(2021) 10 KL CK 0100

In the High Court Of Kerala

Case No : Writ Petition (C) No. 17330 Of 2021

Unicure (India) Limited — APPELLANT

Vs

State Of Kerala — RESPONDENT

Date of Decision : 20-10-2021

Acts Referred:

Citation : (2021) 10 KL CK 0100

Hon'ble Judges : P.B.Suresh Kumar, J

Bench : Single Bench

Advocate : P.Ravindran, M.R.Sabu, Lakshmi Ramadas, Aparna Rajan, Sreedhar Ravindran, M.Ajay, B.Vinitha

Final Decision : Dismissed

Judgement

P.B.Suresh Kumar, J

1. Petitioner is a licensed drugs manufacturer. It is stated that they have been supplying drugs to various Governments including the Government of Kerala for the last so many years. The second respondent, the Kerala Medical Services Corporation Limited (the Corporation) is the undertaking of the State Government procuring and supplying drugs to various Government Hospitals. On 18.11.2016, the Corporation invited tenders for supply of various drugs, and in response to the said invitation, the petitioner offered to supply drugs including Telmisartan Tab IP 40mg. The bid submitted by the petitioner for the said drug was accepted and on receipt of purchase order, the petitioner supplied the said drug to the Corporation.

2. On 26.10.2018, the petitioner was issued Ext.P2 communication by the Corporation stating that the drug, Telmisartan Tab IP 40 mg of Batch No.TSHT519 manufactured and supplied by the petitioner, was declared as "Not of Standard Quality" by the Government Analyst in the Drugs Testing Laboratory of the State Government and the Corporation has, therefore, issued directions to all District Drug Warehouses and hospitals where the said drug has been

supplied, to stop the distribution/use of the same and also to transfer the remaining stock to the quarantine area. Along with Ext.P2, a copy of the Test Report of the Government Analyst referred to therein was also forwarded to the petitioner. Ext.P3 is the copy of the Test Report enclosed along with Ext.P2 communication. The petitioner sent a reply to Ext.P2 communication taking the stand that since the control sample of the drug has passed through all the prescribed parameters, the exposure of the drug to heavy moisture might have been the reason for the adverse report.

3. Later, on 28.12.2018, the Corporation issued Ext.P5 communication to the petitioner on the same lines of Ext.P2 communication, stating that the same drug of Batch No.TSHT515 manufactured and supplied by the petitioner was also declared as "Not of Standard Quality" by the Government Analyst in the Drugs Testing Laboratory. Ext.P6 is the Test Report enclosed along with Ext.P5 communication. The petitioner sent Ext.P7 reply to Ext.P5 communication taking the stand that the sample of the drug tested might not have been the drug manufactured and supplied by the petitioner.

4. On 24.09.2019, the Corporation issued Ext.P8 notice to the petitioner invoking Clause 6.29.8 of the tender notice calling upon them to show cause why the drug mentioned in Exts.P2 and P5 communications shall not be blacklisted for a period of three years. Later, after affording the petitioner an opportunity of hearing, the Corporation passed Ext.P9 order blacklisting the said drug of the petitioner for a period of three years. The petitioner challenged Ext.P9 order in appeal before the Government as provided for in the tender notice. Ext.P10 is the appeal preferred by the petitioner in this regard. Ext.P10 appeal was disposed of by the Government in terms of Ext.P12 order upholding Ext.P9 order. Ext.P12 order was challenged by the petitioner in W.P.(C) No.6506 of 2021 on the ground mainly that the contentions raised by the petitioner in Ext.P10 appeal have not been dealt with by the Government in Ext.P12 order. This Court set aside Ext.P12 order on the aforesaid ground and remitted the appeal to the Government for fresh disposal. Ext.P10 appeal was heard and rejected by the Government again in terms of Ext.P14 order. Exts.P9 and P14 orders are under challenge in the writ petition.

5. Heard the learned Senior Counsel for the petitioner as also the learned Standing Counsel for the Corporation.

6. The learned Senior Counsel for the petitioner has pointed out, at the outset, that Exts.P3 and P6 Test Reports, on the basis of which proceedings have been initiated for blacklisting the drug manufactured and supplied by the petitioner, do not disclose the identity of the manufacturer of the drug as also its batch number. According to the learned Senior Counsel, the impugned orders are liable to be set at naught on that sole ground. Placing reliance on Exts.P3 and P6 Test Reports, the learned Senior Counsel has also pointed out that the drug referred to therein was found to be "Not of Standard Quality", not because the same was not conforming to the parameters prescribed in the Indian Pharmacopoeia, but

due to the reason that the drug was not conforming to its description, namely that the drug was found to be soft and could not be removed from the strip in intact form in the case of the first sample and the drug was found to be in wet condition in the case of the second sample. According to the learned Senior Counsel, such shortfalls can never be a reason for blacklisting a drug which is conforming to the parameters prescribed in the Indian Pharmacopoeia, for the same cannot be due to any reason attributable to the petitioner. It was submitted by the learned Senior Counsel that the shortfalls in the description of the drug, especially as mentioned in the Test Reports can only be due to the exposure of the drug to harsh weather conditions during the course of its storage. The learned Senior Counsel has reinforced the said stand pointing out that the drug in terms of the tender notice needs to be supplied to the Corporation along with the certificate of a laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) to the effect that the drug is conforming to its specifications, and since the Corporation has no case that the drug, when supplied to them, was not conforming to its specification, the manufacturer cannot be blamed at any rate for its subsequent deterioration in description.

