REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 329 OF 2005

UNION OF INDIA & ORS. ….APPELLANTS

VERSUS

M/S. CIPLA LTD. & ANR. ….RESPONDENTS

WITH

CIVIL APPEAL NO. 4005 OF 2004

UNION OF INDIA & ORS. ….APPELLANTS

VERSUS

M/S. MARTIN & HARRIS LABORATORIES LTD. & ANR.

….RESPONDENTS

WITH

CIVIL APPEAL NOS.9609-9610 OF 2016

DR.REDDY'S LABORATORIES LTD. ….APPELLANT

VERSUS

SECRETARY, GOVT. OF INDIA & ANR. …RESPONDENTS

WITH

CIVIL APPEAL NO.9585 OF 2016

UNION OF INDIA & ANR. …APPELLANTS

VERSUS

ISHAAN LABS PVT. LTD. & ANR. …RESPONDENTS

WITH

CIVIL APPEAL NO.9586 OF 2016

UNION OF INDIA & ANR. …APPELLANTS

VERSUS

M/S REMIDEX PHARMACEUTICALS PVT. LTD. & ANR. …RESPONDENTS

AND

CIVIL APPEAL NOS.9561-9584 OF 2016

UNION OF INDIA & ANR. ETC.ETC. …APPELLANTS

VERSUS

M/S. JOHNSON & SMITH CO. & ANR. ETC.ETC. …RESPONDENTS

J U D G M E N T

Madan B. Lokur, J.

(a) The issues that arise in this batch of appeals are as follows:

(i) Whether the notification dated 13th July, 1999 issued by the Central Government under Paragraph 7 of the Drugs (Prices Control) Order,

1995 prescribing the norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion) and packing and process loss of packing materials in packaging was issued mechanically and without any application of mind or is it valid in law?

(ii) Whether the notifications dated 12th July, 2000, 12th July, 2001, 12th July, 2002 and 11th July, 2003 issued by the Central Government under Paragraph 7 of the Drugs (Prices Control) Order, 1995 re-notifying the norms prescribed on 13th July, 1999 were issued mechanically, without any application of mind and without re-determining the norms every year as required by the Drugs (Prices Control) Order, 1995 and are valid in law?

(iii) Whether various notifications issued by the Central Government fixing the retail price or ceiling price of formulations under Paragraphs 8 and 9 (as the case may be) of the Drugs (Prices Control) Order, 1995 without determining the norm for cost of packing material as required by Paragraph 7 of the Drugs (Prices Control) Order, 1995 are valid in law?

(iv) Whether fixing the retail price of a formulation under Paragraph 8 of the Drugs (Prices Control) Order, 1995 without first fixing the sale

price of a bulk drug under Paragraph 3 of the Drugs (Prices Control) Order, 1995 utilized in the manufacture of a formulation is valid in law?

2. We are primarily concerned with the Drugs (Prices Control) Order, 1995 (the DPCO 1995) and for historical reasons with the Drugs (Prices Control) Order, 1970 (the DPCO 1970), the Drugs (Prices Control) Order, 1979 (the DPCO 1979) and the Drugs (Prices Control) Order, 1987 (the DPCO 1987). All these Orders were issued by the Central Government in exercise of powers conferred by Section 3 of the Essential Commodities Act, 1955.

The appeals before us

3. The principal appeal before us and in which the leading submissions were made is **Civil Appeal No. 329 of 2005** filed against Cipla. This appeal is directed against the judgment and order dated 3rd March, 2004 passed in Writ Petition (C) No.41214 of 2003 by the Division Bench of the Allahabad High Court.

4. The challenge in the writ petition was to notifications issued by the Central Government on 12th July, 2000, 12th July, 2001, 12th July, 2002 and 11th July, 2003 re-notifying the norms prescribed by notification dated 13th July, 1999 issued under Paragraph 7 of the DPCO 1995 on the basis of which the retail price of formulations is fixed under Paragraph 8 of the DPCO 1995. It was held by the High Court that these notifications were issued mechanically and without any

application of mind.

5. The consequence of the decision of the Allahabad High Court is that about 40 notifications fixing the retail price and ceiling price of formulations have been invalidated.

6. The High Court also quashed the show cause notice dated 16th August, 2003 issued by the Inspector of Drugs in Varanasi alleging that Cipla had charged higher retail prices than those notified by various notifications. In view of this allegation, the Inspector of Drugs required Cipla to clarify whether it had any order from the National Pharmaceutical Pricing Authority exempting it from compliance with the price notifications and to give the quantities of the formulations sold during the period 1995 till date.

7. **Civil Appeal No. 4005 of 2004** is directed against the judgment and order dated 27th April, 2002 passed by the Division Bench of the High Court of Punjab & Haryana at Chandigarh in C.W. P. No. 15677 of 1999 filed by M/s Martin & Harris Laboratories Ltd.

8. Three issues have been raised in this appeal. The first is whether the inclusion of the bulk drug Diosmin in the First Schedule to the DPCO 1995 is valid or not. The second is whether the ceiling price fixed by the Central Government in the notification dated 20th July, 1998 of the Diosmin formulation was in accordance with the provisions of Paragraph 7 of the DPCO 1995. The third is whether the

ceiling price of the Diosmin formulation could have been fixed under Paragraph 9 of the DPCO 1995 without first fixing the maximum sale price of the bulk drug Diosmin under Paragraph 3 of the DPCO 1995.

9. By an order dated 15th September, 2016 we had declined to go into the first question. We had remanded the matter back to the High Court to reconsider the issue in the light of the decision rendered by this Court in ***Secretary, Ministry of Chemicals & Fertilizers, Government of India v. Cipla Ltd & Others***.[1]

10. As far as the second question is concerned, it is really somewhat similar to the principal issue raised by Cipla, while the third question is quite independent.

11. **Civil Appeal No. 9585 of 2016** filed by the Union of India arises out of judgment and order dated 6th August, 2012 passed by the Division Bench of the High Court of Karnataka at Bangalore allowing Writ Petition (C) No. 6585 of 2004 filed by Ishaan Labs Pvt. Ltd. & another.

12. The first issue raised in this appeal pertains to the validity of the notification dated 11th July, 2003 issued by the Central Government re-notifying the norms for conversion cost, packing and process loss earlier prescribed by the notification dated 13th July, 1999. In this context, the contention of Ishaan Labs is that the notification dated 11th July, 2003 was issued by the Central Government

[1] (2003) 7 SCC 1

mechanically and without any application of mind and that it was rightly quashed by the High Court.

13. The second issue is regarding the validity of the notification dated 3rd September, 2003 fixing the ceiling price of Glipizide formulations under Paragraph 9 of the DPCO 1995. This is consequential to the first issue. The contention of Ishaan Labs is that the requirements of Paragraph 7 of the DPCO 1995 were not adhered to and, therefore, the notification dated 3rd September, 2003 is liable to be struck down.

14. **Civil Appeal No. 9586 of 2016** and **Civil Appeal Nos. 9561-9584 of 2016** arise out of a common judgment and order dated 30th October, 2012 passed by the Division Bench of the High Court of Karnataka at Bangalore in a batch of Writ Appeals and Writ Petitions including those filed by Remidex Pharmaceuticals Pvt. Ltd. and Johnson & Smith Co. & Another. By the impugned judgment and order, the High Court effectively followed its earlier decision dated 6th August, 2012 in W. P. No. 6585 of 2004 filed by Ishaan Labs Pvt. Ltd.

15. The High Court dealt with and struck down the validity of several notifications fixing the ceiling price of formulations under Paragraph 9 of the DPCO 1995. These notifications were struck down because they were based on notifications issued under Paragraph 7 of the DPCO 1995 which in turn were struck down because the requirements of Paragraph 7 of the DPCO 1995 were not

adhered to. The correctness of this decision is before us.

16. One additional contention urged on behalf of one of the respondents (M/s Okasa Limited) is that small scale industries were exempted from the operation of Paragraph 8 of the DPCO 1995 (relating to the retail price of formulations) by a notification dated 2nd March, 1995. It was submitted that fixing the ceiling price of formulations under Paragraph 9 of the DPCO 1995 was a collateral attempt to bypass the effect of the exemption notification dated 2nd March, 1995 and deny its benefit to small scale industries.

17. **Civil Appeal Nos. 9609-9610 of 2016** arise out of judgment and order dated 16th April, 2004 passed by the High Court of Judicature, Andhra Pradesh at Hyderabad in Writ Petitions Nos. 18507 of 1996 and 645 of 1997 filed by Dr. Reddy's Laboratories Ltd.

18. Dr. Reddy's Laboratories manufactures the bulk drug Norfloxacin and formulations from the said bulk drug. The challenge in the High Court was to a notification dated 13th December, 1996 issued under Paragraph 3 of the DPCO 1995 fixing the price of the bulk drug Norfloxacin at Rs.2162/- per kilogram. However, prior to that on 27th December, 1995 the ceiling price of formulations from the bulk drug Norfloxacin was fixed under Paragraph 9 of the DPCO 1995. This notification was also challenged in the High Court. The High Court found no merit in the writ petitions and dismissed them.

19. The primary submission made before us by learned counsel appearing on behalf of Dr. Reddy's Laboratories was that the ceiling price of the Norfloxacin formulations could not be fixed prior to fixing the maximum sale price of the bulk drug Norfloxacin under Paragraph 3 of the DPCO 1995. It was also contended that the requirements of Paragraph 7 of the DPCO 1995 were not adhered to while notifying the ceiling price of Norfloxacin formulations.

Brief background

20. The core issue in this batch of appeals relates to the interpretation and application of Paragraph 7 of the DPCO 1995 and Paragraphs 8 and 9 of the DPCO 1995 – the extent of flexibility available to the Central Government in fixing the retail price and ceiling price of formulations and the rigidity expected by the statutory Order. The specific issue in these appeals relates to the validity of various notifications prescribing the norms for calculating the retail price of formulations under Paragraph 7 of the DPCO 1995 for the purposes of Paragraphs 8 and 9 of the DPCO 1995.

21. Paragraph 7 of the DPCO 1995 reads as follows:

> "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.) x (1+MAPE/100) + ED.
>
> 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;

"MAPE" (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 customs duty and clearing charges." [Emphasis supplied]

22. A perusal of the above provision would show that for calculating the retail price of formulations, the five determining factors are material cost, conversion cost, packing material cost, packing charges and maximum allowable post-manufacturing expenses (or MAPE). During the hearing of these appeals, there was no discussion at all about determination of material cost or MAPE. It

must, however, be mentioned that in one of the appeals a submission was made that the retail price of a formulation could not be fixed without first determining the maximum sale price of a bulk drug in terms of Paragraph 3 of the DPCO 1995. That apart, there was no dispute or grievance made about material cost and MAPE. The dispute centred round fixing the norms for conversion cost, packing material cost and packing charges "every year". There was also a question raised in one of the appeals that in the absence of the cost of packing material being fixed as a norm, the formula for fixing the retail price of formulations under Paragraph 7 of the DPCO 1995 could not operate.

23. According to the Central Government, the norms fixed under Paragraph 7 of the DPCO 1995 have been fixed after due application of mind to the available material and despite the lack of any effective cooperation from the manufacturers/formulators in disclosing information that could have been of further assistance to the Central Government. Additionally, according to the Central Government if the manufacturers/formulators were aggrieved by the retail price and ceiling price fixed on the basis of the norms, they had the remedy (which they did not avail) of having them revised in accordance with the provisions of the DPCO 1995.

24. Before discussing the historical background leading up to the dispute before us, it is necessary to state that there is no dispute that earlier the norms were fixed

under Paragraph 6 of the DPCO 1987 by a notification dated 17th February, 1989 issued by the Central Government and later updated by another notification dated 15th July, 1993 pursuant to the recommendations of the Sankaran Committee. There is no challenge to the 1989 or the 1993 norms.

25. However, it is significant that the norms prescribed by the February 1989 notification pertained to conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging. Norms were not prescribed for cost of packing material. Similarly the July 1993 notification prescribed norms only for conversion cost and packing charges. It did not prescribe any norms for process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging or for cost of packing material.

26. Paragraph 6 of the DPCO 1987 is as follows and its contrast with Paragraph 7 of the DPCO 1995 with reference to determination of norms "from time to time" and "every year" can be easily seen:

> "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.) x (1 + MAPE/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 and includes process loss, **as 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,

"MAPE" means Maximum Allowable Post-Manufacturing Expenses including trade margin referred to in para.7,

"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 50 per cent of the landed cost.

Explanation. — For the purposes of above proviso, "landed cost" shall mean the cost of import of drug inclusive of customs duty and clearing charges." [Emphasis supplied]

27. We have been informed by the learned Solicitor General that today as many as 2147 formulations are manufactured in the country. The number might have been less during the period that we are concerned with, but surely the number would not have been significantly less. But be that as it may, there can be no doubt that the Central Government is concerned with the retail price and ceiling price of an extremely large number of formulations. To this may be added the 'complication' of the variety in which the formulations could be available. These could be in the form of plain tablets, coated tablets, sustained release tablets (all

three categories being small, medium, large and extra large); capsules (soft, hard and sustained release); liquids (syrup and elixirs, suspension, emulsion and malts and paediatric drops); ointments and creams; ampoules; sterile liquid vials; non sterile dry powder and granules; sterile dry powder and sterile dry powder liophylised. The packing of the formulations could be in strips of 10 or 15 or 20 or more or in bottles, or tubes or vials etc. In other words, the task of fixing the retail price and ceiling price of formulations is not only gargantuan but also extremely complex.

