SUPREME COURT OF INDIA

Secy., Ministry of Chemicals and Fertilizers

Vs.

Cipla Ltd.

C. A. Nos. 3375-3384 of 2002

(S. Rajendra Babu, P. Venkatarama Reddi and Arun Kumar, JJ.)

01.08.2003

JUDGEMENT

P. VENKATARAMA REDDI, J.:-

1.1. These appeals by special leave preferred by the Union of India are directed against the common judgment of the Bombay High Court in a batch of writ petitions filed under Art. 226 of the Constitution by the manufacturers/importers of certain bulk drugs and their formulations. The bulk drugs concerned are seven in number. They are : Salbutamol, Theophylline, Cyproflaxacin, Norfloxacin, Cloxacillin, Doxycycline and Glipizide. These bulk drugs and the formulations made out of them are sold within the country and part of the quantities produced are also exported outside the country. The challenge is to the inclusion of the said bulk drugs in the first schedule to the Drugs (Price Control) Order, 1995 (hereinafter referred to as 'the DPCO'). Though the fixation of price pursuant to the provisions of the said order was also challenged in some of the writ petitions, that issue was not gone into by the High Court and at any rate, the mechanics of price fixation is not the contentious issue before us. However, it may be noted that the remedy by way of review is available under paragraph 22 of the DPCO to seek reconsideration of price fixation. The immediate provocation for filing the writ petitions in the High Court seems to be the notices issued by the National Pharmaceutical Pricing Authority, calling upon some of the respondent-companies to

deposit the overcharged amounts in relation to the formulations of scheduled drugs.

1.2. The High Court held that the concerned drugs should not have been brought within the purview of the DPCO, 1995 and consequently, there could be no fixation of price in relation to those drugs. The notices demanding overcharged amounts were quashed. The writ petitions were thus allowed by the Division Bench of High Court.

2.1. The DPCO, 1995 which came into force on 6th January, 1995, was promulgated by the Central Government in exercise of the powers conferred by S. 3 of the Essential Commodities Act, it repealed the earlier DPCO of 1987, under which more number of drugs were subjected to price control. 'Drug' as defined in Drugs and Cosmetics Act is one of the essential commodities.

2.2. According to S. 2(a) of DPCO, 'Bulk Drug' means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or other standards specified in the second schedule to the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation. 'Formulation' is defined to mean 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 in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals.

2.3. Paragraph 3 of DPCO empowers the Central Government to fix, from time to time, a maximum sale price at which the bulk drug specified in the first schedule shall be sold, after making such inquiry, as it deems fit. The opening clause of sub-para (1) spells out the avowed purpose of price control of the scheduled bulk drugs. The declared objective is to regulate the equitable distribution and increasing supplies of the specified bulk drug and making them available at a fair price. There is a prohibition against the sale of bulk drug at a price exceeding the maximum sale price fixed under sub-paragraph (1) plus local taxes, if any. As already observed, we are not concerned here with the modalities of fixation of price. The very inclusion of these bulk drugs in the schedule is being assailed on the ground that it is opposed to the norms laid down by the Central Government itself in the Drug Policy of 1994 and, therefore, the delegated legislative power exercised by the Government is arbitrary and violative of Art. 14 of the Constitution. The plea of the respondents was accepted by the High Court.

2.4. In the Drug Policy document issued on 15th September, 1994, the Central Government noticed that during the last decade, the drug industry had grown significantly in terms of production of bulk drugs and formulations and the export performance of the industry had been commendable, it was said that the pharmaceutical sector had been able to carve a special niche for itself in the international market as a dependable exporter of bulk drugs. The drug policy with regard to pricing has been stated thus in paragraph 9 of the policy paper :

"9. Pricing- The aberrations which have come to notice, in the listing of drugs and their categorization for the purpose of price control, need to be eliminated by the use of transparent criteria applied across the board on all the drugs with the minimum use of subjectivity. The high turnover of a drug is an index of its extent of usage and is considered to meet the requirements of objectivity justifiable on economic considerations. However, the monopoly situation in cases of drugs with comparatively lower turnover has also to be kept in view. Also, as an experimental measure, drugs having adequate competition may not be kept under price control and if this proves successful it would pave the way for further liberalization. In the event, however, of prices of these drugs not remaining within reasonable limits, the Government would reclamp price control."

In paragraph 11, it is stated-

"In the light of the apprehensions expressed in the Parliament on the likely spurt in the prices of medicines, it has been felt that it would not be desirable to allow automaticity in the pricing mechanism. The Government would set up an independent body of experts, to be called the National Pharmaceutical Pricing Authority, to do the work of price fixation. This expert body would also be entrusted with the task of updating the list of drugs under price control each year on the basis of the established criteria/guidelines. . . . . ."

2.5. The Government's resolve to closely monitor the trends of prices of medicines and to take appropriate measures to reclamp price control in case the prices of such medicines rise unreasonably, has been stressed in paragraph 12. Then, we come to the most important paragraph in the Drug Policy i.e., 22.7.2 which bears the heading 'Span of Control.' It sets out the criteria for bringing the drugs under price control. We quote paragraph 22.7.2 :-

22.7.2. Span of Control.-

(i) The criterion of including drugs under price control would be the minimum annual turnover of Rs. 400 lakhs.

(ii) Drugs of popular use in which there is a monopoly situation be kept under price control. For this purpose for any bulk drug, having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90% or more market share in the retail trade (as per ORG) a monopoly situation would be considered as existing.

