* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% ***Pronounced on: 28th April, 2023***

\+ **ARB. A (COMM) 64/2022 & I.As. 14844/2022, 14845/2022**

MEDIPOL PHARMACEUTICAL INDIA PVT. LTD.
128/5 Vishwas Nagar
Delhi-110032

..... Appellant

Through: Ms. Anita Sahani, Advocate.

versus

1. **UNION OF INDIA**
   Through Director General
   Ministry of Health and Family Welfare
   Nirman Bhawan
   New Delhi-110001 ....Respondent no. 1

2. **DEPUTY DIRECTOR OF STORES**
   Ministry of Health and Family Welfare
   West Block No. 1, Wing No. 6
   RK Puram
   New Delhi-110066.

   .... Respondent no. 2

3. **DIRECTOR CENTRAL DRUG TESTING LABORATORY & GOVT. MEDICAL STORE DEPOT.**
   396/A/2 Navjeevan Society
   Dalal Estate Kamathipura
   Post Box No. 4541 Mumbai Central Mumbai
   Maharashtra 400008.

   .... Respondent no. 3

4. **DEPUTY ADDITIONAL DIRECTOR GENERAL GOVERNMENT OF MEDICAL STORE DEPOT**
   Post Box No. 5414
   Mumbai Central Mumbai

   ....Respondent no. 4

Through: Mr. Vikram Jetly, CGSC with Ms. Shreya Jetly, Advocate.

J U D G M E N T

NEENA BANSAL KRISHNA, J

1. An appeal under Section 37 (2) of Arbitration and Conciliation Act, 1996 (*hereinafter referred to as the Act, 1996)* has been preferred against the impugned Order dated 12.7.2022 of the learned sole Arbitrator declining to grant interim stay of the Office Memorandum dated 04.08.2021, de-registering/de-barring the appellant for supply of all drugs/ products to MSO/ GMSDs for a period of 5 years w.e.f 24.10.2019 due to repeated failure of drugs under Category "A" defect by testing laboratories supplied/manufactured by the firm within a period of one year under Section 17 of the Arbitration and Conciliation Act, 1996.

2. The appellant herein had moved an application under Section 9 of the Act for interim relief before this Court in which with the consent of the parties, the sole Arbitrator was appointed, with the directions that the application under Section 9 of the Act be treated and heard by the learned sole Arbitrator so appointed as an application under Section 17 of the Act. Accordingly, the application was considered by the sole Arbitrator and dismissed vide impugned Order dated 12.07.2022.

3. The factual background is that the appellant is a manufacturer of medicines since 1992 and has been supplying generic medicines to Central Government, Ministry of Defence as well as to the State Governments through participation in tenders. During the period of three years i.e., 2019, 2020 and 2021, it has manufactured and supplied 5752

batches of medicines all over India. The appellant bided in Tender No. GMSD/HYD/EQ/2015-16/A/245 & 274 and was awarded the rate contract for 64 items of generic medicines by the Directorate General of Health Services, Ministry of Health and Family Welfare, R.K. Puram, New Delhi. As per the procedure of procurement by the respondent, the appellant on being awarded the Tender, was required to manufacture and supply certain generic medicines like Alprazolam Tab 0.25 mg, Pheniramine Maleate 25 mg, Aspirin 150 mg, Clopidogrel 75 mg, Amitriptyline tab 25 mg and Lorazepam 1 mg, to various depots of the respondents, GMSD at Delhi, Kolkata, Karnal, Chennai, Guwahati, Mumbai and Hyderabad. Before distribution of the medicines to various indentors, the medicines are tested in two laboratories registered with the respondent.

4. The appellant has asserted that while all the medicines supplied were found to be of standard quality by the two laboratories at the time of supply, the same were found to be not of standard quality when the same were tested again by some of the Depots. The appellant has asserted that these tests were done by the depots after a long period of time ranging from 9 to 24 months from the date of supply, which reflects that it is the storage conditions of the medicines which was not conducive and it is not the standard quality of the medicines which was inferior or not according to the specifications.

5. The respondent no. 4 issued a Office Memorandum dated 01.12.2020 de-barring the appellant from manufacturing Alprazolam 0.25 and Pheniramine Maleate IP 25 mg to the appellant after issuing a Show Cause Notice dated 23.09.2019. Further respondent No. 4 issued Office

Memorandum No. PS/D-/Regn/Medipol/2020-21/2795 dated 04.12.2020 modifying the previous Office Memorandum dated 01.12.2020, de-barring/ de-registering the appellant from supply of all drugs to MSO/GMSDs for a period of five years w.e.f 24.10.2019 on the ground that the two drugs under category 'A' supplied by the appellant were not of standard quality within a period of one year.

