(2021) 01 KL CK 0023

In the High Court Of Kerala

Case No : Writ Petition (C) No. 21421 Of 2020

M/S. Bharat Parenterals Ltd — APPELLANT

Vs

State Of Kerala And Ors — RESPONDENT

Date of Decision : 04-01-2021

Acts Referred:
Drugs And Cosmetics Act, 1940 — Section 9(B)

Citation : (2021) 01 KL CK 0023

Hon'ble Judges : N. Nagaresh, J

Bench : Single Bench

Advocate : P. Chandrasekhar, K.K. Mohamed Ravuf, K. Vidya, Satheesh V.T, M. Ajay, Rashmi K.M

Final Decision : Allowed

Judgement

1. The petitioner, a Pharmaceuticals Manufacturing Company, is before this Court seeking to quash Ext.P10 order of the 1st respondent blacklisting one of the products of the Company and to quash Ext.P13 order of the 2nd respondent blacklisting the Company itself for a period of three years.

2. Facts necessary to decide the lis involved in the writ petition are as follows:-

The petitioner has been supplying pharmaceutical products to the 2nd respondent-Kerala Medical Services Corporation Limited for the last several years. The petitioner was a successful bidder in respect of several drugs under Category I, pursuant to notification for the year 2016-'17 dated 27.11.2015. The petitioner submitted their tender in respect of various drugs including Clobazam Tab 5 mg. with minimum shelf life required of 36 months. The tender was accepted by the 2nd respondent. Clauses 6.29.8 and 6.29.9 of Ext.P1 e-tender document, provided as follows:-

"6.29.8. If any two batches of the particular item supplied by the firm during the contract period, fail in any of the quality tests conducted by the tender Inviting Authority and/or by the Drugs Control Department, then that particular product

of that firm will be blacklisted for a period upto 3 years as per Clause 6.39.

6.29.9. In the case of the bidder supplying more than one item during the contract period, and if two or more items supplied by the supplier are blacklisted based on the above process, then the firm itself will be blacklisted as per the procedure detailed in Clause 6.39."

The 2nd respondent as per letter dated 09.03.2016, required the petitioner to supply the items as per the terms and conditions in the tender document.

3. The petitioner was required to supply Clobazam Tab 5 mg. of a total quantity of 23 lakhs units. The petitioner effected supply as against purchase orders issued by the 2nd respondent. The petitioner submitted test/analysis reports furnished by an independent NABL accredited laboratory after testing the drugs of each batch.

4. The 2nd respondent issued show-cause notice dated 03.10.2018 requiring the petitioner to show-cause why the petitioner should not be blacklisted. It was alleged in the show-cause notice that an e-mail had been received from the Drugs Controller on 06.01.2018 stating that batch No.T7026 of Clobazam Tab 5 mg. was declared as "Not of Standard Quality" on statutory sampling and the product was not complying with "dissolution test". The petitioner pointed out to the 2nd respondent that the drug supplied by the petitioner satisfied all requisite tests and dissolution test was not mandatory as the drug was not an IP Drug (Indian Pharmacopoeia Drug).

5. It appears that IP Addendum 2016 was brought into effect from 01.04.2016, by which a test of dissolution was made one of the requisite parameters for Clobazam Tab. All IP specified drugs should have IP monograph with the name of the drug. As the tender in which the petitioner participated for supplying Clobazam Tab 5 mg. was before the IP Addendum 2016. The agreement of the petitioner with the 2nd respondent was for supplying Clobazam Tab 5 mg. (without IP monograph).

