$~68

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\+ W.P.(C) 7597/2018 & CM No. 29055/2018

INDOCO REMEDIES LIMITED ..... Petitioner

Through: Mr Vivek Chib, Ms Pracheta Kar, Mr Asif Ahmed, Ms Ruchira Goel, Mr Kushal Gupta, Mr Rajeev M. Roy, Mr Rajeev K. Pandey and Mr Shambhu Thakur, Advocates.

versus

UNION OF INDIA AND ANR. ..... Respondents

Through: Ms Maninder Acharya, ASG, Mr Kirtiman Singh, CGSC, Mr Vikram Aditya Singh, Mr Waize Ali Noor, Mr Sahil Sood, Mr Harshul Choudhary, Mr Viplav Acharya and Mr Prateek Danda, Advocates for UOI.

**CORAM:**
**HON'BLE MR. JUSTICE VIBHU BAKHRU**

**O R D E R**

**% 26.07.2018**

**VIBHU BAKHRU, J**

1. The petitioner (hereafter 'IRL') has filed the present petition impugning the notice dated 20.11.2017 (hereafter 'the impugned notice') issued by the National Pharmaceutical Pricing Authority (hereafter 'NPPA')

demanding a sum of ₹2,93,57,006/- (₹2,00,95,630/- towards the overcharged amount plus ₹92,61,376/- towards interest at the rate of 15% p.a) for the amount overcharged by the petitioner and not complying with the ceiling price fixed under the Drugs (Price Control) Order, 2013 (hereafter 'DPCO-2013').

2. The impugned notice had been issued on the basis that the petitioner had overcharged for the formulation TRIZ Syrup 60 ml containing CETIRIZINE 5mg/5ml at the rate of ₹42.25/- per injection against the ceiling price of ₹0.55/- per ml (that is, ₹33/- for 60 ml).

***Factual Background***

3. IRL is a Pharmaceutical Company and is engaged in the business of manufacturing and marketing of drugs and pharmaceuticals. This includes TRIZ Syrup 60ml which contains CETIRIZINE of the strength 5mg/5ml (hereafter also referred to as 'the Formulation').

4. In the year 2011, the National List of Essential Medicines (hereafter 'NLEM - 2011') was revised to include CETIRIZINE with the following strengths:-

- CETIRIZINE Tablets 10 mg and
- CETIRIZINE Syrup 5 mg/ 5 ml

5. The DPCO-2013 was issued on 15.05.2013 with NLEM-2011 included as Schedule-I thereto. As noticed above, at the material time

NLEM - 2011 included CETIRIZINE Tablets of the strength 10 mg and CETIRIZINE Syrup of the strength 5 mg/ml.

6. On 28.06.2013, NPPA issued a Price Notification Order fixing the ceiling price of CETIRIZINE syrup with strength 5mg/ml as ₹0.54/-. Subsequently, on 28.04.2014, NPPA issued another Price Notification Order fixing the ceiling price of CETIRIZINE tablets with strength 10 mg as ₹1.92/- per tablet and the ceiling price of CETIRIZINE Syrup-5mg/ml was revised to ₹0.57/-.

7. On 26.02.2015, NPPA issued another Price Notification Order revising the ceiling price of CETIRIZINE Syrup-5 mg/ml to ₹0.59/- and for CETIRIZINE tablet-10 mg to ₹1.94/-. Thereafter, on 02.03.2016, NPPA issued another Price Notification Order revising the ceiling price of CETIRIZINE Syrup-5mg/ml to ₹0.57/- and ceiling price of CETIRIZINE tablets-10mg to ₹1.94/- for 1 tablet.

8. On 16.04.2015, NPPA sent a notice to IRL, *inter alia,* stating that IRL had increased the Maximum Retail Price (MRP) of the formulation from ₹36.80 in December, 2013 to ₹40 in December 2014, which translated to an increase of 8.70% in the MRP of the Formulation. IRL was called upon to explain the reasons for such increase in the MRP and also furnish a consolidated price list of products manufactured or marketed by it.

9. IRL responded to the aforesaid notice dated 16.04.2015, by a letter dated 07.05.2015, *inter alia,* claiming that the NLEM-2011 did not include CETIRIZINE with the strength of 5mg/5ml and, therefore, the Formulation,

which contains CETIRIZINE of the strength 5mg/5 ml, was not included as a 'scheduled formulation' under the DPCO-2013.

10. Thereafter, on 09.05.2016, NPPA issued a Price Notification Order which included CETIRIZINE Oral liquid strength 5mg/5ml. The ceiling price of the same was fixed at ₹0.55/-.

