(2004) 03 AHC CK 0007

In the Allahabad High Court

Case No : C. M.W.P. No. 41214 of 2003

Cipla Ltd. and Another — APPELLANT

Vs

Union of India (UOI) and Others — RESPONDENT

Date of Decision : 03-03-2004

Acts Referred:
Constitution of India, 1950 — Article 226
Drugs (Prices Control) Order, 1995 — Rule 2, 22, 3, 6, 7

Citation : (2004) 2 ACR 1760

Hon'ble Judges : M. Katju, J;K.N. Ojha, J

Bench : Division Bench

Advocate : A.P. Sahi, G.K. Singh and Soli Cooper, for the Appellant; B.N. Singh, S.S.C. and S.C., for the Respondent

Judgement

M. Katju, J.—This writ petition has been filed against the impugned notice/order dated 16.8.2003 issued by the Respondent No. 4, Inspector of Drugs, Varanasi, copy of which is Annexure-11 to the writ petition. The Petitioners have also challenged the notifications dated 12.7.2000, 12.7.2001, 12.7.2002, 11.7.2003 and 25.11.2003, copies of which are Annexures-4 to 7 to the writ petition and Annexure-1 to the amendment application. The Petitioner has prayed for a mandamus directing the Respondents not to enforce and realise the notified price of the drugs referred to in the impugned notice/order dated 16.8.2003.

2. Heard Sri Soli Cooper and Sri. A. P. Sahi, learned Counsel for the Petitioners and Sri B. N. Singh learned senior standing counsel for the Central Government-Respondents.

3. The Petitioner No. 1 is a company registered under the Indian Companies Act and is engaged in the business of manufacturing medicines and drugs including bulk drugs and scheduled formations. The Petitioners are challenging the fixation of the prices of the drugs manufactured by it as being violative of the Drugs Prices Control Order, 1995 (hereinafter referred to as the ''D.P.C.O.''), which has been issued under the Essential Commodities Act.

4. It is alleged in paragraph 6 of the writ petition that under the new Drugs policy an apex body has been constituted known as the National Pharmaceuticals Pricing Authority, which is an independent body of experts entrusted with the task of fixation of prices of such drugs. In order to enforce the policy decision and price fixation to be made by the aforesaid authority the Central Government promulgated the D.P.C.O., 1995, a copy of which is Annexure-2 to the writ petition. Under the D.P.C.O., several drugs are prescribed as bulk drugs vide Rule 2 (a) of the D.P.C.O., 1995, which reads as follows:

2 (a) "bulk drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standard specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formation.

Formulation has been defined in the D.P.C.O., 1995 in Rule 2 (h) as follows:

2 (h) "formulation" means a medicine processed out of, or containing one or more bulk drug or drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include:

(i) any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines ;

(ii) any medicine included in the Homeopathic system of medicine ; and

(iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

5. Ceiling price has been defined in Rule 2 (c) in the D.P.C.O., 1995, as follows:

(c) ceiling price" means a price fixed by the Government for scheduled formulation in accordance with the provisions of Para 9."

Rule 3 (1) of the D.P.C.O., 1995, states:

3 (1) The Government may with a view to regulate the equitable distribution and increasing supplies of a bulk drug specified in the First Schedule and making it available at a fair price, from different manufacturers, after making such inquiry as it deems fit, fix from time to time by notification in the Official Gazette, a maximum sale price at which such bulk drug shall be sold:

Provided that for the purpose of enquiry, in addition to the information required to be furnished by the manufacturers under this Order, the manufacturers shall provide any such additional information as may be required by the Government, and shall allow for inspection of their manufacturing premises for verification through on the spot study of manufacturing processes and facilities and records thereof, by the Government.

Rule 3 (3) of the D.P.C.O., 1995, states:

3(3) No person shall sell a bulk drug at a price exceeding the maximum sale price fixed under sub-paragraph (1) plus local taxes, if any:

Provided that until the price of a bulk drug is fixed, by the Government under sub-paragraph (1), the price of such bulk drug shall be the price which prevailed immediately before the commencement of this Order and the manufacturer of such bulk drug shall not sell the bulk drug at price exceeding the price prevailing immediately before the commencement of this Order.

