(2010) 01 DEL CK 0237

In the Delhi High Court

Case No : Writ Petition (C) 11656 of 2009 and CM Appl No''s. 11533-34 of 2009

Morepen Laboratories Ltd. APPELLANT

Vs

Union of India (UOI) and Others RESPONDENT

Date of Decision : 27-01-2010

Acts Referred:

Citation : (2010) 01 DEL CK 0237

Hon'ble Judges : Dr. S. Muralidhar, J

Bench : Single Bench

Advocate : Vivek Singh and Manish Kaushik, for the Appellant; Ravinder Aggarwal, CGSC for UOI, Purbali Bora, Proxy counsel for Aruna Tiku, for R-3, for the Respondent

Final Decision : Allowed

Judgement

S. Muralidhar, J.—The challenge in this petition by the Petitioner Morepen Laboratories Limited (''MLL'') is to the communications dated 2nd February 2009 issued by the National Pharmaceutical Pricing Authority (''NPPA'') Department of Chemicals & Petrochemicals, Ministry of Chemicals & Fertilizers, Government of India requiring the Petitioner to deposit a sum of Rs. 2,36,55,235/- (including an amount of Rs. 78,85,079/- towards interest) on account of manufacturing/ marketing of scheduled formulation Norpen TZ Tablets at a price higher than the ceiling price notified by the Government by a notification dated 16th September 2005.

2. The challenge in this petition is also to the communications dated 21st April 2008 and 8th April 2009 issued by the NPPA requiring the Petitioner to deposit the amount liable to be paid on the ground of overcharging for the above drug Norpen TZ. It also challenges the recovery certificate dated 9th July 2009 issued by the Assistant Collector, District- New Delhi for recovery of Rs. 2,39,50,925/-.

3. The facts leading to the filing of the present petition are that MLL has its registered office in Himachal Pradesh and has its corporate office in Delhi. The

petitioner is engaged in the business of manufacturing and marketing of pharmaceutical formulations and other products. On 15th June 2005 MLL entered into a distributorship agreement with M/s. Generica India Limited (''Generica''). Generica is engaged in the business of marketing and distribution of pharmaceutical products. Avis Lifesciences (''Avis'') is the marketing arm of Generica. MLL granted Generica all the rights of purchase for resale MLL''s healthcare (branded generics) products in the territories mentioned thereunder. Clause 9 dealing with fixation of price for the drugs reads as under (the word ''Company'' refers to MLL):

9. Price and reimbursements

9.1 Generica shall place orders on the Company and the company shall sell the Company''s products to Generica at such agreed prices the Company shall from time to time fix.

9.2 The Company shall be entitled to a profit margin of at least

(a) 10% on cost of manufactured products on the goods manufactured at the Company''s (Morepen.s) plants, based on new Drug Price Control Order (DPCO);

(b) 5% on purchase cost for goods manufactured from third party under technical cooperation of the Company. Any government levies on account of service tax, education cess etc. shall be reimbursed to the Company by Generica; and

(c) at least 20% on new molecules or brand launches. The profit margin shall be calculated on the value of finished products less excise duty.

(d) Generica agrees to reimburse the cost of hiring (Salary and Travelling Expenses) personnel to carry out the inspection, quality control and other administrative work related to the business covered under the agreement.

In the product list was included Norfloxacin 400 mg and Tinidazole 600 mg under the brand names Normide 400 and Normide TZ (later named Norpen 400 and Norpen TZ).

4. On 23rd August 2005 an order was placed by MLL on Vaibhav Healthcare Pvt. Limited (''Vaibhav'') requiring the latter to manufacture certain drugs at its plants on behalf of MLL (on third party basis). This included Norpen 400 and Norpen - TZ.

5. On 16th September 2005 NPPA issued a notification under para 9 (1) and para 9 (2) of the Drugs (Prices Control) order, 1995 (''DPCO'') fixing the ceiling price of several drugs including Norfloxacin - 400 mg and Norfloxacin TZ 600 mg tablets. The price for a strip/ blister of ten tablets of the aforementioned drug was fixed at Rs. 14.30.

6. It is stated that pursuant to the above order, Vaibhav manufactured Norepen TZ tablets. On 13th July 2007 NPPA wrote to the Managing Director/CEO, M/s.