28. It is also important to remember that the purpose of fixing the retail price and ceiling price of formulations is to make them affordable and ultimately benefit the consumer of medicines. Profits earned by manufacturers/formulators are secondary and 'profiteering' is certainly out of the question. The preamble to the Essential Commodities Act, 1955 provides:

> "An Act to provide, **in the interests of the general public**, for the control of the production, supply and distribution of, and trade and commerce, in certain commodities." [Emphasis supplied by us].

There is no dispute that "drugs" as defined in the Drugs and Cosmetics Act, 1940 is an essential commodity in view of Section 2A read with the Schedule to the Essential Commodities Act, 1955.

Historical background beginning with the Sankaran Committee

29. The DPCO 1987 was issued on 26th August, 1987. Soon thereafter, a

Committee called the Sankaran Committee was set up on 2nd September, 1987 the occasion being that the norms prescribed for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging were last announced a decade ago in 1979 in accordance with the provisions of the DPCO 1979. The Sankaran Committee was set up for a quick revision of the norms and it was mandated to submit its report within three months. It is important to note that Paragraph 6 of the DPCO 1987 provided for the calculation of retail price as per a given formula. One of the factors in the formula is P.M. meaning "cost of the packing material used in the packing of concerned formulation and includes process loss, as a norm fixed from time to time by notification in the Official Gazette in this behalf." Notwithstanding this, the norm for cost of packing material was not prescribed in the notification dated 17th February, 1989 and no objection was apparently raised by any manufacturer of formulations or formulator – at least no objection was brought to our notice by anybody. In other words, as far as the drug industry is concerned the formula given in Paragraph 6 of the DPCO 1987 and Paragraph 7 of the DPCO 1995 could be operated without prescribing the norm for cost of packing material.

30. The Sankaran Committee held its first meeting on 22th September, 1987. During the course of deliberations, it sought the views of the drug industry

associations such as the Organization of Pharmaceutical Producers of India (OPPI) and the Indian Drug Manufacturers Association (IDMA) to enable it to satisfactorily complete its task. The Sankaran Committee also issued a questionnaire to 23 companies (manufacturers/formulators) soliciting some information. Subsequently, the questionnaire was sent to another 12 such companies since the response from the earlier set of 23 companies was somewhat lukewarm.

31. After analyzing all the material available before it, hearing the drug industry associations and visiting a few companies to be acquainted with the actual conversion and production centres in the field, the Sankaran Committee submitted its Report sometime in April, 1988.

32. A few observations from the Report of the Sankaran Committee need mentioning:

(i) The norms for conversion cost, packing charges, process losses for raw materials and packing material were originally notified sometime in 1974 under the DPCO 1970. These norms were re-notified as recommended by the Bureau of Industrial Costs and Prices (for short the BICP) on 3rd May, 1979 vide S.O. No. 259(E) under the DPCO 1979. These norms as notified on 3rd May, 1979 were essentially the same as notified in 1974.

However, with regard to the cost of packing materials, norms were not fixed under the DPCO 1979. The Sankaran Committee observed in this regard as follows:

> "4. No norms have been fixed under DPCO 1979 for cost of packing material. This fluctuates and differs from product to product. The BICP is at present guided by cost ceilings which are reviewed periodically. These have not been statutorily notified as norms. Calculations of these norms are very difficult as a large number of large pack sizes are involved. It is therefore recommended that till such time the norms are worked out by BICP, and these are notified, the actuals may be allowed."

(ii) The Report noted that "While notifying the norms under the Drugs (Prices Control) Order, 1979 the Bureau of Industrial Costs and Prices reviewed the earlier norms by examining the information provided by about 7 of the 36 manufacturers who were asked to submit data and concluded that the norms notified in 1974 were adequate and did not call for any revision."

In other words, the manufacturers/formulators did not provide the necessary information and assistance even to the BICP in its endeavour to determine the norms for conversion costs and packing charges.

33. Faced with this situation, the Sankaran Committee took the following view on the basis of available information:

(a) **Conversion cost:** The increasing cost of production and conversion costs have led to a situation where the existing norms cover less than

50% of the actual costs. In the case of public sector companies like IDPL and HAL they cover less than 30% of the actual costs. Accordingly, it was generally recommended that conversion cost to be increased by 100% over the existing norms.

(b) **Packing charges:** By and large, a similar view (as above) was taken with regard to packing charges namely that the existing norms be increased by 100%.

(c) **Process loss of raw materials and packing materials:** Perhaps due to improved technological processes and efficiencies in manufacturing techniques, the data submitted by the manufacturers "though hesitantly" clearly indicated that the existing norms for process loss of materials were on the higher side. Accordingly, a reduction of 1% (broadly – we are not going into specifics since it is not necessary) was recommended in the norms for process loss on raw materials and packing materials.

(d) **Packing material:** As mentioned above, the cost of packing materials was not fixed under the DPCO 1979 since the cost of packing material fluctuates frequently and also differs from product to product. It was observed that an exercise is being undertaken by the BICP in this regard and until the ceiling cost of packing material is updated by the BICP, it was recommended by the Sankaran Committee that the actuals may be

allowed.

34. Paragraphs 11 and 12 from Chapter 5 (titled Recommendations) of the Report of the Sankaran Committee are important for appreciating why the cost of packing materials was not fixed. These paragraphs read as follows:

> "11. As regards the norms for packing materials costs, the Industry Associations (IDMA & OPPI) represented that packing material costs vary from product to product depending on the nature of the product being marketed and fixation of norms for such type of products may not be justifiable. **They, therefore, requested the Committee to consider actual cost of packing materials.**
>
> 12. The Committee notes that cost of packing material fluctuates frequently and also differs from product to product. **Due to this reason and the fact that fixation of norm for this is very difficult, no norms were fixed in 1979.** No norms have been subsequently recommended by the BICP. The current practice of the BICP is to regulate the claims for packing material cost on the basis of ceiling cost for various packages as approved by Drugs Prices Review Committee. These ceiling costs, we understand, are reviewed periodically by the BICP. While recommending prices of formulations, the BICP is being guided by these ceilings. **However, these have not been notified as norms though statutorily required.** It is obvious that calculation of norms are very difficult as large number of pack sizes and large number of dosage forms of different material are in the market. The Committee recommends that the BICP be requested to up-date the ceilings and recommend to the Department of Chemicals and Petrochemicals that these may be notified as norms. Till such time as these are communicated by the BICP, the actuals may be allowed. It is recommended that while the norms are notified this provision that actuals for packing material costs are allowed till further norms are notified, be included. This will provide for meeting the statutory requirements also. While allowing the actuals it will be necessary to insist on a certificate from the State Drug Controller that a particular dosage form is being packed by a particular material." [Emphasis supplied by us].

35. Paragraph 16 of the Report is relevant for appreciating the strategy for implementation of the recommendations made by the Sankaran Committee and this reads as follows:

> "16. The newly recommended norms are in Annexure VIII. The revised norms are bound to lead to some increase in the prices of formulations. In Annexure IX this Committee has tried to work out the likely impact of recommended norms in the prices of a few select formulations. The effect on 37 representative formulations of various companies is included here. The price increase if the entire recommended norms are announced, varies from 0.45 percent to 47.71 percent. These formulations cover almost all the dosage forms. In view of the substantial increase in the price of a few formulations, this Committee recommends that instead of giving full increase in the norms, that is, implementing the revised norms immediately, **it is suggested that 50% of the increased norms may be announced immediately. At the end of the first year, a further 25% increase in norms may be implemented, the remaining 25% being added at the end of the second year.** The likely effect of such staggered implementation of the revised norms shall result in increase of 0.36% to 26.32 percent change in the existing prices." [Emphasis supplied by us].

36. A perusal of Annexure VIII indicates that the Sankaran Committee recommended fixing of norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials. Significantly, norms for cost of packing materials were not fixed by the Sankaran Committee for the reasons given above and instead, it was recommended that provision for actual cost of packing materials be allowed, as recommended by the drug industry. The discussion in the Sankaran Committee points to a two-fold significance - that from 1979 onwards, at least, the cost of packing material (as a norm) had not been prescribed and that the drug

industry was apparently quite satisfied with the provision of actuals for packing material which could certainly not be to the disadvantage of anybody in the drug industry.

37. The Central Government accepted the Report of the Sankaran Committee and a notification was issued on 17th February, 1989 by which the norms for conversion cost, for packing charges and for process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging were notified with effect from 1st April, 1989.

38. It appears that even though the Sankaran Committee recommended an increase in conversion cost at 25% in the first year (over and above an immediate increase of 50%) and at 25% in the second year and that recommendation was accepted by the Central Government, but it was not implemented. Apparently realizing this, in exercise of powers conferred by Paragraph 6 of the DPCO 1987, a notification dated 15th July, 1993 was issued. By this notification, the norms for conversion cost and for packing charges were increased by 50% in one stroke. The increase in the norms for conversion cost as mentioned in the notification dated 15th July, 1993 tallies with the recommendations made by the Sankaran Committee in Annexure VIII of its Report. However, no change was effected in the norms for process loss of raw materials (other than packing materials in conversion and

packing) and process loss of packing materials in packaging which continued to be as per actuals.

39. At this stage it may be mentioned that pursuant to the study or exercise conducted by the BICP, the Central Government approved the ceiling price of packing material cost and made it applicable from 7th July, 1994. However, this was not notified in the Official Gazette.

Drug Policy, 1994

40. The Government of India announced the new Drug Policy which was issued on 15th September, 1994. Some of the relevant paragraphs of the Policy relate to the background of the earlier Drug Policy of 1986, the necessity of setting up an independent body of experts to be called the National Pharmaceutical Pricing Authority (NPPA) to do the work of price fixation of drugs and formulations and the establishment of a National Drug Authority by a separate Act of Parliament to perform a variety of specified functions. It is not necessary to detail the functions of the National Drug Authority except to say that despite a lapse of more than 20 years the National Drug Authority has not yet been set up.

41. Subsequent to the new Drug Policy of 1994, the DPCO 1995 was notified on 6th January, 1995 by the Central Government and the NPPA was set up on 29th August, 1997.

Masood Committee

42. Instead of taking immediate steps to set up the NPPA in terms of the new Drug Policy, the Central Government set up a Norms Review Committee (called the Masood Committee) on 24th April, 1995 to review the norms recommended by the Sankaran Committee. The terms of reference of the Masood Committee were as follows:

> "The terms of reference of the Committee will include review of the existing norms relating to Conversion Cost (CC), Packing Costs (PC) and Process Losses and working out of norms for Packing Material (PM) and also giving recommendations in regard to related matter such as norms for pro-rata price fixation on the basis of ceiling prices of formulations.
>
> The Committee will submit its recommendations to the Government within a period of 2 months from the date of issue of this office memorandum."

43. During the course of submissions before us learned counsel for Cipla was intensely critical of the Report submitted by the Masood Committee on 31st August, 1995 and, therefore, some broad details of the contents of the Report are necessary.

44. The Masood Committee was of the view that it was necessary to elicit the views of the drug industry before making its recommendations. Accordingly, a meeting was held on 31st May, 1995 in which representatives from various drug industry associations participated. The industry associations represented were the Indian Drug Manufacturers Association (IDMA), the Organization of Pharmaceutical Producers of India (OPPI), All India Small Drug Manufacturers Association (AISDMA) and All India Small Scale Pharmaceutical Manufacturers

Association (AISSPMA). In that meeting the industry associations made the following demands:

a) Ad-hoc relief based on inflation/increase in consumer price index since 1987 should be given.

b) Associations felt that a simplified questionnaire would meet the requirements to give maximum benefit in fastest time and no detailed exercise was required.

c) It was suggested that Cost Audit Reports may be made use of for broad categories of dosage form and escalations be worked out over the existing norms.

d) Additional costs on account of GMP [Good Manufacturing Practices] should be given.

45. Prior to the above meeting, the Masood Committee had prepared a questionnaire for eliciting information from various companies for the purposes of carrying out its duties. This questionnaire (referred to in (b) above) was discussed with the industry associations on 31st May, 1995 when they requested for time to examine it and assured the Masood Committee that their suggestions on the questionnaire would be submitted latest by 8th June, 1995. However, no suggestions were received by the Masood Committee which then issued the questionnaire on 9/12 June, 1995 requesting the manufacturers/formulators to furnish the requisite information by 30th June, 1995. Thereafter, some representations were received requesting for the deletion of some questions but this was not acceded to by the Masood Committee. It is recorded in the Report of the Masood Committee that no unit furnished replies to the questionnaire despite

reminders and requests to the industry through the Department of Chemicals and Petrochemicals for extending necessary cooperation to the Masood Committee. The absence of any response to the questionnaire was perhaps due to the demand of the associations [demand (c) above] to make use of the Cost Audit Reports for working out escalations over the existing norms.

46. Faced with this situation, the Masood Committee had no option but to examine the Report prepared by the Sankaran Committee and also the available Cost Audit Reports (hereinafter referred to as the CARs) for the latest years, namely, 1993-94.

47. With regard to the norms for **conversion cost and packing charges**, the Masood Committee observed in Chapter 3 of its Report that it examined the data in respect of 16 companies which had apparently submitted some information to the Sankaran Committee out of 35 companies to whom the questionnaire had been sent. [Earlier even the Sankaran Committee and the BICP did not receive full cooperation from the drug industry]. The Masood Committee was of the view that since the absorbed cost of conversion costs and packing charges was in the range of more than 50% and up to 82% for 7 out of 16 companies, the conclusion earlier arrived at that absorption was to the extent of 50% of the then prevailing norms appeared to be arbitrary. On an examination of the materials before the Sankaran Committee, the conclusion arrived at by the Masood Committee was that it was not

possible to review the norms. The Masood Committee therefore decided to look into CARs of 1993-94. It was noted that the CARs were available in respect of only 6 companies and some discrepancies were noted in the information made available in the CARs. One of the criticisms made by learned counsel for Cipla was that the Masood Committee considered the CARs of only two companies and that too for only three or four formulations and therefore the conclusion that costs as given in the CARs "have not been allocated in accordance with the established Costing procedures but in an arbitrary manner" was not justified.

