

IN THE HIGH COURT OF DELHI AT NEW DELHI

W.P. (C) 9026 of 2009 & CM APPL 6531/2009

Reserved on: 20th May 2010

Decision on: July 02, 2010

IND-SWIFT LIMITED

..... Petitioner

Through: Mr. P.S. Patwalia, Senior Advocate with
Mr. Pawan Kumar, Advocate

versus

UNION OF INDIA & ORS

..... Respondents

Through: Mr. Sachin Dutta with Mr. Manikya
Khanna, Advocate

CORAM: JUSTICE S.MURALIDHAR

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| 1. Whether Reporters of local papers may be allowed to see the judgment? | No |
| 2. To be referred to the Reporter or not? | Yes |
| 3. Whether the judgment should be reported in Digest? | Yes |

JUDGMENT

1. The Petitioner, being a pharmaceutical limited company, having its registered office in Chandigarh seeks the quashing of an order dated 26th August 2008 passed by the Deputy Director General (MS), in compliance with a letter dated 7th August 2008 of the Directorate General of Health Services ('DGHS'), Government of India permanently deregistering the Petitioner from participation in the business and supply of drugs to the DGHS. The Petitioner also challenges the show-cause notices dated 30th April 2007 and 18th December 2007 issued to it by the DGHS preceding the order of deregistration.

2. According to the Petitioner, the DGHS (Medical Store Organization) [‘MSO’], New Delhi adopted the tender document of the GNCTD for supply of drugs to its Directorate of Health Services. In terms of Clause 9 of the General Conditions for the purchase of drugs and pharmaceuticals on Running Rate Contract, the supplies were to be accompanied by an in-house test report. On receipt of the consignment, the demanding officer was to draw a sample out of each consignment and send it for testing at one of the Government approved testing laboratories located in the National Capital Region of Delhi. If the sample was found not of standard quality, the consignment was to be rejected. Clauses 9 (iv) to (vii) which are relevant for the purpose of the present case read as under:

“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.”

3. It is not in dispute that the Petitioner firm supplied 58 batches of different medicines to the MSO of the DGHS in terms of the tender documents. It is stated that a sample of Tablet Norfloxacin 400 mg supplied by the Petitioner to the government Medical Store Depot, Kolkata in 2007 was tested in two different laboratories of the Government Medical Store Depot at Kolkata and Chennai and the sample was found to be sub-standard in both laboratories with respect to the dissolution test. Based on these test reports on 30th April 2007 a show-cause notice was issued to the Petitioner asking it to show-cause why the said drug should not be deregistered with immediate effect. It is further stated that the said show-cause notice was sent by registered post to the Petitioner at 181, Industrial Area, Phase-II, Chandigarh

and the same was not received back undelivered. It was presumed that the said notice has been served.

4. The case of the Petitioner is that the above show-cause notice was not sent at the correct address of the Petitioner which was 781, Industrial Area Phase-II, Chandigarh. The Petitioner therefore did not receive the notice and could not send a reply. It is submitted that in any event, the two test reports show that the strength of the medicines was found to be good and only dissolution of the medicine was not found to be in conformity with the Indian Pharmacopoeia ('IP'). The Petitioner submits that the reports do not indicate what the standard time of dissolution of the medicine was and in how much time the medicine actually dissolved.

5. On 18th December 2007 the Petitioner was issued a show-cause notice with regard to rejection of another drug Atenolol 100 mg tablet which was declared as sub-standard by the DGHS, Jaipur as the sample did not conform to the test for disintegration as per the IP. A copy of the said test report was enclosed with the show-cause notice. The Petitioner is stated to have replied to the show-cause notice on 24th December 2007 which fact is however denied by the Respondents. The Respondents maintain that since no reply was sent, the Deputy Assistant Director General (Stores), Government Medical Store Depot, New Delhi recommended to the DGHS, MSO that the product i.e. Atenolol 100 mg should be deregistered under category 'A' defect as per the letter dated 2nd August 2001 of the DGHS.

6. Separately on 22nd August 2007 another show-cause notice issued to the Petitioner by the Government Medical Store at Kolkata asking to show-cause why the tablet Atenolol 100 mg supplied by it should not be deregistered. It was mentioned in the said show-cause notice that the sample of the said tablet supplied by the Petitioner in terms of the supply order dated 31st January 2007 of the Government Medical Store at Kolkata was sent for testing and found to be not in conformity with the IP with respect to the disintegration test. The test report of two laboratories, one at Kolkata and the other at Chennai were enclosed with the said show-cause notice.

7. According to the Respondents, the Petitioner did not reply to the said show-cause notice which was issued to the firm at its address i.e. 781, Industrial Area, Phase-II, Chandigarh. As already noticed on 5th March 2008 the Government Medical Store at New Delhi had recommended to the DGHS the deregistration of tablet Atenolol 100 mg under category 'A' defects.

8. On 30th June 2008 a further show-cause notice was issued to the Petitioner at its address at 781, Industrial Area, Phase-II, Chandigarh. The Petitioner's attention was drawn to the fact that two drugs i.e. tablet Norfloxacin 400 mg and tablet Atenolol 100 mg were found to be sub-standard under category 'A' defects. The Petitioner was asked to show-cause why the firm should not be deregistered permanently since two products were declared sub-standard within two consecutive years respectively as per guidelines of MSO dated 2nd August 2001. This was followed by the impugned order dated 26th

August 2008 debarring the Petitioner permanently. According to the Petitioner, it did not receive the aforementioned show cause notice dated 30th June 2008. However, the Petitioner appears to have received the impugned order dated 26th August 2008 which has been challenged in the present petition.