Avis stating that on a perusal of the certain invoices showing sales of Norpen TZ, "it is amply clear that Nopren TZ tablet of the batches mentioned above was printed within higher MRP compared to the notified price of Rs. 14.30." Avis was asked to show cause as to why action should not be initiated against it "to recover the overcharged amount" in terms of para of the DPCO read with the Essential Commodities Act 1955 (''EC Act''). This is followed by a further communication dated 21st April 2008 (this time also addressed to MLL) requiring it to deposit the overcharged amount of Rs. 1,57,70,156/- in respect of Norpen TZ and interest of Rs. 59,13,809/- in terms of Section 7A of the EC Act. It was stated that the failure to deposit the amount within a period of 15 days would attract interest @ 15% per annum.

7. On 9th May 2008 MLL wrote to the NPPA stating that they were not the manufacturers of the drug in question and that Vaibhav had manufactured it. It was stated that pursuant to the order placed on 23rd August 2005 placed on Vaibhav, MLL received the consignment from Vaibhav as evidenced by their invoice dated 25th September 2005.

8. On 2nd February 2009 NPPA again required MLL to deposit the allegedly overcharged amount along with interest. MLL replied on 3rd February 2009 enclosing copies of certain documents to show that they were not liable to pay the allegedly overcharged amount. It appears that on 8th April 2009 NPPA wrote to the Collector, New Delhi asking him to recover the amount of Rs. 2,39,50,925/- from MLL. Pursuant thereto on 9th July 2009 in exercise of the powers vested in him under the Revenue Recovery Act 1890 the impugned recovery certificate dated 9th July 2009 was issued by the Assistant Collector-II, District New Delhi.

9. At the first hearing on 14th September 2009 learned Counsel for the Petitioner was granted time to file an additional affidavit explaining the inter-relationship between the Petitioner on the one hand and Vaibhav, Generica and Avis on the other. Pursuant to the said order the Petitioner on 8th October 2009 filed an affidavit explaining the inter-relationship of the companies. It was explained that in terms of agreement dated 15th June 2005 Norpen tablets were manufactured by Vaibhav on third party basis. It is pointed out that Generica and Avis [whose name was subsequently changed to Veritas Life Sciences Limited (VLSL)] are essentially family owned enterprises. Avis is the marketing arm of Generica. As regards Vaibhav it was merged with M/s. Ankur Drugs and Pharma Limited (ADPL). VLSL and Generica have common promoters, directors and shareholders. MLL has no common director/promoter or any pecuniary interest or any other interest in Vaibhav (now merged with ADPL), or VLSL or Generica except contractual business interests. It was stated that the promoters of MLL had no holding or cross holdings in Generica, or Avis or Vaibhav.

10. The petitioner''s affidavit also explained the billing of the formulation in para 12 which reads as under:

12. I say that from the bill raised by the petitioner company dated 30.9.2005, one strip of the formulation in question in the batch numbers in question was billed at Rs. 9.44 per unit by M/s. Vaibhav Healthcare to M/s. Morepan Laboratories and M/s. Morepen Laboratories billed the said formulation to M/s. Generica at Rs. 9.91 per unit. Thus, M/s. Morepen earned margin charges in each strip amounting to Rs. 9.91 - 9.44 i.e. Rs. 0.47 per unit (app). In any event the price at which petitioner company dealt with the formulation in question was much below the price notified by the Respondent National Pharmaceutical pricing authority. The billing of the formulation and batch No. in question is elaborated as under: Billing from Vaibhav to Morepan - Rs. 9.35 + 1% CST=9.44

Billing from Morepan to Generica - Rs. 9.91 (Morepan received normal margin of 5%) Billing from Generica to Distributors - Rs. 11.46 + VAT extra (VAT ranging from Rs. 6 to Rs. 11.89)

Billing from Distributors to Retailers - Rs. 11.96 + VAT)

It is stated that MLL received margin charges Rs. 1,60,979.80 from Generica for the technical collaboration rendered by MLL.

11. The Petitioner has also placed on record on 8th October 2009 documents showing the list of promoters and shareholders of Vaibhav as well as certificate issued by M/s. Kamal Mahajan & Co. the Chartered accountants of MLL.