48. Notwithstanding the (disputed) discrepancies, the data available in the CARs was analyzed by the Masood Committee to determine whether there was an increase in the conversion cost and packing charges keeping in mind that the Sankaran Committee had based its conclusions on data available in 1985-86/1986-87. The analysis made by the Masood Committee gave a mixed picture of actual costs being equal, higher or lower than the existing norms for conversion cost with respect to various dosage forms. The Masood Committee came to a similar conclusion in the cost of packing charges also.

49. It was then concluded that if the cost allocation in the CARs was as per established costing procedures and the norms recommended by the Sankaran Committee were on a realistic basis, inflation during the period 1986-87 to 1994-95 and increase in energy and other costs should have resulted in the actual

conversion cost being higher than the existing norms. Accordingly, the Masood Committee was of the view that the data available in the CARs could also not be made use of.

50. The Masood Committee also considered other factors including profitability situation as per the CARs, the revision of packing material ceilings from 7th July, 1994, a decrease in total formulation activity coming under price control from 70% under the DPCO 1987 to 50% under the DPCO 1995 and uniform MAPE of 100% under the DPCO 1995 as against 75% and 100% MAPE under the DPCO 1987.

51. On the basis of the analysis and details available from the Report of the Sankaran Committee and the CARs, it was concluded by the Masood Committee that no case was made out for an increase in conversion cost and packing charges without a proper study. The question of an ad hoc increase also did not arise.

52. On the issue of **process loss on raw materials and packing materials**, it may be recalled that this had actually been reduced by the Sankaran Committee. On the basis of the CARs of the 6 companies that were available with the Masood Committee, it was concluded that with high production levels and better capacity utilization as well as new technological processes, the process loss was expected to come down. In any event, since no information was provided to the Masood Committee through the questionnaire sent to the industry and the companies, it was not desirable to recommend any ad hoc reduction in the existing norms. However,

the Masood Committee expressed the view that the existing norms for process loss on raw materials and packing materials were on the high side.

53. With regard to the **packing material cost**, as already noted above, these were subject to ceilings as worked out and recommended by the BICP and approved by the Central Government from time to time. The last such approval was on 7th July, 1994. The Masood Committee decided to adopt packing material costs (without process loss) "as might be available from the study by Drug Cell [of the BICP] and utilise the same for developing norms for Packing Material Cost."

54. The Masood Committee gave its conclusion in Chapter 7 of its Report. Some of the relevant conclusions are given below (not in seriatim):

(i) The Sankaran Committee after estimating the CC & PC [conversion cost and packing charges] for the industry recommended that the differential between the estimated CC and PC and the then existing [norms?], be given in phases. It implied that the industry got the assessed CC & PC for 1986-87 in July 1993 when the third and final increase was allowed. In other words, the industry should have suffered losses on a continuing basis at increasing levels i.e. years subsequent to 1986-87, on two counts (a) assessed CC & PC for 1986-87 was not allowed to be absorbed fully and (b) due to impact of general inflation subsequent to 1986-87.

(ii) The Committee has also examined the actual CC & PC as given in the Cost Audit Reports of six companies with a view to develop norms for the same as suggested by Industry Associations. Analysis of the data did not reveal any logical correlation of cost elements over a large range of products. Discrepancies and anomalies observed in the data have already been described in Chapter 3.

(iii) Non-response to the questionnaire by industry and their insistence that no detailed exercise should be undertaken by the Committee further lends support to the conclusion arrived at by the Committee that the possible cushion in the existing norms and in other inputs more than offsets the

inflation during the period 1986-87 to 1994-95. The Committee, therefore, recommends that no further escalation should be given till replies to the Questionnaire are received and an in-depth analysis done by an Expert Group to assess the escalation/de-escalation required in the existing norms of not only CC, PC and PL (both for raw materials & packing materials) but also overages.

(iv) The other terms of reference …… have been dealt with in Chapters 5 and 6. Based on the information furnished by the industry in response to the questionnaire earlier issued by the BICP, norms for packing material (with process loss) only could be worked out.

55. The recommendations made by the Masood Committee in connection with the terms of reference were given in Chapter 8 of the Report and the relevant recommendations are:

a. On the basis of analysis described in relevant chapters, the revision of existing norms for CC, PC and PL in accordance with established procedures of costing cannot be done without evaluation of the latest data. Taking into account all the relevant factors, the Committee is firmly of the view that **there is no case for any increase in the present norms without study**. Consequently, the question of an ad-hoc increase, does not exist at all.

b. **Norms for packing material costs (without process loss) have been worked out as given in Annex. 5.3 Implementation of these norms in isolation is not recommended** keeping in view the overall profitability scenario of the industry.

c. xxxxx

d. (a) **In-depth study in regard to CC, PC, PL and also overages is necessary** for revision of existing norms/ceilings on a scientific basis and in accordance with the established procedures of costing.

(b) Para 7 of DPCO, 1995 stipulates **yearly revision of norms** for CC, PC, PM and PL and does not provide for any ad-hoc increases. **This calls for developing indices based on in-depth study and effecting revision of all the norms simultaneously every year**.

(c) xxxxx [Emphasis supplied by us]

56. It will be seen from a reading of the Report of the Masood Committee that the industry was not at all inclined to furnish information to the Masood Committee and the exercise which it was tasked to perform could be carried out only on the basis of the Report of the Sankaran Committee and the CARs of 6 companies. According to the Masood Committee this material was clearly inadequate to arrive at any definite conclusion, necessitating the recommendation of setting up an Expert Group to complete the task. Apart from a criticism of the Report, the submission made by learned counsel for Cipla was that all the information required by the Masood Committee was available in the CARs which were with some Ministry or the other of the Central Government, if not with the Ministry of Industry or the Department of Company Affairs. All the CARs could easily be requisitioned by the Masood Committee to fix the norms and this was possible even if the industry did not co-operate with the Masood Committee, more particularly since price fixing is a legislative exercise required to be carried out independently.

57. However, the Masood Committee determined the norms for cost of packing material (without process loss) and these norms were mentioned in Annexure 5.3 of the Report of the Masood Committee' but the Central Government decided not to prescribe the norms for cost of packing material and accepted the view of the

Masood Committee that prescribing the norms for cost of packing material in isolation (and without process loss) would not serve any purpose.

Jharwal Committee

58. After the Report of the Masood Committee was submitted on 31st August, 1995 it appears that there was little or no activity from the side of the Central Government or from the side of the industry in respect of fixing the norms "every year" under the DPCO 1995. Our attention has been drawn to an unspecified "demand" made perhaps sometime in early 1997 for a revision in the norms in the cost of packing material. This was brought out in an official file noting dated 2nd April, 1997 followed by another official file noting of the same date suggesting acceptance of the Report of the Masood Committee, including the recommendation that the norms for cost of packing material (without process loss) could not be implemented in isolation. It also appears from the official file notings placed before us by the learned Solicitor General that the constitution of the NPPA was expected and one of the suggestions put forth in the official file notings was to await the constitution and functioning of the NPPA and authorize it to conduct a thorough study of the type recommended by the Masood Committee.

59. The NPPA was eventually constituted on 29th August, 1997. We are not aware of the activities of the NPPA thereafter except that a meeting was held on 27th January, 1998 by the NPPA with representatives of IDMA and OPPI where

there was a discussion for the need to revise the norms of conversion cost and packing charges. This was followed by a letter dated 27th April, 1998 sent by the industry indicating that the existing norms were based on the data available in 1988 which had become outdated and obsolete and since then there had been a significant increase in the cost of various items that go into the calculation of these norms.

60. Apparently as a result of the dialogue and correspondence between the NPPA and the industry, a Committee called the Jharwal Committee was set up on 8th October, 1998. It may be noted that Dr. Jharwal was the Member Secretary of the NPPA. In its Report submitted on 5th April, 1999 the Jharwal Committee noted that the **packing material cost** ceiling had been revised on 7th July, 1994 by the BICP and thereafter it was revised by the NPPA in February 1998 (again with no objection from the drug industry). Consequently, the only issue addressed by the Jharwal Committee was the fixing of norms for conversion cost, for packing charges and for process loss.

61. The Jharwal Committee had earlier prepared a draft questionnaire (as was done by the Sankaran Committee and the Masood Committee) sometime in October 1998 and circulated it to the industry so that suggestions could be made for appropriate modifications in the questionnaire. The Jharwal Committee met on 28th November, 1998 and finalized the questionnaire in the absence of an adequate

response from the industry. In the next meeting held on 12th December, 1998 the industry expressed its inability to furnish the data in respect of the installed capacity of the companies.

62. Be that as it may, the information required in terms of the questionnaire prepared by the Jharwal Committee was not at all forthcoming from the industry. Faced with these difficulties and in the absence of cooperation from the industry, the Jharwal Committee considered the suggestion of the Department of Chemicals and Petrochemicals for a partial increase in the existing norms of **conversion cost** and **packing charges** based on the inflation factors and till a full-fledged cost study is finalized. Acting upon this suggestion the Jharwal Committee considered several factors as mentioned in its Report as well as the wholesale price index and other relevant factors and felt that it would be adequate and reasonable to compensate for the assessed increase in conversion cost and packing charges only to the extent of 50% of the inflation factor which worked out to 4.5%. This was criticized by learned counsel for Cipla as being totally unrealistic.

63. As already mentioned above since the **packing material cost** had already been revised in February 1998 (after July 1994) no recommendation was made by the Jharwal Committee in this regard. As regards **process loss** the Jharwal Committee felt that there was no appropriate measure available to suggest any ad hoc revision in the absence of factual data and it was suggested that the process

loss may be re-notified at the existing level till revised on the basis of a fresh study already in progress through the NPPA.

64. One important observation made by the Jharwal Committee in its Report relating to the non-cooperation of the industry and its suggestion to defer a detailed study is required to be quoted. This reads as follows:

> "It would also be pertinent to mention that though the Industry Associations (OPPI and IDMA) were impressed upon the need to advise their member companies to furnish the required data to NPPA as early as in October, 1998, there has been a luke-warm response and indifference on their part in furnishing the data. They have even suggested NPPA to defer the detailed study, which is already in progress. NPPA is continuing its effort to complete the study and accordingly sent couple of reminders to the manufacturers, advising them to submit the data expeditiously. However, the response so far has been far from satisfactory."

65. The conclusions of the Jharwal Committee were to the effect that the existing norms of conversion cost and packing charges may be revised by giving an ad hoc increase of only 4.5% in each as an interim measure; there is no need to revise the said norms on an ad-hoc basis beyond 4.5% unless warranted by the outcome of a detailed study already in progress; if the industry does not furnish the required data the same norms may be re-notified every year to meet the requirements of the DPCO 1995 and the norms for process loss may be re-notified at the existing level till revised on the basis of the fresh study already in progress.

66. The Report of the Jharwal Committee and its acceptance by the Central Government led to the issuance of a notification S.O. 578 (E) dated 13th July, 1999

under Paragraph 7 of the DPCO 1995. Through this notification fresh norms were prescribed for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion) and packing and process loss of packing materials in packaging for the purposes of Paragraph 7 of the DPCO 1995. Norms for cost of packing material were not prescribed, apparently since this was permitted on actuals.

Review of the three Reports

67. A review of the Report of the Sankaran Committee, the Report of the Masood Committee and the Report of the Jharwal Committee bring out the following salient points:

1. The drug industry was unwilling to extend its full cooperation in furnishing data required by the Central Government for prescribing the norms as required by the DPCO 1987 and the DPCO 1995. One of the possible explanations for this reluctance put forth by learned counsel for Cipla (it was clarified that Cipla was not a member of any drug industry association after a particular point of time) that the members of the drug industry might not have been willing to part with confidential information which could be used by competitors.
2. Faced with the reluctance of the drug industry to part with necessary data the Central Government had no option but to carry out its exercise of

prescribing norms in terms of Paragraph 6 of the DPCO 1987 and Paragraph 7 of the DPCO 1995 for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion) and packing and process loss of packing materials in packaging. This might have involved some element of ad hoc decision making and guess-work but that was necessitated by the circumstances confronting the expert bodies set up by Central Government.

3. The norms prescribed by the Sankaran Committee appeared to be adequate and actually provided a cushion but required a little tweaking at a later stage due to a variety of factors, including inflation. There does appear to be general acceptance by the drug industry of the norms prescribed pursuant to the Report of the Sankaran Committee. Similarly, there does appear to be general acceptance of the ad hoc measures taken post the Masood Committee and eventually the notification issued by the Central Government pursuant to the Report of the Jharwal Committee in respect of conversion cost, packing charges and process loss.

4. The issue of packing material cost was separately addressed by the Central Government through the BICP and also through decisions taken on 7th July, 1994 and February 1998. The norms for the cost of packing material were not prescribed or notified in the Official Gazette. However,

the drug industry was entitled to work out the cost of packing material on actuals, and it seemed quite satisfied with the result given that the ceiling was fixed in July 1994 and February 1998.

68. Norms were not prescribed "every year" as required by Paragraph 7 of the DPCO 1995 particularly for the years 1995-1996, 1996-1997, 1997-1998 and 1998-1999. We were informed that the "year" is from July to June of the following year. The learned Solicitor General sought to justify the absence of prescribing the norms "every year" as required by Paragraph 7 of the DPCO 1995 for the four years mentioned above. We will be dealing with the submissions in this regard at a later stage.

