2020 INSC 479

REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 2903 OF 2020
(ARISING OUT OF SLP (C) NO. 26349 OF 2019)

MEDIPOL PHARMACEUTICAL INDIA PVT. LTD. ….APPELLANT

VERSUS

POST GRADUATE INSTITUTE OF MEDICAL EDUCATION & RESEARCH AND ANR. ….RESPONDENTS

J U D G M E N T

R.F. Nariman, J.

1) Leave granted.

2) Having heard learned counsel for the parties, it is important to first set out a few basic facts:

i) A notice inviting quotations was issued on 06.07.2015 by the Respondents herein for Clotrimazole Cream 1% 15 gm tube, the quantity being required for the first year and second year, being:

DEMAND	QUANTITY REQUIRED
1st YEAR	3400 tubes
2nd YEAR	3400 tubes

ii) To this N.I.Q., the Appellant submitted its quotation on 09.07.2015, in which it was specified that the shelf life of the said cream would be only 2 years.

iii) After rates were negotiated and re-negotiated, a supply order was issued on 04.11.2015 in which it was clearly stated :

> "8. Not more than 1/6th of the shelf life should have expired when drug pharmaceuticals are received in medical store PGI, Chandigarh."

iv) In accordance with the supply order, the first instalment of 1700 tubes of Clotrimazole Cream was supplied on 18.01.2016, there being no complaint whatsoever in respect of the said supply. However, when the second instalment of 1700 tubes of the self-same Cream was supplied to the Respondent on 08.04.2016, various complaints were made. The first Respondent drew samples on 29.11.2017, which samples were sent for testing to the Government Analyst under Section 25(1) of the Drugs & Cosmetics Act, 1940.

v) The first test report dated 27.03.2018 specifically stated that the sample was received on 26.12.2017. This report, which is dated a few days before the shelf life of the Cream expired, found that the sample was 61.96% w/w as against an acceptable standard of 95-105%.

vi) As a result thereof, two show cause notices were issued on 13.04.2018 and 30.5.2018 by the State Drugs Controller and Drug Inspector respectively to the Appellant in which the Appellant was asked to explain why its licence should not be suspended or cancelled under Rule 85(2) of the Drugs and Cosmetics Rules,

1945 made under the Drugs and Cosmetics Act, which relates to licence to manufacture this product.

vii) The Appellant replied to the show cause notices on 26.04.2018. and 01.06.2018. However, a third show cause notice was issued on 26.09.2018 by the Respondent in which the question as to blacklisting arose for the first time.

viii) The reply of the Appellant to this show cause notice dated 04.10.2018 specifically requested the authorities not to take any action until a final report of the appellate lab, which was pending, was received.

ix) However, without waiting for this report, on 21.01.2019, the Appellant was blacklisted for a period of 2 years. A perusal of this report would show that there are no reasons given for the same. Finally, the appellate lab test report of the Central Drugs Laboratory, Kolkata, dated 19.08.2019 tested a sample that was received on 11.02.2019, that is, long after the expiry date of the Cream, in April, 2018. Even this sample, when tested, yielded a result of 92.01% which is way above the 61.96% that was found in the first test report.

x) A post-decisional hearing, based on this report, was given to the Appellant, and it was then found that the blacklisting order was in order inasmuch as on 18.09.2019 the Drug Committee, which

consisted of a Chairman, two Members, two Special Invitees, one Director and one Convenor, then expressed their views on the arguments of the Appellant stating, *inter alia*, that on testing, the subject drug was found to be only 61.96%, which is markedly below the prescribed standard limit of 95-105%.

xi) As against the decision then taken, the Appellant filed a writ petition in the Punjab & Haryana High Court, which was dismissed by the impugned order dated 17.09.2019. After extracting the appellate lab test report, the Court found that being 3% below 95%, which is the prescribed standard, there was no good ground to interfere with the impugned order of blacklisting.

3) What is clear from the narration of the facts stated above is that the Drug Inspector drew samples on 29.11.2017 which was long after supplies had been made to the Respondent on 08.04.2016 and complaints received. From the date of drawal of samples on 29.11.2017 till the date on which the samples were received by the Government Analyst on 26.12.2017, there is yet another delay of almost one month. Also, owing to no fault of the Appellant, the sample that could be sent to the Central Drugs Laboratory, Kolkata, under Section 25(3) of the Drugs and Cosmetics Act, was received by the aforesaid Laboratory only on 11.02.2019, long after the expiry date of the goods in question, which was in April, 2018.

