

IN THE HIGH COURT OF DELHI AT NEW DELHI

IA No. 11607 of 2012

IN

CS (OS) No.2279 of 2009

In the Matter of:

Bristol-Myers Squibb Company & Ors.

...Plaintiffs

Versus

Mr.M.Adinarayan & Anr.

...Defendants

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NOTE: All concerned parties have been served

Next date of hearing: 01.08.2012

Defendants

Through

Place: Delhi
Date: 30/07/12


Gaurav Barathi
For GLA Law Offices
Advocate for the Defendants

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...Defendants

Reply on behalf of the Defendants to the Application under Order 39 Rule 1 & 2 read with Section 151 of CPC filed by the Plaintiffs

The Defendants above named submit as under:

- 1) At the outset it is submitted that the present application is not maintainable at all since the cause of action for filing of the present application is different and dehors the suit filed by the Plaintiff.
- 2) Further, the Plaintiff has suppressed material facts and tried to project only facts convenient to the Plaintiff so as to mislead the court. The Plaintiff has suppressed the fact that the actual product manufactured and sold by them in the market is a polymorph of Dasatinib, which is a Monohydrate, thus not covered or claimed by the suit patent. Further, the Plaintiff has without any analysis or testing of the Defendant's product proceeded to file the present application, for which reason it is misconceived and ill-

founded. On these grounds the Plaintiff is not entitled to any relief at all.

- 3) All the averments made in the application by the Plaintiff are wrong and denied. None of the averments may be deemed to be admitted for want of traverse.
- 4) The contents of para 1 and 2 are denied save and except matters of record. It is denied that the suit filed by the Plaintiff was maintainable at all. The same was brought by making false allegations.
- 5) With regard to the contents of para 3, it is submitted that in the year 2009 the Defendants had not developed the product and therefore no composition could be filed at that time. Enclosed herewith is the expert affidavit on behalf of the Defendant along with the composition of Defendant's drug DASANAT as **Annexure – R 1(Colly)**.
- 6) The contents of para 4 are wrong and denied. In this regard, it is submitted that the suit filed by the Plaintiffs was itself premature in that it was filed when the Defendant had only applied for marketing license which activity is permissible in law. It is submitted that the suit was not maintainable since activities alleged to be infringing by the Plaintiff were activities protected under Section 107A of the Patents Act. Further, the suit was filed by making false averments that the Defendants have launched a

product called DASANAT in Ukraine. Assuming that the Defendants had launched the product in Ukraine, the suit for infringement could have been brought only in Ukraine; however to harass this Defendant, and even though the patent of the Plaintiff extended only to India the suit was brought in Delhi. It was also alleged that the Defendant was advertising and publishing material about such drug. All of these statements were false as the Defendant at that point never engaged in any of the activities as alleged in the plaint. In the light of these facts, the Defendant filed its written statement denying the averments of the plaint and the fact that it had launched the product DASANAT or advertised the same. It is denied that the statements made in the written statement were false. The statements made in the written statement were based on facts and circumstances that existed at that point. Since the institution of the suit by the Plaintiff, many changes took place and the written statement could not have reflected future events. All of these averments stated in the written statement were correct.

- 7) It is submitted that Defendant supplies vast number of drugs to needy patients suffering from various diseases such as Cancer. It was found that patients of Blood Cancer required higher level of treatment and accordingly this Defendant took up the project of manufacturing polymorphic form of Dasatinib. The Defendant was granted the license to manufacture and market the drug DASANAT on 2nd September 2011 and thereafter, now in May 2012 the Defendant launched the product DASANAT. It is

submitted that the product of the Defendant does not infringe Indian Patent No.209237. In this regard, it is pertinent to note that even the Plaintiff does not manufacture the product corresponding to the suit patent. In any case the suit patent is invalid and a counter claim challenging the validity of the patent is already on record. As such, the Plaintiff cannot enforce its right in respect of the suit patent. In view of these averments, the contents of para 5 are wrong and denied. It is submitted that the product DASANAT does not violate Plaintiff's patent no.203937 as the Defendant produces a hydrate polymorph; i.e monohydrate of DASATINIB which is not covered by the aforesaid suit patent.