11. IRL states that after the Price Notification Order dated 09.05.2016 was issued, it revised the price of the Formulation in accordance therewith.

12. On 16.08.2016, NPPA issued a letter stating that it had observed that IRL had not applied the price fixed in respect of TRIZ – CETRIZINE 5 mg batch no.TAXIJ54 with manufacturing date 01.10.2015 and called upon IRL to explain the reasons for non compliance of the price fixed and to further furnish the consolidated price list for all the products manufactured by it along with certificate from the Chartered/Cost Accountant with batch wise production and sale details. IRL responded to the said letter on 01.09.2016 reiterating its earlier stand that the Formulation was not covered under Price Notification Orders issued prior to 09.05.2016. Since the batch in question was sold in October, 2015 – prior to the issuance of the Price Notification Order dated 09.05.2016 – the ceiling prices as fixed earlier were not applicable.

13. Thereafter, on 07.04.2017, NPPA issued a Show Cause Notice, *inter alia,* rejecting IRL's contentions as not tenable. NPPA asserted that the ceiling price for the said formulation was first notified by a Price Notification Order dated 28.06.2013, whereby the ceiling price was fixed at ₹0.54 per ml (which worked out to ₹32.40 for 60 ml on pro-rata basis).

NPPA alleged that IRL had over charged to the extent of ₹1,92,86,598/- during the period from July, 2013 to May, 2016 and, accordingly, called upon IRL to show cause why action should not be taken for recovery of the over charged amount with interest. IRL responded to the aforesaid Show Cause Notice on 31.07.2017 stating that the Price Notification Order dated 28.06.2013 was inapplicable as it did not indicate the ceiling price for a formulation containing CETIRIZINE of the strength of 5 mg/5 ml. IRL claimed that since the strength of the Formulation did not match the one as was notified in DPCO-2013, the ceiling price as fixed was not applicable to the Formulation. IRL claims that, thereafter, it received a letter dated 10.10.2017 enclosing a letter dated 04.10.2016. In the said letter, it was stated that if IRL did not respond within a period of 15 days, it would be presumed that the petitioner had nothing to say and proper action would be taken under the provisions of DPCO-2013. IRL responded to the aforesaid notice reiterating its stand as noticed above. Thereafter, on 20.11.2017, NPPA issued the impugned notice.

***Submissions***

14. Mr Chib, the learned counsel appearing for IRL referred to paragraph 2(v) of the DPCO-2013, which defines the term 'non-scheduled formulation' to mean "a *formulation, the dosage and strengths of which are not specified in the First Schedule*." He submitted that Schedule I to the DPCO-2013 included CETIRIZINE in only two dosage forms and strength, namely, Tablets of 10 mg and Syrup of 5 mg/ml. Since the dosage and strength of the Formulation was different from the one as listed in Schedule I to the DPCO-2013, the Formulation, was covered within the scope of *"non*

*scheduled formulation"* as defined in paragraph 2(v) of the DPCO-2013. He contended that thus the Formulation was outside the purview of DPCO-2013 and could not be subject to price ceiling under any of the Price Notification Orders issued by NPPA. He relied on the recent judgment of this Court in ***Modi-Mundipharma Pvt. Ltd. v. Union of India and Ors.: W.P.(C) 11802/2016***, ***decided on 17.07.2016*** in support of his contention.

15. Next, Mr Chib, submitted that even if it is assumed that the Formulation in question was included under DPCO-2013 as originally notified, the ceiling price as fixed under Price Notification Orders issued on 28.04.2014, 26.02.2015 and 02.03.2016 could not be applied as the said Price Notification Orders did not provide any ceiling price for CETRIZINE with the dosage and strength manufactured/sold by IRL. He emphasized that the Formulation in question was included under price ceiling for the first time by virtue of Price Notification Order dated 09.05.2016, as it expressly referred to "CETIRIZINE Oral liquid strength 5 mg/5 ml" which was the strength of CETIRIZINE in the Formulation manufactured by IRL.

***Discussion and Conclusion***

16. At the outset, it is relevant to refer to paragraph 8(1) of DPCO-2013, which reads as under:-

> "8. **Maximum retail price**.- (1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:

**Maximum Retail Price = Ceiling Price + Local Taxes as applicable**..."

17. It is apparent from the above that in terms of the DPCO-2013, the obligation to adhere to a ceiling price notified by the Government is applicable only in respect of a "*scheduled formulation"*. In view of the above, the first and foremost question that falls for consideration of this Court is whether the formulation in question is a "scheduled formulation".