6. The petitioner would state that at no point of time the 2nd respondent had insisted the petitioner to supply Clobazam Tab IP 5 mg. having the standard prescribed in IP Addendum 2016. Therefore, the show-cause notice itself was in violation of Ext.P1 tender conditions. Clause 6.5.6 of Ext.P1 tender conditions stated that if the drug is official in Indian Pharmacopoeia, the licence to manufacture the product shall be for IP specification. Since on the date of Ext.P1 tender notification and also on the date on which the petitioner submitted their tender offering, the product was not official in Indian Pharmacopoeia, the petitioner was not required to have a licence to manufacture the said product for IP specification. In view of tender conditions, the 2nd respondent cannot insist that the drug Clobazam Tab 5 mg. should comply IP specification as per the Addendum 2016 of Indian pharmacopoeia.

7. The Managing Director in charge of the 2nd respondent gave an opportunity of

hearing to the petitioner. The petitioner pointed out that the tablets were manufactured by the petitioner as per permission/licence granted in 2013 by the FDCA, Gujarat. The manufacturing facilities were inspected by regulatory officials and licence was granted after satisfying that the petitioner has complied with all statutory requirements. The representatives of the 2nd respondent also inspected the factory and manufacturing units and the 2nd respondent accepted the tender after inspecting the manufacturing unit and having satisfied that the method and procedure followed by the petitioner is in conformity with the Drugs and Cosmetics Act, 1940.

8. The 2nd respondent, however, issued Ext.P5 order blacklisting the petitioner-Company for a period of three years and declared that the writ petitioner will be ineligible to participate in any of the tenders floated by the 2nd respondent during the said period. Aggrieved by Ext.P5, the petitioner filed Ext.P6 appeal before the 1st respondent-State of Kerala. The 1st respondent took a lenient stand treating the issue as a special case. The penalty of blacklisting of the Company was relaxed and the blacklisting was confined to the product Clobazam Tab 5 mg. alone for a period of three years, as per Ext.P10 order dated 07.09.2019.

9. Thereafter, the 2nd respondent issued a further show-cause notice dated 03.02.2020 requiring the petitioner to show-cause as to why the petitioner-company should not be blacklisted for a period of three years. The 2nd respondent alleged that another product of the petitioner, namely Enalapril Maleate Tab IP (Film Coated) was already blacklisted and since the Clobazam Tab 5 mg. is also being blacklisted, the petitioner-company itself is liable to be blacklisted in view of Clause 6.29.9 of Ext.P1. The petitioner submitted reply to the show-cause notice. The 2nd respondent, however, passed Ext.P13 order blacklisting the petitioner-company for three years from 28.09.2020, the date of Ext.P13 order.

10. The petitioner contends that Ext.P13 has been passed without application of mind and in violation of principles of natural justice. Ext.P13 is a non-speaking order passed without considering the contentions of the petitioner. Ext.P13 is vitiated by legal malafides also. The 2nd respondent should not have taken a stand that two products had been blacklisted and the petitioner-company was therefore liable to be blacklisted.

11. The petitioner argued that no offer was made by the petitioner to the 2nd respondent to supply Clobazam Tab 5 mg. as an IP product. The tender conditions did not require the petitioner to supply the said drug as an IP product. No authority has found that the Clobazam Tab 5 mg. supplied by the petitioner is a spurious drug. The petitioner has not violated any of the provisions of Drugs and Cosmetics Act. Blacklisting of a Company is a drastic measure and it can be done only on cogent materials. The petitioner has not violated any of the tender conditions. Therefore, the impugned orders are illegal, contended the petitioner.

12. The 2nd respondent strongly resisted the writ petition filing counter affidavit. The learned Standing Counsel for the 2nd respondent pointed out that Clauses 1.4 and 1.9 of the NIT stipulate that it is the obligation of the manufacturer and supplier to produce and supply drugs of standard quality. Clause 2.3.15 specifically emphasises that supply of drugs in contravention to any of the provisions of the Drugs and Cosmetics Act and supply of all drugs in violation of the tender conditions, will lead to blacklisting of the Firm.

13. The Standing Counsel further pointed out that as per the footnote to Clause 4.1 of the NIT, for drugs included in the Indian Pharmacopoeia, only such standards will apply and for products not included in the current IP but included in its immediate previous edition, the said standards in the previous edition of the IP shall apply.