Even this sample, when tested, yielded a result of 92.01%, which is only roughly 3% below the required minimum standard. What is important to note is that the Government Analyst's report was shown to be completely wrong. Finally, to cap it all, after a post-decisional hearing given to the Appellant, the seven-member Committee opined that there was no reason to recall the blacklisting order based on the result of the first laboratory test report, completely ignoring the appellate test report.

4) On these facts, we find that the impugned decision reflected in the minutes dated 18.09.2019 is wholly perverse inasmuch as it is based only upon the first laboratory test report.

5) The High Court, instead of striking down this decision in judicial review proceedings, went into the appellate laboratory test report itself and stated that as it was 3% below the prescribed percentage of 95%, the blacklisting order ought not to be interfered with.

6) The High Court ought not to have gone into the appellate laboratory test report by itself. It ought to have struck down the impugned decision on the ground that it relied upon something irrelevant, namely, the first laboratory test report and ignored the appellate report. The High Court ought also to have appreciated that the appellate laboratory report was at complete variance with the first laboratory test report - the variation being a huge figure of

30%. This was despite the fact that the appellate laboratory test report tested a sample of the Appellant's product long after its shelf life had expired.

7) Section 25 of the Drugs and Cosmetics Act states as follows:

> "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 to 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 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 of the drug or cosmetic produced before the Magistrate under subsection (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."

8) The decisions of this Court on the aforesaid provision are instructive. In **Medicamen Biotech Ltd. v. Rubina Bose, Drug Inspector** (2008) 7 SCC 196, after extracting the Section, the Court held:

> "13….A reading of the aforesaid provisions would reveal that they lay certain obligations as well as provide safeguards for a person from whom a drug has been seized for analysis or testing as Section 25(3) specifies that unless such a person controverts the correctness of the report submitted by the Government Analyst within 28 days in writing that he intends to adduce evidence to controvert the report of the analyst, it would be deemed to be conclusive evidence of the quality of the drug whereas sub-section (4) of Section 25 obliges the Magistrate on the request of the complainant or the accused or on his own motion to send the fourth sample which has been disputed for fresh testing to the Director of the Central Drugs Laboratory."

After referring to the case law on the subject, the Court arrived at the following conclusion on the facts of the case :

> "19. In the affidavit filed to the petition by Dr. D. Rao, Deputy Drugs Controller, and in arguments before us, it has been repeatedly stressed that the delay in sending of the sample to the Central Drugs Laboratory had occurred as the appellant had avoided service of summons on it till 9-5-2005. This

> is begging the question. We find that there is no explanation as to why the complaint itself had been filed about a month before the expiry of the shelf life of the drug and concededly the filing of the complaint had nothing to do with the appearance of the accused in response to the notices which were to be issued by the Court after the complaint had been filed. Likewise, we observe that the requests for retesting of the drug had been made by the appellant in August/September 2001 as would be clear from the facts already given above and there is absolutely no reason as to why the complaint could not have been filed earlier and the fourth sample sent for retesting well within time. We are, therefore, of the opinion that the facts of the case suggest that the appellants have been deprived of a valuable right under Sections 25(3) and 25(4) of the Act which must necessitate the quashing of the proceedings against them."

9) In **Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu** (2018) 15 SCC 93, after referring to Section 25 of the Act, this Court held as follows:

> "7. The cognizance of the offence(s) alleged in the present case was taken on 4-3-2015 though it appears that the complaint itself was filed on 28-11-2012. According to the appellant the cough syrup had lost shelf life in the month of November 2012 itself. Even otherwise, it is reasonably certain that on the date when cognizance was taken, the shelf life of the drug in question had expired. The Magistrate, therefore, could not have sent the sample for reanalysis by the Central Laboratory.
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> 8. All the aforesaid facts would go to show that the valuable right of the appellant to have the sample analysed in the Central Laboratory has been denied by a series of defaults committed by the prosecution; firstly, in not sending to the appellant manufacturer part of the sample as required under Section 23(4)(*iii*) of the Act; and secondly, on the

> part of the Court in taking cognizance of the complaint on 4-3-2015 though the same was filed on 28-11-2012. The delay on both counts is not attributable to the appellants and, therefore, the consequences thereof cannot work adversely to the interest of the appellants. As the valuable right of the accused for reanalysis vested under the Act appears to have been violated and having regard to the possible shelf life of the drug we are of the view that as on date the prosecution, if allowed to continue, would be a lame prosecution."