Exercise for subsequent years

69. Post the notification dated 13th July, 1999 the next stage for the Central Government was to notify the norms for **2000-2001**. This exercise appears to have been initiated with reference to the norms for the cost of packing material through a letter dated 6th October, 1999 issued by the NPPA to IDMA and similar letters to other associations. What is on record before us is the reply by OPPI to the NPPA of 11th January, 2000 to the effect that a meaningful response could be given if the existing norms for packing material costs were made available and some clarity brought regarding the basis for the ceiling fixed. This letter was viewed by the NPPA as yet another delaying tactic in providing the requisite information.

Apparently realizing this, OPPI addressed a letter to the NPPA on 9th March, 2000 to the effect that an "independent professional consultant" had been assigned the task "to facilitate expeditious compilation of the requisite data" to assist in the development of norms for cost for packing materials. Although it is not clear from the record, but it does appear that the data compiled (if any) by the independent professional consultant engaged by OPPI was not furnished to the NPPA.

70. Quite independently, a dialogue was initiated by the NPPA with the drug industry with regard to fixing the norms for conversion cost and for packing charges. It appears that the drug industry associations had engaged an independent consultant in this regard and a two page report given by the consultant was submitted to the NPPA by a letter dated 2nd March, 2000 by the associations.

71. We have seen the report and it is clearly inadequate. It was pointed out by the NPPA in a letter dated 23rd March, 2000 that no justification had been given in the report for the rise in the industrial average in respect of conversion cost and packing charges nor had any indication been given as to how the industrial average had been worked out as also the source of information.

72. No further material has been brought to our notice with regard to fixing the norms for the year 2000-2001 in terms of Paragraph 7 of the DPCO 1995.

73. As on earlier occasions and in the absence of any further information or data with the NPPA or the Central Government, a decision was taken towards the end of

June, 2000 to notify the existing norms for 2000-2001 without allowing for any change from the norms prescribed on 13th July, 1999. Accordingly, a notification being S.O. 660(E) dated 12th July, 2000 was issued and gazetted.

74. Similarly, for **2001-2002** what is placed before us by the Union of India is a two page official noting dated 9th July, 2001 referring to the Report of the Jharwal Committee. The official file noting further records that despite requests by the NPPA to IDMA and OPPI requisite information was not forthcoming from October, 1998 onward. A reference was made to the letter dated 23rd March, 2000 and that no response to it had been received. In view of this, it was proposed (and that proposal was accepted) that the same norms as were prescribed on 13th July, 1999 may be re-notified as the norms for 2001-2002. There is no dispute that a gazette notification dated 12th July, 2001 was issued in terms of the decision taken.

75. The stalemate continued even thereafter for the next two years **2002-2003** and **2003-2004** with the NPPA and the Central Government insisting on a response to the questionnaires sent for collecting data for fixing the norms under Paragraph 7 of the DPCO 1995 and the reluctance of the associations to supply the data. This resulted in the norms prescribed by the notification dated 13th July, 1999 being re-notified for 2002-2003 by a notification dated 12th July, 2002 and for the year 2003-2004 by a notification dated 11th July, 2003. We do not think it necessary to detail the correspondence between the Central Government and the drug industry

except to say that the non-cooperation and dilly-dallying by the industry in providing necessary information and data continued throughout this period.

76. There were, however, three significant and distinguishing features during this period. The first was that the Central Government decided to take the services of and involve the Cost Accounts Branch of the Department of Expenditure in the Ministry of Finance to undertake a study for the development of norms for conversion cost, packing charges, and process loss. However, nothing substantive came out of this exercise by the Cost Accounts Branch. The second significant development was an unambiguous decision of the drug industry that the information required by the NPPA or the Central Government was already available in the Cost Audit Reports (CARs) of the various companies. The third was the clear view of the drug industry to not cooperate at all with the Central Government in the exercise of reviewing the norms for conversion cost, packing charges and process loss.

77. The Indian Pharmaceutical Association wrote to the NPPA on 9th March, 2002 to the effect that its Executive Council in a meeting held on 8th March, 2002 expressed its inability to participate in the exercise for a study to review the norms for conversion cost, packing charges and process loss.

78. Similarly, IDMA communicated to the Cost Accounts Branch on 10th July, 2003 that its Executive Committee had passed the following resolution:

> "All the major pharmaceutical companies are covered by cost records and cost audit. Hence a cost audit report duly audited by a practicing cost accountant is submitted by these companies to the cost audit branch, Department of Company Affairs, New Delhi. NPPA should be requested to use these readily available audited cost audit reports, for the purpose of revision of CC/PC norms, instead of asking the companies to again send the cost data in separate formats which will be voluminous and time consuming for the industry."

79. The Taxation and Pricing Policy Committee of OPPI, addressed a letter dated 22nd July, 2003 to the Cost Accounts Branch to the effect that the representatives of OPPI and IDMA had suggested in a meeting held on 5th July, 2002 with the NPPA that a study of the conversion cost and packing charges should be based on the CARs already available with the Central Government and that the study should be conducted on that basis.

80. The Cost Accounts Branch informed OPPI by a letter dated 2nd September, 2003 that a study based "entirely on the information available in the cost audit reports might result in the Government not obtaining a total picture of the actual conversion cost, packing charges and process loss in the drug formulation industry. Our aim, when we requested the industry for making available the cost data and other information vide our questionnaire, was to take into account the actual cost implications of all the factors in the drug industry and not restrict it to only those where the cost audit report is available." It was added that despite the availability of the CARs "it was considered appropriate to frame the questionnaire for seeking the company specific information/data relevant to the study under reference. The

questionnaire was circulated to the pharmaceutical units with the purpose of safeguarding the interest of industry and taking them into confidence to develop the realistic CC, PC and PL norms based on the actual cost data/information available with the formulation companies."

81. It will be seen from the above that as far as the drug industry was concerned, the CARs could form the basis for prescribing the norms as required by Paragraph 7 of the DPCO 1995. On the other hand, the Masood Committee had concluded that the data provided through the CARs was not entirely reliable. That apart, to obtain an overall picture of the ground realities, the NPPA, the Central Government and the Cost Accounts Branch felt that the information called for through the questionnaires would be more comprehensive and beneficial rather than the CARs of a handful of manufacturers/formulators.

82. On the basis of the above material, the submission of the learned Solicitor General was that the drug industry did not extend the necessary cooperation expected of it, that the notifications issued by the Central Government prescribing the norms for conversion cost, packing charges and process loss were not mechanically issued but were issued after due application of mind to the available material and that the decisions taken by the Central Government were subject to revision under the provisions of the DPCO 1995 but the manufacturers/formulators did not take recourse to these provisions and instead approached the Courts after

much delay and by way of an after-thought. These submissions were refuted by the learned counsel appearing for Cipla and other manufacturers/formulators.

Judicial review

83. The primary issues before us relate to (i) the legitimacy and soundness of the materials on the basis of which the norms were prescribed for application of the formula given in Paragraph 7 of the DPCO 1995 and on the basis of which the retail price and ceiling price of formulations were fixed under Paragraphs 8 and 9 of the DPCO 1995; (ii) the effect of the failure of the Central Government to prescribe the norms under Paragraph 7 of the DPCO 1995 on a yearly basis, and (iii) the effect of the failure of the Central Government to prescribe the norms for cost of packing material under Paragraph 7 of the DPCO 1995. The issue before us does not relate to the actual norms or actually fixing the retail price or ceiling price of formulations under Paragraphs 8 and 9 of the DPCO 1995 in the sense that there is no dispute that for the purposes of fixing the retail price or ceiling price of formulations under Paragraphs 8 and 9 of the DPCO 1995 the norms were prescribed and the formula given in Paragraph 7 thereof was adhered to. Even otherwise, the actual norms and price fixing on the basis of the norms is out of bounds for us.

(i) Issue of non-application of mind

84. The first submission of learned counsel for Cipla relates to the materials and the non-application of mind resulting in the Central Government prescribing the norms under Paragraph 7 of the DPCO 1995. The challenge to the retail price and ceiling price of formulations fixed through various notifications is only collateral or consequential. In its impugned judgment and order the Allahabad High Court held that there was no application of mind by the Central Government in prescribing the norms for conversion cost, packing charges and process loss. The second conclusion is that the Central Government failed to adhere to the provisions of Paragraph 7 of the DPCO 1995 in not prescribing the norms on a yearly basis.

85. Although there is no direct challenge to the notification dated 13th July, 1999 prescribing the norms under Paragraph 7 of the DPCO 1995 it was submitted that that notification and subsequent notifications were issued without any application of mind. It was in this context that it had become necessary to make a detailed reference to the Reports of the Sankaran Committee, the Masood Committee, the Jharwal Committee, the file notings and correspondence which were the materials before the Central Government and which led to the issuance of the notifications prescribing the norms for conversion cost, packing charges and process loss.

86. Paragraph 7 of the DPCO 1995 consists of two parts – prescribing the norms and applying those prescribed norms to the formula for arriving at the retail price of a formulation. In the first instance, we are concerned with prescribing the

norms under Paragraph 7 of the DPCO 1995 on the basis of the recommendations of the Masood Committee and the Jharwal Committee since it was contended that there was no application of mind in doing so. It may be mentioned that there is no challenge to the norms prescribed as such on the ground of arbitrariness or being *ultra vires* the DPCO 1995 or the Essential Commodities Act, 1955. What is presently questioned is only the application of mind and the soundness of the materials on the basis of which the norms were prescribed, namely, the Masood Committee Report and the Jharwal Committee Report. Learned counsel had no criticism of the Sankaran Committee Report and indeed generally supported its conclusions and recommendations.

87. A perusal of the Report of the Masood Committee and subsequently the Report of the Jharwal Committee clearly brings out that the Central Government initiated a detailed exercise for prescribing the norms but unfortunately the drug industry did not extend its full cooperation in the exercise and declined to provide necessary information and data despite requests and reminders. Therefore, the Central Government was left with no alternative but to notify the norms in compliance with the provisions of the DPCO 1995 on the basis of the materials already available. The first question is, could the Central Government rely on these materials?

88. The Report of the Masood Committee was roundly criticized by learned counsel for Cipla since its exercise was hasty and carried out without any field visits and without considering ground realities. The Report of the Jharwal Committee was also strongly criticized by learned counsel. The general line of criticism was that the Reports of the Masood Committee and the Jharwal Committee were based on flawed reasoning and an incorrect appreciation of the data and facts. As far as the Report of the Masood Committee is concerned, it was also criticized for not recommending the norms – a task it was set up to perform. The Masood Committee merely passed on the buck to another expert body for conducting an in-depth study for recommending the norms for conversion cost and packing charges. However, it must be said that the Masood Committee did some useful work by recommending the norms for cost of packing material but that could not be acted upon by the Central Government in isolation and in the absence of norms on process loss. A significant observation of the Masood Committee related to the stipulation for a yearly notification of norms in terms of the DPCO 1995. The Report of the Jharwal Committee was criticized for taking, amongst others, an unrealistic view of the inflation factor and not really adding anything of value to the Report of the Sankaran Committee.

89. There is no doubt that the Masood Committee Report was the justification for the Central Government not revising the norms recommended by the Sankaran

Committee and the Report of the Jharwal Committee was the basis for revising the norms as notified on 13th July, 1999. These Reports were the antecedent material available with the Central Government for the purposes of Paragraph 7 of the DPCO 1995. Can this "antecedent material" be subject to judicial review or judicial scrutiny and if so to what extent?

90. The criteria for price fixing can be statutory or non-statutory (such as a Report). This distinction was brought out in ***Rayalaseema Paper Mills Ltd. v. Government of A.P.***[2] . In that decision, a committee of officials was appointed to consider the factors relating to fixing the rates of royalty on the forest produce to be supplied to wood-based industries on a sustained basis, and to make recommendations to the Government. The committee made its recommendations which were accepted by the State Government and an appropriate G.O.Ms was issued. The result of the G.O.Ms was that the royalty for bamboo went up considerably and continued to rise every year. The G.O.Ms was then challenged in a writ petition.

91. The submission made by the appellants in that case was that even though "price fixation is neither the function nor the forte of the court, it is neither concerned with the policy nor the rates. But the court cannot deny to itself the jurisdiction to enquire into the question, in appropriate proceedings, whether

[2] (2003) 1 SCC 341

relevant considerations have gone in and irrelevant considerations kept out of the determination of the price."

92. In that context and in response to the submission made, this Court drew a distinction between price fixation governed by statutory considerations and price fixation governed by non-statutory considerations. It was held that on this basis ***Union of India v. Cynamide India Ltd. & Anr.***[3] was distinguishable since it dealt with price fixation based on statutory considerations. In a case of price fixation having its origin on non-statutory materials the scope of judicial scrutiny would be far less. It was said in paragraph 15 of the Report as follows:

> "This Court was examining [in ***Cynamide India***] the scope of judicial scrutiny in the matters of price fixation where it was governed by statutory provisions. The scope of judicial scrutiny would be far less where the price fixation is not governed by the statute or a statutory order. **Where the legislature has prescribed the factors which should be taken into consideration and which should guide the determination of price, the courts would examine whether the considerations for fixing the price mentioned in the statute or the statutory order have been kept in mind while fixing the price and whether these factors have guided the determination. The courts would not go beyond that point.** In the present appeals, there is no law, or any statutory provision laying down the criteria or the principles which must be followed, or which must guide the determination of rates of royalty. No doubt, any arbitrary action taken by the State would be subject to scrutiny by the courts because arbitrariness is the very antithesis of rule of law. But this does not mean that this Court would act as an Appellate Authority over the determination of rates of royalty by the Government….. It is open to the Government to fix such price as it thinks appropriate having regard to public interest, which inter alia, may include interest of revenue, environmental, ecology, the need of

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3 (1987) 2 SCC 720

> mills and the requirements of other consumers. The price is not to be fixed keeping in mind the requirements of the mills alone." [Emphasis supplied].

