BEFORE THE CONTROLLER OF PATENTS

THE PATENTS ACT, 1970

SECTION 15

In the matter of the Patents Act, 1970 (as amended)

and

The Patents Rules, 2003 (as amended)

and

In the matter of Patent Application No. 202221034803 filed by the Applicant

Maharaja Krishnakumarsinhji Bhavnagar
University, Gaurishankar Lake Road,
Bhavnagar, 364 002

and

In the matter of representation by way of opposition under Section 25 (1) of the Patents Act by

(1) Mr. T. Iyer, 124, Anaikkuraipatty, Madurai, Tamil Nadu

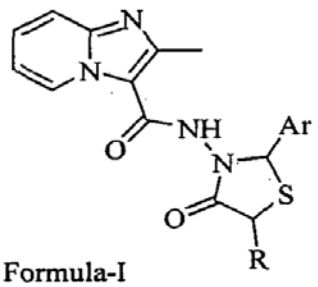
And

(2) Dr. Omprakash Singh Barkhamba, Salarpur Mawana Road, Meerut, Uttar Pradesh

D E C I S I O N

On 17/06/2022, the applicant, Maharaja Krishnakumarsinhji Bhavnagar University, filed a patent application at Patent Office, Mumbai entitled "THIAZOLIDIN-3-YL-IMIDAZO-PYRIDINE-3-CARBOXAMIDE AS ANTIMALARIAL AGENTS" which was assigned the number 202221034803. The said application was published under Section 11A of the Patents Act in the Official Journal of Indian Patent Office dated 22/07/2022 with the following claims:

1. The Thiazolidin-3-yl-Imidazo-pyridine-3-carboxamide of formula I, or its pharmaceutically acceptable salt, metabolites thereof,



Formula-I

wherein R is H or -CH3, -CH2-COOH.
Aryl/heteroaryl ring is substituted by mono or di-substituents with nitro, halogen, N,N-dimethyl, cinnainyl, methyl and methoxy groups or pharmaceutically acceptable salts, derivatives, metabolites thereof.

2. The Thiazolidin-3-yl-Imidazo-pyridine-3-carboxamide of formula I as claimed in claim-1 is,

a. N-(2-(3-chlorophenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[l,2-a]pyridine-3-carboxamide
b. N-(2-(3-fluorophenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[l,2-a]pyridine-3-carboxamide
c. N-(2-(2-hydroxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[l,2-a]pyridine-3-carboxamide
d. N-(2-(4-hydroxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1,2-a]pyridine-3-carboxamide
e. N-(2-(4-hydroxy-3-methoxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[l,2-a]pyridine-3-carboxamide
f. 2-Methyl-N-(4-oxo-2-(o-tolyl)thiazolidin-3-yl)imidazo[l,2-α]pyridine-3-carboxamide
g. 2-Methyl-N-(4-oxo-2-(3,4,5-trimethoxyphenyl)thiazolidin-3-yl)imidazo[l,2-a]pyridine-3 -carboxamide
h. N2-(2-methoxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1,2-a]pyridine-3-carboxamide
i. N-(2-(4-methoxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[l,2-a]pyridine-3-carboxamide
j. 2-Methyl-N-(2-(3-nitrophenyl)-4-oxothiazolidin-3-yl)imidazo[l,2-a]pyridine-3-carboxamide
k. 2-Methyl-N-(2-(4-nitrophenyl)-4-oxothiazolidin-3-yl)imidazo[1,2-a]pyridine-3-carboxamide
l. 2-Methyl-N-(4-oxo-2-styrylthiazolidin-3-yl)imidazo[l,2-a]pyridine-3-carboxamide

3. The one-pot synthesis of Thiazolidin-3-yl-Imidazo-pyridine-3-carboxamide of formula I as claimed in claim-1 optimizing the in-process isolation of intermediate compounds of formulae IV, III and II in presence of a catalyst,

4. The one-pot synthesis of compound of formula 1 as claimed in claim 3 wherein the catalyst is ammonium persulphate (APS).