6. The appellant approached the High Court of Bombay vide Writ Petition (L) No. 9289 of 2020, which set aside the debarment order issued against the appellant directing the respondents that a Show Cause Notice be first issued to the appellant. In compliance of the directions of the Bombay High Court, four Show Cause Notices dated 19.02.2021, 03.03.2021, 09.03.2021 and 25.03.2021 were issued asking the appellant to explain its position as to why it should not be de-barred from supply of aforesaid items to the Medical Store Organisation for a period of three years or permanently w.e.f from the date it was found to be not of standard quality.

7. The Notice dated **19.02.2021** was replied on 05.03.2021 and a detailed representation dated 23.04.2021 was also made by the appellant to respondent no. 4 requesting for a personal hearing but no opportunity was given. The respondent no. 4 arbitrarily and unilaterally issued the impugned revised Office Memorandum bearing no. PS/D-registration-Debarment/Medipol/202021/1923 dated 04.08.2021 stating that five drugs namely Alprazolam, Pheniramine, Aspirin, Amitriptyline, and Lorazepam were found to be of 'not standard quality' and thereby de-barring the appellant for supply of drugs for a period of five years w.e.f 24.10.2019. By way of interim relief under S.17 of the Act, the appellant had sought

interim stay of the debarment, but the interim relief was denied by the impugned Order.

8. The **respondents in their reply have stated** that there are seven Government Medical Store Depots (GMSD) all over India i.e. at Mumbai, New Delhi, Kolkata, Karnal, Guwahati, Chennai and Hyderabad which supply generic medicines, Anti TB medicines, Family Welfare Products, AD syringes, various types of Vaccines and COVID -19 Vaccines all over India and are under the administrative control of Medical Store Organisation (MSO), Ministry of Health and Family Welfare, Government of India. There are 1047 registered indentors under the MSO, out of which 166 indentors are registered under GMSD, Mumbai for Government bodies like Hospitals of CGHS, CRPF, SRPF, BSF, Central prisons etc who place order for supply of medicines to GMSD. The GMSD Mumbai supplies medicines to indentors located in the West Zone like Maharashtra, Goa, Gujarat, Madhya Pradesh, Chhattisgarh etc. It also supplies medicines as per the directions of MSO, New Delhi as and when requirement arises at any place in Delhi. All the registered pharmaceutical manufacturing Companies that are contracted to supply the medicines to MSO/GMSDs, are reputed and well equipped. The highest standards of storage and transportation of medicines are maintained by MSO/GMSDs. The respondent, as per the prescribed procedure, if after initial testing of the samples in two of the Government registered labs, the products are found to be of standard quality, they are sent to the indentors for consumption.

9. The respondent has further explained that initially the medicines were tested in two labs, registered with the Government, in the month of

January, 2019 and the medicines were found to be of standard quality by both the laboratories and accordingly the medicines were distributed to the indentors. On 02.08.2019, the Drug Inspector of Central Drug Standard Organisation (CDSCO (WZ)), Mumbai had visited CGHS Koliwada and conducted a random check and drew samples of various medicines supplied by the appellant and other manufacturers. The collected samples were sent to the Central Drugs Testing Laboratory (CDTL), Mumbai which vide its Report dated 28.08.2019 reported that the samples pertaining to the complainant were not of standard quality and were not in conformity to I.P. 2018 standard with respect to test for dissolution.

10. The Circular dated 23.09.2019 was sent to the indentors to stop consumption of 'Not of Standard Quality' medicines with immediate effect. The balance quantity was re-called from Medical Stores, Koliwada. The respondent has further stated that after the second sample was found to be of 'Not Standard Quality', a Show Cause Notice dated 23.09.2019 was issued by GMSD, Mumbai to the appellant as per the terms and conditions of the Supply Order. The reply given by the appellant to the Show Cause Notices was not satisfactory. The samples were again sent to the Central Drug Laboratory, Kolkata which is the appellate lab of the respondent.

