellants thereafter moved the High Court of Rajasthan under Section 482 of the Code of Criminal Procedure by focussing on the contention that there was non-compliance with the provision contained in Section 23(4)(iii) of the Act on the premise that the Inspector did not deliver one portion of the sample to the appellants. A Single Judge of the High Court declined to accede to the said contention and dismissed the petition filed by the appellants as per the order impugned in this appeal.

Mr. Alok Singh, learned counsel for the appellants contended that non-supply of one portion of sample to the manufacturer, who is joined as an accused in the complaint, has resulted in depriving him of a valuable right to test the correctness of the report of the Government Analyst. Learned counsel further contended that the consequence of such non-supply is that the conclusiveness attached by law regarding the findings mentioned by the Government Analyst is lost and the report of the Government Analyst would not be binding on the manufacturer. In order to examine the correctness of the above contention we may look at the relevant provisions of the Act.

Section 27 of the Act renders a person who manufactures for sale or for distribution, or who sells or stocks or offers for sale any adulterated or spurious drug, liable to a punishment with imprisonment for a time which shall not be less than one year though a maximum is provided. Section 23 of the Act empowers an Inspector to take sample of any drug for the purpose of test or analysis. Section 25 empowers a Government Analyst to whom a portion of the sample has been submitted for test, to deliver a report to the Inspector, in triplicate, stating the facts discerned in the test or analysis.

Section 25(2) of the Act says that the Inspector shall deliver one copy of the report to the person from whom the sample was taken, another copy of the report to the person whose name and address have been disclosed to the Inspector. The third copy shall be retained by the inspector for use in any prosecution in respect of the sample. Section 25(3) of the Act reads thus :

“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

A 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.”

B Learned counsel for the appellants contended that the conclusiveness of the report of the Government Analyst as envisaged in the sub-section 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.

C The aforesaid contention is advanced on a misconception that the mode of challenge against the report of the Government Analyst is by sending the portion of the sample kept with the vendor (the person from whom the sample was taken). The requirement of sub-section (3) is that one of the persons to whom the copy of the report is given, if he wants to challenge the report, D has to notify the trial court or the Inspector concerned of the intention to adduce evidence in controversion of the report. If he does not do so within 28 days of receipt of a copy of the report of the Government Analyst its consequence would be that the facts contained in the report would become E conclusive as against those persons. The notice to be given shall convey the intention of the person concerned, “to adduce evidence in controversion of the report”. If such a notice is given, it is open to the person who gives such notice, to adduce any evidence for the purpose of contradicting the findings in the report. But if such person fails to give any such notice within the said period of 28 days the findings in the report would operate as conclusive F evidence against the person who failed to give such notice.

F One of the modes of challenging the report is indicated in sub-section (4) of Section 25. It reads thus :

G “Unless the sample has already been tested or analysed 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 for 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 H 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.”

If the person who was given a copy of the report of the Government Analyst notifies his intention to challenge the report it is open to the court to forward the portion of the sample kept in the court, to the Central Drugs Laboratory. The sub-section further envisages that any of the parties involved in the criminal proceedings (the accused as well as the complainant) can make a request to the court that the portion of the sample produced by the Inspector before the Magistrate may be sent to the Central Drugs Laboratory. When the said Central Drugs Laboratory sends a report after conducting the analysis or tests, the facts contained therein become conclusive evidence.

In this context it is useful to refer to the procedure prescribed for the Inspector to follow while taking sample of the drug or medicine etc. Section 23 of the Act contains the procedure to be followed. If the sample is taken from a retailer or a distributor, the Inspector shall divide the sample into four portions, seal and mark them and permit the person from whom the sample was taken to add his own seal or mark on such portions of the sample. Sub-section (4) of Section 23 is the relevant provision to be referred to now. It reads thus :

“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.”

In this context it is necessary to extract Section 18A of the Act also which is as under :

“18A. *Disclosure of the name of the manufacturer, etc.* - Every person, not being the manufacturer of a drug or cosmetic or his agent for the

A            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.”