6. Rule 7 of the D.P.C.O., 1995, which is the most important provision for the purposes of this case, reads as under:

7. Calculation of retail price of formulation.--The retail price of a formulation shall be calculated by the Government in accordance with the following formula, namely:

R.P. = (M.C. + C.C. + P.M. + P.C.) + (1 + M.A.P.E./100) + E.D.

Where:

"R.P." means retail price ;

"M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any plus process loss thereon specified as a norm from time to time by notification in the official Gazette in this behalf ;

"C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the official Gazette in this behalf ;

"P.M." means cost of the packing material used in the packing of concerned formulation, including process loss and shall be fixed as a norm every year by notification in the Official Gazette in this behalf ;

"P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the official Gazette in this behalf ;

"M.A.P.E." means (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for manufacturer and it shall not exceed one hundred per cent, for indigenously manufactured scheduled formulations ;

"E.D." means excise duty ;

Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer''s profit which shall not exceed fifty per cent, of the landed cost.

Explanation.--For the purpose of this proviso, "landed cost" means the cost of import of formulation inclusive of the customs duty and clearing charges.

7. Rule 8 of the D.P.C.O., 1995, gives the Central Government the power to fix retail price of the scheduled formulations and Rule 9 of the D.P.C.O., gives it power to fix the ceiling price of the scheduled formulations.

8. Having quoted the relevant clauses of the D.P.C.O., 1995, we may now come to the submissions of Sri Soli Cooper, learned Counsel for the Petitioners. Sri Cooper has firstly submitted that the fixation of prices of the drugs manufactured are not in accordance with Rule 7 of the D.P.C.O., 1995. Sri Cooper has pointed out that before the D.P.C.O., 1995, was issued the D.P.C.O., 1987, was in force. Rule 6 of the D.P.C.O., 1987, reads as follows:

6. Calculation of retail price of formulations.--The retail price of the formulation shall be calculated in accordance with the following formula, namely:

R.P. = (M.C. + C.C. + P.M. + P.C.) ? (1 + M.A.P.E./100) + E.D.

Where:

"R.P." means retail price ;

"M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any plus process loss thereon specified as a norm from time to time by notification in the official Gazette in this behalf ;

"C.C." means conversion cost worked out in accordance with established procedures of costing and may be fixed as a norm from time to time by notification in the official Gazette in this behalf ;

"P.M." means cost of the packing material used in the packing of concerned formulation, includes process loss, a norm fixed from time to time by notification in the official Gazette in this behalf ;

"P.C." means packing charges worked out in accordance with established procedures of costing and may be fixed as a norm from time to time by notification in the official Gazette in this behalf ;

"M.A.P.E." means Maximum Allowable Post-manufacturing Expenses including trade margin referred in para 7 ;

"E.D." means excise duty.

9. Sri Soli Cooper has pointed out that there is a vital difference between the D.P.C.O., 1987 and the D.P.C.O., 1995. In the D.P.C.O., 1987, the conversion cost (C.C.), cost of packing material (P.M.) and the packing charges (P.C.) were to be fixed from time to time, but it was not stated therein that they had to be fixed every year as is mentioned specifically in Rule 7 of the D.P.C.O., 1995. Sri Cooper stated that this is an important distinction between the D.P.C.O., 1987 and the

D.P.C.O., 1995. Sri Cooper stated that this change in the D.P.C.O., 1995 was deliberately made by the Central Government because there was a grievance in the Pharmaceutical industries that costs for producing drugs change every year, and if the C.C., P.M. and P.C. are not changed every year and are changed after several years then the price of the pharmaceutical products will be pegged to the old cost and not reflect the real cost.

10. In paragraph 15 of the writ petition it has been stated that for fixation of the norms of conversion cost, packing cost, etc. no norms were notified in the years 1995-96, 1996-97 and 1997-98. For the first time a notification was issued in 1999 but the same did not notify any norm for packing materials cost till date. A copy of the notification of 1999 is Annexure-3 to the writ petition. Again no notification was issued in the year 2000 specifying any such norms or revision of any such norms as mentioned in Rule 7 of the D.P.C.O., 1995.