11. As per the terms and conditions of the Supply Order, the third and final report from CDL, Kolkata was to be accepted as final. In the final report from CDL, Kolkata dated 12.03.2020, again the samples were found to be 'Not of Standard Quality', being not in conformity with I.P - 2018 standard with respect to test for dissolution. The terms of Supply Order clearly stated that in case of category 'A' defects, the supplier

should be debarred from the supply of that product for three years from the date of failure and for repeated failure of Category 'A' defect within one year, the supply shall be debarred from supply of all the medicines for five years. Consequently, the appellant has been debarred by MSO vide the impugned Memorandum dated 20.11.2020.

12. Admittedly, the Order of Debarment was challenged vide writ petition in the High Court of Bombay, which set aside the debarment notice of the Respondent No. 4 and directed that fresh Show Cause Notice be issued to the appellant on the issue of debarment. The fresh Show Cause Notice dated 19.02.2021 and amended Show Cause Notice dated 03.03.2021 were duly served on the appellant which were duly replied. The respondent finding that the response was not satisfactory, issued the Memorandum dated 04.08.2021 debarring the appellant from supply of all the drugs for a period of five years w.e.f 24.10.2019, the stay of which was sought by the appellant in his application under Section 17 of the Act.

13. The **learned Arbitrator observed that the main grievance** of the appellant was that the debarment of five years was contrary to the guidelines issued by the Ministry of Finance recommending that the debarment should not be for more than two years. However, no such guidelines were placed before the learned Arbitrator by the appellant. Strictly going by the provisions of the Contract as contained in the Supply Order, the medicines were tested during their shelf life in the three laboratories and were found to be of 'Not of Standard Quality'.

14. **The learned Arbitrator held** that it was a matter of trial whether the medicines were found to be not of adequate quality on account of manufacturing defect or because of improper storage. It was also observed

that the essential arguments of the appellant was that the impugned Order of Debarment dated 04.08.2021 was having a cascading effect insomuch as it was not being able to supply or protect its medicines which have already been manufactured.

15. A reference was made to the observations of Hon'ble Supreme Court in the case of *Paschim Banga Khet Mazdoor Samity & Ors. Vs. State of West Bengal and Anr* (1996) 4 SCC 37 wherein it was observed that providing adequate medical facilities to the people is essential part of the obligation undertaken by the Government. Thus, it is responsibility of the Government which runs the hospitals and the Health Centres, to safeguard the right of life of every person and to provide medicine for preserving the human life. Thus, it was concluded that the interim relief which was sought by the appellant was in respect of debarment and not for taking care of the medicines already manufactured and this argument of the appellant did not find any favour with the learned Arbitrator.

16. Accordingly, the impugned order of debarment was refused to be stayed. Aggrieved by the said Order, present appeal has been filed under Section 37 of the Arbitration and Conciliation Act 1996.

17. The **main grounds of challenge** are that the learned sole Arbitrator has failed to appreciate the specific terms of the Contract between the parties and has failed to consider the documents produced by the appellant. An observation has been made that the guidelines, showing the debarment can be for not more than two years, has not been placed on record when in fact the entire guidelines along with the judgements had been filed before the learned Arbitrator. It is further submitted that the appellant had relied upon the judgements namely *Eurasian Equipment*

and Chemicals Ltd. And Ors. Vs. State of West Bengal and Ors. (1975) 1 SCC 70, Ace Integrated Solutions Ltd. vs. Food Corporation of India and Ors. 2019 SCC OnLine Del 8422, Medipol Pharmaceutical India Pvt. Ltd. Vs. Post Graduate Institute of Medical Education and Research and Ors.(2021) 11 SCC 339, Patel Engineering Ltd. Vs. Union of India (2012) 11 SCC 257, BSN Joshi and Sons Ltd. Vs. Nair Coal Services Ltd. (2006) 11 SCC 548, Joseph Vilangandan Vs. Executive Engineer (1978) 3 SCC 36, Radhakrishna Agarwal Vs. State of Bihar (1977) 3 SCC 457, E.P Royappa Vs. State of TN (1974) 4 SCC 3, Ajay Hasia Vs. Khalid Mujib Sehravardi (1981) 1 SCC 722, Ramana Dayaram Shetty Vs. International Airport Authority of India (1979) 3 SCC 489, Dwarkadas Marfatia and Sons Vs. Board of Trustees of the Port of Bombay (1989) 3 SCC 293, wherein it was observed that the blacklisting visits a person with a 'civil consequence' in as much as it casts a slur, attaches a stigma and creates a barrier between the blacklisted person and state entities in matters of commercial transactions and the fundamentals of fair play requires that a person should be afforded an opportunity to represent his case before being put on a blacklist at the hands of a state entity. The Blacklisting has an effect of preventing a person from the privilege and advantage of entering into lawful relationship with the Government for the purpose of gains and creates a disability and thus such orders must confirm to the fundamentals of fair play and an opportunity to represent the case must be given to the appellant before he is blacklisted.