10) The position is no different under *pari materia* provisions of other Acts. Thus, in **Municipal Corporation of Delhi v. Ghisa Ram** (1967) 2 SCR 116, the testing of samples was dealt with by Section 13 of the Prevention of Food Adulteration Act, 1954. This Court held:

> "There can be no doubt that the sub-s. (2) of s. 13 of the Act confers a right on the accused vendor to have the sample given to him examined by the Director of the Central Food Laboratory and to obtain a certificate from him on the basis of the analysis of that sample. It is when the accused exercises this right that a certificate has to be given by the Director of the Central Food Laboratory and that certificate then supersedes the report given by the Public Analyst. If, in any case, the accused does not choose to exercise this right, the case against him can be decided on the basis of the report of the Public Analyst.
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> *xxx xxx xxx*
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> In the present case, we find that the decomposition of the sample, which the respondent desired should be analysed by the Director of the Central Food Laboratory, took place because of the long delay that had occurred in sending the sample to the Director.

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> It appears to us that when a valuable right is conferred by s. 13 (2) of the Act on the vendor to have the sample given to him analysed by the Director of the Central Food Laboratory, it is to be expected that the prosecution will proceed in such a manner that that right will not be denied to him. The right is a valuable one, because the certificate of the Director supersedes the report of the Public Analyst and is treated as conclusive evidence of its contents. Obviously, the right has been given to the vendor in order that, for his satisfaction and proper defence, he should be able to have the sample kept in his charge analysed by a greater expert whose certificate is to be accepted by Court as conclusive evidence. In a case where there is denial of this right on account of the deliberate conduct of the prosecution, we think that the vendor, in his trial, is so seriously prejudiced that it would not be proper to uphold his conviction on the basis of the report of the Public Analyst, even though that report continues to be evidence in the case of the facts contained therein."[1]

On the facts of the case, the Court arrived at the following conclusion:

> "In the present case, the sample was taken on the 20th September, 1961. Ordinarily, it should have been possible for the prosecution to obtain the report of the Public Analyst and institute the prosecution within 17 days of the taking of the sample. It, however, appears that delay took place even in obtaining the report of the Public Analyst, because the Public Analyst actually analysed the sample on 3rd October, 1961 and sent his report on 23rd October, 1961. It may be presumed that some delay in the analysis by the Public Analyst and in his sending his report to the prosecution is bound to occur. Such delay could always be envisaged by the

1 Pages 118-120.

> prosecution, and consequently, the elementary precaution of adding a preservative to the sample which was given to the respondent should necessarily have been taken by the Food Inspector. If such a precaution had been taken, the sample with the respondent would have been available for analysis by the Director of the Central Food Laboratory for a period of four months which would have expired about the 20th of January, 1962. The report of the Public Analyst having been sent on 23rd October, 1961 to the prosecution, the prosecution could have been launched well in time to enable the respondent to exercise his right under s. 13(2) of the Act without being handicapped by the deterioration of his sample. The prosecution, on the other hand, committed inordinate delay in launching the prosecution when they filed the complaint on 23rd May, 1962, and no explanation is forthcoming why the complaint in Court was filed about seven months after the report of the Public Analyst had been issued by him This, is, therefore, clearly a case where the respondent was deprived of the opportunity of exercising his right to have his sample examined by the Director of the Central Food Laboratory by the conduct of the prosecution. In such a case, we think that the respondent is entitled to claim that his conviction is vitiated by this circumstance of denial of this valuable right guaranteed by the Act, as a result of the conduct of the prosecution."[2]

11) Likewise, under Section 24 of the Insecticides Act, 1968, this Court in **State of Haryana v. Unique Farmaid (P) Ltd.** (1998) 8 SCC 190 held:

> "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

2 Pages 120-121.

> 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 Insecticide Inspector or the court before which proceedings are pending that they intend to adduce evidence to controvert the report. In the present cases the Insecticide 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 an 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 Laboratory and in the circumstances of the case the accused have been deprived of that right, thus, prejudicing them in their defence."

