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

Date of decision: 30th NOVEMBER, 2021

IN THE MATTER OF:

\+ **W.P.(CRL) 645/2021 & CRL.M.A. 4723/2021 & 13735/2021**

SANOFI INDIA LIMITED & ANR ...... Petitioners

Through Mr. Dayan Krishnan, Senior Advocate with Mr. Amit Mishra, Mr.Akshat Hansaria, Mr. Mohit Negi, Advocates

versus

UNION OF INDIA & ANR ...... Respondents

Through Ms. Amrita Prakash, CGSC for R-1

\+ **W.P.(CRL) 646/2021 & CRL.M.A.4725/2021**

SH. RANGASWAMY RATHAKRISHNAN IYER ..... Petitioner

Through Mr. Dayan Krishnan, Senior Advocate with Mr. Amit Mishra, Mr.Akshat Hansaria, Mr. Mohit Negi, Advocates

versus

UNION OF INDIA & ANR ...... Respondents

Through Ms. Sunieta Ojha, Advocate

CORAM:
HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

SUBRAMONIUM PRASAD, J.

1. These writ petitions under Article 226/227 of the Constitution of India have been filed for quashing of summoning orders dated 30.09.2019 and 13.01.2020 as well as Order dated 16.01.2021, issuing notice against the

petitioner, and for quashing of Criminal Complaint being CC No. 16817/2019.

2. The facts, in brief, leading to the present case are as follows:-

i. It is stated that in June 2015, the Petitioner Company manufactured the drug *Combiflam*, i.e. Batch No. A150682 (*hereinafter,* "batch in question") and a test analysis result of this batch was conducted by Shagun Testing Laboratories as well as Devansh Testing & Research Laboratory Pvt. Ltd., both being contracted labs for the Government Medical Store Depot, New Delhi. It is stated that both were found to be duly complying with the Disintegration Test parameters. Both the laboratories termed Batch No. A150682 as "Standard Quality".

ii. It is stated that on 24.02.2016, a sample of the same batch was drawn by the then Drug Inspector, Central Drug Standards Control Organisation (CDSCO) North Zone, Ghaziabad, for testing analysis. The sample portion was sent to Government Analyst, Regional Drugs Testing Lab, Chandigarh for testing and analysis as well.

iii. On 06.04.2016, *vide* test report of the Government Analyst, the sample was termed as "Not of Standard Quality". It is stated that the sample had been tested as per the old method of analysis in Indian Pharmacopeia.

iv. On 03.05.2016, a Show Cause Notice (*hereinafter,* "SCN") was issued by the Drug Inspector under Section 18A and 18B of the Drugs and Cosmetics Act, 1940 to the Chief Medical Officer, CGHS Wellness Centre, Pragati Vihar, Delhi-58, directing them to stop usage/distribution and to disclose the name/address of the firm/person from whom the drug had been obtained. The Drug Inspector, CDSCO, also sent an SCN under Section 18A and 18B of Drugs and Cosmetics Act, 1940, along with the test report. An SCN was also sent to the Petitioner-Company along with the test report, but the same was without the sealed sample portion.

v. On 28.05.2016, the Petitioner-Company filed a response to the SCN dated 03.05.2016 informing CDSCO that the SCN had been issued without any sealed sample portion. Further, the response stated that a recalling process of the batch in question had already been initiated and that the probable root cause for the failure in the Disintegration Test could be related to storage conditions in the market as well as formulation aspects. It was further stated that the Petitioner-Company would implement corrective measures in order to avoid such issues in the future.

vi. On 05.07.2016, the Food and Drugs Control Administration (FDCA) sent an SCN to Petitioner No.1 in W.P. (Crl.) 645/2021 with respect to same batch and it was issued without any sealed sample portion. In response to this SCN, the Petitioner-Company filed a reply dated 19.07.2016 wherein it informed FDCA that it had received a similar notice from CDSCO and it had already initiated the recall process of the batch in question.

vii. Thereafter on 23.08.2016, the Petitioner-Company issued a recall closure letter to CDSCO wherein it informed them that it had duly recalled all the samples of the batch in question. A similar recall closure letter was issued to FDCA.