11. In paragraph 22 of the writ petition it has been specifically mentioned that the notification, which had been issued on 13.7.1999 has been mechanically extended in the years 2000, 2001, 2002 and 2003 vide Annexures-4, 5, 6 and 7 to the writ petition. A perusal of the order dated 12.7.2000, a copy of which is Annexure-4 to the writ petition shows that all that has been stated therein is that the validity of the notification 13.7.1999 is extended with immediate effect. Similar notifications have been subsequently issued, copies of which are Annexures-5, 6 and 7 to the writ petition.

12. We agree with Sri Cooper that these notifications have been issued mechanically without applying mind and without making the exercise as is contemplated under the D.P.C.O., 1995, for notification of the norms and thereafter fixation of prices. No notification was issued from 1994 to 1999 and even thereafter it is evident that the notifications which have been issued are simple and mechanical reproduction of the notification dated 13.7.1999.

13. In our opinion every year there has to be a fresh application of mind by the Central Government or the authority constituted by it for fixation of the retail price of drugs and formulations because Rule 7 of the D.P.C.O., 1995, specifically says so. Rule 7 of the D.P.C.O., 1995, requires fixation of norms of C.C., P.M. and P.C. every year by notification in the official Gazette, and this requirement has purposely been made because various costs keep changing and hence the concerned authority must apply its mind to the costs every year and for this purpose also consider the representations of the manufacturers of pharmaceutical drugs before fixing the retail price. The actual cost would ordinarily vary from year to year. The D.P.C.O., 1995 therefore, contemplates an investigation and enquiry by the Government every year considering all the relevant factors and then fixing the norms to be used in all inputs.

14. As rightly pointed out by Sri Cooper, the D.P.C.O., 1995, uses the words "every year", while the D.P.C.O., 1987, used the expression ''from time to time''. Heydon''s rule of interpretation requires us to see the mischief in the old law to

understand the new law (See Maxwell''s ''Interpretation of Statutes'', 12th Edition p. 40).

15. It may be noted that Rule 9 requires that the formula utilized under Rule 7 should take into account "the cost or efficiency or both of major manufacturers of such formulations....." while fixing the ceiling price. This shows that there may be variants in the cost of P.M. or P.C. between individual manufacturers. The Government while fixing the norms on an annual basis should give due regard to the cost of major manufacturers of the product. It is thus crystal clear that the norms fixed and notified in one year would not and cannot under the D.P.C.O., 1995, operate as an input for subsequent years. It is further evident that the inputs notified for one year cannot also be merely extended for subsequent years but have to be specifically and separately notified for each year and must therefore, obviously be preceded by an inquiry and application of mind.

16. In the instant case, there has been no fixation or notification of these inputs for the years in question. Some of the norms, i.e., C.C. and P.C. were notified in 1993 under the D.P.C.O., 1987. After the D.P.C.O., 1995, no norms were notified up to 1999 when C.C. and P.C. were notified. P.M. norms have never been notified. For some dosage forms like inhalers, C.C. and P.C. norms have never been notified at all. However, ceiling price has been fixed under Rule 9 for inhalers. The C.C. and P.C. norms notified in 1999 were mechanically extended in 2000, 2001, 2002 and 2003. In our opinion such an extension is patently and ex facie bad inasmuch as there has been an extension of the earlier notification and not any proper notification of the norms fixed by the Government pursuant to any inquiry and application of mind by the Government. Such an attempt to utilise the norms fixed in the earlier years without any application of mind is in our opinion clearly arbitrary, unlawful and void.

17. In our opinion fairness also requires that before fixing the price every year representations of the pharmaceutical industries should also be considered.

18. The allegations in paragraphs 15, 16, 17, 20, 22 and 24 of the writ petition have not been specifically denied in the counter-affidavit of the Respondents. There is only a bald denial in the counter-affidavit to paragraphs 15 to 20 of the writ petition. In reply to paragraphs 21 and 22 of the writ petition it has been stated in the counter-affidavit that the Government of India made several attempts to collect information from Pharma Industries in 2002, but as there was no cooperation from the pharma industries, the norms notified in 1999 which was having enough cushion for inflation were notified in 2000, 2001 and 2002. The reply to this is contained in para 7 of the rejoinder-affidavit, in which it is stated that no such information was either asked for from the Petitioners nor any such exercise was undertaken. The Petitioners are not aware of any such information sought from the Pharma Industry Association. It is further alleged that the decision of the Government to revise the norms on the basis of ad hoc increase is without foundation. The revision of norms is founded on surmises and conjectures and there is no material for the basis of such revision. Hence the