14. The learned Standing Counsel for the 2nd respondent urged that two batches of Enalapril supplied by the petitioner were declared to be Not of Standard Quality by the Government Analyst. After notice to the petitioner, the 2nd respondent blacklisted the said product Enalapril supplied by the petitioner for a period of three years. Now, since Clobazam Tab 5 mg. supplied by the petitioner was also found to be Not of Standard Quality, the petitioner-company is liable to be blacklisted.

15. According to the 2nd respondent, Ext.P10 was issued by the 1st respondent-appellate authority on erroneous premises. It is not so much relevant that the petitioner was required to supply Clobazam tablets without IP specification. When addendum was brought to the IP in the year 2016, the petitioner was liable to supply Clobazam with the IP specification. This is specifically so in view of the provisions of the NIT and also in view of the statutory requirements. Since the petitioner violated statutory requirements and contract conditions, the Clobazam Tab 5 mg. of the petitioner was blacklisted.

16. Since Enalapril tablets of the petitioner were already blacklisted, Clobazam Tab 5 mg. became the second product of the petitioner which is blacklisted. Therefore, in terms of Ext.P1, the petitioner-company was liable to be blacklisted. The action of the 2nd respondent is keeping in mind public interest and the necessity of not marketing NSQ drugs. Therefore, no interference is warranted in Ext.P13 order, contended the learned Standing Counsel for the 2nd respondent.

17. I have heard the learned counsel for the petitioner, the learned Government Pleader appearing for the 1st respondent and the learned Standing Counsel appearing for the 2nd respondent.

18. Facts are not much in dispute. Ext.P1-NIT was issued on 27.11.2015. Ext.P1 would show that the petitioner was required to supply Clobazam Tab 5 mg., without IP specification. In fact, when Ext.P1 was issued, the Clobazam tablets were not brought under IP specifications. By a letter dated 09.03.2016, the 2nd respondent accepted the offer for supply of Clobazam Tab 5 mg. (without IP

specification) and also requested the petitioner to supply the tablets. It is to be noted that even on the said date, the Clobazam Tab 5 mg. was not brought under IP. It is an admitted position that Clobazam Tab 5 mg. was brought under IP only with effect from 01.04.2016.

19. Ordinarily, when the petitioner has entered into an agreement with the 2nd respondent for supply of Clobazam Tab 5 mg. without IP specification and when the 2nd respondent demanded supply of the agreed Clobazam Tab 5 mg. (without IP specification), the petitioner cannot be found fault with. But, Clause 2.3.15 of Ext.P1 emphasises that supply of drugs in contravention to any of the provisions of the Drugs and Cosmetics Act and the supply of drugs in violation of the tender conditions will lead to blacklisting of the bidders.

20. In this case, the petitioner was put to a precarious situation. Their agreement with the 2nd respondent was to supply Clobazam Tab 5 mg., without IP specification. The Dissolution Test was not a requirement for the said drug. The 2nd respondent also required the petitioner to supply Clobazam Tab 5 mg. without IP specification. The petitioner supplied Clobazam Tabs 5 mg. as required by the 2nd respondent. But, by the time supply was effected, the IP Addendum 2016 was brought into force from 01.04.2016 which mandated IP specification for the drug.

21. There is indeed a statutory duty on the part of the petitioner to comply with IP requirements for the drug once IP Addendum 2016 is brought into force. Perhaps, the petitioner was not aware of the amendment. It is to be noted that the 2nd respondent, who is dealing exclusively in drugs and pharmaceuticals, also did not notice IP Addendum 2016 and required the petitioner to supply the drug complying with IP requirements. It is only when the Drugs Control Authorities noticed the deficiency and brought it to the notice, that the 2nd respondent swung into punitive measures against the petitioner. The petitioner has subsequently revised the formula of the drug to make it IP compliant subsequently, as stated in Ext.P10.