viii. It is stated that on 22.03.2017, a License Suspension Order was issued by the FDCA against the Petitioner-Company for three days, i.e. from 24.04.2017 to 26.04.2017, under Rule 85(2) of the Drugs and Cosmetics Rules, 1945.

ix. It is stated that on 31.12.2017, Managing Director ,i.e. Petitioner No.1 in W.P.(CRL) 646/2021, ceased to be Managing Director of the petitioner/company.

x. Pursuant to the suspension order, on 11.04.2018, the Deputy Drugs Controller (I), CDSCO, Ghaziabad, requested the Deputy Drugs Controller, Ahmadabad to conduct an investigation at the premises of the Petitioner-Company.

xi. In May 2018, the batch in question expired. It is stated that on 06.02.2019, the Deputy Drugs Controller, CDSCO (North Zone) requested Drugs Controller General (India), F.D.A. Bhavan, New Delhi to issue directions for further legal action.

xii. Accordingly, on 25.06.2019, the Drugs Controller

General (India) granted permission to launch prosecution. On 02.02.2019, a complaint was filed against the Petitioners being C.C. No.16817/2019 before Rohini District Court, North West Delhi under Section 18(a)(i) read with Section 16, punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940.

xiii. On 30.09.2019, impugned summoning order was issued by the learned Trial Court. On 13.01.2020, on the ground that the previous summons had not been received, the learned Trial Court issued fresh summons against the Petitioners in CC No.16817/2019. On 25.02.2020, Petitioner No.1 in W.P.(CRL) 646/2021 ceased to be the Director of the Petitioner-Company.

xiv. The learned Trial Court thereafter *vide* impugned Order dated 16.01.2021 issued notice against the Petitioner in CC No.16817/2019.

xv. It is stated that the Petitioners have approached this Court seeking the quashing of the orders passed in CC No.16817/2019 and quashing of CC No.16817/2019.

3. Mr. Dayan Krishnan, learned Senior Counsel appearing for the Petitioners, submits that the impugned orders should be set aside on the ground that the proceedings which have been initiated emanating from CC No.16817/2019 against the Petitioners for the batch in question are barred by limitation. He states that the question which arises in both the writ petitions is that whether the learned Trial Court could have taken cognizance of the

complaint on 30.09.2019 when the same had been barred by limitation under Section 468(2)(c) Cr.P.C.

4. Mr. Krishnan submits that the prescribed period for limitation for launching of prosecution relating to the alleged offences is three years, if the offence is punishable for a term exceeding one year, but not exceeding three years. Mr. Krishnan states that in the instant case, the complaint alleges commission of offences under Section 18(a)(i) read with Section 16, punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940 with imprisonment of up to two years. Therefore, he states that the prosecution herein could only be launched within three years from the date of offence or the date on which the concerned officer came to know about the commission of that offence.

5. Relying upon State of Rajasthan v. Sanjay Kumar & Ors., **1998 (5) SCC 82,** the learned Senior Counsel appearing for the Petitioners submits that the period for calculating limitation will be in terms of the principles laid down in this judgment. Therefore, if the period is calculated from the date of receipt of the government analysis and the Analyst Report, i.e. 21.04.2016, the period of limitation would have ended on 21.04.2019. He submits that the learned Trial Court failed to appreciate that the period of limitation had already ended and that the complaint had been filed after this period of limitation and, therefore, the learned Trial Court could not have taken the cognisance of the same.

6. Mr. Dayan Krishnan, learned Senior Counsel for the Petitioners, argues that as per the law which had been laid down, it is incumbent upon the Court taking cognisance of an offence to first consider the question of limitation, and if the Court finds that the complaint had been filed after the

period of limitation, then it has no jurisdiction to take cognisance. Any order passed by the Court thereafter would, therefore, be without jurisdiction, until and unless the Court condones the delay. Mr. Krishnan states that furthermore the cognizance of the learned Trial Court on 30.09.2019 does not indicate in any manner as to whether the learned Metropolitan Magistrate had satisfied herself that the complaint was not barred by limitation.