B            Thus, the obligation of the Inspector is to give one portion of the sample to the person whose name, etc. have been disclosed as the person from whom the vendor acquired the drug. The requirement of the provision would stand complied with when the Inspector gives one portion of the sample to the person from whom he took the sample, and forward the second portion to the Government Analyst and the third portion to the court (before which the prosecution is pending) and the fourth portion to the person whose name and address, etc. were disclosed by the vendor. This position is made very clear as can be seen from the first proviso to sub-section (3) of Section 23 of the Act. That proviso says that “where the sample is taken from premises whereon the drug is being manufactured, it shall be necessary to divide the sample into three portions *only*.” (emphasis supplied). In such case one portion shall be given to the manufacturer and the remaining two portions are to be dealt with in accordance with clause (i) and clause (ii) of sub-section (4), i.e. one portion to be sent to the Government Analyst and the second to be produced before the court. In such a case, there is no utility for clause (iii) of the sub-section. This aspect of non-utility of the third clause in such a situation is amplified by the words employed in that clause itself, (i.e. “where taken”). In other words, where it is not taken, that clause has no utility.

F            Thus, in a case where the drug or medicine has passed from the manufacturer to a wholesaler (a distributor) and then to a retailer, the obligation of the Inspector (who takes the sample from a retailer) as for giving portions of the sample would end up by giving it to the retailer and also to the distributor (from whom the retailer bought the drug).

G            It was contended that since a manufacturer is not entitled to get a copy of the report of the Government Analyst as of right (when the sample was taken from a retailer) the manufacturer would be disabled from challenging the correctness of the facts stated in the report and such deprivation would visit him with hard consequences as the facts stated in the report would become conclusive evidence against him. Learned counsel submitted 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. This amounts to violation of the

H



fundamental right enshrined in Article 21 of the Constitution, according to the learned counsel.

In support of the above contention learned counsel cited some decisions. In *Drugs Inspector v. M/s. Modern Drugs and another*, (1982) Drugs Cases 26 Madras, a single judge of the Madras High Court considered the contention raised on behalf of a manufacturer, who was convicted under Section 27 of the Act, that non-supply of copy of the report of the Government Analyst and a portion of the sample had deprived him of the right to challenge the correctness of the report. Learned single judge while appreciating the difficulty of the Drug Inspector who was only obliged by law to make four portions of the sample as the maximum, has observed that the legislature should have envisaged a case like the present one where there are number of accused persons who are entitled to have each one portion of the sample and a copy of the report of the Government Analyst. Learned single judge further suggested that the defect in the Act requires rectification. After stating that it was the business of the legislature and not that of the judge, the High Court has chosen to acquit the appellatant manufacturer.

In *Kiran Dev Singh v. State of Himachal Pradesh*, (1990) Drugs Cases 324 (HP), a Division Bench of the High Court of Himachal Pradesh held thus :

“The provisions of the Act, when read in the light of the scheme thereof, lead to the unmistakable conclusion that it is incumbent upon the Drug Inspector to make, a copy of the report of the Analyst as also a part of the sample, available to the manufacturer where his identity becomes known before he is actually proceeded against from the initial stages by being made a party to the complaint filed by the Inspector. This is the mandate of law lest the manufacturer is deprived of an effective opportunity for a defence to the effect that the drug manufactured by him, out of which the sample was drawn is not lacking in necessary standard of quality. The manufacturer should have access to the report and a part of the sample drawn from his product within a reasonable period to enable him to exercise the right of adducing evidence in controversion of the report of the analyst which describes his product as lacking in necessary standards of quality.”

Shir R.N. Trivedi, learned Additional Solicitor General contended that the observations made in those decisions cannot be approved because it is

A open to the manufacturer in prosecution cases against him to adduce evidence  
for controverting the facts stated in the reports of Government Analyst in the  
manner indicated in Sections 25(3) and (4) of the Act. Learned Additional  
Solicitor General invited our attention to a two-Judge Bench decision of this  
B decision the point canvassed before us did not arise, because on the facts  
therein it was admitted that the manufacturer was served with a copy of the  
report of the Government Analyst, but he did not notify his intention to  
adduce evidence in controversion of the said report. The legal position  
canvassed in this case relates to a situation where the Inspector did not serve  
C copy of the report to the manufacturer since he had no legal obligation to  
do so. Now we have to seriously examine the contention of both sides,  
particularly in view of the observations made in the decisions of the High  
Courts cited supra.