18. The expression "scheduled formulation" is defined under sub-clause (zb) of paragraph 2(1) of DPCO-2013, which reads as under:

> "(zb) "**scheduled formulation**" means any formulation, included in the First Schedulewhether referred to by generic versions or brand name;"

19. NLEM-2011, which was adopted as Schedule-I to the DPCO-2013 as initially notified, included the formulation CETIRIZINE. At the material time, the relevant entry read as under:-

"**Added Medicines**

| | | | |
|---|---|---|---|
| Cetrizine | P, S, T | Tablets Syrup | 10 mg<br>5mg/ml |

20. As is apparent from the above, NLEM-2011 included the medicine 'CETRIZINE' with the tablets of strength of 10 mg and syrup with the strength of 5 mg/ml. A plain reading of paragraph 8(1) of DPCO-2013 read with the definition of the expression "scheduled formulation", clearly indicates that the formulation CITRIZINE would fall within the scope of

DPCO-2013. However, it is also relevant to consider the definition of the expression "non scheduled formulation". The said expression is defined under clause (v) of paragraph 2(1) of the DPCO-2013. Prior to 09.03.2015, the said clause reads as under:

> "(v) "**non-scheduled formulation**" means a formulation, the dosage and strengths of which are not specified in the First Schedule."

21. Thus, the main issue to be addressed is whether the Formulation in question is excluded by virtue of paragraph 2(1)(v) of DPCO-2013. A plain reading of clause (v) of paragraph 2(1) of DPCO-2013 indicates that even though a formulation is indicated as included in Schedule I, but if the specific dosage and strength are not specified, the formulation with such dosages and strength which are not specified, would fall within the definition of the expression 'non-scheduled formulation'. This – as the prefix 'non' indicates – would mean that such formulation would not qualify to be considered as a 'scheduled formulation'.

22. A conjoint reading of the definitions of 'scheduled formulation' and 'non-scheduled formulation' indicates that those drugs, which are not mentioned in Schedule I of DPCO-2013 clearly fall outside the scope of price ceiling under paragraph 8(1) of DPCO-2013. They would undisputedly fall outside the purview of the definition of the term 'scheduled formulation' and squarely fall within the definition of the expression 'non-scheduled formulation'. However, there is another set of drugs which on a plain reading of paragraph 2(1)(zb) of DPCO-2013 fall within the scope of the term 'scheduled formulation' but would stand excluded on account of

the specific dosages and strengths not being specified in the said schedule. In respect of such medicines, paragraph 2(1)(v) of DPCO-2013 (which defines the term "non-scheduled formulation") would work as an exclusionary clause.

23. It is also necessary to bear in mind that DPCO-2013 has been issued in exercise of powers conferred by Section 3 of the Essential Commodities Act, 1955 and as per the National Pharmaceuticals Pricing Policy - 2012 (NPPP-2012). One of the stated objectives of NPPP-2102 is to *"put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – essential medicines – at reasonable prices."* This is to ensure that essential medicines can be made available to the masses. Thus, the interpretation of provisions of DPCO-2013 must lean towards including essential medicines within the scope of DPCO-2013 rather excluding them. Accordingly, clause (v) of paragraph 2(1) of DPCO-2013 must be read in a restrictive and not an expansive manner.

24. At this stage, it would also be relevant to bear in mind that NPPP-2012 is materially different from the Drug Policy of 1994, which was implemented by issuing of the Drugs (Price Control) Order, 1995. One of the key principles of NPPP-2012 was to ensure regulation of only essential medicines. This was materially different from the substratal principles of the Drug Policy, 1994, which contemplated controlling the prices of bulk drugs and their formulations. The thrust of NPPP-2012 was to restrict principal control to essential formulations only. This is clearly stated in Paragraph 3.2 of the NPPP-2012, which also indicates the reasons for the change in Policy. Paragraph 3.2 of NPPP-2012 is set out below:-

"3.2 The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations only. This is different from the earlier principle of regulating the prices of specified Bulk Drugs and their formulations adopted in the Drug Policy 1994. The reasons for adoption of this principle of price control of "Formulations Only" are:

(i) That the Bulk Drug – API (Active Pharmaceutical Ingredient) – may not fully reflect the 'Essentiality' of the actual drug formulation – now the subject of focus – due to the possible applicability of the API in manufacture of various formulations which may or may not be considered "Essential" for the larger healthcare needs of the masses.

(ii) The emphasis on price control starting at the bulk drug stage itself has in recent times, resulted in amongst other reasons shifting of manufacture of drugs away from the notified bulk drugs under price control. In fact only 47 bulk drugs out of 74 notified in the First Schedule of the DPCO, 1995 are now under production. This has had a cascading effect on the formulations manufactured from the concerned bulk drugs which in turn has affected the availability of such formulations. The consumer-patient has been adversely affected in the process.