7. Mr. Krishnan also submits that as far as W.P.(CRL) 646/2021 is concerned, the Petitioner therein is an Independent Director and, therefore, he is not liable for any of the actions of the Petitioner-Company in W.P.(CRL) 645/2021. He submits that the learned Trial Court has failed to appreciate that the Petitioner therein cannot be prosecuted for these criminal proceedings as no specific role has been attributed to him under the criminal complaint.

8. Mr. Dayan Krishan, learned Senior Counsel, submits that the learned Trial Court has failed to appreciate that the Respondent has not demonstrated any sufficient cause for the delay in filing CC No.16817/2019 before the learned Trial Court and the learned Trial Court has also failed to appreciate that the Respondent has flagrantly disregarded the timeline prescribed under law. He states that the Respondent's conduct betrays the inevitable impression that either the Respondent was not serious in pursuing prosecution or that the Respondent harbours wanton disdain for the law of limitation. The learned Senior Counsel for the Petitioners has further argued that the learned Trial Court has failed to appreciate that the SCN which had been issued to the Petitioners did not carry with it a test sample of the batch in question and that this test sample was not provided to the Petitioners even

at a later point of time. He submits that there exists an obligation on the Drug Inspector to deliver a sample and the lack of adherence to such an obligation is a ground to challenge the complaint filed by the Drug Authority.

9. Furthermore, Mr. Dayan Krishnan, learned Senior Counsel, submits that the complaint in question was filed by the Respondent after the expiry of the batch in question, thereby depriving the Petitioners of a invaluable right to adduce evidence against the test reports in terms of Section 25(3) of the Drugs and Cosmetics Act, 1940. He, therefore, submits that the entire procedure relating to seizure, analysis and test of the batch in question has been undertaken in a manner which has not been contemplated in law.

10. *Per contra*, Ms. Amrita Prakash, learned CGSC, submits that the contention of the Petitioners that the criminal complaint being CC No.16817/2019 is barred by limitation is not applicable in the instant case. She states that period from 06.02.2019 to 10.07.2019 should be excluded for the reason that a proposal for prosecution had been made by the complainant to the Drug Controller General of India on 06.02.2019, and the approval for the same is only received on 10.07.2019. She places reliance on Section 32(b) of the Drugs and Cosmetics Act, 1940 to contend that unless authorisation was not given by the Central Government to the State Government the complaint could not have been filed. She contends that the sanction was received only on 10.07.2019 and, therefore, the complaints which have been filed on 02.09.2019 cannot be said to be barred by limitation. She submits that proper investigation and inquiry had been conducted as per the procedure established by law without wasting of any time. She, therefore, submits that the criminal complaint against the

Petitioners had been well within the period of limitation, and that the instant case fell within the ambit of Section 470(3) of Cr.P.C. She submits that the time taken to investigate the matter and the time taken to receive permission to initiate further legal action against the Petitioners had to be excluded while accounting the period of limitation as prescribed under Section 469 of Cr.P.C. She further states that the Court had the power to take cognizance of an offence after the expiry of the period of limitations as per Section 473 of Cr.P.C.

11. Ms. Amrita Prakash, learned CGSC, submits that the averment of the Petitioners that they have been deprived of their right under Sections 23 and 25 of the Drugs and Cosmetics Act, 1940, is baseless because the Petitioners had failed to challenge the government analyst report as is evident from their reply letter dated 28.05.2016 against the SCN dated 03.05.2016.

12. In the rejoinder, Mr. Dayan Krishan, learned Senior Counsel for the Petitioners, submits that a reading of Section 470(3) Cr.P.C. reveals that the essential requirement for this Section is previous consent or sanction for prosecution from the Government or any other authority should be obtained; it is a prerequisite. He submits that an internal departmental approval is not contemplated under this Section and that the Respondents have failed to justify how the criminal complaint is not *ex facie* barred by limitation, nor have they even filed an application under Section 473 Cr.P.C.

13. Heard Mr. Dayan Krishan, learned Senior Counsel for the Petitioners, and Ms. Amrita Prakash, learned CGSC, in W.P.(CRL) 645/2021 and Ms. Sunieta Ojha, learned Counsel for the Respondents in W.P.(CRL) 646/2021, and perused the material on record.

