

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

% **Date of decision: 18th May, 2016.**

+ **W.P.(C) 9089/2015 & CM No.20576/2015 (for stay)**

**PFIZER PRODUCTS INDIA PRIVATE LIMITED
& ANR**

..... Petitioners

Through: Mr. P. Chidambram, Sr. Adv. with
Mr. Cyrus Avdershir, Mr. Rahul
Dwarkadas, Mr. Yuvraj Choksy and
Ms. Aayushi Sharma, Advs.

Versus

UNION OF INDIA

..... Respondent

Through: Mr. Sanjeev Narula, CGSC with Mr.
Ajay Sondhi, Mr. Ajay Kalra, Mr.
Rishikant Singh and Ms. Gunjan
Sharma, Advs.

CORAM:

HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

1. The petition, (i) impugns the notice-cum-order dated 15th September, 2015 of the respondent Drugs Controller General (India) (DCGI) rejecting the representation dated 10th July, 2015 of the petitioner with respect to the drug "Medrol" and reserving the right for initiating legal proceedings against the petitioner; (ii) seeks a mandamus to the respondent DCGI to re-consider the representation of the petitioner; and, (iii) seeks to restrain the respondent DCGI from enforcing the impugned notice-cum-order dated 15th September,

2015 with respect to drug 'Medrol' or from taking any other coercive measure under the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder.

2. It is the case of the petitioner (petitioner No.2 is the Senior Manager (Legal) of the petitioner No.1):

- (a) that the petitioner has been importing the drug 'Medrol' from 'Pfizer Italia S.r.l.' Ascoli, Italy;
- (b) that as per Rule 96(1)(vii) of the Drugs and Cosmetics Rules, 1945, the statutory period of the life of a drug not specified under Schedule P of the Rules should not exceed 60 months from the date of manufacture;
- (c) that the Assistant Drugs Controller, Karnataka vide notice dated 25th June, 2015 directed the petitioner not to sell and / or distribute and to return and destroy certain batches of the drug 'Medrol';
- (d) that the Drugs Inspector, Chennai also vide notice dated 6th July, 2015 directed the petitioner to not dispose of the stock of the drug 'Medrol' for a period of 20 days therefrom followed by show cause notice dated 7th July, 2015;

(e) that the aforesaid action was by reading the date of expiry mentioned on the packaging of drug 'Medrol' as 61 months and which is in violation of Rule 96(1)(vii) of the Rules supra;

(f) that though the Drugs Authorities of the States of Maharashtra and Orissa also issued notice to the petitioner but did not follow the same;

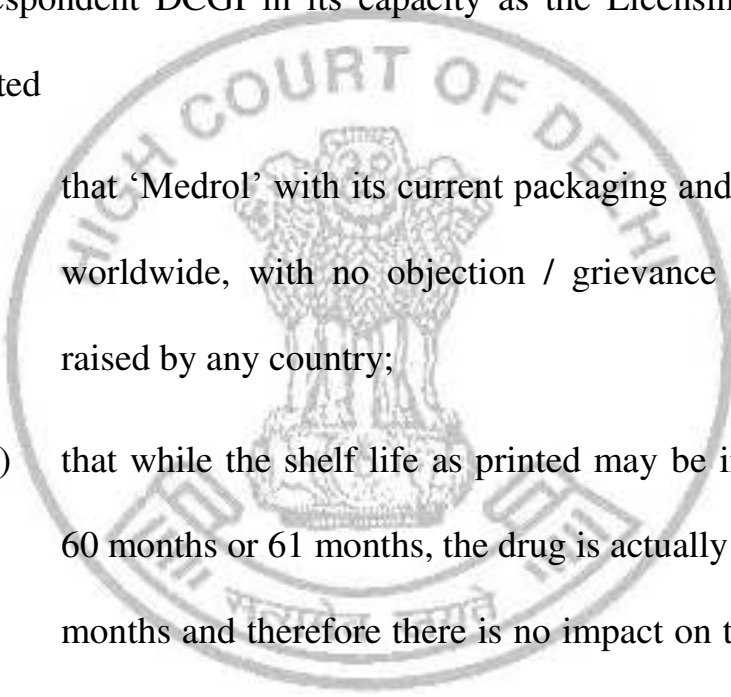
(g) that the petitioner represented in response to all the aforesaid notices that the date of expiry printed on the packaging of drug 'Medrol' was of 60 months only and not of 61 months and that the drug was actually stable for 62 months;

(h) that the petitioner filed writ petition under Article 226 of the Constitution of India before the High Court of Madras with respect to the proceedings initiated against it and vide interim order wherein, on the undertaking of the petitioner, not to sell the subject stock of the drug 'Medrol' beyond December, 2017, further action against the petitioner was stayed;

(i) that the petitioner also instituted a petition under Article 226 of the Constitution of India in the High Court of Karnataka and by

interim order wherein, action against the petitioner was stayed, on the petitioner issuing a clarification that the drug already on the shelves of medical stores for distribution shall not be kept for sale beyond 60 months from the date of manufacture indicated on its packaging;