notifications are invalid and have been made without following the procedure prescribed under the D.P.C.O., 1995. Paragraphs 5.5., 5.6 and 5.7 of the counter-affidavit have been replied in paragraph 8 of the rejoinder-affidavit, in which it is stated that the allegations contained therein are wrong. It is for the first time that a query has been made and to which reply has been submitted by the Petitioners vide Annexures-R.A. 1 and R.A. 2 to the rejoinder-affidavit. It is further alleged that till today no data has been provided nor any questionnaire has been provided to the Petitioners. On the contrary, the Petitioners have submitted their cost accounts data in detail, which they have been doing every year regularly without fail. The Respondents are trying to put the blame on the Petitioners by making incorrect allegations. The Petitioners are always ready to cooperate with the Respondents but the Respondents are under an equal obligation to follow the guidelines of the D.P.C.O., 1995, for collecting information on each and every aspect objectively every year. Even otherwise the data of cost accounts already provided by the Petitioners could have been taken into account by the Respondents, but they have failed to do so.

19. In our opinion even assuming that the Petitioners were not cooperating in the supply of relevant material for fixation of the norms mentioned in Rule 7 of D.P.C.O., 1995 (though there is no basis for this averment) that does not absolve the Government from fixing the norms every year after collecting relevant material from its own sources and agencies. The Government has got several agencies, and hence even if the Petitioner is not supplying the relevant materials regarding norms mentioned in Rule 7 of the D.P.C.O., 1995, the Government can utilise its agencies for collecting these norms. It is undisputed that the Government has not fixed the norms every year. Hence the argument that the Petitioner was not cooperating in fixation of the norms mentioned in Rule 7 of the D.P.C.O., 1995, in respect of C.C., P.M. and P.C. is neither here nor there, and it is only the ipse dixit of the Respondents.

20. In our opinion it is totally irrelevant for the Government to contend that it had sought some information which it allegedly did not get. No particulars have been given of whether any information was sought from the Petitioners. The Petitioners have in fact categorically denied that any information was sought from them which was not given. The Petitioners as well as all other major manufacturers file cost audit reports every year with the Government and these contain all the relevant data. In our opinion even if some information is not received by the Government, it must nevertheless proceed to notify the norms on such information as it is able to gather through its agencies. This cannot possibly be an excuse for refusal to carry out a mandatory requirement of law. Any fixation of price done without such notification of norms as required under paragraph 7 of the D.P.C.O., 1995, would necessarily be void irrespective of the reason why the same was not notified. Furthermore, once norms are notified, they have to be reviewed and fresh notifications issued every year. A notification issued in one year cannot be mechanically extended in subsequent years. Each year, there has to be a fresh application of mind, a fresh consideration of all

relevant factors and a fresh notification of the norms based upon such considerations. Even according to the Government, the notification of norms in 1999 was done ad hoc and without any proper consideration of relevant factors. This would make such notification ex facie bad. What is worse is that the norms notified on an ad hoc basis in 1999 was mechanically extended in 2000, 2001, 2002 and 2003. Admittedly no exercise was undertaken in each of these years to consider relevant factors and arrive at the proper norms. As pointed out by Sri Cooper, the norms for P.M. have never been notified till date. It is also clear from the provisions of the D.P.C.O., 1995, that there is no power in the Government to merely extend the norms as has been sought to be done. Obviously, therefore, the norms for C.C. and P.C. notified in 1999 were merely ad hoc as admitted in the counter-affidavit. The mechanical extensions thereafter are violative of the D.P.C.O., 1995 and must, therefore, be held void. Furthermore, there has been no notification of P.M. norms at all, and thus any price fixation under Rule 7 of the D.P.C.O., 1995, would automatically lack one vital input. Any price fixation without one of the inputs would be violative of Rule 7 of the D.P.C.O., 1995.