14. List of dates which are undisputed are as under:

a) June 2015 - drugs manufactured.

b) 24.02.2016 samples were drawn.

c) 06.04.2016 report given by the Government analyst.

d) 11.04.2016 report sent by the lab to the drug inspector.

e) 21.04.2016 report received by the drug inspector.

f) 03.05.2016 show cause notice issued under Section 18(a)(1) and 18(B) of the Drugs and Cosmetics Act.

g) 28.05.2016 detailed reply to the show-cause notice was sent.

h) 06.02.2019 proposal for prosecution given to Drug Controller.

i) 25.06.2019 sanction given.

j) 10.07.2019 sanction received.

k) 02.09.2019 complaint was filed.

15. The short question which arises for consideration is that whether the complaint is barred under Section 468 Cr.P.C or not. In order to delve into the issue at hand, it is pertinent to first understand the contours of Section 468 of the Cr.P.C. Section 468 has been reproduced as under:-

> *"**468**. Bar to taking cognizance after lapse of the period of limitation.*
> *(1) Except as otherwise provided elsewhere in this Code, no Court shall take cognizance of an offence of the category specified in sub- section (2), after the expiry of the period of limitation.*
> *(2) The period of limitation shall be-*
> *(a) six months, if the offence is punishable with fine only*
> *(b) one year, if the offence is punishable with imprisonment for a term not exceeding one year;*
> ***(c) three years, if the offence is punishable with imprisonment for term exceeding one year but not exceeding three years.***

(3) For the purposes of this section, the period of limitation in relation to offences which may be tried together, shall be determined with reference to the offence which is punishable with the more severe punishment or, as the case may be, the most severe punishment." (emphasis supplied)

16. Section 468 Cr.P.C. stipulates that after the lapse of the period of limitation, a bar is instituted that prevents the Court from taking cognizance of an offence of the categories which are enumerated under Section 468(2) Cr.P.C. This bar can only be relaxed under Section 473 Cr.P.C. according to which any Court has the discretion to take cognizance of an offence after the expiry of the period of limitation. However, such cognizance needs to be accompanied with a reasonable explanation as to how the Court satisfied itself in extending the period of limitation (See State of Himachal Pradesh v. Tara Dutta, **AIR 2000 SC 297**).

17. Now, as per Section 468(2) Cr.P.C., the period of limitation for any offence which is punishable with an imprisonment term exceeding one year, but not exceeding three years, is three years. Therefore, if a complaint is filed after three years of the alleged offences as per Section 468(2)(c) Cr.P.C. taking place, then a Court will be barred from taking cognizance of the same and any Order that is rendered pursuant to this will be without jurisdiction.

18. The Supreme Court in State of Rajasthan v. Sanjay Kumar & Ors., **1998 (5) SCC 82,** while dealing with Section 468 Cr.P.C. has observed as follows:-

"6. In the Code of Criminal Procedure, 1973, Chapter XXXVI has been added prescribing limitation for

taking cognizance of certain offences with a view to expedite the process of detection and investigation of crimes and also to ensure observance of the principle of fairness in the trial of the offences by barring belated prosecution. Delay in prosecution of offences causes undue hardship as it keeps the sword hanging on the heads of accused persons and it also results in the material evidence getting vanished. This chapter applies to all such offences for which punishment prescribed is less than three years. But it does not apply to offences for which punishment prescribed is more than three years and to economic offences under various Acts, which are excluded under Central Act 12 of 1974 or any State Acts. It contains seven sections (467-473). Section 467 defines the expression "period of limitation" used in the chapter. Section 468 creates bar to taking cognizance of offences after lapse of period of limitation. Sections 469 to 473 deal with various aspects of computation of limitation. Of the aforementioned provisions, we are concerned with Sections 468 and 469. Sub-section (1) of Section 468 ordains that no court shall take cognizance of an offence of the category specified in sub-section (2), after the expiry of the "period of limitation" prescribed thereunder. This, however, is subject to the other provisions of the Code. Sub-section (2) postulates different period of limitation for offences with reference to the punishment provided for them; if the punishment provided for an offence in any Act is only fine, the period of limitation fixed is six months; if the offence is punishable with imprisonment for a term not exceeding one year, the period of limitation prescribed is one year and if the offence is punishable with imprisonment for a term exceeding one year but not exceeding three years, the period of limitation laid down is three years. And sub-section (3) spells out the rule of limitation in cases of joinder of charges; if a person is tried for more offences than one, then the *period of limitation will be determined with reference to the offence which is punishable with the more severe punishment or, as the case may be, the most severe punishment; for example, if a person is tried for various offences and some of them are punishable with fine and some with imprisonment for a term less than a year and some for which the punishment is provided up to three years, then the period of limitation for all the offences, if they are tried together, will be three years."*

