(2011) 12 DEL CK 0399

In the Delhi High Court

Case No : LPA 633 of 2010

Ind-Swift Ltd. APPELLANT

Vs

Union of India and Others RESPONDENT

Date of Decision : 16-12-2011

Acts Referred:
Constitution of India, 1950 — Article 226, 227

Citation : (2012) 2 BC 10 : (2012) 186 DLT 356

Hon'ble Judges : Siddharth Mridul, J;A.K. Sikri, J

Bench : Division Bench

Advocate : P.S. Patwalia with Mr. Arvind Nagar, Mr. Pawan Guglani, Mr. Aman Preet Rahi, for the Appellant; Sachin Datta, CGSC, for the Respondent

Final Decision : Dismissed

Judgement

A.K. Sikri, Acting Chief Justice

The Facts:

1. The appellant is a company registered under the Companies Act, 1956 having its registered office at Chandigarh. The appellant claims that it belongs to Ind-Swift Group which is a well established name in the pharmaceutical industry which has broadened its horizons by placing profound and sparkling footprints on multifarious diversified fronts and has steadily and surely scripted its success story filled with enviable milestones and pioneering breakthroughs. The group today has annual turnover of about Rs. 1000 crores. The appellant was enlisted as a supplier for certain categories of pharmaceutical drugs to the respondent No. 2, namely, Director General of Health Services (DGHS) which comes under the Ministry of Health and Family Welfare. The appellant was enlisted as such after undergoing the tendering process. For this purpose, the respondents had adopted the tender document of NCT New Delhi for supply of those drugs. The supplies were to be made in accordance with the conditions stipulated in those tender documents. Such supplies were to be preceded by inspection and testing

at the instance of the respondents. Testing was to be done at one of the Government approved testing laboratories located in National Capital Region of Delhi. The contractual conditions also provide that if the sample is not found to be of standard quality, not only the consignment could be rejected, the firm could be debarred from supplying that drug for a period of two years. Relevant conditions in this behalf contained in clauses 9(iv) to (vii) are in the following terms:

9 (iv) If the product is found to be not of standard quality, the total cost of test will be recovered from the supplier. The supplier will however, make full payment of entire consignment against the particular invoice irrespective of the fact that part of the supplied stores may have been consumed. Where a drug supplied by the tenderer is found to be "Not of Standard Quality" the firm will be debarred from supplying that drug for a period of two years. No further orders will be placed to the firm for that particular drug and rate contract for that particular drug will be cancelled. Where more than one drug supplied by the manufacturer is found to be of, "Not of Standard Quality" the firm will be debarred from supplying any drug for a period of two years.

(v) If two items of the firm are declared as "not of standard quality" by a government approved laboratory, then the firm will be debarred to participate in tender for all its items for a period of two years.

(vi) In case of immunological agents, firms are debarred to participate in the tender for five years, for that particular immunological agent in which there had been a batch failure/substandard report from any authorized testing laboratory. Five years would be counted from the date of such report.

(vii) The test report from an approved laboratory would be final and no representation would ordinarily be entertained. In exceptional cases, where the report of a duly approved laboratory is not acceptable by the firm and the firm represents giving sufficient reasons why a second test is warranted, a retesting may be undertaken. A fresh sample of that batch would be taken for testing in approved laboratory different from the previous one. The report received would be taken as final and action taken accordingly. No more representation would be entertained in this regard afterwards. Cost of retesting would be borne by the firm challenging the initial test result.

Further, clause 28 of the supply order form issued by the Government Medical Store at Chennai to the appellant reads as under:

28. In the event of drugs supplied found substandard in laboratory test, the following action will be taken against the firms

(i) For Category "B" defects, the manufacturer will be debarred for supply to MSO of that particular product declared not of standard quality for a period of three years.

(ii) If the manufacturer fails in supply of quality medicine of any other drug of

standard quality during the next year, his products shall be debarred for supply through MSO and also to the market permanently.

(iii) In regard to category "A" defects, the supplier should be debarred for the supply of that product for 3 years and for repeated failure of similar nature, the supplier shall be debarred from supply of all products permanently.