93. In these appeals, we too are presently concerned with a stage anterior to actual price fixation namely recommending and prescribing the norms that would eventually form the basis for fixing the retail price and ceiling price of formulations. The view expressed in ***Rayalaseema Paper Mills*** would, in our opinion, apply to the Reports of the Masood Committee and the Jharwal Committee set up by the Central Government for recommending the norms for the purposes of Paragraph 7 of the DPCO 1995. The Reports were antecedent materials, non-statutory and recommendatory and could have been rejected by the Central Government. The Masood Committee did not (and perhaps could not) recommend any norms for conversion cost, packing charges and process loss, except for cost of packing material (without process loss). The Masood Committee was alive to the statutory requirement of prescribing the norms on a yearly basis and therefore referred to it.

94. However, as far as the Report of the Jharwal Committee is concerned, the Central Government accepted and implemented it by issuing a notification on 13th July, 1999 under Paragraph 7 of the DPCO 1995 – but still did not prescribe the norms for cost of packing material recommended by the Masood Committee, an issue that will be considered later.

95. While learned counsel for Cipla might have serious differences of opinion with the recommendations of these particular non-statutory Reports, generally a challenge to Reports prepared by expert bodies is not easy but is subject to lesser judicial scrutiny. To rephrase what was said in ***Prag Ice and Oil Mills and Anr. v. Union of India***[4] a factor here or a factor there that should have been taken into account but has been ignored should not invalidate the Reports - mere errors in the Reports are not subject to judicial review.

96. That there can be a legitimate difference of opinion (sometimes serious) between two expert bodies is not at all unusual. In ***Shri Sitaram Sugar Co. Ltd. v. Union of India***[5] the decision of the Central Government was supported by the recommendations of the Tariff Commission. These recommendations were criticized in some respects by the BICP. Some members of the sugar industry accepted the views of the Central Government while some did not. Considering the overall circumstances, the Constitution Bench observed that the conclusions of the Central Government are expert conclusions which were not shown to be arbitrary, discriminatory, unreasonable or *ultra vires*. Reliance was placed upon the following passage from ***Railroad Commission of Texas v. Rowan & Nichols Oil Company***[6]:

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4 (1978) 3 SCC 459
5 (1990) 3 SCC 223
6 311 US 570, 85 L Ed 358, 362

> "Nothing in the Constitution warrants a rejection of these expert conclusions. Nor, on the basis of intrinsic skills and equipment, are the federal courts qualified to set their independent judgment on such matters against that of the chosen State authorities.... When we consider the limiting conditions of litigation — the adaptability of the judicial process only to issues definitely circumscribed and susceptible of being judged by the techniques and criteria within the special competence of lawyers — it is clear that the Due Process Clause does not require the feel of the expert to the supplanted by an independent view of judges on the conflicting testimony and prophecies and impressions of expert witnesses".
>
> This observation is of even greater significance in the absence of a Due Process Clause."

97. The feel of the expert is important, if not conclusive. Insofar as we are concerned, two expert Committees made their recommendations. These recommendations were then examined and considered by the Central Government and on the basis of the expert conclusions arrived at, the norms were prescribed by a notification dated 13th July, 1999 issued under Paragraph 7 of the DPCO 1995. Under the circumstances, the question of judicial scrutiny of the Reports of the Masood Committee and the Jharwal Committee and the acceptance of their recommendations by the Central Government is not only limited, but in this case it does not arise. It cannot be said that the notification dated 13th July, 1999 was based on no material or was issued without any application of mind. Learned counsel for Cipla may disagree with the contents of the materials, but cannot ignore their existence or that they were considered by the Central Government.

98. Fixing the price of any commodity is not only difficult but also tricky. There is material to be considered, a bundle of factors to be considered and appropriate

weight is to be given to the material and the factors. This is not easy to decide and there will always be some criticism with regard to either the material utilized or the factors considered or the weight attached to the materials and factors. In matters pertaining to drug formulations, it is not only an issue of demand and supply but also the ability of a common person to afford the formulation. At the same time, the manufacturer must also make some profit and be in a position to invest in research and development. There simply cannot be any mathematical precision in fixing the price of a commodity. More than enough elbow room or a play in the joints is required to be given in such matters – and even then the price fixing authority may commit an error. Once this is appreciated, it will be realized that the task before the Central Government in prescribing the norms was not easy.

Failure to consider the cost audit reports

99. Learned counsel for Cipla contended that assuming the drug industry did not extend any cooperation in providing necessary data, the CARs were nevertheless material available and they could be and should have been made use of for recommending the norms by the Masood Committee and the Jharwal Committee to the Central Government. In other words, relevant material was not considered.

100. The value or utility of the CARs has already been mentioned above, which is that the Masood Committee did not find the information contained in whatever CARs were available to be fully reliable. This view was accepted by the Central

Government. Even the Cost Accounts Branch of the Department of Expenditure in the Ministry of Finance did not find the CARs of particular use for the purposes of prescribing the norms. Additionally, no study could be based entirely on the CARs. We must accept the opinion of expert bodies in this regard. We do not have any contrary expert opinion on the subject and must go by the existing expert views. Proceeding on this basis, it would be incorrect on the part of Cipla and indeed the drug industry to say and contend that whatever information is required by the Central Government for fixing the norms was already available in the CARs and nothing more need be supplied to the Central Government.

101. Assuming the submission of Cipla and the drug industry to be correct, it would certainly not have been a problem at all for each company to fill up the questionnaires sent by each of the Committees, if all the information required by the questionnaires was already available in the CAR of each company. Assuming again that the required information could be extracted by each Committee from the CAR, it could more easily be extracted by each company from its own CAR and provided to the Masood Committee and the Jharwal Committee. Under these circumstances, it is inexplicable why the drug industry declined to fill up the questionnaires sent to their member companies from time to time. There is certainly more to it than meets the eye.

102. It is true, as contended by learned counsel for Cipla that no manufacturer/formulator is under an obligation to furnish whatever information is required by the Central Government including information that might be confidential. But that does not mean that absolutely no information should be supplied by any company or incomplete information should be supplied by a very few of them. It would certainly be more appropriate for each company to have responded to the questionnaires sent with a communication that some particular information is not being furnished for reasons of confidentiality. But no such courtesy was extended. While there may not be a statutory obligation on each manufacturer/formulator to furnish information for prescribing the norms, there is certainly a moral and social obligation on them to furnish information so that appropriate norms could be notified not only for their benefit but also for the benefit of the consumers. The preamble to the Essential Commodities Act, 1955 cannot be forgotten. By not furnishing the information required, the drug industry pushed the Central Government into a corner leaving it with no option but to prescribe the norms on the basis of available material and later re-notify the norms.

103. It is also true that fixing the price of formulations based on the norms prescribed under Paragraph 7 of the DPCO 1995 is a legislative activity which the Central Government was obliged to carry out on its own research and assessment, assuming there was no cooperation from the manufacturers/formulators. The

efforts made by the Masood Committee and the Jharwal Committee for prescribing the norms for the purposes of Paragraph 7 of the DPCO 1995 were steps leading up to this legislative activity. It is nobody's case that no preliminary steps were taken or that no exercise was undertaken for arriving at appropriate norms - the steps and exercise were in fact undertaken through expert Committees but the material used in the exercise and the resultant Reports were criticized by learned counsel appearing for Cipla. We are of the view that given the circumstances that the two Committees were faced with and given the virtual non-cooperative attitude of the drug industry, the Central Government prescribed the norms and Cipla and the drug industry were obliged to accept them as notified without much ado. It cannot be that the drug industry does not supply necessary information and data to the expert Committees appointed by the Central Government and then blames the Central Government for taking a decision without necessary information and data.

104. The failure of the drug industry to extend effective cooperation appears to be an endemic problem. A situation somewhat similar to the one that we are concerned with had arisen in ***Union of India v. Swiss Garnier Life Sciences***.[7] In that decision, it was noticed by this Court that communications were sent to the manufacturers/formulators of a particular formulation to provide reasons why that formulation should not be classified as a derivative of another formulation. In

[7] (2013) 8 SCC 615

paragraph 4 of the Report, it was noted that the requisite information was not furnished, even after a substantial lapse of time and a reminder. This observation was reiterated in paragraph 44 of the Report and it was held that in view of the refusal of the manufacturers/formulators to furnish the detailed information, the Central Government was well within its jurisdiction to resort to Paragraph 11 of the DPCO 1995 and fix the price of the formulation on the basis of information available.

105. Similarly, in ***Secretary, Ministry of Chemicals and Fertilizers v. Cipla Ltd.***[8] it was observed by this Court in paragraph 8.4 of the Report that bulk drug producers did not disclose necessary information to the Central Government, despite a request having been made in that regard and that there was no good reason why the relevant information should be withheld. It was observed:

> "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 the writ petitioners and there is no good reason why they should withhold all this relevant information and harp on the ORG data. There is no need to resort to guesswork when the actual figures are available at the doorsteps of the respondents."

106. Be that as it may, our conclusion on this aspect of the matter is that the antecedent materials (the Reports) on the basis of which the norms were

[8] (2003) 7 SCC 1

recommended and then prescribed under Paragraph 7 of the DPCO 1995 are subject to lesser judicial scrutiny, limited perhaps only to the application of completely erroneous principles. The burden for demonstrating the application of completely erroneous principles is heavy as it is and it is heavier still if the antecedent material is prepared by experts. The onus of discharging the heavy burden must necessarily fall on the challenger, and Cipla has not been able to sustain the challenge. There can be and are differences of opinion but we cannot and will not reconsider the opinion of experts, particularly in matters of economic affairs or other economy related issues unless there is extremely strong reason to do so.

107. We end this discussion with a conclusion arrived at by the Constitution Bench in ***Shri Sitaram Sugar Co. Ltd.*** in paragraph 49 of the Report:

> "Where a question of law is at issue, the court may determine the rightness of the impugned decision on its own independent judgment. If the decision of the authority does not agree with that which the court considers to be the right one, the finding of law by the authority is liable to be upset. Where it is a finding of fact, the court examines only the reasonableness of the finding. When that finding is found to be rational and reasonably based on evidence, in the sense that all relevant material has been taken into account and no irrelevant material has influenced the decision, and the decision is one which any reasonably minded person, acting on such evidence, would have come to, then judicial review is exhausted even though the finding may not necessarily be what the court would have come to as a trier of fact. Whether an order is characterised as legislative or administrative or quasi-judicial, or, whether it is a determination of law or fact, **the judgment of the expert body, entrusted with power, is generally treated as final and the judicial function is exhausted when it is found to have "warrant in the record" and a rational basis in law**: See *Rochester Tel.*

Corp. v. *United States*[9]. See also *Associated Provincial Picture Houses Ltd.* v. *Wednesbury Corporation*[10]." [Emphasis supplied]

This view was reaffirmed in paragraph 58 of the Report in the following words:

> "Price fixation is not within the province of the courts. **Judicial function in respect of such matters is exhausted when there is found to be a rational basis for the conclusions reached by the concerned authority.** As stated by Justice Cardozo in *Mississippi Valley Barge Line Company* v. *United States of America.*[11]
> "The structure of a rate schedule calls in peculiar measure for the use of that enlightened judgment which the Commission by training and experience is qualified to form.... It is not the province of a court to absorb this function to itself.... **The judicial function is exhausted when there is found to be a rational basis for the conclusions approved by the administrative body.**" [Emphasis supplied]

108. For the above reasons we disagree with the Allahabad High Court and hold that the various notifications issued under Paragraph 7 of the DPCO 1995 in 1999 and thereafter prescribing the norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion) and packing and process loss of packing materials in packaging were issued after due application of mind and based on available material duly examined by an expert body. The notifications were not arbitrarily issued nor were they discriminatory in any manner at all nor were they issued mechanically nor could it be said that they were issued without any application of mind.

Re-notification of norms

109. Another facet of the submission of learned counsel for Cipla was that the

9 307 US 125 (1939) : 83 L ed 1147
10 (1948) 1 KB 223 : (1947) 1 All ER 498
11 292 US 282, 286-287 : 78 L ed 1260, 1265

same norms prescribed by the notification dated 13th July, 1999 could not have been notified mechanically year after year and the fact that the norms were simply re-notified from 2000 to 2003 is a clear indication of non-application of mind by the Central Government to the issue at hand. In response, the learned Solicitor General referred to ***Shri Malaprabha Coop. Sugar Factory v. Union of India***.[12] In that decision, it was noted that the levy sugar prices for the 1975-76 sugar season were notified at the same level as those in the previous season. This Court took the view that the re-notification could not be faulted on grounds of arbitrary exercise of power for several reasons mentioned in paragraph 84 of the Report. In other words, the concept or principle of re-notification is not unheard of and there is no illegality *per se* in re-issuing the norms without any change, but the reasons for re-notification ought to exist – re-notification should not be a short-cut method to be routinely employed.

110. What then are the reasons that prompted the Central Government to re-notify the norms prescribed by the notification dated 13th July, 1999? On the one hand, there was virtual non-cooperation from the drug industry in providing information to the Central Government despite repeated requests and reminders even by expert Committees constituted for the purpose. On the other there was a perceived statutory obligation on the Central Government to notify the norms every year and

[12] (1994) 1 SCC 648

that responsibility could not be effectively discharged without the cooperation of the drug industry. Therefore the Central Government, faced with an extra-ordinary situation and a stalemate putting the consumers of an essential commodity at the mercy of the drug industry, had no option but to re-notify the existing norms in public interest on the basis of the available material.