19. The Supreme Court in Sarah Mathew v. Institute of Cardio Vascular Diseases, **(2014) 2 SCC 62,** has delineated the object of the bar of limitation, and has observed as follows:-

> ***"24.** Read in the background of the Law Commission's Report and the Report of the JPC, it is clear that the object of Chapter XXXVI inserted in the Criminal Procedure Code was to quicken the prosecution of complaints and to rid the criminal justice system of inconsequential cases displaying extreme lethargy, inertia or indolence. The effort was to make the criminal justice system more orderly, efficient and just by providing period of limitation for certain offences. In Sarwan Singh [State of Punjab v. Sarwan Singh, (1981) 3 SCC 34 : 1981 SCC (Cri) 625 : AIR 1981 SC 1054] , this Court stated the object of the Criminal Procedure Code in putting a bar of limitation as follows : (SCC p. 36, para 3)*
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> > *"3. ... The object of the Criminal Procedure Code in putting a bar of limitation on prosecutions was clearly to prevent the parties from filing cases after a long time, as a result of which material evidence may disappear and also to prevent abuse of the process of the court by filing vexatious and belated prosecutions long after the date of the offence. The object which the statutes seek to subserve is clearly in consonance with the concept*

of fairness of trial as enshrined in Article 21 of the Constitution of India. It is, therefore, of the utmost importance that any prosecution, whether by the State or a private complainant must abide by the letter of law or take the risk of the prosecution failing on the ground of limitation."

20. The question which arises in the instant case is whether Criminal Complaint No.16817/2019 would fall under the category of Section 468(2)(c) CrPC and, as a result, whether the learned Trial Court was barred from taking cognizance of the same and whether any Order which was passed in pursuance of this complaint has been done so without jurisdiction.

21. A perusal of the material on record indicates that the complaint under Section 18(a)(i) read with Section 16 punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940, which stipulates the penalty for manufacture and sale etc. in contravention of Chapter IV of the Act, entails an imprisonment term which shall not be less than one year and which may extend to two years. Therefore, this punishment squarely falls within the bracket of one to two years as has been envisaged under Section 468(2)(c) of the Cr.P.C.

22. Furthermore, the report which has been prepared by the government analyst wherein the batch in question was found to be "Not of Standard Quality" was done so on 06.04.2016. However, the Criminal Complaint No.16817/2019 was only filed on 02.09.2019. As per the period of limitation, in terms of Section 468(1)(c) CrPC, the same had expired on 20.04.2019.

23. Taking into account, the law of limitation on this aspect and the material which has been placed before this Court, this Court is of the opinion

that the complaint ought to have been filed within three years from the date report was received from the Drug Inspector i.e. on 21.04.2016. The complaint ought to have been filed on or before 21.04.2019. The period of limitation had indeed expired when the Criminal Complaint No.16817/2019 had been filed on 02.09.2019 and, therefore, cognizance of the same could not have been taken by the learned Trial Court.