- 8) The contents of para 6 are wrong and denied. It is denied that as of June 11, 2012, the Defendants had not entered the market. The information obtained by the investigator is incorrect and denied.
- 9) The contents of para 7 are wrong and denied. It is denied that the Hon'ble Court has passed any order restraining the Defendant in any manner.
- 10) With regard to the contents of para 8, it is submitted that the Defendant's product were already launched in the market. The Plaintiff having failed to obtain desired orders from this Hon'ble Court through their first attempt on June 13, 2012, have filed the present application making false allegations and trying to project as if there was a second launch of products by the Defendants, which is incorrect and denied. In any case, the product of the

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Defendant is not covered by the suit patent and hence these allegations by the Plaintiff are not tenable at all.

- 11) The contents of para 9 & 10 are wrong and denied. It is submitted that the Defendant had already launched their product as of June 2012. The Plaintiff is only trying to exaggerate existing facts and mislead the Hon'ble Court.
- 12) The contents of para 11 are wrong and denied. It is submitted that the Defendant have not suppressed any material facts. As such the Defendants were not restrained and on account of the market demand, obtained a license for a polymorphic form of Dasatanib. The same is not covered by the suit patent.
- 13) The contents of para 12 are wrong and denied. It is submitted that these averments reflect the bad faith and misconduct of the Plaintiff than the Defendant. It is denied that the Defendant suppressed or concealed any facts from the Drug Controller. It is submitted that under the Drugs & Cosmetics Act, 1940, there is no requirement for disclosure of any patent status. Such information is not called for by the Drug Controller. It is further submitted that the Plaintiff having failed to obtain appropriate orders against this Defendant on June 13, 2012, approached the Drug Controller. A perusal of the show cause notice dated 20.06.2012 clearly reveals that the notice was issued at the behest of the Plaintiff. Further, the Drug Licensing Authority had issued letter suspending the licence of the Defendants. This order was

challenged in the High Court of Uttarakhand and the High Court of Uttarakhand has passed an order dated 25th July, 2012 directing that the said order (of suspension of licence) shall remain in abeyance. The Hon'ble High Court of Uttarakhand has remanded the matter to the Drug Licensing Authority directing it to consider the reply of the Defendant to the show cause notice and to pass a reasoned and speaking order after hearing the Defendant.

- 14) The contents of para 13 are wrong and denied. It is denied that the acts of manufacture or sale of DASANAT by the Defendant amounts to infringement of any rights of the Plaintiff since the Plaintiff has failed to prove that the product of the Defendant is covered by the suit Patent.
- 15) The contents of para 14 & 15 are wrong and denied. It is denied that the Defendant has indulged in any blatant infringing activities as alleged. It is denied that Defendants are disobeying any orders of this Hon'ble Court. It is denied that any loss or harm will be caused to the Plaintiff or that they would loose substantial sale. It is submitted that the Plaintiff as of date, caters to hardly 5% of patients. Hence, there is no question of any loss as alleged by the Plaintiff. It is further submitted that the product of the Plaintiff costs around Rs.1,67,000/- per month (for 60 tablets). The cost per year to a patient is about Rs.22 lakhs. Whereas the product of the Defendant costs Rs.8,800/- per month to a patient. Being a drug for treatment of disease such as Blood

Cancer, the product is required for the public at large and needy patients cannot be left without any treatment. The Plaintiff has not established any prima facie case. The balance of convenience and equities are in favour of the Defendant. In view of the public interest involved also, no injunction is merited as prayed for by the Plaintiff.


16) The prayer clause is denied.

It is therefore, prayed that the application filed by the Plaintiff be dismissed with costs.

Defendants

Through

Place:
Date:


Gaurav Barathi
For GLA Law Offices
Advocate for the Defendants

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IN THE HIGH COURT OF DELHI AT NEW DELHI
I.A. NO. OF 2012
IN
C.S (OS) NO. 2279 OF 2009

IN THE MATTER OF:

BRISTOL MYERS SQUIB CO. & ORS.