18. It is stated that the alleged tests reports conducted by the various laboratories on the request of respondent, have not been supplied to the appellant. Moreover, despite making a request for personal hearing, no

opportunity was granted to the respondent. It is merely stated that the reply given by the appellant was found to be not satisfactory without giving any reason. Furthermore, the appellant had supplied 300 batches of different medicines to respondent no. 4 and *'not of standard quality'* Report has been issued in respect of batches of five drugs only. The appellant had offered to remove the batches of all five drugs that were found not to be of standard quality and replace them with fresh medicine. Despite the bona fide and genuine request of the appellant, the respondent no. 4 has proceeded to debar the appellant from supply of all its products for a period of five years.

19. For the same reason, the debarment of the appellant for all the drugs despite there being non-satisfactory report in respect of only five drugs is arbitrary and not sustainable in law. Furthermore, it has not been appreciated by the learned sole Arbitrator while passing the impugned Order, that the same drug of the same batch received by the other depots has not been found 'not of standard quality'. Moreover, these drugs were reported to be okay at the time of receipt by the respondents. The drugs have been reported to be of 'not of standard quality' after eight to twenty-four months of their supply to the same depots.

20. It is only 12 batches out of 5752 batches supplied by the appellant i.e. 0.20% of total production which has been declared as *'not of standard quality'*. Pertinently, out of 12 *'not of standard quality'* samples, 9 of them were supplied to GMSD which clearly demonstrates that the problem was not in the products supplied by the appellant but in the handling and storage condition of the respondent because at the time when the material was supplied, it was found to be okay and it deteriorated over

a period of 8 to 24 months of storage in any of the depot of GMSD.

21. It is asserted that action of respondent no. 4 could have been justified had the medicines of same batch supplied to the other depots, had also failed. The respondent no. 4 has taken a draconian action on the basis of ten batches out of total of 300 batches supplied which is contrary to all cannons of reasoning. Not giving the benefit to the appellant of other 290 batches of different medicines, is against all cannons of fair play.

22. Moreover, in the Show Cause Notice dated 19.02.2021 and in the revised Notice dated 03.03.2021,were issued to explain why the appellant should not be debarred for three years or permanently. However, the blacklisting has been done for a period of five years.

23. The consequence of debarment was that BPPI, KMSCL, a Government of Kerala department, also cancelled all its contracts with the appellant Company. The appellant has also been stopped from participating in any other Tenders floated by the Government of India and other State Governments and because of its debarment, it has also lost its eligibility on account of previous three years minimum turnover clause i.e. the appellant will lose its eligibility to participate in any Government tender for life time and such debarment would practically not be limited to five years. The entire hard work and experience of the appellant for the last thirty years would become useless. It has also not been able to participate in the forthcoming tender of DHS, Government of Delhi due on 31.05.2022.

24. It is asserted that the business of the appellant has come to a standstill and families of about 250 employees, Directors, vendors and all other stake holders have been put to stay without following principles of

natural justice. Hence, a prayer is made that the impugned Order dated 12.07.2022 passed by the learned sole Arbitrator may be set aside and the Office Memorandum dated 04.08.2021 debarring the appellant for a period of five years, may be stayed.

25. The **respondent on the other hand,** had re-affirmed its stand that the drugs on random sampling were found to be not of standard quality and after giving proper Show Cause Notices and considering the response of the Appellant, the Order of Debarment has been made in accordance with the terms as contained in the Supply Order. The debarment was on account of repeated failure of the drug supplier manufacturer within a period of one year under Category 'A' as noticed by the Testing laboratories. It is asserted that due procedure and the terms of Agreement have been dully followed and the appeal is without merit and is liable to be dismissed.

26. The **respondent has argued** that the Hon'ble Supreme Court has consistently held that an arbitral award should not be lightly interfered with under Section 34 or Section 37 of the Act. For this reliance has been placed on *Renusagar Power Co. Ltd. Vs. General Electric (1994) Supp. 1 SCC 644, ONGC Vs. Saw Pipes, (2003) 5 SCC 705, Hindustan Zinc Ltd Vs. Friends Coal Carbonisation, (2006) 4 SCC 445 and Associate Builders Vs. DDA (2015) 3 SCC 49.* It is further argued that the judicial scrutiny and interference by the appellate court under Section 37 of the Act is even more restricted than Section 34 petitions.