(iii) The task of pricing both the bulk drug and the formulation makes it complicated and time consuming without commensurate direct benefits to the consumer who is actually affected only by the price of the final end product, i.e. the formulation – made from the bulk drug rather than its bulk constituents.

(iv) The price control in the form of formulations only ensures more specific pricing control of the required medicine which

is in the interest of the consumer from the point of view of the actual prescription by the Doctor. This aspect is more important for a country like India where there is large asymmetry in the information between the doctor and the patient.

(v) Since the bulk drug manufacturer is constrained to sell at a fixed price, the manufacturer is always likely to give preference to an existing buyer rather than to a potential new entrant. This constrains the emergence of new companies and formulations in the price-controlled segment and is inherently anti-competitive and also does not benefit the consumer-patient for the same reason."

25. It is trite law that exclusionary clauses of a beneficial legislation are to be read narrowly. This is so to ensure that the beneficent impact of the Act is not diluted. It is also well settled canon of statutory interpretation that of statutes must be interpreted, in so far as possible, to further public interest. In the present case, the purpose and object of the DPCO-2013 is to ensure the availability of medicines at affordable prices. Thus, the provisions of the DPCO-2013 must be interpreted purposively in a manner so as to further this object.

26. In ***Sheikh Gulfan and Ors. v. Sanat Kumar Ganguli: AIR 1965 SC 1839***, the Supreme Court had explained that any exception to a beneficent legislation must be construed narrowly. In ***U. P. Bhoodan Yagna Samiti, U. P. v. Braj Kishore and Ors.: (1988) 4 SCC 274***, the Supreme Court observed that "*it is well settled that in order to interpret a law one must understand the background and the purpose for which the law was enacted."* In that case, the Court declined to accept that the landless

businessmen in a city would fall within the scope of the expression, "landless persons" as that would surely not further a purpose of the scheme of Bhoodan and the movement of Shri Vinoba Bhave.

27. In the context of the present case, the reference to dosage and strengths as used in clause (v) of paragraph 2(1) DPCO-2013 as it existed prior to 09.03.2015 cannot be read in a literal sense and must be interpreted in a meaningful manner to further the purpose of DPCO-2013.

28. In the aforesaid view, the expression "non-scheduled formulation" in the context of excluding medicines that are specified in Schedule-I but not of the specified strengths and dosages, must be read in the manner to exclude only those medicines where unspecified dosage/strength result in a qualitative difference to the formulation. In other words, the dosage and strength on the basis of which the medicines specified in Schedule I are sought to be excluded, must necessarily mean dosages and strength which have an effect of resulting in a different product. Mere quantitative differences would be insufficient to establish any material difference from the scheduled formulation. Plainly, dilution in the strength of a medicine or increasing the concentration would have little effect on the product. For example, a tablet of the strength of 250 mg and a tablet of 500 mg would have little difference in the product. A patient, who has been prescribed to take two such tablets of 250 mg, could take one tablet of 500 mg strength. In such cases, there would be little added advantage or disadvantage in using one or the other. Similarly, a medicine may be given in the form of a tablet or a capsule, the dosages and strengths of the medicines in this respect may differ but the essential product remains the same. In these cases, it would be

difficult to accept that although the drug falls within the expression 'scheduled formulation' as defined in Paragraph 2(1)(zb) of DPCO-2013, the same should, nonetheless, be excluded merely because the dosage or strength – which has no material effect on the Formulation in question – is not specified. However, there are formulations, which use innovative forms or route of administration that render the formulations materially different from the one listed in Schedule-I of DPCO-2013 even though the medicine remains the same. Such formulations would qualify to be non-scheduled formulations if not specifically included.

29. In the present case, there is no material difference between the Formulation and the CETRIZINE as included in NLEM-2011. The Formulation manufactured by IRL is only a dilution of the strength (of CETRIZINE) as specified in Schedule I. Clearly, such variation in the strength of the medicines would be wholly insufficient to exclude the same from Schedule I of the DPCO-2013.

30. In ***Union of India and Anr. v. Swiss Garnier Life Sciences & Ors.: (2013) 8 SCC 615***, the Supreme Court had also noticed a news items appearing in the newspaper insinuating the drug companies were following a strategy by which they were replacing price controlled products by alternatives in the same class. Surely, accepting a mere dilution in the strength of medicine is insufficient to exclude the same Schedule-I of the DPCO -2103. Such interpretation would be an open invitation for all drug manufacturers to tweak the strength of their formulations so as to escape the price control regime under the DPCO-2013. Plainly, this would frustrate the object of the legislation. More importantly, it is impossible to accept that

legislative intent was to exclude formulations from Schedule I merely on the basis of dilution or concentration in the strength of the medicines as specified.