(iii) Drugs in which there is sufficient market competition viz., at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would be kept in check by the forces of market competition. The Government may determine the ceiling levels beyond which increase in prices would not be permissible.

(iv) Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the Government would take appropriate measures, including reclamping of price control.

(v) For applying the above criteria, to start with, the basis would be the data up to 31st March, 1990 collected for the exercise of the review of the Drug Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority as detailed in para 22.7.4(i).

3. The central theme of the arguments is that the norms set out in sub-paras (i), (ii) and (iii) have not been adhered to by the Government while framing the first schedule to DPCO in purported implementation of the drug policy. There was either deviation from the criteria set out or there was no scientific or rational assessment of the factors relevant to the norms. Most of the arguments centered round the interpretation of the three clauses in para 22.7.2 - an exercise which is usually associated with the construction of statutes. The sum and substance of the arguments on behalf of the respondents is that the seven bulk drugs get excluded from the span of control under one or more norms spelt out in para 22.7.2, whereas the stand of the appellants is that the concerned bulk drugs were included in the schedule only after being satisfied that they came within the ambit of price control criteria. It is also the contention of the appellant that the Government's decision to bring these important bulk drugs within price control is in accordance with the objectives underlying in S. 3 of the Essential Commodities Act, particularly, the interests of consumers. Every attempt was made to examine the facts and figures by an Expert Group of the Standing Committee, keeping in view the prescribed norms in Drug Policy. It is pointed out that the High Court cannot go into the intricacies of price fixation under Art. 226 of the Constitution or sit in judgment over the exercise done by experts.

4.1. It is axiomatic that the contents of a policy document cannot be read and interpreted as statutory provisions. Too much of legalism cannot be imported in understanding the scope and meaning of the clauses contained in policy formulations. At the same time, the Central Government which combines the dual role of policy-maker and the delegate of legislative power, cannot at its sweet will and pleasure give a go-bye to the policy guidelines evolved by itself in the matter of selection of drugs for price control. The Government itself stressed the need to evolve and adopt transparent criteria to be applied across the board so as to minimize the scope for subjective approach and, therefore, came forward with specific criteria. It is nobody's case that for any good reasons, the policy or norms have been changed or became impracticable of compliance. That being the case, the

Government exercising its delegated legislative power should make a real and earnest attempt to apply the criteria laid down by itself. The delegated legislation that follows the policy formulation should be broadly and substantially in conformity with that policy; otherwise it would be vulnerable to attack on the ground of arbitrariness resulting in violation of Art. 14.

4.2. In Indian Express Newspapers v. Union of India ((1985) 1 SCC page 641), the grounds on which subordinate legislation can be questioned were outlined by this Court. E. S. Venkataramiah, J. observed thus : AIR 1986 SC 515 : 1985 Tax LR 2451

para 73

"A piece of subordinate legislation does not carry the same degree of immunity which is enjoyed by a statute passed by a competent Legislature.' Subordinate legislation may be questioned on any of the grounds on which plenary legislation is questioned. In addition it may also be questioned on the ground that it does not conform to the statute under which it is made.

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It may also be questioned on the ground that it is unreasonable, unreasonable not in the sense of not being reasonable, but in the sense that it is manifestly arbitrary. In England, the Judges would say "Parliament never intended authority to make such rules. They are unreasonable and ultra vires."

4.3. True, the breach of policy decision by itself is not a ground to invalidate delegated legislation. But, in a case like this, the inevitable fallout of the breach of policy decision which the Government itself treated as a charter for the resultant legislation is to leave an imprint of arbitrariness on the legislation. When the selection or classification of certain drugs is involved for the purpose of price control, such selection or classification should be on rational basis and cannot be strikingly arbitrary. No doubt, in such matters, wide latitude is conceded to the legislature or its delegate. Broadly, the subordinate law making authority is guided by the policy and objectives of primary legislation disclosed by preamble and other provisions. The delegated legislation need not be modelled on a set pattern or pre-fixed guidelines. However, where the delegate goes a step further, draws up and announces a rational policy in keeping with the purposes of enabling legislation and even lays down specific criteria to promote the policy, the criteria so evolved become the guide posts for its legislative action. In that sense, its freedom of classification will be regulated by the self-evolved criteria and there should be demonstrable justification for deviating therefrom. Though exactitude and meticulous conformance is not what is required, it is not open to the Government to go hay-wire and flout or debilitate the set norms either by giving distorted meaning to them or by disregarding the very facts and factors which it professed to take into account in the interest of transparency and objectivity. Otherwise, the legislative act of the delegate in choosing some drugs for price control while leaving others will attract the wrath of Art. 14. That is why the Union of India has taken the

stand throughout that it stood by the policy while framing the legislation and that there was every endeavour to apply the criteria spelt out in the Drug Policy of 1994 before including the drugs in question in the first schedule. The correctness of this contention should, of course, be examined.

5.1. With this prologue, let us proceed to analyse the three relevant criteria in the drug policy. According to the first criterion, for bringing the drugs under the price control, the minimum annual turnover of the drug should be 400 lacs. However, this requirement is qualified by and subject to the criteria laid down in (ii) and (iii). Where a monopoly situation prevails in respect of any bulk drug, the minimum annual turnover requirement gets reduced to 100 lacs. The monopoly situation is deemed to exist where there is a single formulator commanding 90% or more market share in the retail trade (as per ORG data). According to the 3rd criterion, even if minimum annual turnover exceeds 400 lacs, the drug will be kept outside price control in case there is sufficient market competition. The yardstick for assessing whether there is sufficient market competition, according to Cl. (iii) is that there are at least five producers of the particular bulk drug and at least ten formulators and none of them have more than 40% market share in the retail trade (as per ORG data).