27. In *McDermott International Inc. vs. Burn Standard Co. Ltd. And Ors* (2006) 11 SCC 181, it was observed that the Court cannot correct the errors of the Arbitrators and the supervisory rule of the Courts is at the

minimum level since the parties to the agreement make a conscious decision to exclude the court's jurisdiction by opting for arbitration as they prefer the expediency and finality offered by it. It is therefore submitted that the appeal is without merit and is liable to be dismissed.

28. **Submissions heard.**

29. At the outset before considering the merits of the case it would be pertinent to define the scope of interference under Section 37(2) of the Act, 1996. Admittedly, the Order under challenge has been made by the learned Arbitrator under Section 17 of the Act declining to stay the Order of debarment/de-registration of the appellant by the respondents.

30. **Section 5 of the Act** defines the extent of judicial intervention. It reads as under:

> *"5. Extent of judicial intervention – notwithstanding anything contained in any other law for the time being in force, in matters governed by this part, no judicial authority shall intervene except where so provided in this part."*

31. The preamble to Act, 1996 also provides that it is an Act to consolidate and amend the law relating to domestic arbitration, international commercial arbitration and enforcement of foreign arbitral awards and also to define the law relating to conciliation and for matters connected therewith or incidental thereto. From a bare perusal of Section 5 it may be concluded that a court must endeavour to promote the arbitral process and must circumscribe their judicial interference. It is only in extreme and rare cases that the court may interfere in the discretionary orders passed under Section 17 by the High Court in exercise of its appellate jurisdiction under Section 37 of the Act. The discretionary

orders by their very nature are amenable to judicial interference to a far lesser degree than other orders.

32. The scope of interference in appeal of a discretionary order passed by a judicial forum stands authoritatively delineated in *Wander Ltd. vs. Antox India (P) Ltd.* 1990 Supp SCC 727, wherein it was observed that the appellate court shall not interfere in exercise of discretion by the courts of first instance and substitute its own discretion except where the discretion has been shown to have been exercised arbitrarily, capriciously or perversely or where the court had ignored the settled principles of law regulating grant or refusal of interlocutory injunctions. An appeal against exercise of discretion is to be an appeal on principle. The appellate court shall not reassess the material and seek to reach a conclusion different from the one reached by the court below if the view taken was reasonably possible on the material available. The appellate court would normally not be justified in interfering with the exercise of discretion under appeal solely on the ground that if it had considered the matter at the trial stage, it may have come to a different conclusion. If the discretion has been exercised in a reasonable and judicial manner, the fact that the appellate court would have taken a different view may not justify interference with the exercise of discretion by the trial court in passing the order.

33. These principles were referred to by Gajendragadkar J. in *Printers (Mysore) (P) Ltd. vs. Pothan Joseph* AIR 1960 SC 1156, wherein a reference was made to the observations by Viscount Simon in *Charles Osenton & Co. Vs. Johnston* 1942 AC 130, wherein it was observed that the principles for interference of the discretional orders by the Court in appeal are well established and the settled principles have to be applied in

the individual case on their facts.

34. The Co-ordinate Bench in *Augmont Gold Pvt. Ltd. vs. One 97 Communication Limited* 2021 4 SCC OnLine Del 4484 observed that the legislature consciously and deliberately provided only for filing of objections under Section 34 against a final Award, but has made the interlocutory orders made by the Arbitral Tribunal amenable to Appeal under Section 37(2) of the Act, 1996. The differential dispensation may not be immediately forthcoming either from the provisions of the Act or from the Statement of objects and reasons thereto. However, since the Act, 1996 itself contemplates differential treatment to interlocutory orders under Section 16 and 17 vis-a-vis a final award, the intent of legislature has to be respected. Section 37 (2) envisages Appeal to the Court from the orders passed by the Arbitral Tribunal either under Section 16 or granting or refusing to grant interim measure under Section 17 of the Act.