111. We have adverted to the issues that confronted the Central Government during this period, namely, the unambiguous decision of the drug industry not to extend any cooperation to the Central Government in arriving at appropriate norms for the purposes of Paragraph 7 of the DPCO 1995. The views of the Indian Pharmaceutical Association and the IDMA have already been referred to. The insistence of the drug industry to work out the norms on the basis of the CARs was another stumbling block staring at the face of the Central Government. The Cost Accounts Branch of the Department of Expenditure in the Ministry of Finance, a neutral body in that sense, had clearly expressed the view that the norms could not be effectively determined only on the basis of the CARs. Finally, the non-cooperation of the drug industry from October 1998 onwards was another road block. The overall attitude of the drug industry appears to be one of profit making or preserving commercial interests, while the concern should really be of promoting consumer interest. Faced with these competing interests, the Central Government sided with the consumer and cannot be faulted for it. The Central

Government did not act in a routine or mechanical manner in re-notifying the norms every year from 2000 onward. In our opinion, the explanation put forward by the learned Solicitor General deserves acceptance.

112. We conclude that the re-notification of the prescribed norms in the period 2000 to 2003 was not mechanical or without any application of mind. The materials were before the Central Government and there was no change in the content of the materials. If there was, the drug industry failed to effectively point it out as a result of their non cooperative attitude. We also hold that re-notification of the prescribed norms is *per se* not impermissible and in the present case it was justified in the circumstances.

Challenge to the actual norms prescribed

113. In ***Prag Ice & Oil Mills*** it was held that price fixation is really legislative in character since it satisfies the tests of legislation. Similarly, in ***Cynamide India*** it was held that price fixation is more in the nature of a legislative activity than in any other. Price fixation may affect manufacturers and producers or commodities but those who are most vitally affected are the consumers. Similarly, in ***Glaxosmithkline Pharmaceuticals Ltd. v. Union of India***[13] it was held that price fixation by the Central Government under the DPCO is in the nature of a legislative measure and the dominant object and purpose of such price fixation is

[13] (2014) 2 SCC 753

the equitable distribution and availability of commodities at a fair price. A similar view was expressed by a Constitution Bench of this Court in ***Shri Sitaram Sugar Company Ltd.*** when it was said: "Price fixation is in the nature of a legislative action even when it is based on objective criteria founded on relevant material." In ***Saraswati Industrial Syndicate Ltd.*** **v.** ***Union of India***[14] this Court was more specific when it said that "Price fixation is more in the nature of a legislative measure even though it may be based upon objective criteria found in a report or other material."

114. The norms fixed by the Central Government are of general application, they are not intended to benefit or harm any particular manufacturer or formulator and indeed no manufacturer or formulator is required to be heard (or was heard) in the determination, they are notified in the Official Gazette for the information of the general public and in arriving at the norms the general attributes of legislative activity are attended to by the Central Government for the benefit of the consumers. The notification of the norms therefore has the character of legislative activity.

115. No submission was made before us to the effect that the formula given in Paragraph 7 of the DPCO 1995 was not applied *proprio vigore* by the Central Government. The statutory criterion for price fixing is the formula given in

[14] (1974) 2 SCC 630

Paragraph 7 of the DPCO 1995. Whether this formula has been operated as it should be is certainly subject to judicial review. Therefore, while operating the formula, if the Central Government did not take conversion cost into consideration (for example) or took into consideration some factor not in the formula then, the Court could certainly strike down the retail price or the ceiling price so fixed by the Central Government on the ground that relevant factors were ignored or irrelevant factors were taken into consideration. No such allegation was made and no such contention was advanced by learned counsel for Cipla. Therefore, we need not dwell on this aspect.

(ii) Yearly prescription of norms

116. It may be recalled that prior to 1995, the norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging were prescribed by notifications issued on 17th February, 1989 and 15th July, 1993 in exercise of powers conferred by Paragraph 6 of the DPCO 1987. When the DPCO 1995 was issued, it provided for a 'transitional' provision through Paragraph 8(5) and Paragraph 27 thereof.

117. Paragraph 8(5) of the DPCO 1995 provides that the retail price of a scheduled formulation shall, until the retail price thereof is fixed under the DPCO

1995, be the price which prevailed immediately before the commencement of the DPCO 1995.[15] Paragraph 8 of the DPCO 1995 reads as follows:

> **"8. Power to fix retail price of scheduled formulations.** – (1) The Government may, from time to time, by order, fix the retail price of a Scheduled formulation in accordance with the formula laid down in para. 7.
>
> (2) Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilises such bulk drug in his scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government in Form III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.
>
> (3) The retail price of a formulation once fixed by the Government under sub-paragraphs (1) and (2) shall not be increased by any manufacturer except with the prior approval of the Government.
>
> (4) Any manufacturer, who desires revision of the retail price of a formulation fixed under sub-paragraph (1), shall make an application to the Government in Form III or Form IV, as the case may be, and the Government shall after making such enquiry, as it deems fit within, a period of two months from the date of receipt of the complete information, fix a revised price for such formulation or reject the application for revision for reasons to be recorded in writing.
>
> (5) Notwithstanding anything contained in the foregoing sub-paragraphs the retail price of a scheduled formulation, of a manufacturer shall, until the retail price thereof is fixed under the provisions of this Order, be the price which prevailed immediately before the commencement of this Order, and the manufacturer of such formulation shall not sell the formulation at a price exceeding the price prevailing immediately before the commencement of this Order.
>
> (6) No manufacturer or importer shall market a new pack, if not covered under sub-paragraph 3 of para 9, or a new formulation or a new dosage

[15] "Retail price includes ceiling price (fixed under Paragraph 9 of the DPCO 1995). Retail price is defined in Paragraph 2(s) of the DPCO 1995 as follows: "retail price" means the retail price of a drug arrived at or fixed in accordance with the provisions of this Order and includes a ceiling price."

> form of his existing scheduled formulation without obtaining the prior approval of its price from the Government.
>
> (7) No person shall sell or dispose of any imported scheduled formulation without obtaining the prior approval of its price from the Government."

Similarly, Paragraph 27 of the DPCO 1995 provides that any notification issued under the DPCO 1987, unless it is inconsistent with its provisions will be deemed to have been issued under the corresponding provision of the DPCO 1995. Paragraph 27 of the DPCO 1995 reads as follows:

> "27. **Repeal and saving**.- (1) The Drugs (Prices Control) Order, 1987 is hereby repealed.
>
> (2) Notwithstanding such repeal, anything done or any action taken, including any notification or Order made, direction given, notice issued or exemption granted under the Drugs (Prices Control) Order, 1987, shall in so far as it is not inconsistent with the provisions of this Order, be deemed to have been done taken, made, given, issued or granted, as the case may be, under the corresponding provisions of this Order."

Ex facie therefore, there is no error in continuing the norms prescribed under the DPCO 1987 even after the promulgation of the DPCO 1995. However, the question is whether this arrangement can continue indefinitely?

118. The DPCO 1995 came into operation on 6th January, 1995. Ordinarily therefore the first notification under Paragraph 7 thereof ought to have been issued in July 1995, or soon thereafter. (We were told by the learned Solicitor General that the year for prescribing the norms is from July to June of the following year. It is for this reason that the various notifications under Paragraph 7 of the DPCO

1995 were issued in July). Perhaps the Masood Committee was constituted on 24th April, 1995 for this purpose and initially it was required to submit its Report on or before 30th June, 1995 but time was extended till 31st August, 1995.

119. Whatever be the position, the fact is that the Central Government did not notify the norms on a yearly basis for four years 1995-1996, 1996-1997, 1997-1998 and 1998-1999. We are really concerned with the default for this period. The NPPA was set up on 29th August, 1997 and the Jharwal Committee was set up on 8th October, 1998 more than two years and three years respectively after the DPCO 1995 was issued. The purpose of setting up the Jharwal Committee was to revise the norms applicable since 15th July, 1993. Pursuant to the Report of the Jharwal Committee the Central Government did issue a notification on 13th July, 1999 under Paragraph 7 of the DPCO 1995. On the issue under consideration, we are presently not concerned with the period 1999 onwards till 2004.

120. Paragraph 7 of the DPCO 1995 gives the formula for arriving at the retail price of a formulation. The application of the formula is undoubtedly mandatory and the Central Government cannot contend that the retail price of a formulation can be fixed *de hors* the formula. The question is whether the norms mentioned in Paragraph 7 of the DPCO 1995 are required to be prescribed every year even if there is no perceived qualitative or quantitative change in them. In other words, is the prescription of norms every year mandatory even though circumstances do not

warrant any such prescription and what is the consequence if the Central Government does not prescribe the norms every year – is it fatal to the notifications issued under Paragraphs 8 and 9 of the DPCO 1995 whereby the retail price and ceiling price of formulations was fixed?

121. The purpose of determining and prescribing the norms every year is limited to the requirement of fixing the retail price of formulations in terms of the formula given in Paragraph 7 of the DPCO 1995. The Central Government set up the Masood Committee in April 1995 precisely for this purpose. However its work was stymied by the drug industry through its non-cooperation. It is true that notwithstanding the road block set up by the drug industry, the Central Government could very well have determined and prescribed the norms as required by Paragraph 7 of the DPCO 1995. Why didn't the Central Government do so?

122. There are several reasons that can be culled out from the Report of the Masood Committee for the Central Government not determining and prescribing the norms in 1995 and thereafter for the next three years. Firstly, according to the Masood Committee the drug industry had been provided a sufficient cushion by the acceptance of the recommendations of the Sankaran Committee. Under the circumstances continuing with the norms for conversion cost and packing charges prescribed under the DPCO 1987 would not have disadvantaged the manufacturers/formulators in any manner.

123. Secondly, the packing material ceilings had been recently upwardly revised from 7th July, 1994 and the manufacturers/formulators could take advantage of the cost of packing material on actuals. Surely, this was beneficial to them.

124. Thirdly, according to the Masood Committee with high production levels and better capacity utilization as well as new technological processes, the process loss on raw materials and packing material ought to have come down. But since the drug industry did not provide necessary information through the questionnaire sent to the drug industry and the companies, an ad hoc reduction in the existing norm for process loss fixed by the Sankaran Committee was not recommended by the Masood Committee. This too was to the advantage of the manufacturers / formulators. Actually, the Masood Committee expressed the view that the existing norms for process loss on raw materials and packing materials was on the high side.

125. Fourthly, the Masood Committee noted that there was a decrease in total formulation activity coming under price control from 70% under the DPCO 1987 to 50% under the DPCO 1995 and uniform MAPE of 100% under the DPCO 1995 as against 75% and 100% MAPE under the DPCO 1987. Even this was advantageous to the manufacturers/formulators.

126. Whichever way the issue is looked at, it is clear that the manufacturers/formulators were not put to any disadvantage in the retail price

fixed on the basis of the norms prescribed under the DPCO 1987. Therefore, we are of opinion that under these circumstances, the *bona fides* of the Central Government in not prescribing the norms every year certainly cannot be doubted.

127. That apart, the provisions of Paragraph 8(5) and Paragraph 27 of the DPCO 1995 come to the aid of the Central Government and these provisions enabled the continuation of the norms prescribed under Paragraph 6 of the DPCO 1987 and saved the notifications issued under the provisions of Paragraphs 8 and 9 of the DPCO 1995. This 'arrangement' certainly could not have carried on indefinitely, but the recalcitrance of the drug industry pushed the Central Government into a corner leaving it with little option but to continue the 'arrangement' till an alternative was found through an in-depth study. This is perhaps where the Central Government erred. It should have set up the NPPA soon after announcing the new Drug Policy in 1994 and it should have enacted a legislation constituting the National Drug Authority in terms of the Drug Policy, 1994. Had these steps been taken, the Central Government would not have to face litigation in different parts of the country. What is tragic is that even today, there does not seem to be any sign of the Central Government taking any steps to constitute a statutory National Drug Authority.

128. But be that as it may, although several notifications issued between 1995 and 1999 were collaterally challenged by the manufacturers/formulators, we were not

shown any notification in which the retail price or the ceiling price was varied to their detriment. Assuming there was such a notification, a manufacturer/formulator was entitled to question the adverse revision by moving an application under the provisions of Paragraph 8(4) and Paragraph 22 of the DPCO 1995. No such application was moved by any manufacturer/formulator. Paragraph 22 thereof reads as follows:

> **"22. Power to review**.- Any person aggrieved by any notification issued or order made under paras. 3, 5, 8, 9 or 10 may apply to the Government for a review of the notification or order within fifteen days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper :
>
> Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer, importer or distributor, as the case may be, shall sell a bulk drug or formulation, as the case may be, at a price exceeding the price fixed by the Government of which a review has been applied for."

It was contended that a revision could not be sought since norms were not fixed and for the purposes of challenging the retail price or the ceiling price fixed under Paragraphs 8 and 9 (as the case may be) of the DPCO 1995 it was necessary to know the norms fixed. We propose to deal with this issue a little later.

129. A question of seminal importance arises, namely, whether the legislative activity of prescription of norms every year is at all necessary even if there is no occasion to change or modify the retail price of a formulation. Is the exercise of determining the norms by the Central Governments required to be mechanically

carried out every year as a ritual? Perhaps not. It is not necessary to revise the retail price or ceiling price of every formulation every year – and if there is no such mandate, then it must follow that there is no mandate to prescribe the norms every year under Paragraph 7 of the DPCO just for the sake of it. What consumer interest would an annual change in retail price serve in the context of over 2000 formulations? What has to be seen by the Central Government, in the larger context, is whether the drug industry is losing out in any manner and whether the consumers of formulations are being put to any discomfort. A fine balance has to be struck and if the Central Government has been successful in doing that, as it appears, then carrying out an annual ceremonial procedure or annual academic exercise of determining and prescribing the norms under Paragraph 7 of the DPCO 1995 regardless of whether there is any necessity to do so is not mandatory.