12) Though the aforesaid judgments pertain to criminal prosecutions under the Drugs and Cosmetics Act, Prevention of Food Adulteration Act and Insecticides Act, yet, they lay down that a valuable right is granted to a person who is sought to be penalized under these Acts to have a sample tested by the Government Analyst that is found against such person, to be tested by a superior or appellate authority, namely, the Central Drugs Laboratory. These judgments lay down that if owing to delay which is predominantly attributable to the State or any of its entities, owing to which an article which deteriorates with time is tested as not containing the requisite standard, any prosecution or penalty inflictable by virtue of such sample being tested, cannot then be

sustained. We have seen that on the facts of this case, the sample drawn and analyzed by the Government Analyst was delayed for a considerable period resulting in the sample being drawn towards the end of its shelf life. Even insofar as the samples sent to the Central Drugs Laboratory, there was a considerable delay which resulted in the sample being sent and tested 8 months beyond the shelf life of the product in this case. It is thus clear that the valuable right granted by Section 25 of the Drugs and Cosmetics Act kicks in on the facts of this case, which would necessarily render any penalty based upon the said analysis of the sample as void.

13) When it comes to the penalty of blacklisting, the classic formulation of principles in regard to blacklisting have been laid down in **Erusian Equipment & Chemicals Ltd. v. State of West Bengal** (1975) 1 SCC 70. This Court put it thus:

> "12**.** Under Article 298 of the Constitution the executive power of the Union and the State shall extend to the carrying on of any trade and to the acquisition, holding and disposal of property and the making of contracts for any purpose. The State can carry on executive function by making a law or without making a law. The exercise of such powers and functions in trade by the State is subject to Part III of the Constitution. Article 14 speaks of equality before the law and equal protection of the laws. Equality of opportunity should apply to matters of public contracts. The State has the right to trade. The State has there the duty to observe equality. An ordinary individual can choose not to deal with any

person. The Government cannot choose to exclude persons by discrimination. The order of blacklisting has the effect of depriving a person of equality of opportunity in the matter of public contract. A person who is on the approved list is unable to enter into advantageous relations with the Government because of the order of blacklisting. A person who has been dealing with the Government in the matter of sale and purchase of materials has a legitimate interest or expectation. When the State acts to the prejudice of a person it has to be supported by legality.

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17. The Government is a Government of laws and not of men. It is true that neither the petitioner nor the respondent has any right to enter into a contract but they are entitled to equal treatment with others who offer tender or quotations for the purchase of the goods. This privilege arises because it is the Government which is trading with the public and the democratic form of Government demands equality and absence of arbitrariness and discrimination in such transactions. Hohfeld treats privileges as a form of liberty as opposed to a duty. The activities of the Government have a public element and, therefore, there should be fairness and equality. The State need not enter into any contract with any one but if it does so, it must do so fairly without discrimination and without unfair procedure. Reputation is a part of a person's character and personality. Blacklisting tarnishes one's reputation.

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19. Where the State is dealing with individuals in transactions of sales and purchase of goods, the two important factors are that an individual is entitled to trade with the Government and an individual is entitled to a fair and equal treatment with others. A duty to act fairly can be interpreted as meaning a duty to observe certain aspects of rules of natural justice. A body may be under a duty to give fair consideration to the facts and to consider the

> representations but not to disclose to those persons details of information in its possession. Sometimes duty to act fairly can also be sustained without providing opportunity for an oral hearing. It will depend upon the nature of the interest to be affected, the circumstances in which a power is exercised and the nature of sanctions involved therein.
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> 20. Blacklisting has the effect of preventing a person from the privilege and advantage of entering into lawful relationship with the Government for purposes of gains. The fact that a disability is created by the order of blacklisting indicates that the relevant authority is to have an objective satisfaction. Fundamentals of fair play require that the person concerned should be given an opportunity to represent his case before he is put on the blacklist."