(j) that the petitioner, vide its representation dated 10th July, 2015 to the respondent DCGI in its capacity as the Licensing Authority, represented

- 
- (i) that 'Medrol' with its current packaging and label is sold worldwide, with no objection / grievance having been raised by any country;
 - (ii) that while the shelf life as printed may be interpreted as 60 months or 61 months, the drug is actually stable for 62 months and therefore there is no impact on the quality of the drug;
 - (iii) that the drug is a fast moving drug and therefore the possibility of it being in the market close to its expiry date is inequitable;

(iv) that the petitioner had a practice of calling back the drugs including 'Medrol' from the stockist 6 months prior to the expiry date;

and sought permission to sell the concerned batches of 'Medrol' in the market and its warehouse with the undertaking of the petitioner that such batches would not be sold after December, 2017 and seeking extension of the expiry of the blister-packs / strips of 'Medrol' for such batches to 61 months based on the stability data submitted by the petitioner;

(k) that the respondent DCGI vide impugned notice-cum-order has refused to consider the request of the petitioner for extending the period of expiry of 'Medrol' on the ground that the petitioner after being found to be non-compliant with the statutory provisions could not seek such relief and has otherwise rejected the request of the petitioner for allowing continued sale of concerned batches of 'Medrol';

(l) that the petitioner without prejudice to its rights and contentions has already initiated proceedings to ensure that all future batches of

the drug 'Medrol' which are to be imported into India bearing the label not exceeding 60 months from the date of manufacture, thereby removing the ambiguity if any in the label / pack.

3. This petition is confined only to the stocks of the 'Medrol' already imported.

4. The petition came up first before this Court on 21st September, 2015 when the senior counsel for the petitioner (i) contended that the date of manufacture and the date of expiry of the drug are mentioned, say as October, 2014 and October, 2019; (ii) contended that according to the petitioner, the same amounts to prescribing the expiry period of 60 months only from the date of manufacture; (iii) however the Authorities at Chennai and Bangalore are treating the same as specifying the expiry period of 61 months; (iv) that Rule 96(1)(vii) prescribes the period of expiry for drugs other than those specified in Schedule P, of 60 months from the date of manufacture but the proviso thereto empowers the respondent DCGI to extend the same, if satisfactory evidence is produced by the manufacturer to justify such an extension; (v) that the petitioner, without prejudice to its contention that the period of expiry mentioned is of 60 months only, vide its representation dated 10th July, 2015 to the respondent DCGI sought

extension of the period of expiry to 61 months, placing material and data before the respondent DCGI to justify the extension of the period of expiry to 61 months; (vi) that the respondent DCGI however without studying the said material has rejected the said request, for the reason of the petitioner being in violation of Rule 96(1)(vii).

5. Being *prima facie* of the view that a statutory authority as the DCGI could not refuse to exercise the discretion vested in it under proviso to Rule 96(1)(vii) for the reason given in the impugned notice-cum-order dated 15th September, 2015 i.e. of the petitioner being non-compliant of statutory and regulatory requirement, specially when question whether the petitioner was at all non-compliant was pending before two High Courts and being further of the view that the entire controversy would be put to rest if the respondent DCGI were to, on the basis of the data and material submitted by the petitioner, determine, whether the drug 'Medrol' indeed has expiry of 61/62 months as was contended by the petitioner, the counsel for the respondent appearing on advance notice was asked to, without prejudice to his rights and contentions, take instructions, whether the respondent DCGI was willing to consider the data and material submitted by the petitioner to determine

whether the drug 'Medrol' had expiry of 61 or 62 months and how much time would it take.

6. On the next date of hearing i.e. 22nd September, 2015, upon the counsel for the respondent DCGI informing that the said evaluation would take about 7 to 14 days time, without prejudice to the respective rights and contentions, the respondent DCGI was directed to study the material / data submitted by the petitioner and to report whether the drug 'Medrol' of the petitioner had the stability period of 62 months as claimed by the petitioner. In the interregnum, consequential action against the petitioner pursuant to the impugned notice-cum-order dated 15th September, 2015 was also restrained.

7. The counsel for the respondent DCGI on the next date of hearing i.e. 15th October, 2015 handed over in the Court a report *inter alia* to the effect that the data submitted by the petitioner did not prove that the systematic stability studies of product 'Medrol' were conducted by the petitioner beyond 60 months and did not prove that the final conclusion was arrived at by petitioner to assign shelf life of more than 60 months to the drug.

8. The matter was adjourned to 19th October, 2015 for petitioner to respond.

9. On 19th October, 2015, the petitioner filed an additional affidavit in response to the report of the Joint Drug Controller and the counsels were heard on the aspect of the future course of action, if any in this petition and orders were reserved.