2. Under this contract, the appellant supplied 58 batches of different medicines to the Medical Store Organization of DGHS. The sample of Tab. Norfloxacin 400 Mg. supplied by the appellant to the Government Medical Store Depot, Kolkata in the year 2007 was tested in two different laboratories of the Government Medical Store Depot at Kolkata and Chennai. These samples were found to be of sub-standard quality with respect to the dissolution test as per the report of both the laboratories. This led the respondent to issue show cause notice dated 30.4.2007 to the appellant asking the appellant to show cause as to why the aforesaid item of medicine be not deregistered with immediate effect. Copies of the test reports from the two laboratories were also enclosed with the show cause notice. As per the appellant, the said notice was sent at an incorrect address and, therefore, was not received by the appellant. For this reason, the appellant could not submit any reply thereto. In any case, it is the explanation of the appellant that even as per these reports, only dissolution of the medicine was not found to be in conformity with the Indian Pharmacopeia (IP), but the strength of the medicines was found to be good. Moreover, the reports never indicated as to what was the time of dissolution of medicines and in how much time the medicine had been dissolved. These relevant details, according to the appellant, were missing in all reports.

3. On 18.12.2007, another show cause notice was issued by the respondents. It pertained to rejection of another drug, namely, Tab. Atenolol 100 Mg. which was found to be of sub-standard quality by the CGHS, Jaipur as the sample did not conform to the test of disintegration as per the IP. Along with the show cause, the said report was enclosed by the respondent. According to the appellant, it had sent reply dated 24.12.2007 specifically pointing out that the drug was of standard quality as after the test in the laboratory of the appellant, the sample was coming out 9 minutes against NMT 15 minutes. As per the respondents, no such reply was received.

4. Thus, according to the respondents, replies to both the show cause notices were not furnished by the appellant. Accordingly, Deputy Assistant Director General (Stores), Government Medical Store Depot, New Delhi recommended to DGHS, MSO that the product, i.e. Atenolol 100 Mg. should be deregistered. On 30.6.2008, a further show cause notice was issued to the appellant at 781, Industrial Area, Phase-II, Chandigarh which is stated to be its correct address. This show cause notice pertains to both the drugs, namely, Tab. Norfloxacin and Tab. Atenolol which were found to be of sub-standard under category "A" defects. It was followed by orders dated 26.8.2008 debarring the appellant permanently. The appellant maintained that it had not received even this show cause notice

and, therefore, could not reply to the same. However, receipt of the debarring order dated 26.8.2008 was accepted by the appellant.

5. The respondent-DGHS displayed on its website a list of companies which were deregistered. This move was taken on 1.3.2009. Name of the appellant also appeared in that list. It is after this display on website that the appellant made representation dated 13.3.2009 seeking review of the debarment order dated 26.8.2008 but with no results.

6. At this stage, the appellant challenged the orders dated 26.8.2008 by filing writ petition in this Court under Articles 226/227 of the Constitution of India seeking quashing of the said orders whereby the appellant had been permanently deregistered from participating in the business and supply of drugs to the DGHS. The appellant challenged show cause notices dated 30.4.2007 and 18.12.2007 by means of WP(C) No. 9026/2009. The notice was issued in this writ petition pursuant whereto, respondents filed their counter affidavit contesting the prayers made in the writ petition. Thereafter, matter was heard which resulted in delivering judgment dated 2.7.2010 by the learned Single Judge of this court. Vide this judgment, finding no merit in the petition, the same is dismissed with costs of Rs. 20,000/-

The impugned judgment:

7. After taking into consideration the relevant facts which have already been narrated above, the learned Single Judge took notice of the submissions of both the parties. It was noted that the bone of contention between the parties was about the failure of the aforesaid two products, namely, failure to pass "dissolution test" and "disintegration test". The learned Single Judge noted that though as per the test reports of the Government Laboratories at Kolkata, Chennai and Jaipur two drugs had resulted in repeated failures, the appellant could be debarred for category "A" defect only if the respondent was satisfied that the disintegration was beyond "marginal variations" which had to be found on a case to case basis. In order to demonstrate that the disintegration was beyond marginal variation, the respondent filed additional affidavit dated 19.5.2010 explaining the testing procedure specified with regard to the disintegration and dissolution test in the IP. Copies of the relevant medical literature were enclosed with the said additional affidavit. It was submitted by the respondents that the procedures under the IP were such that any marginal variation in the dissolution test was taken care of. As far as the disintegration test was concerned, the test would be satisfied even if all the six tablets have not disintegrated completely within the time specified in the IP. If one or two tablets failed to disintegrate, the same was treated as a marginal variation and the test was repeated on 12 additional tablets. The test would stand fulfilled if not less than 16 of the total 18 tablets tested disintegrated. Where only 1 or 2 tablets out of the 18 failed to disintegrate, it was treated as a marginal variation as the test is said to be satisfied. It is pointed out that medicine from a tablet that fails the disintegration or the dissolution test may not be absorbed and reach their site of

action and therefore be rendered ineffective.

8. Explaining this procedure in the context of Tab. Norfloxacin, the respondents had explained that there was repeated confirmation of the failure of the tablets in question in terms of four test reports from two different laboratories located at different places and tests done by different analysis at different points of time which was sufficient proof that the supplies were defective. As per the respondents, the defects were more than marginal "inasmuch as marginal variations are taken care of during testing itself". As regards Tab. Atenolol 100 Mg., the respondents pointed out that it was tested at three testing laboratories and declared to be not of standard quality with respect to disintegration test by each. Keeping in view that there was repeated confirmation of failure of the item in terms of the three test reports, was proof enough that the supplies were defective and it amounted to more than marginal variation. The respondents also pointed out that in another batch of Tab. Atenolol 100 Mg., i.e. Batch No. AGT-113 which was supplied to the Government Medical Store Depot, New Delhi in the year 2006, samples were sent for testing at two different laboratories at Kolkata and Chennai and thereafter at CGHS, Jaipur. It was found to be of sub-standard quality with respect to disintegration test. In terms of Condition No. 7 of MOS guidelines dated 2.8.2001, it was a case of repeated irregularities. The learned Single Judge while dismissing the writ petition recorded following reasons which persuaded the Court to take this course of action:

(i) The Court lacks expertise to sit in judgment over the correctness of test reports of the different laboratories at Kolkata, Chennai and Jaipur and therefore, has to proceed on the basis of the test reports and the state of affairs reflected in them.

(ii) Although the Petitioner has made much of the failure of the reports to clearly indicate the time of dissolution and the extent by which it exceeded the permissible time, the fact is that the procedure under the IP accounts for marginal variations adequately meets this objection. In any event, the Court has no means to assess whether the conclusion arrived at by the Government test reports was correct or not. This cannot be examined in a petition under Article 226 of the Constitution.

(iii) There is no merit in the contention of the Petitioner that it did not receive any of the show-cause notices. Even if there is force in the contention that the two show cause notices in respect of the failure of tablets Norfloxacin 400 mg meeting the IP standards was addressed to the Petitioner at a wrong address, in its letter addressed to the DGHS dated 13th March 2009 the Petitioner appears to acknowledge the receipt of such notices showing its address at 781, Industrial Area, Phase-II, Chandigarh. However, the said letter refers to the said fact that the Petitioner "had received very minor Dissolution related show cause notice in April 2007."

(iv) As regards the show cause notice in relation to the failure of tablet Atenolol

100 mg in the disintegration test, there is no reason why the Petitioner would not have received such notices.

(v) Even if the Petitioner was unable for any reason to reply to such show cause notices earlier, it is no longer prejudiced as it can put forth its case in these proceedings. On merits, the Petitioner does not have convincing explanation as to why the test reports should be disbelieved.