22. Therefore, it is amply clear that though there was statutory violation, the violation was not deliberate. The drug Clobazam Tab 5 mg. supplied by the petitioner was not spurious drug as defined in Section 9-B of the Drugs and Cosmetics Act, 1940 though it was not IP compliant from 01.04.2016. This exceptional situation was taken note of by the appellate authority, which in Ext.P10 order observed as follows:-

"Government have examined the contentions of both the parties in detail. There is absolutely no illegality or arbitrariness from the part of Kerala Medical Services Corporation Ltd. in having blacklisted the firm based on the statutory test report. However, at the same time, it is to be admitted that blacklisting of a company is indeed a drastic step which can even lead to the complete shut down of the company and as such it is to be definitely tested against the proportionality principle. Here, in the present case, it appears that there is no that much

violation of rules involving criminal/fraudulent intent or glaring negligence leading to serious defects which are to be dealt with heavy hand warranting blacklisting of the firm straight away before blacklisting the said product. Here, no instances of selling grossly sub standard, adulterated, spurious or imitation drug products with fake licence. Though cannot take it up for granted, here the representative of the firm is seen to have contended that they were not aware of the inclusion of the drug in the IP at first and they revised the formula of the drug to make it statute compliant during 2018 itself. It is very embarrassing to see that even Kerala Medical Services Corporation was not aware of the inclusion of the product in the IP subsequent to the tender process, till the said test report was received. Moreover, as per clauses 6.28.11, 6.28.12 & 6.28.38 of the tender document, only if 2 or more products supplied by a firm failed in quality, the penalty of blacklisting need be resorted to. Though there is grave violation of Drugs & Cosmetic Act, 1940, in not having made the drug, statute complaint, subsequent to the inclusion of the same in the IP, the present case is an odd one for the first time happening in the tender process of Kerala Medical Services Corporation Limited."

Accordingly, the 1st respondent treated the issue as a special case, and modified the blacklisting of petitioner-company as blacklisting of the product Clobazam Tab 5 mg. alone for a period of three years. This Court do not find any illegality in Ext.P10 order of the 2nd respondent-appellate authority.

23. The argument of the counsel for the petitioner that the issue before the appellate authority being legality of blacklisting the petitioner-Company, the appellate authority ought to have confined its consideration on the said issue alone and should not have blacklisted Clobazam Tab 5 mg., cannot be accepted. The issue before the appellate authority was the non-compliance of IP specification of Clobazam Tab 5 mg. based on which the Company was blacklisted. The appellate authority has all the powers of the original authority while considering an appeal. The appellate authority has only modified the punishment and imposed a lesser one which the 2nd respondent could have imposed, and it cannot be said to be illegal or irregular.

24. However, subsequent to Ext.P10 appellate order, the 2nd respondent initiated fresh proceedings to blacklist the petitioner-Company entirely on the specious ground that another product of the petitioner, namely Enalapril Maleate Tab IP (Film Coated) was blacklisted earlier as per an earlier order dated 08.03.2018 and and since Clobazam Tab 5 mg. also stands blacklisted as per Ext.P10, the petitioner-Company itself is liable to be blacklisted in view of Clause 6.29.9 of Ext.P1 and the 2nd respondent passed Ext.P13 order blacklisting the petitioner-Company for three years. It is true that the provisions contained in Ext.P1 enable the 2nd respondent to blacklist the petitioner-Company if two of its products are blacklisted during contract period. The question is whether the 2nd respondent has exercised the power to blacklist the petitioner in a fair and judicious manner. Though the issue of blacklisting a Firm/Company falls within the realm of

contract, there cannot be arbitrariness in exercise of powers of blacklisting by the State and instrumentalities of the State. Arbitrariness and discrimination in such matters will warrant and justify judicial review of such action by a writ court.