9. On 1st March 2009 the DGHS displayed on its website a list of companies that had been deregistered. At serial No. 17 the Petitioner's name was included. Thereafter, the Petitioner made a representation to the Respondents on 13th March 2009 seeking a review of the order but to no effect. Thereafter, the present petition was filed.

10. The case of the Respondents is that two drugs i.e. Norfloxacin 400 mg and Atenolol 100 mg manufactured by the Petitioner had repeatedly failed the dissolution test and the disintegration test as per the IP norms within two consecutive years respectively. Reliance is placed on the circular dated 2nd August 2001 issued by the DGHS which makes it clear that in regard to Category 'A' defects where there are repeated failures of a similar nature, the supplier shall be debarred from supply of products permanently. It is submitted that inasmuch as both drugs had Category 'A' defects the Petitioner attracted permanent debarring.

11. On 28th April 2010 this Court passed the following order:

“1. A bone of contention between the parties in the present case is about the failure of two of the Petitioner’s products namely Norfloxacin and Atenolol to pass “dissolution tests”. There are test reports of the government laboratories at Kolkata, Chennai and Jaipur which have been relied upon by the Respondents to show that there were repeated failures of these two drugs to pass the above test. However, for the purposes of debarment of the Petitioner for a category ‘A’ defect the Respondents would have to be satisfied that the disintegration was beyond “marginal variation” which had to be viewed on a case to case basis. The test reports placed on record only state that the drug in question has failed the dissolution test but do not indicate whether it is beyond the marginal variation.

2. Mr. Sachin Datta, learned counsel for the Respondents states that he will examine the records and file a further affidavit explaining what is the extent of the failure of the dissolution test of these two drugs. In addition, Mr. Sachin Datta, learned counsel states that he will also place on record a copy of the report of the test purportedly undertaken at the laboratory in Delhi as is evidenced by the letter dated 5th March 2008 at page 156 of the paper book. The affidavit be filed within two weeks.

3. List on 20th May 2010.”

12. On 19th May 2010 the Respondents filed an additional affidavit explaining the testing procedure specified with regard to the disintegration and dissolution tests in the IP. Copies of the relevant medical literature were enclosed with the said additional affidavit. It is submitted 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.

13. The Respondents point out that a few batches of Norfloxacin 400 mg were got tested from two testing laboratories and were declared to be not of standard quality with respect to dissolution test on the basis of four test reports, two of which were undertaken at Government Medical Store Test Laboratories at Kolkata and two at the test laboratories at Chennai. It is pointed out that this repeated confirmation of the failure of the tablet in terms of four test reports “from two different laboratories located at different places and test done by different analysis at different point of times is sufficient proof that the supplies were defective.” The defects were more than marginal “inasmuch as marginal variations are taken care of during testing itself.” As regards tablet Atenolol 100 mg, it was tested at three testing laboratories and declared to be not of standard quality with respect to the disintegration test by each. Again the repeated confirmation of failure of the item in terms of the three test reports was sufficient proof that the supplies were defective. It is denied that there was only marginal variation.

14. In another batch of tablet Atenolol 100 mg i.e. Batch AGT-113 which was supplied to the Government Medical Store Depot, New Delhi in the year 2006 the samples were sent for testing to two different laboratories at Kolkata and Chennai. It is pointed out that labeling was not properly imprinted as per the Drugs and Cosmetics Act, 1940. It was got re-tested by CGHS, Jaipur. It was found to be of sub-standard quality with respect to the disintegration test. In terms of the Condition No.7 of MOS Guidelines dated 2nd August 2001 it was clearly a case of repeated irregularities.

15. The supply order form issued by the Government Medical Store at Chennai to the Petitioner contains Clause 28 which 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.”

16. Clause 7 of the terms and conditions of the supply order enclosed to the supply order form states that “repeated instances of the irregularities in compliance of the supply order will be watched and the names of the defaulting firms are liable to be removed from the list of approved contractors of this depot.”

17. This Court has heard the submissions of Mr. P.S. Patwalia, learned Senior counsel appearing for the Petitioner and Mr. Sachin Datta, learned counsel for the Respondents.

18. It is submitted by Mr. Patwalia, learned Senior counsel that the testing of the samples should be done soon after the sample is received before the conditions of weather, storage and handling have their effect on the tablets. Since the tablets in question passed in the other centres, it is submitted that at the laboratories where the temperatures were high the disintegration and dissolution test failed. It is further submitted that the show cause notice for blacklisting was never received by the Petitioner and it was passed without affording an opportunity of being heard to the Petitioner. A reference is also made to an order of the Madhya Pradesh High Court in Writ Petition No. 4616 of 2008 (*M/s. Zest Pharma v. Union of India*) in which an interim order was passed with regard to the blacklisting order.

19. It is further submitted that debarment of the Petitioner is an extreme step which would tantamount to the civil death of the Petitioner since it is a major supplier to the DGHS. Without prejudice to the above contentions, it

is submitted that permanent debarment in any event is disproportionate and uncalled for.

20. Having considered the submissions of learned counsel for the parties, this Court is not persuaded to interfere in the matter. The reasons for this conclusion are as follows:

(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.

21. There is no merit in this petition and it is dismissed as such with costs of Rs. 20,000/- which will be paid by the Petitioner to the Respondents within four weeks from today. The pending application also stands dismissed.

S. MURALIDHAR, J.

2nd JULY, 2010
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