21. In para 9 of the rejoinder-affidavit it is stated that the Petitioner company and all other such companies are being put to irreparable loss which shall seriously affect the Drug manufacturers in case the Respondents are allowed to continue enforcing the notifications which they are doing. It is false to allege that the Pharma Companies are intentionally withholding the latest data.

22. It is obvious from the facts that the norms of the costs mentioned in Rule 7 were not fixed every year as was the mandatory requirement of Rule 7.

23. We agree with the submission of the Sri Soli Cooper that the impugned notifications are illegal as they have been issued in violation of Rule 7 of the D.P.C.O., 1995, for the reasons already mentioned above.

24. Apart from the above, Sri Soli Cooper has also submitted that impugned notice and notifications are illegal because without fixation of the price of the bulk drugs, the Government cannot fix the price of the scheduled formulations. He has relied on the decision of the Punjab and Haryana High Court in Martin and Harris Laboratories Ltd. and Another Vs. Union of India (UOI) and Others,

25. We are in agreement with the aforesaid decision of the Punjab and Haryana High Court, because unless the price of bulk drugs is fixed under Rule 3 of D.P.C.O., 1995, it is not possible to properly fix the price of the scheduled formulation because formulation is made out of that bulk drug.

26. One of the inputs which is required to be considered for fixation of the price of a formulation under Rule 7 would include the cost of the bulk drug (as a part of the material cost M.C.). Obviously, therefore, if the price of the bulk drug is not fixed, there can be no method to calculate the price of the formulation under Rule 7. Thus, the fixation of a price of a formulation without fixing the price of the bulk drug would be clearly void. Shri Cooper is hence right in his submission on this point.

27. This second argument of Sri Soli Cooper applies to the formulations listed in paragraph No. 4 of the supplementary-affidavit of Sri. R. Gopalakrishnan dated 29.9.2003 and we are in agreement with the argument of Sri Soli Cooper on this point also.

28. Sri B. N. Singh, learned Counsel for the Central Government states that the Petitioners have an alternative remedy to approach the Central Government for review under Rule 22 of the D.P.C.O., 1995. It is well-settled that alternative remedy is not an absolute bar to filing a writ petition vide State of U.P. v. Md. Nooh AIR 1958 SC 86 ; State of Uttar Pradesh and Others Vs. Indian Hume Pipe Co. Ltd., ; Union of India (UOI) Vs. T.R. Varma, ; N.T. Veluswami Thevar Vs. G. Raja Nainar and Others, and Commissioner of Income Tax, New Delhi Vs. Rao Thakur Narayan Singh, , etc.

29. In State of West Bengal Vs. North Adjai Coal Co. Ltd., , the Supreme Court held:

It was submitted that a revision application lay to the Board of Revenue and without moving the Board of Revenue, the Respondent could not file a petition before the High Court. There is no substance in this contention. It is true that normally before a petition under Article 226 of the Constitution is entertained, the High Court would insist that the party aggrieved by the order of the quasi-judicial Tribunal should have recourse to the statutory authorities which has power to give relief. But that is a rule of practice and not of jurisdiction. In appropriate cases, the High Court may entertain a petition even if the aggrieved party has not exhausted the remedies available under a statute before the departmental authorities. In the present case, in the view of the High Court a case was made out for its interference with the order passed by the Deputy Commissioner and we see no reason to hold that the High Court had not properly exercised jurisdiction in this case.

30. Similarly in Ram and Shyam Company Vs. State of Haryana and Others, , it was held:

Ordinarily it is true that the Court has imposed a restraint in its own wisdom on its exercise of jurisdiction under Article 226 where the party invoking the jurisdiction has an effective, adequate alternative remedy. More often, it has been expressly stated that the rule which requires the exhaustion of alternative remedies is a rule of convenience and discretion rather than a rule of law. At any rate it does not oust the jurisdiction of the Court. In fact in the very decision relied upon by the High Court in The State of Uttar Pradesh Vs. Mohammad Nooh, , it is observed ''that there is no rule, with regard to certiorari as there is with mandamus, that it will lie only where there is no other equally effective remedy''. It should be made specifically clear that where the order complained against is alleged to be illegal or invalid as being contrary to law, a petition at the instance of person adversely affected by it, would lie to the High Court under Article 226, and such a petition cannot be rejected on the ground that an appeal