24. Furthermore, the contention of the learned CGSC that a complaint could not be filed without obtaining an authorisation in writing cannot be accepted. Chapter IV of the Drugs and Cosmetics Act, 1940 deals with manufacture, sale and distribution of drugs and cosmetics. Section 32 of the Drugs and Cosmetics Act, 1940, which provides for cognizance of offences reads as under:

> *"32 Cognizance of offences. — [(1) No prosecution under this Chapter shall be instituted except by—*
>
> > *(a) an Inspector; or*
> >
> > *(b) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or*
> >
> > *(c) the person aggrieved; or*
> >
> > *(d) a recognised consumer association whether such person is a member of that association or not.*
>
> *(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.]*
>
> *(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter."*

25. A perusal of Section 32 of the Drugs and Cosmetics Act, 1940 shows that prosecution can be instituted by an Inspector or by any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government or the person aggrieved or a recognised consumer association whether such person is a member of that association or not. This Section stipulates that sanction has to be obtained under Chapter (IV) of the Drugs and Cosmetics Act, 1940. Admittedly, the petitioner is accused of an offence covered under Chapter (IV) of the Drugs and Cosmetics Act, 1940. Section 32 of the Drugs and Cosmetics Act, 1940 only stipulates as to who is authorised to file a complaint. The complaint in this case is filed by Inspector whose authorisation is not required. Section 32 of the Drugs and Cosmetics Act, 1940 does not require sanction to be obtained from the competent authority for filing the complaint.

26. Chapter IVA of the Drugs and Cosmetics Act, 1940 lays down the provisions relating to Ayurvedic, Siddha and Unani drugs. Section 33M of the Drugs and Cosmetics Act, 1940 which deals with offences falling under chapter IVA of the Drugs and Cosmetics Act, 1940 reads as under:

> *"**33M**. Cognizance of offences.—*
> *(1) No prosecution under this Chapter shall be instituted except by an Inspector 1[with the previous sanction of the authority specified under sub-section (4) of section 33G].*
> *(2) No Court inferior to that 2[of a Metropolitan Magistrate or of a Judicial Magistrate of the first class] shall try an offence punishable under this Chapter."*

27. A perusal of Section 33M shows that for an offence under Chapter IVA of the Drugs and Cosmetics Act, sanction of the authority specified under sub-section (4) of section 33G is required. There is no requirement of obtaining any sanction for an offence under Chapter IV of the Drugs and Cosmetics Act.

28. In the present case the report has been received by the Drug Inspector on 21.04.2016 and, therefore, the *terminus quo* for limitation would start from 21.04.2016. The complaint which has been filed on 02.09.2019 is, therefore, clearly out of the limitation period prescribed under Section 468 of the Cr.P.C.

29. The right which is accrued to the accused as a result of the expiry of the limitation period is a valuable right that flows from the accused's right to a speedy and fair trial as conceptualized under Article 21 of the Constitution of India. Accordingly, the cognizance that is taken by a Court in view of Section 473 Cr.P.C. extending the limitation period requires notice to be issued to the accused, hearing of both the accused and the complainant, and the consequent decision must display the Court's application of mind and should provide reasons for extending the limitation.

30. It is trite law that it is the duty of the Court to see whether a complaint has been filed within limitation or not. Though Section 473 Cr.P.C states that extension of period of limitation cannot be granted if the Court is satisfied on the facts and in the circumstances of the case that the delay has been properly explained or that it is necessary so to do in the interests of justice. There is no material on record to show that the Trial Court sought for any reasons for condoning the delay and further nothing is there to show that the State has made any endeavour to explain the delay in filing the

complaint. The reason given by the learned CGSC that the complaints can be instituted only after getting the authority from the State under Section 32(a) of the Drugs and Cosmetics Act cannot be accepted in this case for the reason that no sanction is required for instituting a complaint in an offence under Chapter IV of the Drugs and Cosmetics Act, 1940.

31. A reading of the impugned Orders of the learned Trial Court in conjunction with the law of limitation reveals to this Court that the learned Trial Court has erred in taking cognizance of Criminal Complaint No.16817/2019 and that the impugned Order dated 30.09.2019 fails to justify as to why the issue of limitation was not raised in the impugned Order.

32. In light of the above observations, this Court directs for the quashing of Criminal Complaint No.16817/2019 and, therefore, sets aside the impugned Orders dated 30.09.2019, 13.01.2020 and 16.01.2021emanating from the Criminal Complaint No.16817/2019.

33. Accordingly, the writ petitions are allowed and disposed of along with the pending application(s), if any.

SUBRAMONIUM PRASAD, J

NOVEMBER 30, 2021

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