(vi) The terms and conditions appended to the supply order make it abundantly clear that repeated failure would result in permanent deregistration of the firm. The Respondent cannot be said to have acted arbitrarily or illegally in issuing the impugned order where there were two repeated failures of two different drugs of the Petitioner for two consecutive years to satisfy the dissolution and disintegration tests in terms of the IP. It is not possible to conclude that result would have been any different had the Petitioner replied to the show cause notices at the relevant point in time.

(vii) It is not correct that it is only Clause 9 of the terms and conditions of the General Conditions, that would apply if the test reports of the government approved laboratories fail. The supply order forms, copies of which have been enclosed with the additional affidavit of the Respondents, clearly state that repeated instances of irregularities would result in the defaulting firm being removed from the list of approved contractOrs. It cannot, therefore, be said that Respondents have acted arbitrarily in issuing the impugned order dated 26th August 2008.

Present Appeal:

9. Challenging the aforesaid order, instant appeal is preferred by the appellant. It is the submission of the appellant that the learned Single Judge has completely failed to appreciate that the challenge of the appellant in the writ petition was primarily to the contravention of the principles of natural justice as well as to the prescribed testing procedure etc. under the statute and the same had not even been rebutted by the respondents herein in their reply to the petition of the appellant. It is further submitted that the learned Single Judge fell into grave error while noting that there was no merit in the contention of the appellant herein that it did not receive any of the show cause notices without appreciating that even a bare perusal of the notices indicated that some of the notices had not been sent to the correct address of the appellant and others had contained as annexure the copies of the test reports in question which were illegible and therefore could not be responded to by the appellant herein in its response to the said show cause notices. It is submitted that the learned Single Judge failed to take note of the fact that the appellant had represented in detail to the respondents at the earliest possible opportunity and that in itself indicated the bonafides of the appellant herein.

10. To put it in nutshell, relying upon clause 9 of the tender documents (as extracted above) and insisting that show cause notices were sent at incorrect

address and were not received by the appellant, the challenge to permanent ban order is predicated on the following:

(a) As per Clause 9, there could be debarment only for a period of two years whereas the appellant was debarred permanently.

(b) Samples of drugs were required to be sent for testing immediately whereas in these cases, the samples were sent much after the supplies. It was submitted that the failure was only in dissolution of the drug which could be attributed to the faulty storage of these drugs by the respondents, after taking delivery.

(c) In any case, it was marginal variation and could not be said to be beyond marginal variation and, therefore, debarment order was unwarranted.

(d) Principles of natural justice were not followed.

11. Mr. Patwalia, learned senior counsel took pains to take us through various documents in support of his submissions. He also referred to various judgments in support of his proposals which we shall notice at the appropriate stage.

12. Mr. Sachin Datta, learned standing counsel for the Union of India, refuted the submissions of appellant''s counsel. His plea was that the notices were in fact received by the appellant but it is the appellant who never cared to give any reply thereto. In any case, it was accepted that second show cause notice, i.e. notice dated 30.6.2008 which pertained to both the drugs was sent at correct address and the impugned order was passed when no reply was given to even this notice and, therefore, alleged non-receipt of the earlier two notices in respect of the two drugs would not make any difference. He thus submitted that principles of natural justice were duly complied with. He also referred to the test reports to demonstrate that it was a case of more than marginal variation and the action taken was perfectly justified. Learned counsel supported the reasons given by the learned Single Judge in the impugned judgment.

13. In so far as argument of violation of principles of natural justice is concerned, we are one with the learned Single Judge and do not find any merit in this argument. There seems to be some substance in the argument of Mr. Sachin Datta that even the first show cause notice may have been received by the appellant inasmuch as in its representation dated 13.3.2009, the appellant has itself referred to the first show cause notice of April, 2007. In any case, there is no dispute that the second show cause notice dated 30.6.2008 was not only sent at correct address, receipt thereof has been specifically admitted by the appellant in its rejoinder to the counter affidavit filed in the writ petition wherein appellant has justified non mentioning of the show cause notice dated 30.6.2008 in the writ petition by taking the following defence:

In this regard, it is most respectfully submitted that the receipt of the said show cause notice dated 30.06.2008 was not mentioned or averred in the writ petition purely on account of the petitioner not being aware of the receipt of such notice. It is submitted that even assuming though not admitting at the outset that the

same notice was received by the petitioner, it would not necessarily imply that the petitioner was also aware of the same. It is relevant to note that the petitioner is a large organization and it is very likely that the said notice though received was inadvertently misplaced before it could be brought to the attention of the relevant department within the petitioner company. It is submitted that there is no reason whatsoever for the petitioner to have suppressed the said notice when the proposed penalty sought to be levied by the said notice was itself being challenged on several grounds before this Hon''ble Court.