12. A counter affidavit has been filed by NPPA. It is asserted that the Petitioner "in collusion with M/s. Avis Life Sciences was found to be indulging in the sale of the scheduled formulation based on Norfloxacin bulk drug by selling the same at higher price than the prices notified by the answering respondent." It is pointed out that para 14 of the DPCO "clearly casts an obligation on the manufacturer to comply with the notified prices by issuance of price list/supplementary price list to the dealers, State Drug Controllers and the Government indicating reference to such price fixation or revision as the case may be." In the counter affidavit it is further stated:

The contention of the petitioners that they were only facilitator in providing technical cooperation for consignment of formulation Norpen TZ, is also completely wrong, baseless and hence denied. It is respectfully submitted that the petitioners in collusion with the manufacturing and marketing companies have deliberately and willfully charged a price of Rs. 60/- for a pack of 10''s tabs as against notified prices of Rs. 14.30. Therefore, the petitioners have deliberately and willfully sold the formulation at a price which was 4 to 5 times higher than the notified prices in order to gain unauthorized financial enrichment at the cost of consumers.

13. It is contended that from the communication dated 3rd February 2009 from MLL along with its enclosures it was noticed that "third party arrangements were made by them with other companies for procuring the above said scheduled formulations of Norpen TZ to avoid the rigours of price control with intention to

gain unauthorized benefit at the cost of the consumers." Reference is made to Clauses 1, 9.1, 12.1 and 12.2 of the distributorship agreement which, according to the Respondent NPPA, confirmed that "brand for the formulation is owned by the Petitioner company and the prices for the formulations were being fixed by the Petitioner." It is contended that the subject formulation was sold to the consumers at a price of Rs. 60/- which was almost 5 times the price notified by the NPPA.

14. Reference is made to the judgment dated 15th April 2008 passed by the Bombay High Court in N.R. Jet Enterprises Limited v. National Pharmaceutical Pricing Authority Writ Petition(C) 4264 of 2003 where the High Court rejected the challenge by those petitioners to the price fixation order and notice issued to them under DPCO to recover the overcharged amount. It is stated that an SLP against the said order has been filed in Supreme Court but no stay was granted of the recovery. Reference is also been made to the order dated 12th November 2002 passed by the Karnataka High Court in Smithkline Beecham Pharmaceuticals (India) Limited v. Union of India Writ Petition (C) No. 38973 of 1998 in which it was held that DPCO was applicable to products manufactured prior to the date of the notification. An SLP is stated to be pending against the said judgment as well.

15. Mr. Vivek Singh, learned Counsel appeared for the Petitioner and Mr. Ravinder Aggarwal, learned Counsel for the Respondent.

16. Learned Counsel for the Petitioner urges that in terms of DPCO it is only the importer, retailer, distributor or wholesaler who could be made liable for overcharging beyond the price fixed by the notification under the DPCO. He points out that MLL does not answer the description of any of these entities in terms of the DPCO. He refers to the packaging in which Norpen TZ is sold. It clearly indicates that the drug is marketed by Avis and manufactured by Vaibhav. The Petitioner''s name figures as a technical collaborator. He submits that the impugned orders seeking to make the Petitioner liable for overcharging for Norpen TZ tablets and the consequential recovery certificate issued by the Assistant Collector are wholly untenable in law. He further submits that additional documents filed by the Petitioner clearly make out that there is no interconnection between the Petitioner and the other entities including Avis, Vaibhav and Generica. He submits that the allegation that the Petitioner acted in collusion with these entities and by-passed the DPCO was wholly without basis. He points out that the orders passed by the Bombay High Court and Karnataka High Court do not have relevance to the present petition inasmuch as the Petitioner is not in any manner liable under the DPCO.

17. Mr. Ravinder Agarwal, learned Counsel for the Respondent on the other hand refers to the clauses of the distributorship agreement and submits that the control of MLL over the process of manufacturing and marketing is complete. The drug in question figures in the schedule to the said agreement and therefore, the ultimate control for its manufacturing and marketing vests with MLL. He submits

that although the packaging shows Avis to be the marketing agent and Vaibhav to be the manufacturer, the most prominent name on display in the packaging is that of MOREPEN and therefore, the Petitioner cannot escape liability for overcharging of the price of Norpen TZ tablets.

18. In order to appreciate the above submissions, reference may be made to the various provisions of DPCO. Para 2 (m) defines "manufacturer" to mean any person who manufactures a drug. The term ''manufacture'' in relation to any drug in terms of para 2 (l) includes any process or part of a process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business.

19. Learned Counsel for the Respondent tried to stretch the language by interpreting the word "manufacture" occurring in Section 2(1) to include the role of MLL in terms of the distributorship agreement.