35. In *Augmont Gold Pvt. Ltd.* (supra) the Co-ordinate Bench differentiated between the scope and ambit of Section 37 while considering the interlocutory orders and the final awards. It was observed that the appellate court may within its defined limitations, modify the award, something which is beyond the scope of Section 34 of the Act. If the court finds that the interest of justice would be met by modifying the decision of the Arbitral Tribunal, it can do so in exercise of its appellate jurisdiction under Section 37, though it is prohibited from doing so under Section 34 of the Act. This is one of the inevitable sequelae of the legislative dispensation in conferring on courts, appellate jurisdiction over orders passed under Section 17 by the Arbitral Tribunal, granting or refusing to grant interim protection.

36. In *Dinesh Gupta vs. Anand Gupta* 2020 SCC OnLine Del 2099 the Co-ordinate Bench of this Court observed that there can be no gainsaying the proposition that while exercising any kind of jurisdiction over arbitral orders or arbitral awards, whether interim or final or with the arbitral process itself, the court is required to maintain an extremely circumspect approach. When an arbitrator resolves the dispute through the process of arbitration, it is always required to be borne in mind that arbitration is intended to be an avenue for alternate dispute resolution and such resolution is entitled to be given due respect and except for the reasons explicitly set out in the 1996 Act, it is ordinarily immune from judicial interference. Having said that, the appellate court under Section 37 while exercising its jurisdiction may consider whether the Arbitrator has acted in accordance with law and can always question the exercise of discretion. However, the court has to be mindful of its limitations in interfering with the decisions of the Arbitrator especially when the decision is taken at the discretionary level and is at an interlocutory stage.

37. In *Sanjay Arora vs. Rajan Chadha* (2021) 3 SCC (Del) 654 while making a reference to the observations made in *Augmont Gold Pvt. Ltd.* (supra) and *Dinesh Gupta* (supra) the Coordinate Bench held that the considerations guiding exercise of appellate jurisdiction under Section 37(2)(b) are fundamentally not really different from those which govern exercise of jurisdiction under Section 34 of the Act. It is only when the order suffers from patent illegality or perversity that the court would interfere with the order of the Arbitral Tribunal under Section 37 of the Act.

38. Further, in *Supreme Panvel Indapur Tollways Private Limited vs.*

National Highways Authority of India 2022 SCC OnLine Del 4491 after making a reference to the aforesaid cases it was concluded that the guidance available in the judgments of Supreme Court in *Printers (Mysore) (P) Ltd.* and *Wander Ltd.* (supra) are sufficient to enjoin considerable circumspection in an appellate court's interference with discretionary interlocutory orders limited to the narrow category of cases as enumerated therein. The reasoning given is the basis of the observations made in *Green Infra Wind Energy Ltd. vs. Regen Powertech Pvt. Ltd.* 2018 SCC OnLine Del 8273 and *Sona Corporation India Pvt. Ltd. vs. Ingram Micro India Pvt. Ltd.* 2020 SCC OnLine Del 300. However, the subsequent judgments of this Court have given an additional line of reasoning and enjoins a purposive interpretation based on the provisions of the Act, 1996.

39. In the light of the circumspect approach mandated in the aforesaid judgments, the facts of the present case need to be considered.

40. The petitioner by way of present application had sought injunction against the debarment/de-registration Order of five years from marketing all kinds of medicines, that has been issued against it.

41. At the outset, it may be observed that debarment/derecognization has serious financial implications and must not be lightly imposed unless compelling circumstances exist. The Apex Court has expounded the effects of blacklisting or debarment in *M/s Erusian Equipment & Chemicals Ltd. vs. State of West Bengal and Another* (1975) 1 SCC 70 wherein it was observed as under:

"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."*

42. In *Gorkha Security Services vs. Government (NCT of Delhi)* 2014 SCC OnLine SC 599 the Supreme Court had observed as under:

> *"With blacklisting many civil and/or evil consequences follow. It is described as "civil death" of a person who is foisted with the order of blacklisting. Such an order is stigmatic in nature and debars such a person from participating in government tenders which means precluding him from the award of government contracts."*

43. In *Medipol Pharmaceutical India Private Limited vs. Post Graduate Institute of Medical Education and Research and Another* (supra), the Apex Court observed that the blacklisting has the effect of preventing a person from the privilege of entering into a lawful relationship with the Government for the purpose 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. It was thus concluded that the only legal limitation upon the exercise of such an authority by the State is to act fairly and rationally without being arbitrary in any way.