The said criteria have to be worked out with reference to the data available up to 31st March, 1990 which means, the relevant facts and figures relating to the financial year 1989-90 have to be taken into account. This is not in dispute.

5.2. As already noted, there is no quarrel about the criteria that has been laid down. It is not the case of the Union of India that any different criteria had been applied while promulgating the DPCO of 1995. The controversy revolves round its actual application or methodology of working out the criteria. What is the annual turnover made up of? In other words, how to work out the turnover figures? Is there sufficient market competition as contemplated by Cl. (iii)? It is with reference to these two aspects that the Government's stand has not been accepted and the writ petitioner's contention found its acceptance by the High Court.

5.3. First, we shall take up the issue of 'annual turnover.' The stand of the appellant, as discernible from the affidavits on record sworn to by the officials of the Department of Chemicals and Petrochemicals, Government of India is that the turnover of bulk drug ought not to be mixed up with retail sale data of the formulations of that bulk drug; in other words, the retail sale data pertains to formulations of a bulk drug and not to the bulk drug itself. The broad manner in which the turnover has been assessed is indicated in paragraph 8 of the rejoinder affidavit filed in S.L.Ps. It is stated that the expert group of the Standing Committee which went into the whole issue of exclusion/inclusion of drugs under price control "took the data for turnover of the bulk drugs comprising of the value of its total production in the country and value of weighted average of landed cost of total imports into the country, as the basis for viewing the price scenario from different points of view." It is then stated in paragraph 10. "In the further respectful submission of the petitioner the intent behind using the said word (turnover) has been to determine the extent of

usage of a bulk drug in the country (emphasis supplied). This was the measure adopted by the expert group in case of each bulk drug by taking into account the aggregate of its total imports into the country and its total indigenous production in the country. This has been the connotation of the word 'turnover' at various levels throughout the deliberations and in implementation of the policy through DPCO 1995 and was never confined to the narrow connotation of the word 'sales turnover.' In short, it is submitted (vide paragraph 13) that the value of total production plus imports of the bulk drug in the country determines the annual turnover for the purpose of Cls. (i) and (ii) of para 22.7.2. As a corollary to this stand, the contention advanced on behalf of the Union of India is that export sales could also be taken into account in arriving at the annual turnover. According to the respondents (writ petitioners), the annual turnover could only mean sales of bulk drug within the country either in the same form or by way of formulations and it has nothing to do with export sales. The entirety of production and imports cannot be regarded as turnover. It is submitted by the respondents that the bulk drugs are sold mostly in the form of formulations and the quantities of bulk drugs utilized in such formulations are given in ORG data. From this, the bulk drug turnover can be easily ascertained. The sales of the bulk drugs as such to the institutions etc., will be negligible i.e., about 15%, as per the certificate issued by ORG in one of the cases. It is, therefore, commented that the contention that the ORG data does not afford the basis for ascertaining the annual turnover of the bulk drug, is untenable.

5.4. The High Court, substantially agreeing with the contentions of the respondents-writ petitioners held that the expression 'turnover' occurring in Drugs Policy can only mean domestic sales figures and nothing else. Export sales cannot be included within the ambit of turnover. The High Court observed that the concepts of 'turnover' and 'market share' are interrelated and inter-dependent. The expression 'turnover,' if interpreted in a contextual and purposive manner, would not include exports. The extent of usage of the bulk drug in the country would be determinative of turnover. By taking the export sale figures and the value of entire production of bulk drugs into account, the Central Government had acted contrary to its own guidelines contained in Drug Policy, 1994. The High Court then proceeded to discuss whether each of the drugs concerned could be brought within the purview of DCPO, 1995 and answered that question in favour of the writ petitioners.

5.5. Before proceeding further, we may notice that the National Pharmaceutical Pricing Authority (NPPA) constituted by the Government of India considered the representation of Bulk Drugs Manufacturers Association (BDMA) on the subject to inclusion/exclusion of drugs under DPCO. The NPPA passed a reasoned order rejecting the representation on dt. 6-4-1998. In that order, the issues raised by BDMA regarding exclusion of six out of eight drugs with which we are concerned, were considered by the said authority. There was however no consideration as regards two drugs, namely, Doxycycline and Glipizide, probably because the representation did not cover those two drugs.

5.6. Before we take up the issue of export sales, it is necessary to understand the true import and expanse of the expression 'turnover' occurring in Cl. (i) of para 22.7.2 of the Drug Policy, 1994. What is the 'turnover' contemplated by the said paragraph? Can it be equated to the value of imported bulk drug and its production, as contended by the appellant OR should it be equated to the

actual sales within the country? Should the export sales be included in turnover? These are the questions to which this Court has to address itself.