25. In Kulja Industries Ltd. (M/s) v. Chief General Manager, W. T. Project. BSNL and others [(2014) 14 SCC 731), while dealing with the issue of blacklisting, the Hon'ble Apex Court held that where there is arbitrariness in State action, Article 14 springs up and judicial review strikes such an action down. Every action of the state executive authority must be subject to rule of law and must be informed by reason. Whatever be the activity of the public authority, in such monopoly or semi-monopoly dealings, it should meet the test of Article 14 of the Constitution. The Hon'ble Apex Court further held that 'debarment' is recognised and often used as an effective method for disciplining deviant suppliers/contractors who may have committed acts of omission and commission or frauds including misrepresentations, falsification of records and other breaches of the regulations under which such contracts were allotted. What is notable is that the debarment is never permanent and the period of debarment would invariably depend upon the nature of the offence committed by the erring contractor.

26. In Gorkha Security Services v. Govt. of NCT of Delhi and others [(2014) 9 SCC 105], the Hon'ble Apex Court described the action of blacklisting which is termed as "civil death". In the judgment in Medipol Pharmaceutical India Private Limited v. Post Graduate Institute of Medical Education and Research and others [2020 (9) ADJ 369], the Hon'ble Apex Court held that the State need not enter into any contract with anyone but if it does so, it must do so fairly without discrimination.

27. In the case of the petitioner herein, the petitioner Company was blacklisted by the 2nd respondent as per Ext.P5 order, based on the fact that Clobazam Tab 5 mg. supplied by the petitioner-company did not satisfy the IP specifications. The said action was challenged by the petitioner before the 1st respondent-Appellate Authority. The Appellate authority heard the petitioner and the 2nd respondent. The Appellate Authority specifically found that in the petitioner's case there is not that much violation of rules involving criminal/fraudulent intent or glaring negligence leading to serious defects which are to be dealt with a heavy hand warranting blacklisting. The Appellate Authority further found that there is no instance of petitioner selling grossly substandard, adulterated, furious or imitation drug products with a fake licence. While arriving at such conclusion, the Appellate Authority noted that even the 2nd respondent was not aware of the inclusion of the product in the IP subsequent to the tender process till the test report was received. The appellant authority rightly found that the case of the petitioner deserves leniency and limited the blacklisting to the product Clobazam Tab 5 mg. for a period of three years. The Appellate Authority therefore obviously felt that the blacklisting of the company itself would be too harsh punishment in the facts and circumstances of the case.

28. However, the 2nd respondent even thereafter and in spite of the specific

findings of the 1st respondent-Appellate Authority, ventured to dig out blacklisting of another product of the petitioner-company and passed Ext.P13 order blacklisting the petitioner-company on the ground that since two of the products of the petitioner-company have been blacklisted, the company itself is liable to be blacklisted in view of the provisions contained in Ext.P1. The action of the 2nd respondent can be only termed as arbitrary. The 2nd respondent could have brought the blacklisting of one product of the petitioner to the notice of the Appellate Authority and justify the blacklisting of the petitioner-company as per Ext.P5 order. The 2nd respondent did not opt to do so.

29. The Appellate Authority took into consideration the entire facts and circumstances leading to Ext.P5 order of blacklisting. The appellate authority was of the view that the supply of Clobazam Tab 5 mg. not satisfying IP specification by the petitioner is an exceptional case which requires a lenient approach. The appellate authority was of the view that blacklisting of the petitioner-Company based on supply of Clobazam Tab 5 mg., was unwarranted and accordingly imposed a lesser punishment.

30. When the appellate authority was of the view that blacklisting of petitioner-Company based on supply of Clobazam Tab 5 mg. was unjustified, the 2nd respondent should not have clubbed the said issue with blacklisting of another product of the petitioner-company earlier, so as to again blacklist the petitioner-Company. By Ext.P13, the 2nd respondent has tried to overreach the appellate authority and to render Ext.P10 appellate order nugatory, which is impermissible.

The writ petition is therefore partly allowed. Ext.P13 order of the 2nd respondent is set aside.