lies to the higher officer or the State Government. An appeal in all cases cannot be said to provide in all situations an alternative effective remedy keeping aside the nice distinction between jurisdiction and merits. Look at the fact situation in this case. Power was exercised formally by the authority set up under the Rules to grant contract but effective and for all practical purposes by the Chief Minister of the State. To whom do you appeal in a State administration against the decision of the Chief Minister? The clich? of appeal from Caeser to Caeser''s wife can only be bettered by appeal from one''s own order to oneself. Therefore, this is a case in which the High Court was not at all justified in throwing out the petition on the untenable ground that the Appellant had an effective alternative remedy.

31. In the present case, the question involved is of great legal importance as the Pharmaceutical industry is a very essential industry for the nation and hence an important legal issue should not be postponed but should be decided expeditiously. Moreover, we are of the opinion that a review application under Rule 22 would really be an appeal from Caesar to Caesar because the Central Government has already expressed its opinion in the detailed counter-affidavit filed by it before us. Hence, we are deciding the writ petition on merits.

32. Sri B. N. Singh, learned Counsel for the Central Government has stated that there are several similar writ petitions filed in several High Courts which are pending, and hence this petition should not be entertained.

33. In reply Sri Soli Cooper submitted that in the Bombay High Court the issue was whether seven drugs fell within the ambit of bulk drugs in the Drug Policy of 1994. Hence, there was no question of fixation of the prices in that petition, and instead the dispute was whether those drugs could be regarded as controlled drugs or not. The Bombay High Court decided the writ petition in favour of the Petitioners and in appeal the Supreme Court remanded the matter and it is pending before the Bombay High Court. Since the question involved in the petition before the Bombay High Court was totally different it has no relevance to the present case.

34. As regards the petition filed in Karnataka High Court Remidex Pharmaceuticals Private Limited and Anr. v. Union of India and Anr.the same was allowed by learned single Judge, vide Remidex Pharmaceuticals Private Limited, Bangalore and another Vs. Union of India and another, , (a copy of which is Annexure-8 to the writ petition). Letters patent appeal against that judgment is pending before a Division Bench of the Karnataka High Court. The Petitioners has already filed a writ petition in the Karnataka High Court, which has been tagged with the aforesaid appeal of Remidex Pharmaceuticals Pvt. Ltd.

35. Sri Soli Cooper submitted that the Petitioner had to file this writ petition in Allahabad High Court because the impugned order/notice dated 16.8.2003, was issued by the Inspector of Drugs, Varanasi, who is an authority in U.P. We are in agreement with the Sri Soli Cooper that this Court is not prohibited from deciding

this writ petition on the facts of the case.

36. For the reasons given above this writ petition is allowed. The impugned notice/order dated 16.8.2003 as well as notifications dated 12.7.2000, 12.7.2001, 12.7.2002, 11.7.2003 and 25.11.2003 are quashed. The fixation of price of drugs mentioned in paragraph 4 of the supplementary affidavit is illegal and is also quashed. However, it is open to the authority concerned to fix the price of formulations afresh in accordance with law. The notifications referred to in the impugned order dated 16.8.2003 are also quashed.

37. Before parting with this case we would like to mention that the Indian Pharmaceutical Industry has dramatically changed over the last half century, from being traders in imported drugs in the fifties, to major bulk drug producers by the eighties. During this transitional period our pharmaceutical units have mastered the technology of bulk drug production by their own research and adaptation, and today they produce more than 250 bulk drugs, emphasizing on import substitution and use of indigenous raw materials.

38. At present the Indian pharmaceutical industry has about 300 large units, 1,700 medium size units and about 8,000 small scale units throughout the country. The total turnover of these units in 2002-2003 was about Rs. 26,000 crores, and exports were wroth about Rs. 10,000 crores.