5.7. 'Turnover' in its ordinary sense connotes amount of business usually expressed in terms of gross revenue transacted during a specified period (vide Collins Dictionary). Broadly speaking, it represents the value of the goods or services sold or supplied during a period of time. The amount of money turned over or drawn in a business during certain period, is another shade of meaning. We need not refer to the definition of 'turnover' in Sales Tax and other fiscal enactments reliance on which was placed by some of the learned counsel as they are not quite relevant for the purpose of understanding the expression 'turnover' occurring in a policy document. Nor should we seek any assistance from the definition of 'sale turnover' occurring in DPCO in a different context and for a different purpose. Going by its ordinary meaning and the way in which it is commonly understood in trade and commerce, it is difficult to equate turnover to the value of stock acquired either by means of imports or production. For instance, the entire stock in trade, say, lying in a godown and not calculated in business, cannot be regarded as turnover, even giving broadest meaning to the expression 'turnover.' The reasoning which could be spelt out from the order passed by NPPA (referred to supra) and in the counter-affidavits filed by the appellants that indigenous production plus imports furnishes an indicia of the total business in the country in relation to a particular bulk drug, cannot be accepted. It is only what is sold out and marketed that could be legitimately regarded as turnover of the specified drug. It may be that in the absence of availability of reliable data regarding sales, the import value and production value could be the basis to estimate the sale value after giving due allowance to various factors such as wastage, unsold stocks etc. But, treating the turnover as nothing but the value of stock produced or imported during a given period will be doing violence to the ordinarily accepted meaning of the expression 'turnover.' There can be no presumption that the entire stock of bulk drug produced or imported during the year had been sold out during that year either in the form of formulations or otherwise. However, we would like to make it clear that the production and import statistics are not altogether irrelevant. They are relevant in the sense that they furnish some basis for estimating the sales when there is no other reliable and comprehensive data of sales available.

5.8. The question whether export sales should also be taken into account in computing the annual turnover needs to be discussed now. There can be no doubt that the meaning of the expression 'turnover' either in its ordinary or legal sense includes export sales. But, we must have regard to the terms and objectives of the policy and try to understand that expression accordingly. Para 9 of the Drug Policy, 1994 makes it clear that the high turnover of a drug is an index of its extent of usage. 'Usage' has obvious reference to consumption and consumption within the domestic market. Whether the drug is extensively used within the country is one of the considerations kept in view to clamp price control. The export potential of the drug or its usage in foreign countries could not have been the reason to notify the specified drugs for price control. If there is any doubt in this regard, it is dispelled by what is stated in paragraph 10 of the rejoinder affidavit which we quoted supra. To repeat, it was stated therein that the intent behind using the word 'turnover' has been to determine the extent of usage of a bulk drug in the country. It is also pertinent to note that the Govt. of India has not come forward with any explanation as to why export sales also should be taken into account in assessing the turnover as per the criteria laid down in the Drug Policy. For all these reasons, we are in agreement with the High Court that the export sales ought to have been excluded while

calculating the turnover. How far the exclusion of export sales would make any difference is a different matter.

5.9. Another grey area which has surfaced in the backdrop of the Drug Policy, 1994 is whether for the purpose of Cl. (iii), the expression 'formulators' should be confined to single ingredient formulators or it should extend to multi-ingredient formulators as well. The NPPA while rejecting the representation of the Bulk Drug Manufacturers' Association, referred to the clarification issued by the Government of India in its communication dated 10-6-1997 addressed to one of the writ petitioners which is as follows :

"The basis of the single ingredient formulation as against that of the combination formulation (for purpose of calculating market share), is not only justified on account of predominance of single ingredient formulation, on over all basis, but also vindicates the objective of "promoting the rational use of drugs in the country" mentioned in paragraph 1(b) of the "Modifications in Drug Policy, 1986." The principle of covering only single ingredient formulations, for purposes of calculating market share is a transparent, objective and verifiable principle and hence suitable for policy issues. Formulations of a bulk drug, containing one or more other bulk drug are not comparable in terms of their sales values. Therefore, it is practically not possible to apply the criteria relating to market share of a formulator of a bulk drug on the basis of data of its combination formulations, across the board, in a transparent, objective and verifiable manner as required for policy issues."

It is, therefore, contended by the Union of India that only single ingredient formulations have to be taken into account for the purpose of working out the criterion in Cl. (iii) and that the number of single ingredient formulators of the concerned bulk drug is not discernible from ORG data. Of course, it is the contention of the respondents that no such distinction can be drawn. It is contended that such distinction is irrational.

In our view, the clarification given by the Government of India reflects a reasonable view point and it cannot be said that by adopting such approach, a distorted meaning is given to the expression 'formulator' much against the spirit of the policy. At any rate, two views are possible and it is not for the Court to decide which view is preferable.

6. Before closing the discussion on the controversies surrounding the criteria evolved in the Drug Policy, there is one argument of the learned Solicitor General which we would like refer to. The learned Solicitor General argued that the expression 'may' occurring in Cl. (iii) of para 22.7.2 of the Drug Policy confers discretion and flexibility in approach to the Government of India. Even if a particular bulk drug stands outside price control by the application of such criteria, the discretion is still left to the Government to include the drug in the schedule for good reasons. This argument cannot be countenanced for the simple reason that it is not the case of the Government that for any particular reason or reasons, the bulk drug concerned was brought within the purview of price

control, though the drug qualifies for exclusion under Cl.(iii). Even assuming that the discretion is available in terms of the policy, the factum of exercising such discretion for relevant reasons should be disclosed. In the absence of such disclosure, the Court must proceed on the basis that the Government stood by the criteria and saw no need to deviate therefrom.

7.1. Now it is necessary to advert to the nature of the claim made by the writ petitioners in relation to each of the bulk drugs, the stand taken by the Union of India and the conclusions of the High Court.

