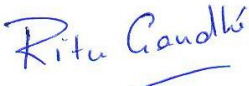


FORM 30
THE PATENTS ACT ,1970
(39 of 1970)
and
THE PATENTS RULES, 2003
TO BE USED WHEN NO OTHER FORM IS PRESCRIBED
[See sub-rule (2) of Rule 8]

1. Name of the applicant/ Patentee /Other	We, CADILA HEALTHCARE LIMITED			
2. Complete address including postal index number/code and State along with e-mail ID, telephone, mobile and fax number.	House no.	Zydus Tower,	Telephone No.	+91-124- 4849700;
	Street	Satellite Cross Roads	Mobile No.	+91-11-30165700;
				+91- 9205965311
	City	Ahmedabad	Fax No.	+91-124
	State	Gujarat		4849798/799
	Country	India		
	Pin Code	380 015	E-mail ID	sna@sna-ip.com
3. Application No. / Patent No.	257/MUM/2012			
4. Relevant section / rules	Section 14 and Rule 28			
5. Purpose of request	Filing a reply to the Official letter dated 26 April 2018 and the hearing held on 22 May 2018.			
6. Details of request	A detailed reply to the objections raised in the Official letter dated 26 April 2018 and the hearing held 22 May 2018 is enclosed herewith.			
7. To be signed by applicant				
8. Name of the natural person who has signed along with designation and official seal, if any.	Ritu Gandhi IN/PA-1010] Subramaniam & Associates			
	To, The Controller of Patents, The Patent Office, At New Delhi			

Our Ref: DRG /SNP 6717

29 May 2018

The Controller of Patents
The Patent Office
Boudhik Sampada Bhawan
SM Road, Antop Hill,
Near Antop Hill Post Office,
MUMBAI-400 037

Hearing u/s 14 held on: 22.05.2018
Kind Attention: Dr. Subendu Kundu
(Deputy Controller of Patents & Designs)

Dear Sirs,

Re: CADILA HEALTHCARE LIMITED
Indian Application No. **257/MUM/2011**
Filed on : 31 January 2011

We write with reference to the Official letter dated 26 April 2018 and the hearing held on 22 May 2018 in the above-mentioned patent application.

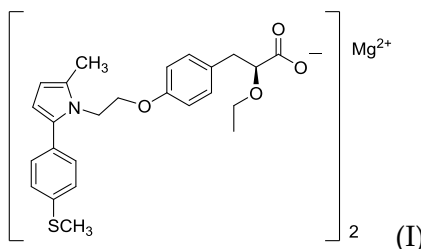
We are grateful to the Learned Controller for providing us an opportunity of oral hearing. We are also grateful to the Learned Controller for considering our submissions. The submissions made during the oral hearing are reiterated below:

It is respectfully submitted that the claims of the present invention have been amended. Claim 2 has been deleted. With the current amendments claim number is reduced from 2 to 1. The amendments carried out in claims have necessitated retyping of claims. The retyped claims along with marked up copy of the claims are submitted herewith. It is further submitted that the amended claims fall within the scope of the invention and no new matter has been added. The Learned Controller is respectfully requested to consider the submissions below in the light of revised claims.

Invention u/S 2(1)(i)

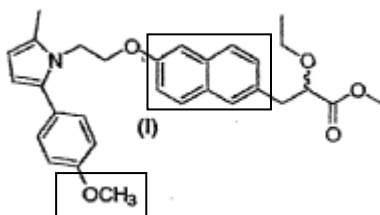
The Learned Controller has referred to compound disclosed in Example 66(preparation 11) of D1 and has held that Saroglitazar Magnesium claimed in the present invention lacks inventive step in view thereof. The applicant respectfully disagrees with the Learned Controller and submits that claim 1 is inventive in view of D1.

The present invention claims Saroglitazar Magnesium in claim 1. Saroglitazar Magnesium is approved in India (Trade name: Lipaglyn) for the treatment of Diabetic Dyslipidemia and is represented by following formula:



Emergency Contact Number: +91- 9205965311

D1 in example 66 provides compound namely - (R/S) Methyl-2-ethoxy-3[6-[2-[2-(4-methoxyphenyl)-5-methyl-pyrrol-1-yl]ethoxy]naphthalen-2-yl] propianoate (Example 66) - and is represented by the following formula



The structural differences of the compounds disclosed in D1 and claimed in the present invention are highlighted above. The compound of D1 has naphthalene group as compared to phenyl group of the present compound. Further the compound of D1 has methoxy group as compared to methylthio group of the presently claimed compound. D1 does not suggest or provide motivation to replace naphthalene group with phenyl group and methoxy group with methylthio group.