7. Per contra, the learned Standing Counsel for the Corporation took me through the various terms in the tender notice and submitted that the shortfall of the drug supplied by the petitioner as indicated in Exts.P3 and P6 Test Reports is sufficient to initiate proceedings for blacklisting the product. It was also pointed out by the learned Standing Counsel that it is the obligation of the supplier to use packing materials of sufficient strength to prevent damage during storage in the climatic conditions of the State throughout the shelf life of the drug in terms of the tender notice. The learned Standing Counsel has strongly refuted the argument of the learned Senior Counsel for the petitioner that moisture at the place where the drug was stored is the cause for deterioration of description of the drug. It was argued by the learned Standing Counsel that even if the moisture at the places where the drug was stored is the cause for the deterioration of description of the drug, the petitioner alone could be responsible for the same, for the quality of the packing materials used by them should be the reason for the same. The learned Standing Counsel reinforced the said submission pointing out that if damp or wet or moist environment in the storage area should cause deterioration of the description of the drug, then every other drug stored in the same area should have also been deteriorated in description. It was further argued by the learned Standing Counsel that the question whether a drug was in order when it was supplied is irrelevant insofar as its stability and the shelf life is concerned and there is no basis for the contention that the drug was conforming to its specifications when it was supplied. As regards the contention of the learned Senior Counsel for the petitioner that there is no reference about the particulars of the manufacturer, batch etc. in the Test Reports, it was pointed out by the learned Standing Counsel that as per the procedure in place, samples are being sent for testing, after masking the details

of the manufacturer and batch number of the drug by assigning code numbers and the Test Reports are identified as and when received after decoding the code numbers assigned to the samples. It was pointed out that the said procedure is followed in order to ensure that no manipulation takes place in the process of testing and it is on account of the said reason that the particulars of the manufacturer and batch number of the product are not mentioned in the Test Reports.

8. I have considered the contentions advanced by the learned counsel for the parties on either side.

9. It is seen that in Ext.P4 reply, the petitioner has not disputed the identity of the sample. Of course, in Ext.P7 reply sent to Ext.P5 communication, the petitioner has expressed doubt as to the identity of the sample on the ground that the product supplied by them to the Corporation was not having dosage description as in the case of the sample, the particulars of which are described in Ext.P6 Test Report. It is seen that in the light of Ext.P7 communication, a clarification was sought by the Corporation from the Drugs Controller and he has clarified in terms of the letter dated 28.09.2019 that there was an error in Ext.P6 Test Report in as much as instead of "having dosage line on the tablet", it was erroneously mentioned as "having dosage on the tablet". It is seen that the objection raised by the petitioner as to the identity of the sample in the reply to the show cause notice issued by the Corporation has been rejected by the Corporation in Ext.P9 order on the basis of the said clarification of the Drugs Controller. Despite that, in Ext.P10 appeal preferred against Ext.P9 order, the petitioner has disputed the identity of the samples covered by the Test Reports on the ground that the same do not reveal the identity of the manufacturer and the particulars of the batch. Ext.P12 order passed by the Government initially in Ext.P10 appeal reveals that it was explained by the Corporation in the course of the hearing of the appeal that the particulars of the manufacturer and batch number of the samples would be masked while forwarding the same for testing and the reports are identified, once they are received, with reference to the code number assigned to the sample. Exts.P3 and P6 Test Reports show the code number assigned to the samples referred to therein and the petitioner does not dispute the said fact. Though Ext.P12 order was set aside by this Court in W.P.(C) No.6506 of 2021, when the appeal was taken up afresh for hearing by the Government pursuant to the judgment in the said writ petition, the petitioner is not seen to have raised before the Government the contention regarding the identity of the product. Be that as it may, the petitioner does not also specifically dispute the identity of the samples in the writ petition. Instead, they only reiterate that the Test Reports do not disclose the identity of the manufacturer, a fact which the Corporation does not dispute. Insofar as the Corporation does not dispute the fact that the Test Reports do not disclose the identity of the manufacturer, if at all the petitioner maintains the stand that the samples tested by the laboratory are not the samples of the products manufactured and supplied by them, according to me, they should have challenged the decoding process

claimed to have been done by the Corporation. As noted, the petitioner has not challenged the decoding process undertaken by the Corporation in the appeal preferred before the Government. They have also not raised such a contention when the appeal was taken up for hearing after the decision of this Court in W.P.(C) No.6506 of 2021. In the circumstances, I am of the view that the contention raised by the petitioner as regards the identity of the samples covered by Exts.P3 and P6 Test Reports, is only to be rejected and I do so.