10. The respondent DCGI in its impugned notice-cum-order dated 15th September, 2015 has recorded:

- (i) that as per Rule 96(1)(vii), the drug must bear on its label the date of its manufacture as well as the date of expiry and this shall not exceed 60 months from the date of manufacture;
- (ii) that from the perusal of the label of 'Medrol', it is apparent that the total period of shelf life of the drug counted as 61 months instead of 60 months as prescribed;
- (iii) the contention of the petitioner that the period of expiry read as 60 months only was untenable and interpretation has to be done in accordance with the Rules;

(iv) that though the petitioner had been granted various approvals for importing of the drug but the same did not amount to approving the period of expiry in excess of 60 months;

(v) that the practice followed by the petitioner, of withdrawal of the drug from the market six months prior to its expiry, was not relevant;

(vi) that similarly the contention of the petitioner that the drug being a fast moving one, did not have the possibility of being used beyond 60 months, was also not acceptable;

(vii) the assurance of the petitioner that it will ensure that all future batches that are imported will bear the labeling as desired by respondent DCGI was also unwarranted, as it was not the desire of the respondent DCGI but the mandate of the law which the petitioner is to comply with;

(viii) that the respondent DCGI was not concerned with the actions initiated by the State Authorities;

(ix) that with reference to the contention of the petitioner that DCGI should exercise its power as provided in the proviso to Rule 96(1)(vii) of extending the period of expiry, the said power cannot be exercised

for a firm or a company which has been found to be in non-compliance of the statutory and regulatory requirements; the reasons as given by the petitioner in its representation cannot be held to be satisfactory evidence as mentioned in the proviso and hence the DCGI was refraining from exercising the powers as provided under this proviso;

(x) that in view of the aforesaid, the relief as was being sought by the petitioner was untenable and cannot be considered in view of the aforementioned reasons and thus the request of the petitioner for allowing the continued sale of the concerned batches of 'Medrol' was declined; the other request of extending the expiry of batches to 61 months was also accordingly declined in terms of the above reasons;

(xi) that as the petitioner has been found to be importing and marketing the product in violation of Drugs and Cosmetics Rules, 1945, CDSCO may reserve its rights for initiating other legal proceedings against the petitioner without prejudice to the said order in accordance with the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945.

11. As would be obvious from above, the notice-cum-order dated 15th September, 2015 impugned in this petition (a) rejects the contention of the petitioner, of the period of expiry on its existing label being read as 60 months; and (b) rejects the request of the petitioner for considering extension of period of expiry in exercise of powers under proviso to Rule 96(1)(vii) supra. Else, it reserves right to take other action against the petitioner.

12. As far as the second grievance aforesaid is concerned, the same stands addressed, by this Court having by interim order in this petition directed the respondent DCGI to consider on merits the request of the petitioner for extension of period of expiry and by rejection thereof by the respondent DCGI. The writ petition to the said extent thus does not survive. Though the petitioner has in the additional affidavit filed found fault with the said decision/consideration but that, strictly speaking, is not in the domain of the writ petition.

13. As far as the first grievance with respect to the impugned notice-cum-order aforesaid is concerned, the same is already subject matter of adjudication before the High Courts of Madras and Karnataka. I therefore do not deem it appropriate to entertain the same in this petition. In fact

when this petition had come up first before this Court on 21st September, 2015, I had entertained doubts, whether this High Court was the appropriate High Court to entertain the said challenge, since the lis was already pending in the High Court of Madras and the High Court of Karnataka who were seized of the matter; however, owing to the refusal of the respondent DCGI to consider the request of the petitioner for extension of period of expiry being not subject matter of the petitions before those High Courts, directions as aforesaid were issued. However, now that the said aspect no longer survives, I am of the view that it would not be appropriate for this Court to also entertain this petition on a matter which is squarely in issue before the other two High Courts approached prior to approaching this Court and when there are no consequential effects thereof within the jurisdiction of this Court.

14. That leaves the prayer in the petition, of restraining the respondent DCGI from taking any further steps in pursuance to the impugned notice-cum-order dated 15th September, 2015.

15. This Court cannot pass any peremptory order to the said effect. At this juncture, it is not known whether the respondent DCGI would take any step for which rights have been reserved in the impugned order. As and when

the respondent DCGI takes any step, it will be open to the petitioner to take appropriate remedy with respect thereto.

16. No further orders are thus deemed necessary in this petition.

17. Needless to state that with the disposal of this petition, the interim order would also stand vacated. The Supreme Court in ***Abhimanyoo Ram Vs. State of U.P.*** (2008) 17 SCC 73 has held that the Courts, at the time of passing the final order should balance the rights and equities arising from the interim order in the proceedings. This Court by interim order in this petition having restrained the respondent DCGI from consequential action pursuant to impugned notice-cum-order dated 15th September, 2015 against the petitioner, it is deemed appropriate to bind the petitioner to its statement, of withdrawing the drugs from the market six months prior to their expiry, by directing the petitioner to withdraw all stocks of the drug 'Medrol' with the date of expiry to which objection has been taken by the respondents, six months before the prescribed date of expiry, so that there is no possibility of the drug being consumed by anyone in the 61st month (according to the respondent DCGI) of its manufacture. Liberty is also given to the petitioner to, if so desires, impugn the rejection by the respondent DCGI on merits of

its application for extension of the period of expiry in exercise of powers under proviso to Rule 96(1)(vii) of the Rules.

No costs.

RAJIV SAHAI ENDLAW, J.

MAY 18, 2016

bs..