...PLAINTIFFS

Versus

MR. M. ADINARAYAN & ANR

...DEFENDANTS

AFFIDAVIT

I, Madineedi Adinarayana, aged about 50 years, R/o House No. 12-13-266, Street No. 15, Tarnaka, Secunderabad, 500017, presently, do hereby solemnly state and affirm as under:

1. That I am the Defendant no.1 in the present suit. I am also the Company Secretary and General Manager (Corporate Affairs) of the Defendant No.2 herein and am duly authorised and competent to swear this affidavit on behalf of both the Defendants.
2. That the accompanying reply has been drafted by my counsel under my instructions. I have read and understood the same. I hereby state that the said reply be read and treated as part and parcel of the present affidavit and the contents of the same is not reproduced herein for the sake of brevity.
3. That the contents of the accompanying reply are true and correct to the best of my knowledge derived from the records kept by the Defendant no.2.

For NATCO PHARMA LIMITED

M. Adinarayana

M. ADINARAYANA
Company Secretary & G.M.
(Legal & Corporate Affairs)

DEPONENT

VERIFICATION:

Verified at Hyderabad on this 26th day of July 2012, that the contents of my abovesaid affidavit are true and correct to the best of knowledge and belief and nothing material has been concealed therefrom.

ATTESTED

S. B. ... LL.B.,
ATTORNEY AT LAW

26 JUL 2012

For NATCO PHARMA LIMITED

M. Adinarayana

M. ADINARAYANA
Company Secretary & G.M.
(Legal & Corporate Affairs)

DEPONENT

Annexure - R1 (Colly)

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**IN THE HIGH COURT OF DELHI AT NEW DELHI
ORDINARY ORIGINAL CIVIL JURISDICTION**

CS (OS) No.2279 of 2009

Bristol-Myers Squibb Company & Ors.

...Plaintiffs

Versus

Mr.M.Adinarayan & Anr.

...Defendants

AFFIDAVIT

I, Dr Konakanchi Durga Prasad, aged 55 r/o Flat No.203, Plot No. 50/A, Jaisakthi Enclave, Kalyan Nagar Venture-III Hyderabad 500018, s/o.K. Satyanarayana do hereby state on solemn affirmation as under.

1. That I am serving as Vice President, Research & Development at Natco Pharma Limited. I am a PhD with 21 years of experience in the field of Synthetic organic chemistry including X-ray crystallography. I am aware of the fact that Natco Pharma has a product called 'DASANAT'.
2. I have been given a sample compound of Batch No. 700272 (of DASANAT) and have been asked to analyze the same for its crystal habit. Accordingly, I have performed X-ray crystallography analysis of the compound. The same is a hydrate polymorph i.e. monohydrate of Dasatinib. The relevant X-ray crystal diffraction pattern is attached herewith, as annexure-I.
3. I note that Indian patent No. 203937 is drawn to 2-amino thiazole 5-carboxamide compounds. However, the claims of this patent do not cover the monohydrate which was produced and manufactured by the Defendant.



K. Durga Prasad
DEPONENT

VERIFICATION

I say that the contents of Paras 1-2 are true and correct to the best of my knowledge and information as they are based on experiments performed by me. No part of this affidavit is false and nothing material has been concealed therefrom.

Verified at Hyderabad on this 19th day of July, 2012.



ATTESTED

I. KISHORE BABU
B.Com., B.L.,
ADVOCATE & NOTARY
11-77, Golnaka, A.N.I, R.R. Dist
SECUNDERABAD-10, A.P. INDIA
APPOINTED BY GOVT. OF A.P

K. Jayashankar
DEPONENT

19/07/2012

Date – 02.05.12

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Bio Data of Dr.K.Durga Prasad

Name: Dr.Konakanchi Durga Prasad

Date of Birth: 01.07.1956

Nationality: Indian

Marital Status and Children: Married and have one son.

Educational Qualifications:

- M.Sc in Organic Chemistry from Kanpur University in the year 1979.
- Ph.D in chemistry from National Institute of Technology, Warangal in the year 2004.