10. The fact that the proceedings initiated to blacklist the drug manufactured and supplied by the petitioner is one in terms of the provisions in the tender notice is not in dispute. Clauses 6.29.3 and 6.29.8 of the tender notice read thus:

"6.29.3 Drugs failing in descriptions such as change of colour, chipping, breaking, being/becoming fragile or soft, appearance of spots, being/becoming sticky, presence/appearance of particulate matters/flakes etc make the drug unfit for use and hence will be deemed as Not of Standard Quality summarily for the purposes of the tender and all clauses applicable to Not of Standard Quality Drugs shall apply to such drugs even if the drug has not been tested in the laboratory. Use of primary and secondary packaging material not suitable or appropriate or adequate enough to preserve the properties of the drug during its entire shelf life period will also cause the drug to be deemed as Not of Standard Quality for the purpose of the tender."

x x x x x x x

"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"

The extracted clauses would show that if any two batches of a particular drug supplied by a manufacturer fail in description such as breaking, being/becoming fragile or soft, being/becoming sticky etc., such drug is liable to be treated as "Not of Standard Quality", even if such deterioration in description occurs on account of use of primary and secondary packaging material not suitable or appropriate or adequate enough to preserve the properties of the drug during its entire shelf life, for the purposes of the tender and the various clauses therein. In other words, proceedings can be initiated for blacklisting such drugs also in terms of Clause 6.29.8 of the tender notice. The petitioner cannot therefore be heard to contend that the deterioration in description of the drug, as in the instance case, is not a ground on which the drug could be blacklisted.

11. As noted, the Corporation does not dispute the fact that the drug covered by the Test Reports was in order when the same was supplied to them. Similarly, the petitioner does not dispute the fact that the drug referred to in the Test Reports have deteriorated in description in the course of time. The case of the Corporation is that even if a drug was in order when it was supplied, it is liable to be blacklisted, if it is found to be deteriorated in description during the shelf life

of the drug, whereas the case of the petitioner is that such deterioration in description due to harsh weather conditions in which drug was stored, cannot be a reason for blacklisting the drug. The question arising for consideration, therefore, is whether the Corporation is empowered to blacklist a drug which was conforming to its specifications when supplied, for its deterioration in description during its shelf life.

12. Clause 6.26.11 of the tender notice categorically provides that it is imperative that the drugs supplied are in proper packaging capable of protecting the drug throughout their shelf life and any drug supplied without following the above condition is liable to be rejected. The clause aforesaid in the tender notice reads thus:

6.26.11 All items supplied should retain prescribed Quality & maximum potency throughout the shelf life and should have minimum 80% shelf life from the date of manufacture when supplied to the Corporation. It is imperative that the drugs supplied are in proper packaging capable of protecting the drug throughout their shelf life. Any drug supplied without following the above conditions will be rejected.

Clause 6.28.12 of the tender notice provides that strip packs of the drugs shall be in plastic covers and sealed air tight first before packing in the unit cartons. Further, Clause 6.28.13 of the tender notice provides that the packing materials should be able to prevent damage or deterioration during transit and storage in the climatic conditions of Kerala throughout the shelf life of the drugs. The clauses aforesaid in the tender notice read thus:

6.28.12 Strip packs shall be packed in plastic covers and sealed air tight first before packing in unit cartons.

x x x x x

6.28.13 The primary, secondary units, bottles and packing materials should be of sufficient strength to withstand the weight of other boxes stacked on it, (as per stacking norms) while on transit and on storage and also should be able to prevent damage or deterioration during transit and storage in the climatic conditions of the Kerala throughout shelf life of items. The tertiary carton of every dispatch should be minimum 5 ply cardboard made of virgin craft paper (120gms) and minimum bursting strength of 7kg/cm2 in order to prevent damage during transit. The Tender inviting Authority shall arrange for the repacking of drugs, if it is found that the packing materials are damaged or deteriorated during storage in the warehouses or user institutions, and such additional cost shall be deducted from the amount payable to the default supplier.

As noted in paragraph 10 above, if any two batches of a particular drug supplied by a manufacturer fail in description, even if such deterioration in description occurs on account of use of packaging material not suitable or appropriate or adequate enough to preserve the properties of the drug during its entire shelf

life, the drug is liable to be blacklisted in terms of the tender notice. If the clauses in the tender notice extracted above are understood in that background, it can be seen that a drug which was in order at the time when it was supplied, but deteriorated in description thereafter, is liable to be blacklisted. Needless to say that a drug which was in order at the time of supply, but deteriorated in description thereafter on account of the harsh weather conditions, can also be subject matter of a proceedings for blacklisting, for such deterioration in description can only be due to the use of packaging materials not suitable or appropriate or adequate enough to preserve the properties of the drug in the climatic conditions of the State during the entire shelf life period of the drug. The contention taken by the petitioner that the deterioration in description of the drug is due to the harsh weather conditions in which the drug was stored and therefore the drug cannot be blacklisted is, therefore, unsustainable.

The writ petition, in the circumstances, is without merits and the same is, accordingly, dismissed