7.2. Salbutamol: According to the writ petitioner-Company, the annual turnover for the year ending March, 1990 was Rs. 171.17 lacs based on the ORG data. The sales of formulations in domestic market has been taken as the basis to calculate the consumption. It is then multiplied by the notified price prevalent during the relevant period. It is the further case of the writ petitioner that there were as many as 24 formulators including the petitioner, none of whom had the market share of more than 40%. Admittedly, there were more than five bulk drug producers. The writ petitioner-Company, therefore, claimed the benefit of exclusion both under clauses (i) and (iii) of para 22.7.2 of the Drug Policy, 1994. The Government of India took the stand that the bulk drug turnover was Rs. 11.50 crores based on the value of domestic production and imports. Moreover, there were only seven known formulators of the bulk drug. Therefore, it is contended that the drug Salbutamol does not qualify for exclusion either under clause (i) or (iii). The High Court accepted the claim of the petitioner-Company on the ground that in the counter-affidavit filed by the Union of India, there was only a bald denial and the details given by the writ petitioners were not controverted.

7.3. Theophylline: The writ petitioners claimed exclusion under clause (iii). The names of six bulk drug producers and 31 formulators were given in the writ petition. In the counter-affidavit, it was merely stated that there were less than five known manufacturers of bulk drug and less than 10 known formulators of the bulk drug and therefore the drug Theophylline did not qualify for exclusion under clause (iii). The High Court observed that the particulars furnished by the petitioner were not effectively controverted, there being only a bald denial. It was therefore held that the drug ought not to have been brought under price control.

As per the statement furnished by the learned Solicitor General at the time of hearing, the fact that there were more than five bulk drug producers, was accepted but the number of formulators was given as seven. Therefore, the dispute is confined to the number of formulators, the term 'formulator' being understood in the sense in which the Government of India explained in its clarificatory letter dated 6-4-1998.

7.4. Cloxacillin: The writ petitioners concerned are said to be the manufacturers of formulations made out of Cloxacillin. There is no dispute that the annual turnover at the relevant time was much more than 400 lacs. The writ petitioners claimed exclusion of the drug Cloxacillin on the basis of clause (iii) of para 22.7.2. According to them, there were as many as 16 bulk drug producers and 23 formulators in respect of Cloxacillin and none of the formulators had more than 40% market share

as per the ORG figures for the year 1989-90 (up to March, 1990). The High Court accepted the case of the petitioners on the ground that the factual particulars were not controverted, but there was only a bald denial in the counter-affidavit filed by Union of India. The counter-affidavit of Union of India is not found either in S.L.P. paper books or the original record of High Court. However, the stand of Union of India, as is clear from the reply dated 6-4-1998 of the NPPA sent to the Bulk Drug Manufacturers' Association as well as the Grounds of SLP is that the number of single ingredient formulators of the drug was less than 10. According to the statement furnished by the learned Solicitor General in the course of the arguments, the number of formulators were only two. The NPPA clarified the position thus:

"The Association has claimed that the highest market share of single formulator is 21.89%. This claim is based on consideration of sale values of both single ingredient and combination products of Cloxacillin. However, the highest market share of single drug ingredient formulation of a particular formulator works out to 93.07% which is more than the stipulated level of 40%."

Thus, there is controversy regarding the number of formulators and their market share.

7.5. Cyproflaxacin: The 2nd petitioner in writ petition No. 3449 of 1996, namely, Ranbaxy Laboratories Ltd. produced the said bulk drug during the relevant period and captively consumed the same in the manufacture of formulations marketed under the brand name of Cifran both in India and foreign countries. The petitioner in W. P. No. 1974 of 2000 is Cipla Ltd. Inter alia, it is engaged in the manufacture and sale of formulations of the drug Cyproflaxacin. According to Ranbaxy Ltd., the annual domestic turnover of the drug for the year ending March, 1990 was Rs. 238 lacs and according to the Cipla Ltd., it was Rs. 243 lacs excluding the hospital and institutional sales to the extend of 15%. It is therefore contended that the drug stands excluded under clause (i) of para 22.7.2 of the Drugs Policy. It is their further contention that there was no monopoly situation as contemplated by clause (ii) inasmuch as there was no single formulator having 90% or more market share in the retail trade as per ORG data. The said turnover was calculated on the basis of estimated consumption purportedly arrived at with reference to the data relating to sales formulations given in ORG publication. The quantum of consumption was then multiplied by the then prevailing market price. However, a different method of calculation of turnover was spelt out in the representation dated 7-3-1995 submitted by Ranbaxy Ltd., to Government of India (vide Ext. B in W. P. No. 3449 of 1996). According to that calculation, the turnover is Rs. 280 lacs.

In the counter-affidavit, the turnover given by the writ petitioners has been disputed. It is stated that ORG data relates to formulation sales and it does not give data in regard to quantities and values of bulk drug involved. It was also stated that Cyproflaxacin was included in the first schedule on the basis of criterion in clause (i) since the turnover in 1989-90 was taken as Rs. 980 lacs based on the landed cost of imports of the drug. It is then stated that the data in regard to indigenous production is not available.

The High Court merely referred to the contention of the writ petitioners regarding the turnover and accepted the same on the ground that there was only bald denial in the affidavit in reply. Surprisingly, the High Court extended the benefit of exclusion under clause (iii) also, though it was never the case of the writ petitioners. The High Court stated that there were admittedly 16 bulk drug producers and 20 formulators, though, no such case was set up by either of the writ petitioners. In the ORG data furnished by the petitioner in W. P. No. 3449 of 1996 and in the representation submitted to the Government of India, only the names of seven formulators was mentioned. Thus, there was an obvious error in the High Court's judgment. The plea of discrimination which was raised for the first time in the rejoinder affidavit filed in W. P. No. 3449 of 1996 also found favour with the High Court.