Experience:

- Total 30 years of industrial experience.
- 6 Years, i.e. from April 1980 to June 1986, in M/S MacMOHAN Pharmaceutical, Jeedimetla, Hyderabad, worked as Approved Analytical Chemist.
- 7 Years i.e. from July 1986 to Nov 1991, in M/S INGA Pharmaceuticals, Nacharam Industrial Estate, Nacharam, Hyderabad, In-charge Quality Control laboratory and from Dec1991 to Sep 1993, in M/S INDO German Alkaloids, Mahakali Caves Road, Andheri East, Mumbai, as In-charge, Research and Development wing Dr.Patani Scientific and Industrial Research. Here worked on Natural product isolation, their characterization and semi-synthetic process development for active Pharmaceutical Ingredients.
- 17 Years, i.e. from Oct 1993 to till today, in M/S Natco Research Centre R & D division of Natco Pharma Limited Pharmaceuticals, B-13 Industrial Estate, Sanathnagar, Hyderabad. Here joined as Scientist in the synthetic R& D section and since involved in the process development of about 30 APIs, 25NCEs and about 40 custom synthesis intermediates. Here presently positioned as Vice-President – R &D, looking after three synthetic lab, two isolators, Molecular Modeling, XRD and NMR department etc.

Publications 1. Acta Cryst. (2007). E63, 565-567.

Voriconazole, an antifungal drug

K.Ravikumar, B-Sridhar, K.D.Prasad and A.K.S Bhujanga Rao.

K Durga Prasad

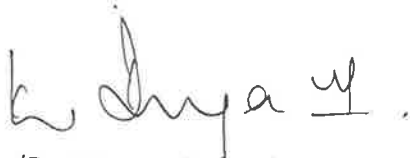
12

2. Indian Journal of hetrocyclic Chemistry, 2008, 18(1): 13-16
SYNTHESIS AND SPECTRAL STUDIES OF 1-PHENYL-4ARYL /ALKYLAMINOPYRAZOLO [3,4-D]
PYRIMIDINES.

Maddula LVV Pavan Kumar Chemistry division, School of science and Humanities, VIT
University, Vellore-632014, Prasad K Durga, Natco Research Centre, Natco Pharma Ltd
Hyderabad-500 018, Vijayakumar V.

3. Pharmaceutical chemistry journal 2010, volume 44, Number11, pages 642-645

4. A list of 12 patents is attached.



(Dr. K.Durga Prasad)

Vice -President - R &D,

Natco Research Centre,

B-13, Industrial Estate Sanathnagar.

Hyderabad -500 018

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M. L. : 13/UA/2010

Batch No. (समूह संख्या) 700272
Mfg. Date (उत्पादन तिथि) 05/2012
Exp. Date (समाप्ति तिथि) 04/2014
M.R.P. Rs.
अधिकृत मूल्य: 8900.00
(Inc. of all taxes)
(सभी कर सहित)

* Trade Mark

Made in India by:

NATCO
PHARMA LIMITED



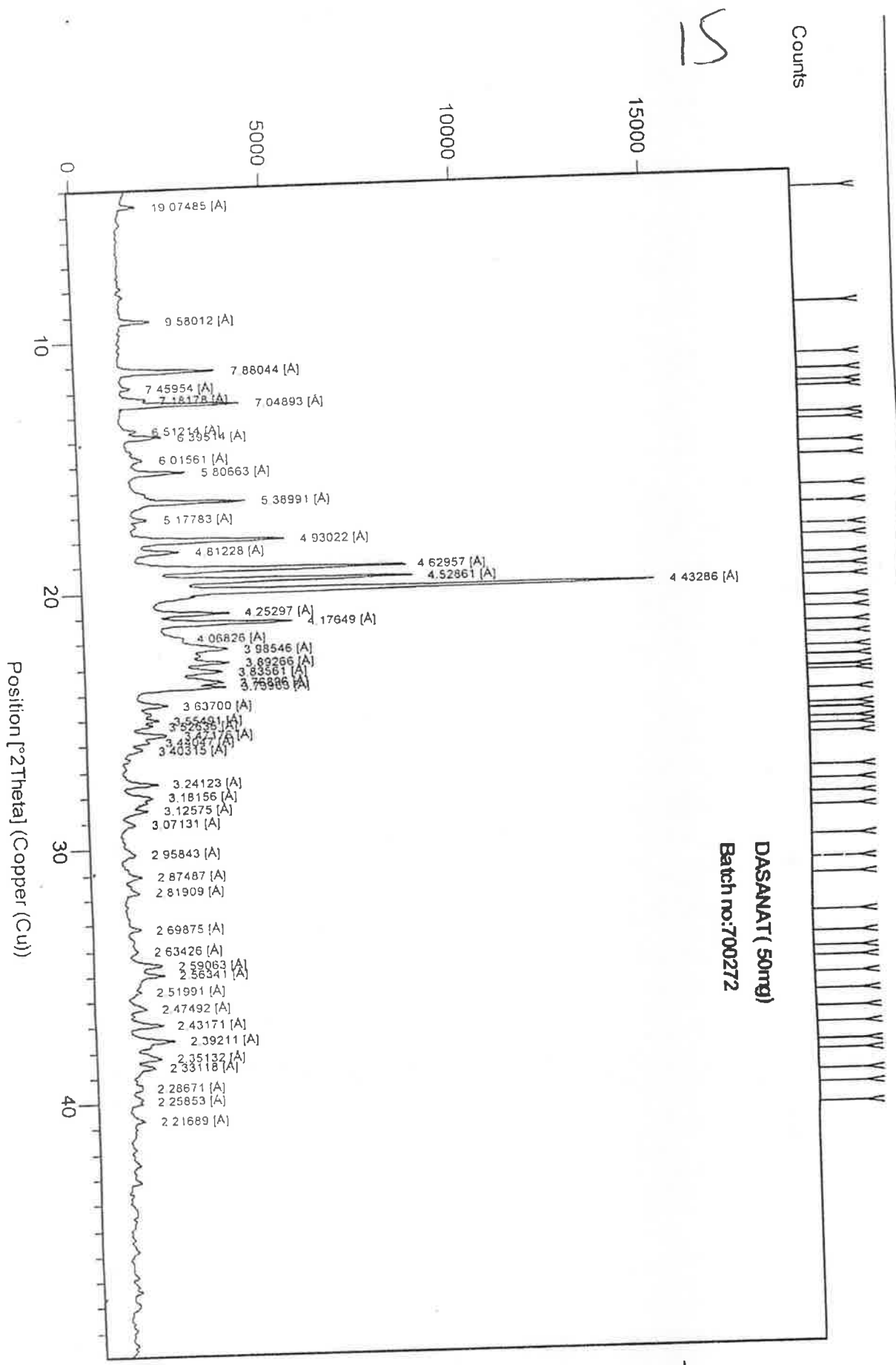
Plot No. A-3, UPSIDC Industrial Area,
Selaqui, Dehradun-248 197, Uttarakhand.
Regd. Office: Natco House, Road No.2,
Banjara Hills, Hyderabad - 500 033.

Handwritten signature/initials.

Anchor Scan Parameters

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Sample Identification: DASANAT(50mg)-700272
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Measurement Date / Time: 6/15/2012 4:07:41 PM
Operator: Administrator
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End Position [°2Th.]: 49.9791
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Scan Step Time [s]: 93.8400
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PSD Mode: Scanning
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Divergence Slit Size [°]: 0.4785
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Diffractometer Number: 0
Goniometer Radius [mm]: 240.00
Dist. Focus-Diverg. Slit [mm]: 91.00
Incident Beam Monochromator: No
Spinning: Yes

K. J. a y



Handwritten signature

Peak List

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14.7138	6.01561	3.63
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16.4331	5.38991	22.44
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20.0142	4.43286	100.00
20.8700	4.25297	18.19
21.2566	4.17649	30.30
21.8290	4.06826	9.21
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27.4966	3.24123	6.47
28.0226	3.18156	5.45
28.5335	3.12575	4.59
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31.0838	2.87487	3.42
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33.1689	2.69875	2.52
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39.3712	2.28671	2.06
39.8832	2.25853	2.08
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DASANAT(50mg)-700272

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