Further, it is not denied that this notice was sent at the correct address. It is also not denied that the debarment notice sent at the same address was received by the appellant.

14. Thus, even if we ignore the earlier show cause notices (though there is no reason to do so), show cause notice dated 30.6.2008 was self-sufficient which pertained to both the drugs. Admittedly, no reply was given to this show cause notice. Impugned debarment order, therefore, does not suffer from any procedural infirmity. The duty cast on the respondent was to give an opportunity to show cause before taking such an action which was duly complied with.

15. Coming to the contention of the appellant that though show cause notices pertained to debarment in respect of those particular drugs, but the debarment order was general in nature completely shutting out the appellant from supplying the drugs, we find that even this argument is devoid of any merit inasmuch as show cause notice dated 30.6.2008 was for permanent debarment. In view of our aforesaid finding, judgment of the Supreme Court in the case of Erusian Equipment and Chemicals Ltd. Vs. State of West Bengal and Another, would be of no assistance to the appellant. This judgment lays down that blacklisting of a contractor has serious civil and/or evil consequences as it has the effect of depriving the person of equality of opportunity in the matter of public contract. A person who has been dealing with the Government in the matter of sale and purchase of materials has a legitimate interest or expectation. Therefore, when the State acts to the prejudice of a person, it has to be supported by the legate. For this reason, before order of blacklisting is passed, principles of natural justice demand that opportunity of hearing is to be given to the person sought to be blacklisted by serving a notice. As we stated above, this has been done in the instant case.

16. We would now like to deal with the argument on the merits of the case, namely, whether the test reports indicated marginal variation warranting any such action or the variation was more than marginal falling in the category "A" defect and further whether it was a case of repeated failure of similar nature as the consideration of this aspect is paramount having regard to the contractual conditions. If it is marginal defect, then no action is permissible. On the other hand, if it is category "A" defect, then only particular batch in respect of which defect is found is to be debarred for a period of three years. If it is a category "A" defect, then supply of that product can be debarred for a period of three years.

Only if it is a case of repeated failure of similar nature that debarment can be permanent.

17. It is not in dispute that even as per the respondents, two drugs failed only in dissolution test, namely, it did not conform to the time meant for dissolving the said tablet. There is no dispute about the quality of medicines, otherwise. Therefore, the first question would be as to whether the medicines failing in dissolution test would mean that it can be treated as more than marginal variation. In the additional affidavit filed by the respondents in the writ proceedings, it is specifically pointed out, and there is no denial to this, that the acceptance criteria of a dissolution test under procedure specified in the Indian Pharmacopeia (IP) has itself taken care of any marginal variation in the dissolution test. It is further explained that in case of disintegration test, the test is met if all the six tablets have disintegrated completely within the time specified in IP. If one or two tablets fail to disintegrate, the same is treated as marginal variation and the test is repeated on 12 additional tablets and the test is met if not less than 18 tablets tested disintegrate. Where only 1 or 2 tablets out of 18 failed to disintegrate, the same is treated as marginal variation and even in such a situation, the test is satisfied. Likewise, in the case of dissolution test in the first round of testing, each unit has to satisfy a value of D + 5 per cent (as per IP monograph of tablet Norfloxacin, D is not less than 70% of stated amount of Norfloxacin). In case any of the units fail to achieve the said acceptance criteria, the test is carried out on another 6 units and the acceptance criteria is modified. The acceptance criteria at the second stage is that the average of 12 units should be equal to or greater than D and no unit is less than D -15 per cent. In case a tablet fails at this stage also, further testing is carried on an additional 12 tablets. The acceptance criteria is further reduced. The acceptance criteria is that the average of 24 units is equal to or greater than D and not more than two units are less than D -15 percent and no unit is less than D -25 percent. Thus, for satisfying the test, it is enough if the overall average is achieved and even if a few tablets do not meet the criteria, the same does not ipso facto result in failure of the test/rejection.