It is respectfully submitted that even if a person skilled in the art refer to D1, there is no basis to select this compound. Once a person skilled in the art tests the compounds disclosed in D1, he will know that the compound is inferior to at least those compounds for which biological data is provided in the specification of D1 (for e.g. compound nos. 209, 235 & 265 of D1). Accordingly, a person skilled in the art would reject pursuing it further with the compound of example 66.

The applicants have already provided comparative data with respect to various compounds of D1 while filing a reply to the first examination report.

The applicants had also studied the triglyceride lowering effects of the two compounds. The applicants observed that the compound 66 (of example 66) of D1 shows 25.8 % reduction in serum triglyceride levels at 3 mg/kg p.o. dose, whereas Saroglitazar Magnesium of the present application showed almost 61.9% triglyceride lowering effect at 1 mg/kg p.o. dose. Thus, the triglyceride lowering efficacy of compound of current claim 1 (Saroglitazar magnesium salt) was significantly higher as compared to the cited compound of D1 in Swiss albino mice. These observations are provided in the affidavit enclosed herewith as Annexure "A".

Therefore, D1 fails to teach or suggest or motivate a person skilled in the art to arrive at compound claimed in the present invention. Accordingly claim 1 is inventive in view of D1. The Learned Controller is accordingly requested to waive the objection.

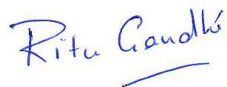
Non-patentability u/S 3

It is respectfully submitted that claim 2 has been deleted. Accordingly, this objection stands moot.

We respectfully submit that in the response filed all the objections of the Learned Controller have been met and all the requirements of The Patents Act, 1970 have been complied with. We, therefore, believe that the present application is in the order for grant and request the Learned Controller to issue a Letters Patent Document on the above-mentioned application.

In the event, if any substantive issue remains, we confirm that the applicants will be happy to discuss the same with the Learned Controller.

Yours sincerely,



Ritu Gandhi
[IN/PA-1010]

Enclosures:

Annexure A

Clean copy of amended claims

Marked up copy of amended claims



ગુજરાત ગુજરાત GUJARAT

BK 249860

તારીખ:..... માટે..... સને ૨૦૧૮

નામ: 19 APR 2018

સરનામું: શ્રી હેમકુમાર વાસુદેવભાઈ ત્રિવેદી
લા. નં.: - એસ. બી. - ૬૩/૧૯૮૬
અમદાવાદ-સીટી સીવિલ કોર્ટના સહોદી
લેનાર ની સહીX:.....
શ્રીમતે. પટેલ

CADILA HEALTHCARE LTD.
R & D CENTRE,
SURVEY NO. 396/403,
OPP. SARVOTAM HOTEL,
NR. NOVA PETROCHEMICALS,
VILLAGE : MORAIYA,
AHMEDABAD - 382 213

SR. No. 2165 DT. 25/5/2018
DIVYABALA N. MODI
NOTARY
GOVT. OF GUJARAT



IN THE MATTER OF THE PATENTS ACT, 1970
(AS AMENDED BY THE PATENT AMENDMENT ACT,
2005)

AND

IN THE MATTER OF THE PATENTS RULES, 1972
(AS AMENDED BY THE PATENT AMENDMENT RULES
2006)

AND



IN THE MATTER OF AN APPLICATION FOR PATENT

APPLICATION NO : 257/MUM/2011

APPLICANTS : CADILA HEALTHCARE LIMITED

DATE OF FILING : 31 January 2011

TITLE: TREATMENT FOR LIPODYSTROPHY

AFFIDAVIT

I, Suresh Giri, M.V.Sc., Ph.D., hereby declare as follows:

1. I work as Deputy General Manager, Department of Pharmacology & Toxicology, Zydus Research Centre, the R&D division of Cadila Healthcare Limited, the assignee of the above-identified patent application.
2. I have over 15 years of experience in the pharmaceutical industry and currently lead a team of scientists studying efficacy, metabolism and toxicities of drugs against various therapeutic targets. I received a Doctor of Philosophy in Veterinary Pharmacology and Toxicology from MAFSU, Bombay Veterinary College, Mumbai.
3. My previous affidavit filed as Annexure 6 along with response to First Examination Report on 4 December 2017 described the triglyceride lowering effect of Saroglitazar Magnesium in Swiss albino mice. Saroglitazar Magnesium of the present application showed almost 61.9% triglyceride lowering effect at 1 mg/kg p.o. dose (Pl. refer Table 10 of the affidavit).
4. When compound 66 of D1 was tested in a similar study it showed 25.8 % reduction in serum triglyceride levels at 3 mg/kg p.o. dose. **Thus, the triglyceride lowering efficacy of compound of current claim 1 (Saroglitazar magnesium salt) was significantly higher as compared to the cited compound of D1 in Swiss albino mice.**
5. Based on the above, it is evident that even at a higher dose (3 mg/kg, p.o.) the cited compound of D1 showed much lower triglyceride lowering efficacy as compared to the compound of claim 1 (saroglitazar magnesium salt) at a lower concentration 1 mg/kg, p.o.)
6. The compound of the present invention is thus effective in the treatment of Diabetic Dyslipidemia (first approved treatment globally), it has the unexpected advantage of showing good efficacy at a substantially low dose. This, unexpected results have tremendous commercial as well as medical significance and hence represent a substantial technical advancement.

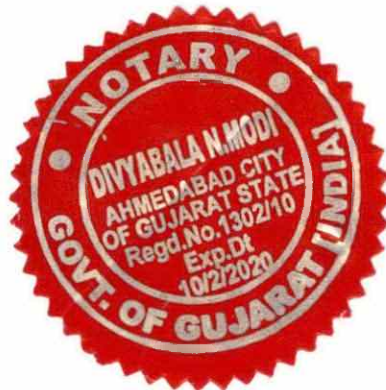


VERIFICATION

I, Suresh Giri, an Indian national, Deputy General Manager, Department of Pharmacology & Toxicology, Zydus Research Centre, the R&D division of Cadila Healthcare Limited, do hereby solemnly confirm that the contents of paragraphs mentioned herein above are true to my knowledge and no part of this affidavit is false and nothing is concealed therefrom.

()

DEPONENT



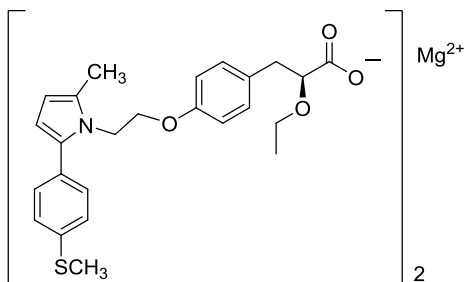
SOLEMNLY AFFIRMED
BEFORE ME

DIVYABALA N. MODI
NOTARY
GOVT. OF GUJARAT /



We claim:

1. A compound of formula (I)



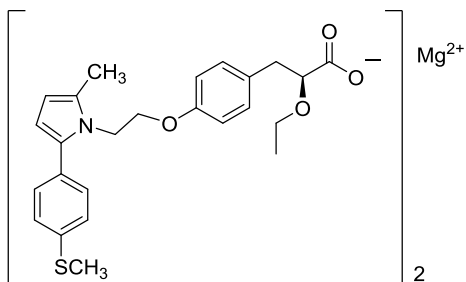
Dated this the 30th day of January 2012.

Ritu Gandhi

[Ritu Gandhi] [IN/PA-1010]
of SUBRAMANIAM & ASSOCIATES
Attorneys for the Applicant

We claim:

1. A compound of formula (I)



- ~~2. The compound as claimed in claim 1 for preparing a composition useful for the prevention and treatment of lipodystrophy.~~

Dated this the 30th day of January 2012.

Ritu Gandhi

[Ritu Gandhi] [IN/PA-1010]
of SUBRAMANIAM & ASSOCIATES
Attorneys for the Applicant