130. The Central Government cannot be compelled to perform a legislative activity or legislative exercise that is of no consequence and is perhaps ritualistic. We are of opinion that while the formula given in Paragraph 7 of the DPCO 1995 must be mandatorily adhered to for fixing the retail price of a formulation, the requirement of prescribing the norms every year is discretionary and would depend upon the exigencies of the situation – it might be every year or less frequently or more frequently.

131. It was also contended by learned counsel for one of the respondents before us that there was a qualitative difference between the DPCO 1987 and the DPCO 1995 in as much as under the DPCO 1987 the norms were required to be prescribed from time to time under Paragraph 6 thereof. However, as far as the DPCO 1995 is concerned the norms were required to be prescribed on a yearly basis under Paragraph 7 thereof. The submission was that the principles known as *Heydon's mischief rule*[16] are clearly applicable and there was a conscious decision by the Central Government to switch over from prescribing the norms from time to time to fixing the norms on a yearly basis. Since the norms were not fixed on a yearly basis under the DPCO 1995, the retail prices fixed by the Central Government on the formulations on the basis of Paragraph 7 of the DPCO 1995 were illegal and liable to be struck down.

132. What was the mischief, if any, sought to be remedied? Nothing has been told to us in this regard by learned counsel. Given the scheme of the DPCO 1995 there was no mandate of prescribing the norms under Paragraph 7 of the said DPCO every year. We therefore merely note the submission for whatever it is worth.

(iii) Failure to prescribe the norms for cost of packing material

133. We may recall that the Sankaran Committee had noted that the norms for cost of packing material were not prescribed from 1979 onward. Far from

[16] Heydon's Case, Neutral Citation Number: [1584] EWHC Exch J36

objecting to this, the drug industry had itself requested the Sankaran Committee to permit the cost of packing material to be taken on actuals. The Sankaran Committee accepted this suggestion while taking into account the inherent difficulty in prescribing any norm for cost of packing materials. We may draw attention to the notification dated 17th February, 1989 followed by the notification dated 15th July, 1993 both issued under Paragraph 6 of the DPCO 1987 in this regard. Neither notification made any provision for cost of packing material as a norm. The notification dated 17th February, 1989 prescribed norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging. The notification dated 15th July, 1993 prescribed norms only for conversion cost and packing charges. No manufacturer or formulator made any grievance or complaint regarding the failure of the Central Government to prescribe the cost of packing material as a norm.

134. The situation has not changed at all over the years. The silence of the drug industry continued as is evident from the fact that even 15 years later a notification was issued by the Central Government on 11th August, 2004 under Paragraph 7 of the DPCO 1995 prescribing the norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion and packing) and process loss of packing materials in packaging – but not for cost of

packing material as a norm. Despite this, we were told by learned counsel appearing for the parties that there has been no dispute about price fixation since 2004 due to the absence of a norm for cost of material.

135. In other words, it does appear to us that the drug industry was content with being allowed to take the cost of packing material on actuals rather than insisting on the Central Government issuing a notification prescribing the norms for cost of packing material. We believe that in fact there was no necessity of fixing the cost of packing material as a norm for the purposes of Paragraph 7 of the DPCO 1995 and that there was no fatal error in the notifications issued under Paragraph 7 of the DPCO 1995 from 1999 onward. This also adds to our conclusion that prescribing the norms every year under Paragraph 7 of the DPCO 1995 was a discretionary exercise.

136. As mentioned above, we can quite understand if the formula given in Paragraph 7 of the DPCO 1995 is not strictly adhered to by the Central Government while working out the retail price of a formulation. But if the drug industry is itself quite content with being given the benefit of actuals in material cost rather than having a norm fixed in that regard, then there is no obligation on us to completely upset the apple cart and quash a few dozen notifications at the behest of only a couple of respondents. If we do so, we would be acting to the detriment of the entire drug industry (except one – and we must mention that not many other

manufacturers and formulators are before us), but we would also provide no advantage to the consumers who have already purchased the formulations more than a decade ago and have no hope of getting a refund on their purchase. Additionally, we would really be serving no public or societal interest in quashing a few dozen notifications under these circumstances.

137. We may mention *en passant* that the ceiling price fixed by the BICP on 7th July, 1994 and thereafter revised by the NPPA in February 1998 in respect of packing materials has not been questioned (let alone challenged) by anybody.

(iv) Other submissions

138. It was contended by learned counsel appearing on behalf of Dr. Reddy's Laboratories Ltd. that the retail price or the ceiling price of a formulation could not have been fixed by the Central Government without first fixing the maximum sale price under Paragraph 3 of the DPCO 1995 of the bulk drug utilized in the formulation. We are unable to accept this submission. In the first place, there is no obligation on the Central Government to fix the maximum sale price of every bulk drug, whether it is in the First Schedule to the DPCO 1995 or not. In fact, if a bulk drug is not in the First Schedule to the DPCO 1995 the Central Government is not empowered to fix its maximum sale price. There could also be a situation where a formulation consists of two or more drugs, one of which is not a scheduled drug. In that event, if the contention of learned counsel is accepted then it would

mean that the retail price or the ceiling price of that formulation cannot be fixed. This is surely not the intention of the DPCO 1995 nor is it a possible manner of reading the DPCO 1995. If the DPCO 1995 were to be read in the suggested manner, then every drug would have to be included in the First Schedule to the DPCO 1995 as a pre-condition to fixing the retail price or ceiling price of a formulation which contains that drug. This would be doing utmost violence to the plain provisions of the DPCO 1995 and for this simple reason we are unable to accept the submission of learned counsel. The learned counsel has unfortunately overlooked that a formulation can contain one or more bulk drugs including a bulk drug not included in the First Schedule to the DPCO 1995.

139. It has also been argued before us by learned counsel representing a small scale industry that the ceiling price of formulations fixed under Paragraph 9 of the DPCO 1995 denied the benefit of an exemption notification dated 2nd March, 1995 available to small scale industries. We are not inclined to take this argument with any degree of seriousness particularly since it seems to suggest that the Central Government acted with a *mala fide* intent. There is no warrant for such an assumption and no such allegation or averment has been made in the pleadings. The issuance of a notification under Paragraph 9 of the DPCO 1995 is a legislative exercise of power and to say that it was resorted to for denying the benefit of an exemption to small scale industries can hardly be given any credence. However, if

the submission was intended to convey the difficulty faced by small scale industries, it can hardly be helped. There is nothing in the DPCO 1995 to suggest that a small scale industry is kept out of the rigour of the DPCO 1995. It is equally bound by any retail price or ceiling price fixation by the Central Government.

140. It was then contended on behalf of the manufacturers/formulators that the delegate of a power cannot travel beyond its authorization. Reliance in this regard was placed on ***V.K. Ashokan v. Assistant Excise Commissioner***[17] and ***District Collector, Chittoor v. Chittoor District Groundnut Traders Association.***[18] There can be no dispute about this proposition. It was further contended that if the delegate exceeds the powers conferred upon it by the principal, then the order passed by the delegate is void *ab initio* and cannot even be ratified. In this regard, reliance was placed on ***Marathwada University v. Seshrao Balwant Rao Chavan***.[19] The issue in the present case is not that the delegate (the Central Government) had exceeded its jurisdiction - the issue is that the Central Government failed to exercise the power vested in it by Paragraph 7 of the DPCO 1995. It is this that is under challenge and not the exercise of power in excess of jurisdiction. The decisions cited on behalf of the manufacturers/formulators in this regard are therefore not quite relevant. In any event, we have already dealt with the issue of the purported failure of the Central Government to comply with the

17 (2009) 14 SCC 85
18 (1989) 2 SCC 58
19 (1989) 3 SCC 132

requirement of prescribing the norms under Paragraph 7 of the DPCO 1995 and repetition is not necessary.

141. We may mention that relying upon ***Associated Provincial Picture Houses Ltd. v. Wednesbury Corporation***,[20] ***Mayor & C Westminster Corporation v. London and North Western Railway***,[21] ***Barium Chemicals Ltd. v. Company Law Board***[22] and ***State of U.P. v. Renusagar Power Co.*** [23] the Constitution Bench observed in ***Shri Sitaram Sugar Company Ltd.*** that "A repository of power acts ultra vires either when he acts in excess of his power in the narrow sense or when he abuses his power by acting in bad faith or for an inadmissible purpose or on irrelevant grounds or without regard to relevant considerations or with gross unreasonableness." It was then concluded in paragraph 52 of the Report:

> "The true position, therefore, is that any act of the repository of power, whether legislative or administrative or quasi-judicial, is open to challenge if it is in conflict with the Constitution or the governing Act or the general principles of the law of the land or it is so arbitrary or unreasonable that no fair minded authority could ever have made it."

142. To this we may add that the action of a repository of power is also amenable to judicial review if it is contrary to or violates the mandatory requirement of a subordinate legislation. Therefore, if the Central Government does not adhere to the formula given in Paragraph 7 of the DPCO 1995 and fixes the retail price or

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20 (1948) 1 KB 223 : (1947) 1 All ER 498
21 1905 AC 426,430 : 93 LT 143
22 1966 Supp SCR 311
23 (1988) 4 SCC 59

ceiling price of formulations without following the formula laid down, the notification issued by the Central Government under Paragraph 8 or Paragraph 9 of the DPCO 1995 (as the case may be) is liable to quashed as being contrary to law. However, no instance has been pointed out to us compelling us to use our power of judicial review and quash the notifications under consideration.

Alternative remedy

143**.** The learned Solicitor General was quite vehement in his submission that if any manufacturer or formulator was aggrieved by the fixing of any the retail price or ceiling price of any formulation, there was an alternative remedy available in the DPCO 1995 to ventilate and articulate the grievance. There is no reason why no one actually sought any revision or review of any of the price notifications before us. In this context it was pointed out that several constituents of the drug industry had taken resort to alternative procedures (including Cipla) and therefore it is not as if the alternative remedy is illusory.

144. In response, it was contended that there was hardly any material before Cipla to meaningfully resort to the alternative remedy provided under the DPCO 1995. Additionally, the norms were not prescribed on an annual basis and in the absence of the norms it was not possible for anyone to make an effective case for revision or review of any retail price or ceiling price notification. Reference was made to Form III in the Second Schedule to the DPCO 1995.

145. Form III is a Form of application for approval or revision of the price of scheduled formulations. This requires, in paragraph 13 thereof, information relating to the break-up of the retail price of a formulation. Our attention was drawn to sub-paragraph (b) [Conversion Cost (as per norms)] and sub-paragraph (c) [Packing Material Costs (Per Sl. No. 15 or as per norms)]. The submission was that an effective application could not be made without the norms being prescribed. As mentioned above, the norm for conversion cost was prescribed first by the notification dated 17th February, 1989 and then by the notification dated 13th July, 1999 (and subsequent notifications). It is difficult to accept the submission that despite these notifications a manufacturer or formulator was unaware of the norms for conversion cost. As far as the norm for packing material cost is concerned, sub-paragraph (c) provides an option to the applicant – either the information mentioned in paragraph 15 may be provided or the norms may be provided. Paragraph 15 requires the applicant to provide information pertaining to the pack, batch size (tablets / gms etc.), name of the packing material, rate per unit, quantity required per batch and value of packing material/batch nos./kgs etc. (in rupees). Therefore, even if the norm for cost of packing material is not prescribed, the applicant can provide the requisite information (based on actuals) for the purposes of making an effective application for revision of the price of a scheduled formulation. Incidentally, the Form also confirms that no manufacturer or

formulator is placed at any disadvantage if the norm for packing material cost is not prescribed under Paragraph 7 of the DPCO 1995 but actuals are allowed.

146. The efficacy of the alternative remedy provided in the DPCO was the subject matter of consideration in ***Cynamide India Ltd.*** The contention urged therein was that for the purposes of price fixing, facts and figures were arbitrarily assumed by the Central Government. Rejecting this, it was held by this Court in paragraph 31 of the Report as follows:

> "……We do not propose to delve into the question whether there has been any such arbitrary assumption of facts and figures. We think that if there is any grievance on that score, the proper thing for the manufacturers to do is bring it to the notice of the Government in their applications for review. The learned counsel argued that they were unable to bring these facts to the notice of the Government as they were not furnished the basis on which the prices were fixed. On the other hand, it has been pointed out in the counter-affidavits filed on behalf of the Government that all necessary and required information was furnished in the course of the hearing of the review applications and there was no justification for the grievance that particulars were not furnished. **We are satisfied that the procedure followed by the Government in furnishing the requisite particulars at the time of the hearing of the review applications is sufficient compliance with the demands of fair play** in the case of the class of persons claiming to be affected by the fixation of maximum price under the Drugs (Prices Control) Order." [Emphasis supplied by us]."

We have no doubt that if any manufacturer or formulator had taken the trouble of preferring a revision or review application, all necessary material would have been made available to the complainant for an effective representation. We are satisfied that none of the parties before us was precluded by circumstances from preferring a revision or review for corrective measures in relation to the retail price or ceiling

price of any particular formulation – in fact, we are told by the learned Solicitor General that some of them did.

147. Strictly speaking, in view of the availability of an alternative and efficacious remedy available under the DPCO 1995 read with the decision of this Court in ***Cynamide India Ltd.*** the writ petitions filed by the manufacturers and formulators before us ought not to have been entertained by the concerned High Courts, but we leave it at that.

Forum shopping

148. The learned Solicitor General submitted that Cipla was guilty of forum shopping inasmuch as it had filed petitions in the Bombay High Court, the Karnataka High Court and also an affidavit in the Delhi High Court as a member of the Bulk Drug Manufacturers Association and had eventually approached the Allahabad High Court for relief resulting in the impugned judgment and order dated 3rd March, 2004. It was submitted that since Cipla had approached several constitutional Courts for relief, the proceedings initiated in the Allahabad High Court clearly amount to forum shopping.