D Section 25(3) of the Act says that any document purporting to be a  
report signed by a Government Analyst shall be evidence of the facts stated  
therein "and such evidence shall be conclusive". The only exception provided  
in the sub-section is, if the person from whom the sample was taken or the  
person whose name, etc., have been disclosed under Section 18A, gives notice  
in writing that he intends to adduce evidence in controversion of the report  
he has the liberty to disprove it. Of course there is a time limit fixed for giving  
E such notice. According to the provision, such notice shall be given within 28  
days of receipt of a copy of the report.

F 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? There is yet another  
situation when a manufacturer can be arraigned in the case. It is envisaged  
in Section 32A of the Act. It reads thus :

G "32A. *Power of Court to implead the manufacturer, etc.* - Where, at  
any time during the trial of any offence under this Chapter alleged  
to have been committed by any person, not being the manufacturer  
of a drug or cosmetic or his agent for the distribution thereof, the  
Court is satisfied, on the evidence adduced before it, that such  
manufacturer or agent is also concerned in that offence, then, the  
Court may, notwithstanding anything contained in sub-sections (1),  
(2) and (3) of section 319 of the Code of Criminal Procedure, 1973,  
H proceed against him as though a prosecution had been instituted

against him under section 32.”

A

What would such a manufacturer, who is impleaded as per the above provision, do when he too is not entitled to be supplied with either a portion of the sample or even a copy of the report of the Government Analyst?

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 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 indicted 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.

B

C

D

E

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 subsection. 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

F

G

H

A 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.

C In *Vetcha Venkata Raju v. State of Andhra Pradesh*, (1994) Drugs Cases 94 (AP) a manufacturer was prosecuted in a situation similar to the present case and he was convicted by the trial court which was confirmed by the Sessions Court. He raised a contention before the High Court of Andhra Pradesh that he is precluded from exercising a valuable right to get the sample examined by the Central Drugs Laboratory as provided under Section 25(4) of the Act because the portion of the sample or copy of the report was not supplied to him. As against the said contention the Public Prosecutor in that case pointed out that any other manufacturer also would be under such a disability if he is prosecuted in exercise of the powers under Section 32A of the Act because there is no provision for serving him with a copy of the report in such situation. A Single Judge of the Andhra Pradesh High Court, in the wake of the above contentions, observed that if the manufacturer is prosecuted by impleading him as per Section 32A of the Act he cannot claim the right to be supplied with a copy of the report of the Government Analyst, but if he is prosecuted in consequence of the disclosure made under Section 18A such manufacturer would be entitled to a portion of the sample as well as a copy of the report of the Government Analyst. According to learned Single Judge, failure to supply such things to the manufacturer who was made an accused as per Section 18A could cause prejudice to him. But no such prejudice can be caused by a manufacturer impleaded under Section 32A of the Act, according to the learned single judge. Consequently the conviction and sentence passed on the manufacturer in that case were set aside by the High Court.

H We are unable to understand the rationale in drawing a hiatus between a manufacturer who is arraigned as an accused at the first instance itself and another manufacturer who is arraigned in exercise of the powers under

Section 32A of the Act, as regards his right to challenge a document purporting to be the report of the Government Analyst. The right to challenge the report must, as of right, be available to both such manufacturers who are prosecuted for the offence. A

When the provision can be interpreted in such a way as to avert absurd consequences in the manner indicated above it is not congenial to the interest of criminal justice to acquit the manufacturers of forbidden medicines or drugs on a technical ground that there is a lacuna in the legislation by not supplying copy of the report of the Government Analyst to the manufacturer in certain situations. To adopt the course of acquitting such offending manufacturers only on the legislative lacuna (if at all it is lacuna) would be hazardous to public health and the lives of the patients to whom drugs are prescribed by medical practitioners would be in jeopardy. Hence, when the legislative provision is capable of being interpreted as we did now, the courts need not feel helpless in administering criminal justice in accordance with the objects sought to be achieved by the statute. B C D

In the result we dismiss this appeal.

B.S.

Appeal dismissed.