7.6. Norfloxacin: The writ petitioner seeks exclusion from the purview of DPCO on the basis of clause (iii) of para 22.7.2 of the Drugs Policy. It is the case of the petitioner that there were at least 28 bulk drug manufacturers and 20 formulators and no single formulator had more than 40% market share as per the ORG figures. The names were given in the writ petition. However, the stand taken in the counter-affidavit filed by the Government of India is that there were only three manufacturers of the bulk drug and the ORG data does not disclose the number of bulk drug producers. As regards the formulators, the stand taken is that the number of single ingredient formulators using the said bulk drug is not discernible from the ORG data. It is, therefore, contended that the twin conditions of a minimum of five bulk drug producers and at least 10 formulators are not satisfied. The High Court accepted the plea of the writ petitioner on the ground that there was only a bald denial in the counter-affidavit and no specific particulars were given to controvert the contention of the petitioner. In the order passed by NPPA in response to the representation of Bulk Drug Manufacturers' Association, it is stated that as per the records available, there were only three bulk drug manufacturers in the country during 1989-90. However, the names were not furnished either in this document or the counter-affidavit.

As per the ORG data, the market share of the formulation sold by the petitioner-Company was 39.56% (vide annexure at page 38 of the original writ petition record) which, as pointed out by NPPA, is technically lower than 40%. We may add that it is perilously close to 40%. It should also be noted that the writ petitioner did not furnish any details of production to show that the bulk drug manufacturers mentioned by it or at least five amongst them actually produced the bulk drug.

7.7. Doxycycline: It is the case of the writ petitioner that it manufactures and sells single ingredient formulation containing the bulk drug Doxycycline in a concentration of 100 mg per capsule under the brand name of Doxy-1. The annual turnover of the bulk drug Doxycycline, according to the writ petitioner, was Rs. 316 lacs. It is seen from the tabular statement appended to Annexure A to the writ petition at pages 85-86 of the original record, the petitioner arrived at the total domestic consumption of the bulk drug with reference to the ORG data pertaining to sales of formulations in the market. It is the further case of the writ petitioner that as per ORG data, there were at least 19 formulators producing Doxycycline based formulations and none of them had more than 40% of market share in retail trade. Therefore, the petitioner claimed that the bulk drug Doxycycline should have been excluded from the purview of price control in terms of under clauses (i) and (iii) and that monopoly situation contemplated by clause (ii) has no application because no single manufacturer had 90% or more market share in retail trade.

The stand of the Government has been that the turnover of Doxycycline was above 400 lacs during the relevant period and therefore it comes under price control. Further, it is their case that clause (ii) has no application because the turnover is above 400 lacs. It is also averred in the counter-affidavit that the retail trade sale data is not relevant since the need to calculate market share does not arise. Moreover, since indisputably, there is only one manufacturer of the bulk drug, i.e., Ranbaxy Limited, the exclusion criteria laid down in clause (iii) of para 22.7.2 is not applicable.

In paragraph 89 of the judgment under appeal, the High Court having merely referred to the arguments of the learned counsel for the petitioner, accepted the case of the petitioner on the ground that in the affidavit-in-reply filed by the Government, there was only bald denial and that the particulars were not controverted. Moreover, the High Court was under an apparent misapprehension that the Writ Petitioner sought the benefit of exclusion under clause (iii) also. The core controversy, as already noticed, is regarding the quantum of turnover. The Union of India took the stand that the turnover was above 400 lacs. In the statement filed by the learned Solicitor-General at the time of argument, the figure was given as 471.77 lacs. However, the appellant did not furnish any details as to the calculation of turnover.

7.8. Glipizide: The writ petitioner-USV Limited is a manufacturer of the bulk drug 'Glipizide' which is sold under the brand name of Glynase. It does not appear that there was any other producer of bulk drug during the relevant period. It is the case of the writ petitioner that the annual turnover for the year ending 31st March, 1990 was only Rs. 82 lacs and that clause (ii) is not therefore attracted. The writ petitioner estimated the turnover figure by arriving at the consumption of the bulk drug in various formulations and by multiplying the same by the MRP (Maximum Retail Price). The ORG data relating to sales of formulations was furnished.

The stand of the Central Government is that production data was not available for the year 1989-90 and the turnover of the bulk drug was determined by the expert group on the basis of the landed cost of imports during the year to the tune of Rs. 322.50 lacs. As there was only one formulator as reported in ORG survey of March, 1990, monopoly situation was considered to be existing "since one formulator was having 100% market share as on 31-3-1990". Disputing the assertion of the writ petitioner that as per ORG data furnished in Ext. F to the writ petition, there was no single formulator having 90% or more market share in retail trade, it is pointed out in Paragraph (iv) of the counter-affidavit that Ext. F includes formulations based on the bulk drugs other than Glipizide. It is further stated in the same para of the counter that there is only one formulation, namely, Glynase based on Glipizide and in respect of that, the writ petitioner had 100% market share.

Thus, the dispute mainly centres round the quantum of turnover.

The High Court observed that "even assuming that the petitioners were the sole manufacturers of the said drug, as the turnover was below Rs. 100 lacs, the monopoly situation, as envisaged in para 22.7.2 (ii) of Drug Policy, 1994 does not apply and as such the said drug ought to be kept out of the purview of DPCO, 1995". The plea of discrimination between this drug and another anti-diabetic

drug known as Insulin also found favour with the High Court.