149. We are not at all in agreement with the learned Solicitor General. Forum shopping takes several hues and shades and Cipla's petitions do not fall under any category of forum shopping.

150. A classic example of forum shopping is when a litigant approaches one

Court for relief but does not get the desired relief and then approaches another Court for the same relief. This occurred in ***Rajiv Bhatia v. Govt. of NCT of Delhi and others***.[24] The respondent-mother of a young child had filed a petition for a writ of *habeas corpus* in the Rajasthan High Court and apparently did not get the required relief from that Court. She then filed a petition in the Delhi High Court also for a writ of *habeas corpus* and obtained the necessary relief. Notwithstanding this, this Court did not interfere with the order passed by the Delhi High Court for the reason that this Court ascertained the views of the child and found that she did not want to even talk to her adoptive parents and therefore the custody of the child granted by the Delhi High Court to the respondent-mother was not interfered with. The decision of this Court is on its own facts, even though it is a classic case of forum shopping.

151. In ***Arathi Bandi v. Bandi Jagadrakshaka Rao***[25] this Court noted that jurisdiction in a Court is not attracted by the operation or creation of fortuitous circumstances. In that case, circumstances were created by one of the parties to the dispute to confer jurisdiction on a particular High Court. This was frowned upon by this Court by observing that to allow the assumption of jurisdiction in created circumstances would only result in encouraging forum shopping.

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[24] (1999) 8 SCC 525
[25] (2013) 15 SCC 790

152. Another case of creating circumstances for the purposes of forum shopping was ***World Tanker Carrier Corporation v. SNP Shipping Services Pvt. Ltd. and others***[26] wherein it was observed that the respondent/plaintiff had made a deliberate attempt to bring the cause of action namely a collision between two vessels on the high seas within the jurisdiction of the Bombay High Court. Bringing one of the vessels to Bombay in order to confer jurisdiction on the Bombay High Court had the character of forum shopping rather than anything else.

153. Another form of forum shopping is taking advantage of a view held by a particular High Court in contrast to a different view held by another High Court. In ***Ambica Industries v. Commissioner of Central Excise***[27] the assessee was from Lucknow. It challenged an order passed by the Customs, Excise and Service Tax Appellate Tribunal (the CESTAT) located in Delhi before the Delhi High Court. The CESTAT had jurisdiction over the States of Uttar Pradesh, NCT of Delhi and Maharashtra. The Delhi High Court did not entertain the proceedings initiated by the assessee for want of territorial jurisdiction. Dismissing the assessee's appeal this Court gave the example of an assessee affected by an assessment order in Bombay invoking the jurisdiction of the Delhi High Court to take advantage of the law laid down by the Delhi High Court or an assessee affected by an order of assessment made at Bombay invoking the jurisdiction of the Allahabad High Court

[26] (1998) 5 SCC 310
[27] (2007) 6 SCC 769

to take advantage of the law laid down by it and consequently evade the law laid down by the Bombay High Court. It was said that this could not be allowed and circumstances such as this would lead to some sort of judicial anarchy.

154. Yet another form of forum shopping was noticed in ***Jagmohan Bahl and another v. State (NCT of Delhi) and another***[28] wherein it was held that successive bail applications filed by a litigant ought to be heard by the same learned judge, otherwise an unscrupulous litigant would go on filing bail applications before different judges until a favourable order is obtained. Unless this practice was nipped in the bud, it would encourage unscrupulous litigants and encourage them to entertain the idea that they can indulge in forum shopping, which has no sanction in law and certainly no sanctity.

155. Another category of forum shopping is approaching different Courts for the same relief by making a minor change in the prayer clause of the petition. In ***Udyami Evam Khadi Gramodyog Welfare Sanstha and another v. State of Uttar Pradesh and others***[29] it was noticed by this Court that four writ applications were filed by a litigant and although the prayers were apparently different, the core issue in each petition centred round the recovery of the amount advanced by the bank. Similarly, substituting some petitioners for others with a view to confer jurisdiction on a particular Court would also amount to forum shopping by that group of

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28 (2014) 16 SCC 501
29 (2008) 1 SCC 560

petitioners.

156. Finally and more recently, in ***Supreme Court Advocates on Record Association v. Union of India (Recusal Matter)***[30] Justice Khehar noticed yet another form of forum shopping where a litigant makes allegations of a perceived conflict of interest against a judge requiring the judge to recuse from the proceedings so that the matter could be transferred to another judge.

157. The decisions referred to clearly lay down the principle that the Court is required to adopt a functional test *vis-à-vis* the litigation and the litigant. What has to be seen is whether there any functional similarity in the proceedings between one Court and another or whether there is some sort of subterfuge on the part of a litigant. It is this functional test that will determine whether a litigant is indulging in forum shopping or not.

158. Keeping all these examples in mind with several other nuances and also keeping the functional test in mind, we have examined the relief claimed by Cipla in the different High Courts and find that they have no substantive connection whatsoever with the relief claimed in the Allahabad High Court.

159. Be that as it may, we have examined the submissions made by the learned Solicitor General in respect of each of the writ petitions filed by Cipla.

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30 (2016) 5 SCC 808

160. The Bulk Drug Manufacturers Association had filed W.P. No. 5578 of 1997 in the Delhi High Court in which it had challenged the inclusion of 8 bulk drugs in the First Schedule of the DPCO 1995. Among the bulk drugs whose inclusion was challenged were Salbutamol, Theophylline, Ciprofloxacin and Norfloxacin.

161. The Delhi High Court required the members of the Bulk Drug Manufacturers Association to file an affidavit stating that they would be bound by the orders passed by the Delhi High Court. Pursuant to this direction, Cipla filed an affidavit in the Delhi High Court on 24th May, 1999 stating that any final decision taken on the question of the inclusion or exclusion of Salbutamol and Theophylline in W.P. No.5578 of 1997 will be binding on Cipla subject to any appeal preferred thereon. It was also disclosed by Cipla that it had already filed a writ petition in the Bombay High Court on 9th April, 1999 to the effect that Salbutamol be exempted from price control under the DPCO 1995.

162. As mentioned above, on 9th April, 1999 Cipla had filed a writ petition being W.P.No.1749 of 1999 in the Bombay High Court. The challenge therein was to the inclusion of bulk drugs Salbutamol and Theophylline in the First Schedule of DPCO 1995.

163. Cipla also filed Writ Petition No.1974 of 2000 in the Bombay High Court on 22nd September, 2000 seeking exclusion of the bulk drug Ciprofloxacin from the ambit of price control under the DPCO 1995. It was contended that it should be

excluded from the First Schedule of the DPCO 1995.

164. Cipla filed a third writ petition in the Bombay High Court being W.P. No.2019 of 2000. This was filed on 28th September, 2000 and the challenge was to the inclusion of the bulk drug Norfloxacin within the ambit of price control under the DPCO 1995.

165. Cipla also filed writ petitions in the Karnataka High Court being W.P. Nos.33989-34011 of 2000. In these writ petitions, several notifications issued under Paragraph 8 and Paragraph 9 of the DPCO 1995 as well as demand notices issued to Cipla were under challenge.

166. We find that almost all the notifications under challenge in the Karnataka High Court were also the subject matter of challenge in the Allahabad High Court. However, Cipla had disclosed before the Allahabad High Court that it had filed writ petitions before the Karnataka High Court. There was therefore no concealment of any facts by Cipla. We also find that the consequence of allowing the three writ petitions filed by Cipla in the Bombay High Court would have had an impact on the notifications challenged in the Allahabad High Court, but that impact would have been collateral and consequential. We are of opinion that under these circumstances, Cipla ought to have disclosed the filing of writ petitions in the Bombay High Court, but at this stage we do not think it appropriate to non-suit Cipla only on this ground.

167. The proceedings in the Allahabad High Court were initiated as a result of a show cause notice issued to Cipla. No similar show cause notice and no similar factual circumstances existed in any of the other High Courts in which Cipla had initiated proceedings. It cannot, therefore, be said that Cipla had indulged in forum shopping in any manner whatsoever.

Two comments

168. Before parting with these appeals, we would like to make two comments: Firstly, with regard to the manner in which the Union of India has handled the litigation. We find that by and large, very little or scanty material was placed by the Union of India before the concerned High Courts, particularly the Allahabad High Court. On the other hand, several volumes of documents have been filed in this Court, though after permission. Such a practice deserves discouragement and we do so. There are several reasons for this. It tends to degrade the importance of proceedings in the High Court and could subsequently embarrass the High Court which might inadvertently base its decision on insufficient material resulting in the possibility of an incorrect decision which is liable to be set aside. It might also cause serious prejudice to a litigant because it is for the first time in this Court that the entire material is made available to a litigant placing him/her at a disadvantage in dealing with issues of importance. It certainly places an unnecessary and totally avoidable burden on this Court which is required to deal with the material as a

court of first instance. Under such circumstances this Court does not have the benefit of the opinion of the High Court while dealing with an appeal. All in all therefore, for the better adjudication of disputes and for the convenience of all concerned, it would be more appropriate for the Union of India, as indeed for all litigants to place on record all the material before the court of first instance, whether it is a district court or a High Court. We need say no more on this subject.

169. Secondly, the learned Solicitor General specifically and repeatedly requested us to comment on the grant of interim orders by the High Courts in matters concerning economic issues and particularly in matters pertaining to the sale of formulations at the retail price or ceiling price fixed by the Central Government through notifications issued under the DPCO. Certain interim orders were brought to our notice restraining coercive action against a manufacturer/formulator when a price notification was under challenge. It is true that such an interim order could have a huge impact on society.

170. In ***Cynamide India*** this Court expressed the view that an interim order should not have the effect of staying the implementation of a notification fixing the price of a formulation under the DPCO. That would be against public interest and, therefore, ought not to be made by a Court unless it is satisfied that no public interest is going to be served. This is what this Court had to say in paragraphs 37 and 38 of the Report:

> "We notice that in all these matters, the High Court granted stay of implementation of the notifications fixing the maximum prices of bulk drugs and the retail prices of formulations. We think that in matters of this nature, where prices of essential commodities are fixed in order to maintain or increase supply of the commodities or for securing the equitable distribution and availability at fair prices of the commodity, it is not right that the court should make any interim order staying the implementation of the notification fixing the prices. We consider that such orders are against the public interest and ought not to be made by a court unless the court is satisfied that no public interest is going to be served.
> .....
>
> In matters of fixation of price, it is the interest of the consumer public that must come first and any interim order must take care of that interest."

171. Under these circumstances, we are clearly of the view that in matters where public interest is involved, the Court ought to be circumspect in granting any interim relief. The consequence of an interim order might be quite serious to society and consumers and might cause damage to public interest and have a long term impact. We make it clear that it is not our intention to suggest to any Court how and in what circumstances interim orders should or should not be passed but it is certainly our intention to make it known to the Courts that the time has come when it is necessary to be somewhat more circumspect while granting an interim order in matters having financial or economic implications.

172. We would also like to draw the attention to the Drug Policy, 1994 which mentions that as far as the drug industry is concerned, there are about 250 large units and about 8000 small scale units in operation. These units produce about 350 bulk drugs, and as we have mentioned above more than 2000 formulations. The

Drug Policy, 1994 also mentions that the production of bulk drugs in 1993-94 is in the region of Rs.1320 crores and for the same period the production of formulations is in the region of Rs. 6900 crores. In other words, not only is the drug industry in the country extremely large with heavy financial stakes but there is lot at stake in it not only for the industry but also for the consumers. For this reason, the Courts have to extremely cautious in interfering in any manner whatsoever with the working of the drug industry. Any interference by the Courts would have wide ranging repercussions not only in commercial terms but also for the people of the country.

Conclusion

173**.** Our answer to the questions identified are as follows:

a Whether the notification dated 13th July, 1999 issued by the Central Government under Paragraph 7 of the Drugs (Prices Control) Order, 1995 prescribing the norms for conversion cost, packing charges and process loss of raw materials (other than packing materials in conversion) and packing and process loss of packing materials in packaging was issued mechanically and without any application of mind or is it valid in law? Our answer to this is that the notification is valid and that the notification was not issued mechanically or without any application of mind.

b Whether the notifications dated 12th July, 2000, 12th July, 2001, 12th July, 2002 and 11th July, 2003 issued by the Central Government under Paragraph 7 of the Drugs (Prices Control) Order, 1995 re-notifying the norms prescribed on 13th July, 1999 were issued mechanically, without any application of mind and without re-determining the norms every year as required by the Drugs (Prices Control) Order, 1995 and are they valid in law? Our answer is that the notifications are valid and were not issued mechanically or without any application of mind and that it was not necessary to re-determine the norms every year.

c Whether various notifications issued by the Central Government fixing the retail price or ceiling price of formulations under Paragraphs 8 and 9 (as the case may be) of the Drugs (Prices Control) Order, 1995 without determining the norm for cost of packing material as required by Paragraph 7 of the Drugs (Prices Control) Order, 1995 are valid in law? Our answer is in the affirmative.

d Whether fixing the retail price of a formulation under Paragraph 8 of the Drugs (Prices Control) Order, 1995 without first fixing the sale price of a bulk drug under Paragraph 3 of the Drugs (Prices Control) Order, 1995 utilized in the manufacture of a formulation is valid in law? Our answer is in the affirmative.

174. In view of the above, the appeals filed by the Union of India are allowed. The impugned judgments and orders are set aside. The appeals filed by Dr. Reddy's Laboratories Ltd. are dismissed. No costs.

…...……J
(Madan B. Lokur)

.....……J
(R.K. Agrawal)

New Delhi;
October 21, 2016