31. The expression 'dosages and strength' as used in the DPCO-2013 is used in a wide sense and includes variations in forms and route of administration as well as is apparent from a plain reference to Schedule-I.

32. Clause (v) of paragraph 2(1) of DPCO 2013 was substituted with effect from 09.03.2015 to read as under:-

> "2(1)(v) "**non-scheduled formulation**" means a formulation, which is not included in Schedule-I."

33. As is apparent, the words 'dosages and strengths' were deleted from the definition of the term 'non-scheduled formulation'. With the aforesaid amendment, the provisions of paragraph 2(1)(zb) and 2(1)(v) of DPCO-2013 have been harmonised. Thus, any medicine which is included in Schedule I of DPCO-2013 would be a scheduled formulation and any medicine which is not, would be a non-scheduled formulation.

34. It is also relevant to note that this was followed by amending Schedule I of DPCO-2013 to now adopt NELM-2015 instead of NLEM-2011. Schedule-I as amended also included certain explanations. Explanation (1) and (2) are relevant and read as under:

> "(1) Any dosage form of a medicine, other than the dosage form included in this Schedule, but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics or

pharmacodynamics or efficacy-safety profile over the dosage form mentioned in the list shall be considered as included. To elaborate, if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included. However, such different dosage forms should be considered differently for purposes such as procurement policy, pricing, etc. This principle also applies to all other dosage forms e.g. oral liquid dosage forms, injectables, topical dosage forms, etc.

(2) Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/ controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc."

35. The aforesaid explanations were included pursuant to the recommendations included in the "Report of the Core Committee for Revision of NLEM-2015.

36. Explanation 1 now expressly provided that any dosage form, which is not included in Schedule I, but in same strength which does not have any significant difference in terms of pharmacokinetics/pharmacodynamics/efficacy-safety profile over the dosage form mentioned in the list, should be considered as included in Schedule I.

37. By virtue of Explanation 2, the formulations that were developed through incremental innovation or novel drug delivery system such as Sustained release or Controlled release were unless specified in Schedule I,

expressly to be excluded from Schedule I. Plainly, medicines with such added qualities or attributes that are substantial enough to render the product itself dissimilar to the one entered in Schedule-I, cannot be assumed as covered by an entry in Schedule-I, which does not specifically indicate so. This is also the substratal rationale of clause (v) of paragraph 2(1) of DPCO-2013 as it existed prior to 09.03.2015.

38. The reliance placed by Mr Chib on the decision in the case of ***Modi-Mundipharma Pvt. Ltd. v. Union of India and Ors.*** (*supra*) is misplaced. In that case, it was held that even if a medicine is mentioned in Schedule I, but the specific dosages and strength has not been specified, the same would fall within the definition of non-scheduled formulation. The said observations were made in the context of a product where medicine in question involved an innovative delivery system, which was not specified in Schedule-I to the DPCO-2013. Such medicines which involve a different delivery system such as Controlled Release and Sustained Release would by itself mean that the products as mentioned in Schedule I (which do not specifically refer to any such innovative delivery system) is materially different from the products which involve such innovation. Thus, the definition of the expression "non-scheduled formulation" (as existing prior to 09.03.2015) must be read with an added qualification that the difference in the dosages and strengths are such as would result in a material change in the product itself (medicine). Thus, if a medicine is mentioned in Schedule I but the specific dosage and strength has not been specified, the same would be 'non-scheduled formulation' provided that the dosage and strength (which are not specified in Schedule I) have a material bearing on the

product and are of such nature that it would not be reasonable to consider the product as the one as specified in Schedule I.

39. In the present case, it is, *ex facie,* clear that there is no material difference in the medicine as specified in Schedule I - CETRIZINE Syrup 5mg/ml and oral syrup 5mg/5ml and the latter would only be a diluted version of the former.

40. In view of the above, this Court is of the view that the Formulation in question was included in Schedule I and was fully covered within the scope of DPCO-2013.

41. The next question to be considered is whether the Formulation in question was covered within the Price Notification Orders issued under DPCO-2013. The first such order was issued on 28.06.2013 where the selling price was fixed at ₹0.54/-. The same would, plainly, be applicable and would not exclude the formulation in question merely because it was a diluted version of the scheduled formulation - CETRIZINE Syrup.

42. In view of the above, the present petition is unmerited and is, accordingly, dismissed. The pending application stands disposed of.

**VIBHU BAKHRU, J**

**JULY 26, 2018**
**MK**