8.1. We are of the view that the approach of High Court in considering the question of applicability of criteria laid down in the Drugs Policy in relation to each of the above drugs is not correct and the High Court failed to address itself to various crucial aspects as indicated below:

8.2. ORG data does not give full and clear picture of the turnover of bulk drug. ORG data relates to sales of formulations made either exclusively out of the bulk drug or in combination with other drugs. The formulations containing the particular bulk drug either wholly or in part reach the consumers through normal trade channels. The particulars of sales of such formulations entering the retail market are compiled by ORG. Bulk drug sales as such are not covered by ORG data. At best, from ORG data, it may be possible to deduce the consumption of bulk drug on estimated basis especially if it is the only drug used in that formulation. Moreover, direct sales to institutions such as hospitals and Government organizations are not reflected in ORG compilation. According to the certificate filed in some of the cases, such sales would be about 14%. It is also borne out by the same certificate issued by the Associate Research Director of ORG (Ext. 'C' to W. P. No. 1974 of 2000 and Annexure 1 to written submission) that out of this 86%, the ORG data covers about 90% of the retail market sales. This is what the certificate says:-

"The Retail Pharma Market in India contributes to 86% of the total market and the remaining 14% towards Hospital and Institutional sales.

I would like to confirm that out of this 86% of Retail Pharma Market, ORG-MARG covers around 90% through the Retail Store Audit (RSA)."

8.3. One more aspect which deserves notice is that from the ORG data, it may not be possible to ascertain whether the formulation is made up of single ingredient of the bulk drug or it has multi-ingredients. We have held that the Government of India's view that single ingredient formulators alone should be taken into account for the purpose of the criteria in clause (iii) of para 22.7.2 of Drugs Policy cannot be said to be against the policy or otherwise unreasonable.

8.4. Sales of bulk drugs effected during the year by bulk drug producers including some of the respondents herein would have furnished the best indicia of domestic sale turnover of bulk drug. But, those details were not disclosed. Secondly, if the bulk drug produced was consumed by any bulk drug producer or importer and the drug was sold in the form of formulations, the statistics regarding the quantum of bulk drug utilized in such formulations and the value thereof must have been within the knowledge or reach of writ petitioners and there is no good reason why they should withhold all this relevant information and harp on ORG data. There is no need to resort to guess-

work when the actual figures are available at the doorsteps of the respondents. Moreover, some of the respondents have arrived at the estimates by varying methods without reference to actual data available with them. For instance, in the case of the Drug Cyproflaxacin, we have adverted to different methods of calculation given by the writ petitioners which yield different results. If we go by the estimates of turnover made by the respondents, there is vast difference between the value of the bulk drug worked out by them and the sale value of formulations. Moreover, in relation to some of the drugs, there is vast variation between the quantity produced and imported and the quantity said to have been utilized in formulations sold in the market. These factors should have put the High Court on guard to subject the petitioners' version to close and critical scrutiny.

8.5. When the burden was on the writ petitioners to substantiate their plea of violation of Article 14 and when the plea predominantly rested on facts and figures, the High Court should have examined the intrinsic worth and credibility of the version put forward with regard to the turnover figures. The High Court oversimplified the whole issue by addressing itself to the only question whether there was effective rebuttal of the averments by the Union of India. The callousness on the part of the officials concerned in not meeting the points raised squarely and leaving the scope for ambiguity should not, in our view, be a ground to accept whatever is falling from the writ petitioners. The material placed before the Court should have been critically examined before reaching a conclusion that Article 14 is violated. The High Court should have also examined whether the writ petitioners withheld the relevant date which they were in a position to produce and if so, what would be its effect. None of these aspects received attention of the High Court. Before striking down the legislation, the High Court should have realized that those who challenged the legislation should lay firm factual foundation in support of their plea. The complaint of violation of norms set out in the policy leading to the alleged infraction of Article 14 depends, in the ultimate analysis, on facts and figures. As already observed, ORG data is neither comprehensive nor conclusive and moreover in regard to some of the drugs, the data does not in unequivocal terms, support the case of the writ petitioners. In such a situation, further probe and analysis was required which the High Court failed to do. The version of writ petitioners regarding the quantum of turnover was accepted to be correct on its face value. That apart, in the light of the clarification given by us that single ingredient formulators alone could be legitimately taken into account in the context of clause (iii), the need for reconsideration by the High Court becomes inevitable. We are, therefore, of the view that the crucial issues regarding the applicability of criteria laid down in para 22.7.2 of the Drugs Policy require reconsideration by the High Court from various angles indicated supra in the light of the legal position enunciated and the observations made in this judgment.

8.6. We have broadly indicated the aspects on which the High Court could have focused its attention before reaching the conclusion it did. Nothing preclues the High Court from having regard to other aspects or material which it considers relevant to test the correctness of the writ petitioners' claims. However, we would like to clarify one thing, if, on reconsideration, the turnover of any drug is found to be very close to the figure-400 or 100 lacs, as the case may be, the relevant criterion must be deemed to have been satisfied. As we said earlier, mathematical accuracy is not what is required.

8.7. There is one more point which we have to deal with, i.e., the alleged discrimination between

one drug and another. The High Court upheld such plea raised in rejoinder affidavit in relation to the drugs 'Cyproflaxacin' and 'Glipizide'. We unhesitatingly vacate the findings of the High Court in this regard because we are of the view that the reasons given by the High Court for upholding such plea are too tenuous to merit even prima facie acceptance.