39. Sri Soli Cooper learned Counsel for the Appellant has placed before us a statement showing the prices of some drugs in India and other countries, which indicate that the drugs are cheapest in India as compared to drugs in Pakistan, U.S.A., U.K., Indonesia, etc. Thus, Ciprofloxacin HCL costs Rs. 29 per pack in India, Rs. 423.86 in Pakistan, Rs. 2352.35 in U.S.A., Rs. 1185.70 in U.K. and Rs. 393 in Indonesia. Similar comparative prices are given in the chart given below:

Drugs & Dosage Pack Prices in India Prices in Pakistan Prices in U.S.A. Prices in U.K. Prices in Indonesia

(Rs.) (Rs.) (Rs.) (Rs.) (Rs.)

Anti infectives

Ciprofloxacin HCL 500 mg. tabs 10?s 29.00 423.86 2,352.35 1,185.70 393.00

Norfloxacin 400 mg. tabs 10?s 20.70 168.71 1,843.66 304.78 130.63

Ofloxacin 200 mg. tabs 10?s 40.00 249.30 1,973.79 818.30 204.34

Cefpodoxime Proxetil 200 mg. tabs 6?s 114.00 357.32 1,576.58 773.21 264.00

Anti Ulcerants

Diclofenac Sodium 50 mg tab 10?s 3.50 84.71 674.77 60.96 59.95

Ranitidine 150 mg tabs 10?s 6.02 74.09 863.59 247.16 178.35

Omeprazole 20 mg caps. 10?s 22.50 578.00 2,047.50 870.91 290.75

Lansoprazole 30 mg caps 10?s 39.00 684.90 1,909.64 708.08 226.15

Cardiovasculars

Atenolol 50 mg tab 14?s 7.50 71.82 753.94 N.A. 119.70

Amlodipine Besylate 5 mg. tabs 10?s 7.80 200.34 660.21 388.28 78.42

Antivirall Fungal

Zidovudine 100 mg caps 10?s 77.00 313.47 895.90 996.16 331.65

Lamivudine 150+Zidovudine 300 mg tabs 10?s 274.00 N.A. 4,988.62 4,767.02 N.A.

Anti-histamine

Caterizine 10 mg. tabs 10?s 6.00 35.71 927.29 262.19 57.50

Anti Anxiolofics/Psychofics

Alpramazoo 0.5 mg tab 10?s 7.00 160.57 446.81 N.A. 31.05

Fluoxetine 20 mg caps 10?s 25.80 444.53 1,416.42 395.79 143.40

Anti-Cancer

Boposide 100 mg injection Vial 190.00 554.69 6,210.30 1,217.43 242.90

Cholesterol Reducer

Atorvastatin 10 mg tab 10?s 39.00 N.A. 1,102.92 537.74 565.95

Simvastatin 10 mg. tabs 10?s 35.00 283.05 1,149.79 537.74 187.00

Antiasthmatic

Salmeterol 25 mcg+Fluticasone 50 mcg inhaler 120 does 210.00 N.A. N.A. 1,628.25 782.65

Urology

Sildenafil Citrate 50 mg. tabs 4?s 48.00 N.A. 1,744.93 1,614.89 1,356.93

Note.--1. Retail prices in India and wholesale prices in other countries considered.

2. Conversion rate of Exchange considered: 1 USD = Rs. 45.50, 1 GBP = Rs. 83.51 PAK Rs. = Rs. 0.84, I Indonesian Rp = Rs. 0.005.

(3) Source for prices: USA Prices --RED BOOK 2002

UK PRICES--UK MIMS FEB., 2004

PAKISTAN--PHARMAGUIDE JUNE, 2002-2003

INDIA--IDR NOV./DEC., 2003.

40. Thus, the prices of drugs is already very low in India as compared to other countries including Pakistan. The pharmaceutical industry in India is hence rendering great service to the Indian people by providing them drugs at affordable prices. However, if the cost of production of these drugs is not examined every year as required by Rule 7 of the D.P.C.O., 1995, the result may well be that the retail sale price may become less than the cost of production, which will destroy the pharmaceutical industry built up by our enterprising businessmen over the last few decades by their hard work. Hence it is the duty of the Government to properly follow the rules in the D.P.C.O., 1995 and not violate them. The Government must also ensure that the signing of the TRI Ps Agreement does not result in destruction or serious harm to our indigenous pharmaceutical industry which was built up after Independence by the hard work of our entrepreneurs over several decades, and that the people of India continue getting drugs and formulations even after 1.1.2005 at affordable prices.