20. Clause 8 of the distributorship agreement between MLL and Generica reads:

8. The distribution rights of the products manufactured by the company itself or manufactured by a third party under technical cooperation of the company, are reserved for Generica on national basis and the same shall not be given to any other party during the currency of the Agreement. If Company receives any trade enquiry directly, the same would be first passed on to Generica.

However, if Generica fails to cater that market to the satisfaction of the company, the company has full right to, operate in that territory in the manner it deems fit.

21. Thereafter in Clause 9.2 different rates of profit margin fixed for MLL dependent on whether the goods are manufactured at MLL''s plants or elsewhere. Therefore, that can be two possible situations. One where MLL itself manufactures drugs and the second where it is manufactured by a "third party under technical cooperation of MLL".

22. As far as the present case is concerned, the additional affidavit filed by the Petitioner brings out clearly that the manufacturing of the Norpen TZ tablets was by Vaibhav and not MLL. The packaging of the tablets no doubt prominently displays the name MOREPEN but it also makes it clear that drug is marketed by Avis and manufactured by Vaibhav. It states "technical cooperation with Morepen Laboratory Limited." It nowhere states that MLL is the manufacturer of the drug. Therefore, it is not possible to accept the contention of learned Counsel for the Respondent that MLL should be considered to be manufacturer in terms of para 2 (l) read with 2 (m) of the DPCO only because its name is displayed prominently in the packaging. Clearly MLL is neither a retailer in terms of Section 2(d) of DPCO or a wholesaler in terms of 2(y) DPCO. It is not even the case of the Respondent that in the present context the MLL is an importer or distributor of the drug in question.

23. Counsel for the Respondent then referred to paras 16 and 18 DPCO to urge that the Petitioner can still be made liable. Paras 16 and 18 DPCO read as under:

16. Control of sale prices of bulk drugs and formulations - No person shall sell any bulk drug or formulation to any consumer at a price exceeding the price specified to the current price list or price indicated on the label of the container or pack thereof, whichever is less, plus all local taxes, if any, payable.

18. Manufacturer, distributor or dealer not to refuse sale of drug - Subject to the provisions of the Drugs and Cosmetics Act 1940 (23 of 1940) and the Rules framed thereunder:

(a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons;

(b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

24. It is clear that in order to bring the Petitioner within the ambit off any of the above clauses which would have to be shown that the Petitioner in fact sold the drug in question who acted as manufacturer, distributor and retailer. As already noticed, the Petitioner has not taken part in any of the process for making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution. In respect of the consignment of Norpen TZ in respect of which the impugned orders have been issued, it is Vaibhav which is the manufacturer. The marketing entity is Avis (now VLSL). There is nothing to show that MLL sold the drug in question by overcharging beyond the notified price. Therefore, this Court fails to appreciate how MLL can be brought within the ambit of paras 16 and 17 DPCO and made liable. It is not as if the Respondents cannot, in terms of the above provisions of the DPCO, proceed against the other entities who are in fact disclosed to be the manufacturer and marketing agent of the drug in question. There is at present no provision in the DPCO to fasten liability on an entity whose name figures on the packaging of a drug as technical collaborator. That may be a lacuna in the DPCO but then the court has to interpret the law as it finds it. It is not possible for the court to stretch the language of the provisions to fasten liability under the DPCO on MLL, which is a technical collaborator in the manufacture of the drug Norpen TZ.

25. The allegation that MLL acted in collusion with Avis, Generica and Vaibhav to by-pass the DPCO is not based on any material. Such an assertion appears to be based on a mere surmise. This Court also fails to appreciate how the decisions of the Bombay High Court in N.R. Jet Enterprises Limited (supra) and of the Karnataka High Court in Smithkline Beecham Pharmaceuticals (India) Limited (supra) have any application to the facts of the present case. The Respondents have been unable to even prima facie show that in terms of the DPCO MLL is liable for the price of Norpen TZ being higher than the notified price.

26. Consequently, the impugned communications dated 21st April 2008, 2nd February 2009, 8th April 2009 issued by the Respondents and the recovery certificate dated 9th July 2009 issued by the Assistant Collector, District New Delhi are hereby quashed.

27. The writ petition is accordingly allowed with costs of Rs. 10,000/- which will be paid by the Respondents to the Petitioner within a period of four weeks from today. The pending applications also stand disposed of.