18. Explaining the importance of the dissolution test, which according to the respondents cannot be undermined or downplayed, it is clarified that tablet when taken orally should first disintegrate into small pieces and then further dissolve before it can be absorbed into blood circulatory system of the patient from the elementary canal. After absorption of the medicine, it is transported via blood circulatory system to the site of action/organ or cells where the active ingredients of tablet, i.e. medicine has to act and produce the intending effect/ cure of disease. Therefore, medicines from a tablet failing in disintegration or dissolution test may not be absorbed and reached their site of action and hence, become ineffective and produce no cure for the disease in the patient. Thus, the dissolution of the medicine in time becomes important as it determines the effectiveness of the tablet.

19. The aforesaid analysis given by the respondents is convincing and thus, it cannot be said that merely because a medicine failed in dissolution test, it has to be treated as a marginal variation.

20. Reverting to the issue as to whether it was a case of repeated failure, the respondents in their additional affidavit explained that there are three events of failure of medicine supplied by the appellant. The particulars of these instances with test reports are given in the said additional affidavit.

21. In Jagdish Mandal Vs. State of Orissa and Others, , a decision relied upon by the appellant, the Supreme Court has laid down the parameters of judicial review and interference in the contractual matters relating to Government contracts/ tende Rs. We are not concerned here with the case of award of tender as it is a case of debarment/blacklisting on the purported ground of defective supplies in the execution of the contract. The Supreme Court in the aforesaid judgment clarified that power of judicial review will not be invoked to protect private interest at the cost of public interest or to decide contractual disputes. Interference in contractual matters in exercise of power of judicial review is permissible only if (i) the process adopted or decision made is mala fide or intended to favour someone, or (ii) the same is so arbitrary and irrational that no responsible authority acting under law could have arrived at it, or (iii) it affected the public interest. The Court further held that cases involving blacklisting or imposition of penal consequences on a contractor stand on different footing as they may require a higher degree of fairness in action.

22. On the touchstone of the aforesaid judgment, we have to see whether there was any material irregularity in the decision making process or the impugned decision was irrational, unreasonable or arbitrary. In view of our aforesaid discussion, we are compelled to record that we do not find it to be so.

23. However, before parting with, we would like to deal with one submission of Mr. Patwalia which he had emphasized with much force and passion. His argument was that it was not a case justifying permanent debarment. He also mentioned that though the company had supplied the medicines to various procurement agencies (under the same batch as well) and the tests, as a mandatory requirement before indentation, were conducted by all the said procurement agencies, but the same was not approved by only Kolkata and Chennai. He further argued that the definition of "Category A" defects as laid down by the DGHS, New Delhi, itself allows a scope for marginal variation in respect of the "Disintegration/Dissolution test" to be viewed on case to case basis. No doubt, respondent has passed the order of permanent debarment as it perceives repeated failures, we are of the view that having regard to the nature of test/failures, medicines of the appellant failed three times only; the appellant professes itself to be a giant in pharmaceutical industry with more than 1000 crores of turnover per year, blacklisting for ever may have very serious repercussions. The Apex Court has emphasized that such blacklisting should normally be for specified/limited periods and not on permanent basis. The

appellant was debarred in August, 2008 and has suffered this debarment order for more than three years. It would be, therefore, in the fitness of things if the respondents can reconsider the matter and take a decision for putting the ban for specific period instead of permanent ban. However, we make it clear that it is only a suggestion to the respondents and the respondents may take an appropriate view on this aspect.

24. With these observations, the appeal is dismissed finding no merit therein. There shall be no order as to costs.