14) This judgment has been followed in several later judgments. Thus, in **Patel Engineering Ltd. v. Union of India** (2012) 11 SCC 257, this Court after referring to judgment in **Erusian Equipment** (supra), then held:

> "15. It follows from the above judgment in *Erusian Equipment case* [(1975) 1 SCC 70] that the decision of the State or its instrumentalities not to deal with certain persons or class of persons on account of the undesirability of entering into the contractual relationship with such persons is called blacklisting. The State can decline to enter into a contractual relationship with a person or a class of persons for a legitimate purpose. The authority of the State to blacklist a person is a necessary concomitant to the executive power of the State to carry on the trade or the business and making of contracts for any purpose, etc. There need not be any statutory grant of such power. The only legal limitation upon the exercise of such an authority is that the State is to act fairly and rationally without in any way being arbitrary—thereby such a decision can be taken for some legitimate

> purpose. What is the legitimate purpose that is sought to be achieved by the State in a given case can vary depending upon various factors."

In **Kulja Industries Ltd. v. Chief General Manager, Western Telecom Project BSNL** (2014) 14 SCC 731, this Court referred to the leading judgment of **Erusian Equipment** (supra) and subsequent decisions of this Court, following the ratio of this decision, as follows:

> "18. The legal position on the subject is settled by a long line of decisions rendered by this Court starting with *Erusian Equipment & Chemicals Ltd.* v. *State of W.B.* [(1975) 1 SCC 70] where this Court declared that blacklisting has the effect of preventing a person from entering into lawful relationship with the Government for purposes of gains and that the authority passing any such order was required to give a fair hearing before passing an order blacklisting a certain entity. This Court observed: (SCC p. 75, para 20)
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> > "*20*. Blacklisting has the effect of preventing a person from the privilege and advantage of entering into lawful relationship with the Government for purposes of gains. The fact that a disability is created by the order of blacklisting indicates that the relevant authority is to have an objective satisfaction. Fundamentals of fair play require that the person concerned should be given an opportunity to represent his case before he is put on the blacklist."
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> Subsequent decisions of this Court in *Southern Painters* v. *Fertilizers & Chemicals Travancore Ltd.* [1994 Supp (2) SCC 699 : AIR 1994 SC 1277] ; *Patel Engg. Ltd.* v. *Union of India* [(2012) 11 SCC 257 : (2013) 1 SCC (Civ) 445] ; *B.S.N. Joshi & Sons Ltd.* v. *Nair Coal Services Ltd.* [(2006) 11 SCC 548] ; *Joseph Vilangandan* v. *Executive Engineer (PWD)*

> [(1978) 3 SCC 36] among others have followed the ratio of that decision and applied the principle of audi alteram partem to the process that may eventually culminate in the blacklisting of a contractor.
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> 19. Even the second facet of the scrutiny which the blacklisting order must suffer is no longer res integra. The decisions of this Court in *Radhakrishna Agarwal* v. *State of Bihar* [(1977) 3 SCC 457 : (1977) 3 SCR 249] ; *E.P. Royappa* v. *State of T.N.* [(1974) 4 SCC 3 : 1974 SCC (L&S) 165] ; *Maneka Gandhi* v. *Union of India* [(1978) 1 SCC 248] ; *Ajay Hasia* v. *Khalid Mujib Sehravardi* [(1981) 1 SCC 722 : 1981 SCC (L&S) 258] ; *Ramana Dayaram Shetty* v. *International Airport Authority of India* [(1979) 3 SCC 489] and *Dwarkadas Marfatia and Sons* v. *Port of Bombay* [(1989) 3 SCC 293] have ruled against arbitrariness and discrimination in every matter that is subject to judicial review before a writ court exercising powers under Article 226 or Article 32 of the Constitution."

15) We have seen in the present case that the post-decisional hearing proved to be an eyewash as the seven-member Committee did not even refer to the findings of the appellate report, which showed that the Government Analyst's report was wholly incorrect, 61.96% being widely off the mark. Given the fact that there is considerable unexplained delay on the part of the Drug authorities and the Respondent resulting in the first and second samples being tested late – the second sample being tested 8 months after its shelf life had expired – it is clear that the order of blacklisting dated 21.02.2019, as confirmed by the order dated 18.09.2019, is

infirm and is therefore, set aside. Concomitantly, the impugned High Court judgment is also set aside.

16) The appeal is allowed in the aforesaid terms.

……..... J.
(ROHINTON FALI NARIMAN)

……..... J.
(NAVIN SINHA)

New Delhi;
August 05, 2020.