8.8. In the case of Cyproflaxacin in W. P. No. 3449 of 1996 it was contended that two bulk drugs, namely, Mefenamic Acid and Amikacin Sulphate were wrongly and arbitrarily deleted from the DPCO, 1995. It is difficult to comprehended as to how there could be infraction of Article 14 merely because a few bulk drugs were excluded from the purview of DPCO on a reconsideration. The exclusion of some drugs, even if such exclusion is unjustified, cannot be a ground to claim exclusion of other drugs on the so called principle of parity. Logically, if the High Court's view has to be accepted, the entire Schedule should be invalidated for the simple reason that one or two drugs, which were not eligible for exclusion in the light of the policy guidelines were excluded, it would then lead to a starting result frustrating the very objective of regulating the price of essential drugs. That apart, the turnover figures of the said two drugs furnished by the writ petitioner and referred to by the High Court, do not establish that they fall within the policy guidelines. Regarding Mefenamic Acid, what all is stated in paragraph 16 of the rejoinder affidavit is that the turnover of this drug has been "over Rs. 4 crores between 1988-89 to 1991-92 and yet it was excluded for reasons not known to the petitioners". Nothing has been stated as to how the turnover for the relevant year was arrived at. No information was furnished regarding the number of bulk drug producers and formulators and their market share. Evidently, the petitioner made only a halfhearted attempt to put forward a plea of discrimination, but, it succeeded in its attempt. Coming to the other drug Amikacin Sulphate, even according to the petitioner, the import value of the drug in 1989-90 was Rs. 3.5 crores, which is much below the limit of Rs. 4 crores and even if there was a single formulator having a market share in excess of 40%, that does not make any difference. That apart, the Government of India clarified in one of the counter-affidavits filed in the High Court that on the scrutiny and verification of details submitted by the manufacturers, these two drugs were subsequently deleted from the First Schedule having regard to the criteria laid down in the policy.

We have, therefore, no hesitation in reversing the conclusion of the High Court that the exclusion of the said two drugs from DPCO amounted to hostile discrimination.

8.9. Regarding 'Glipizide', the plea of discrimination between this drug and another anti-diabetic drug known as insulin, found favour with the High Court. The High Court, in paragraph 90 of the judgment referred to the argument that Insulin having 441 lacs turnover as on 31st March, 1990 was included in DPCO of 1995, but subsequently excluded from price control and held that there was discrimination on that account. The High Court evidently proceeded on an erroneous assumption that Insulin was excluded from the schedule. The averments in paragraph 22 of the writ petition No. 5219/1996 are otherwise. The plea of discrimination was aimed at the drug known as Glibelclamide, which was excluded from the DPCO of 1987 and continued to remain excluded from the DPCO of 1995. The respondent did not even aver that the said drug had the turnover of more than 100 lacs and therefore it would fall within the mischief of clause (ii). On the basis of a bald plea, the infraction of Article 14 ought not to have been countenanced. The finding of the High Court in this regard is palpably wrong.

9. We now summarize the conclusions as under:

1. Where the Central Government as the delegate of legislative power announces a rational policy in keeping with the purposes of enabling legislation and even lays down specific criteria to promote the policy, the criteria so evolved become the guide-posts of its legislative action. While classifying the drugs for the purpose of price control, it is not open to the Government to flout or debilitate the set norms which it professed to follow in the interest of transparency and objectively. Otherwise, there will be an element of arbitrariness and the delegated legislation will not withstand the test of Article 14.

2. The expression 'turnover' in Drug Policy, 1994 represents the sale value of bulk drug sold as such or in the form of formulations.

3. Export sales should not be taken into account while computing turnover.

4. The sum total of production and imports of bulk drug cannot be equated to turnover, though they are not altogether irrelevant in calculating the turnover.

5. ORG data does not give exhaustive account of turnover of bulk drug. It may furnish the basis for estimating the turnover, but is not the sole guide.

6. For the purpose of criterion No. (iii) of the Drug Policy, the single ingredient formulators alone ought to be taken into account as clarified by the Govt. of India.

7. Burden lies on those who challenge the legislation on the ground of violation of Article 14 to make out their case by furnishing all the relevant material which is within their reach and knowledge. There should be frank disclosure of material facts, moreso, when the plea is founded on certain factual aspects. The mere vagueness or lack of clarity in the stand taken by the Union of India does not by itself advance the case of the writ petitioners.

8. The plea of writ petitioners ought to have been tested and subjected to scrutiny in the light of all relevant factors instead of merely considering whether the particulars furnished by the petitioners were effectively controverted or not. Such an approach of the High Court is wholly impermissible

while deciding the validity of legislation-plenary or delegated, from the standpoint of Article 14.

9. The plea of discrimination between one drug and another is unfounded and should not have been accepted by the High Court.

10. In the result, the judgment of the High Court is set aside and the writ petitions out of which these appeals arise shall stand restored to the file of the High Court and the High Court will have to consider afresh the relevant aspects concerning the criteria laid down in para 22.7.2 of the Drug Policy, 1994 in relation to each drug, having due regard to the observations made in the judgment. The High Court may endeavour to expedite hearing of the writ petitions.

11. The appeals are accordingly allowed without costs. We also consider it just and proper to give liberty to the appellant and the concerned statutory authorities to recover 50% of the 'overcharged' amounts pending fresh determination by the High Court. Accordingly, we direct stay of recovery of 50% of the 'overcharged' amount subject to the payment of remaining 50% within the period of four weeks from the date of communication of the amount payable by each of the writ petitioners.

Order accordingly.