44. In this backdrop, the action of respondents is to be considered to

determine if its action is arbitrary. It is not in dispute that the petitioner had been awarded a rate contract for 64 items of generic medicines vide Tender No. GMSD/HYD/EQ/2015-16/A/245 & 274. In terms of the Tender, the medicines were supplied to various Depots of the respondent GMSD at Delhi, Kolkata, Karnal, Chennai, Guwahati, Mumbai and Hyderabad. The medicines got tested from the two laboratories registered with the respondent and then distributed to various indentors, after they were found to be of *"standard quality"*. However, these medicines when tested again by some of the depots, were found to be "not of standard quality" leading to debarment from marketing of all medicines for a period of five years.

45. The basic contention of the appellant is that the medicines at the time of supply to GMSD were found to be of "*standard quality*" when tested in the laboratory. It is only subsequently when they were tested by the vendors after 8-24 months, they were found to be of "not standard quality". It is essentially not an issue of there being any deficiency or sub-standard quality in the medicines but of the storage and supply. Therefore, the appellant cannot be penalized by being de-registered/ debarred.

46. **Clause 26.3 (B)** of the Tender provides the stipulations for rejection and penalty. The relevant part of the Clause reads as under:

> *"**26.3 <u>Rejection and Penalty Clause</u>***
> *(A) ...*
> ***Penalty in the event of failure in laboratory test***
> *(B) In case any item is found substandard either at the inspection stage or during the shelf life of the*

> *item, the report of the Government approved laboratory shall be accepted by the firms. If the same is disputed by the firms giving the reasons, the sample will be sent to Central Drug Laboratory, Kolkata and the report of CDL will only be accepted as final.*
>
> *In the event of drugs supplied found substandard in laboratory test, the following deregistration/ debarment action will be taken against the manufacturing unit and contract holding firms.*
>
> *(i) For Category 'B' defects, the manufacturer and contractor will be debarred for supply to MSO of that particular product declared not of standard quality for a period of three (3) years from the date of failure.*
>
> *(ii) In regard to category 'A' defects, the supplier should be debarred for the supply of that product for three years from the date of failure and for repeated failure of category 'A' defect within one year from previous date of failure, the supplier shall be debarred from supply of all the products for five (5) years."*

47. Admittedly, as per the terms of the Tender, the medicines which were found to be of *sub-standard quality*, were again tested at the appellate lab at Central Drug Laboratory, Kolkata and were found to be "*not of standard quality"*. The penalty envisaged under Clause 26.3 (B)(ii) in respect of category "A" medicines was that the supplier shall be debarred for three years from the date of failure and in case of repeat failure of category "A" defect within one year from the previous failure, supplier shall be debarred from supply of all the products for five years.

48. In the present case, the de-registration/ debarment of the appellant for all medicines for a period of five years has been done strictly in

accordance with the terms of the tender. The appellate lab testing of the medicines was done at CDL, Kolkata, as was the agreed procedure in terms of Clause 26.3 and the medicines being found *"not of standard quality"* within one year of previous set of medicines, it has been blacklisted. Prima facie, there exists no case in favour of the appellant for grant of any interim stay of debarment/ de-registration.

49. While appreciating the contention of the appellant that it has led to huge financial loss to it, it cannot be overlooked that the products under consideration are medicines and involve the issue of public health. Even if one sub-standard medicine is marketed, it can result in human loss which cannot be compensated in any terms. As has been observed in *Union of India and Ors. vs. Cipla Limited and Anr.*, (2017) 5 SCC 262, wherein similar matter was being considered, in matters where public interest is involved, the court ought to be circumspect in granting interim relief. The consequential interim relief might be quite serious to society and consumers and might cause damage to public interest and have a long-term impact. The courts must also exercise more circumspection while dealing with interim orders in matters having financial or economic implications. The relevant portion of the judgment is as under:

> *"In matters* ***where public interest in involved, the Court ought to be circumspect in granting any interim relief.*** *The consequence of an interim order might be quite serious to society and consumers and might cause damage to public interest and have a long-term impact.* ***It is not the intention to suggest to any court how and in what circumstances interim orders should or should not be passed but it is certainly our intention to make it known to the courts that the time has come when it is necessary to be somewhat more***

> ***circumspect while granting an interim order in matters having financial or economic implications.***
>
> ***Not only is the drug industry in the country extremely large with heavy financial stakes but there is a lot at stake in it not only for the industry but also for the consumers.*** *For this reason, the courts have to be extremely cautious in interfering in any manner whatsoever with the working of the drug industry. Any interference by the courts would have wide-ranging repercussions not only in commercial terms but also for the people of the country."*

50. It is not in dispute that the order of debarment dated 20.11.2020 was challenged by the appellant by way of Writ Petition before the Bombay High Court which had set aside the Debarment Notice and directed a fresh Show Cause Notice to be issued to the appellant. The Show Cause Notice thereafter was duly served to which a reply was given, but the same was found to be not satisfactory and the Debarment Order for supply of all the medicines for five years w.e.f 24.10.2019 was issued.

51. The grievance of the appellant is that though the Show Cause Notice was issued, but it was merely an eye wash as the reply given by the appellant was not considered and it was also not supplied with the findings/ details of the appellate laboratory test reports. The learned counsel on behalf of the appellant has argued that there is no prima facie evidence that the tests have been conducted correctly entailing such severe penalty of debarment.

52. At this juncture it is pertinent to refer to *Ind-Swift Limited vs. Union of India and Others. W.P. (C) 9026 of 2009 & CM APPL 6531/2009,* wherein this court observed that a Court lacks expertise to sit in judgment

over the correctness of test reports of the different test laboratories and therefore, has to proceed on the basis of the test reports and the state of affairs reflected in them and in any event, the Court has no means to assess whether the conclusion arrived at by the Government test reports was correct or not.

53. Learned Counsel for the appellant has placed reliance on *Medipol Pharmaceutical India Private Limited vs. Post Graduate Institute of Medical Education and Research and Another* (supra). However, the said judgment is not applicable to the facts in hand since it had set aside the debarment on finding that the lab testing had not been done correctly. In the present case, the stay of debarment has been sought at the initial stage which is not tenable in the given circumstances. This contention of the appellant can therefore, be considered only at the time of final stage and the judgment of *Medipol Pharmaceutical India Private Limited (supra)* is distinguishable on facts. No prima facie case has been made out in the present case as has been rightly observed in the impugned Order.

54. The appellant has raised the issue of there being an irreparable loss as the debarment/de-registration is for all the medicines produced by the appellant, whereby all the medicines that have been already manufactured, are prevented from distribution resulting in huge financial loss and serious financial implication for the appellant. Learned counsel on behalf of the appellant had argued that such debarment has resulted in irreparable damage and loss which cannot be compensated. It is argued that the financial loss is on two accounts; (1) for the reason not being able to sell or market the medicines already manufactured and (2) the cascading effect of such debarment. In the future Tenders, the appellant would not be able

to meet the requirement of previous three years of minimum business turnover on account of this de-registration preventing him from participating in the tender process for the next five years. This impacts his right to trade and profession and to earn his livelihood and is violative of Article 19 of the Constitution of India.

55. Though, what is being argued may seem logical and a matter of concern, but it cannot be disregarded that any medicine of sub-standard quality if marketed can result in loss of human life, which cannot be compensated. On the other hand, any business loss which may be caused to the appellant on account of wrong decisions of the State, the same can be compensated by way of damages. There is no irreparable loss for if it is later found that debarment was wrong, whatever is the business loss can easily be compensated in terms of money.

56. As observed in *Bharat Parenterals Limited vs. State of Gujarat* 2022 SC OnLine Guj 1746, the Gujarat High Court while emphasizing on the Zero Tolerance Policy of the State to reject the bid of the appellant on the ground of he having been blacklisted observed that the reason why Zero Tolerance Policy was adopted by the State cannot be subjected to judicial scrutiny, when the State is asserting that the health of general public is of paramount importance and there cannot be any compromise in the quality of any tablets or drugs being administered to the general public and the State refused to accept the blacklisted petitioner.

57. While the derecognization/debarment may have serious repercussions for the appellant, the consequences of such medicines which are found to be *"sub-standard quality"* on the consumers need to be also balanced. Any interference by the Court would have wide-ranging

ramifications not only in commercial terms, but also on the people of the country.

58. The balance of convenience does not lie in favour of the appellant since the medicines have been found to be sub-standard in accordance with the procedure established and the balance of convenience is to be weighed between the financial interest and the human life.

59. The action taken by the respondents cannot be faulted and such grounds taken by the appellant cannot be accepted at the cost of the common man. Therefore, there is no merit in the appeal which is hereby dismissed.

60. The pending applications also stands disposed of.

(NEENA BANSAL KRISHNA)
JUDGE

APRIL 28, 2023
pa/va