5. The Thiazolidin-3-yl-Imidazo-pyridine-3-carboxamide of formula I, or its pharmaceutically acceptable salt as claimed in claim 1 for the treatment of Malaria.

6. The Thiazolidin-3-yl-Imidazo-pyridine-3-carboxamide of formula I, or its pharmaceutically acceptable salt as claimed in claim 6 for the treatment of Plasmodium falciparum.

The application was examined under Section 12 and 13 of the Act and as per the provision under Rule 24C of the Patents Rule 2003, as amended and First Examination

Report (FER) was issued on 29/08/2022. The applicant filed response dated 22/11/2022 to the FER issued, well within the prescribed time period.

On 09/01/2023, the opponent, Mr. T. Iyer, filed a pre-grant opposition by way of representation U/S 25(1) of the Patents Act at Patent Office, Mumbai relying on specific grounds of opposing the grant of patent to the instant application. The grounds relied upon are (i) Section 25(1)(b) of Patents Act - Novelty or anticipation by prior publication; (ii) Section 25(1)(e) of Patents Act - Lacks inventive step; (iii) Section 25(1)(f) of Patents Act - Not an invention and (iv) Section 25(1)(g) of Patents Act - Clarity and insufficiency.

The representation of the opponent was forwarded to the applicant dated 24/03/2023 as per the provision U/R 55(3) of the Patents Rule, 2003, as amended to file statement and evidence if any U/R 55(4) of the Rule. The applicant then filed statement and evidence the same day dated 24/03/2023 to meet the requirement U/R 55(4) of the Rule.

Both the opponent and the applicant were issued hearing notice dated 18/05/2023 to appear for the hearing, online, on 15/06/2023 at 3.00 PM by sharing the system generated VC link to hear both sides i.e. the grounds of pre-grant opposition relied upon by the opponent and the statement and the evidence submitted by the applicant to defend the representation.

The opponent, Mr. T. Iyer, vide a mail dated 11/06/2023 filed an Interlocutory Petition (IP) along with an affidavit in the above identified pre-grant opposition matter, without taking any reference to the hearing notice issued to him dated 18/05/2023 and the already fixed hearing dated 15/06/2023, to which as if he is not aware of. In the IP it was sought from the Controller to explain as to why the case which was being handled by a Controller earlier got transferred to another Controller presently handling the proceedings who may be biased while taking decision to go in favour of the applicant. The transfer of case from one Controller to the other is done as per the provision under Section 73(4) of the Patents Act by the Controller of Patents and the opponent before the outcome of his pre-grant opposition has taken a narrow view of it. However, the contention of the opponent was noted, without rescheduling the hearing fixed on 15/06/2023, the argument of the opponent was supposed to be discussed in the hearing. For this issue there required no reason the same should have been passed to the applicant for a reply. Neither, the opponent appeared for the hearing nor any intimation was given to the Controller that they are not attending the hearing. The move of the opponent not to appear for hearing without citing any reason thereof appears to be an attempt to delay the proceedings. As per the scheme hearing was conducted as scheduled. The opponent was contacted over the contact details shared with this office on the day of hearing; however, it was not reachable. The alternative contact number provided in fact was verified to be the number which does not belong to the opponent.

The applicant deliberated on the grounds of opposition relied upon by the opponent during the hearing and requested to rely on the statement and evidence filed by them on

24/03/2023. As there were few objections to the language of the amended claims available on record, the same during the hearing was agreed upon by the applicant to correct.

Further vide mail dated, 27/06/2023, the opponent informed the Controller that they have dispatched the courier containing the original documents as attached herewith vide speed post [**ET256333075IN**] dated 10/06/2023 which have been delivered to Patent Office, Mumbai on 15/06/2023 as per the Official status of Indian speed post (https://www.indiapost.gov.in/_layouts/15/dop.portal.tracking/trackconsignment.aspx), and seeking receipt of the same. Again the opponent mentioned nothing on the hearing notice issued to him although the date of hearing was over by then.

Upon viewing the file wrapper, it was noticed that one more opposition was filed dated 10/07/2023, by the opponent, Dr. Omprakash Singh Barkhamba of Salarpur Mawana Road, Meerut – 250001, Uttar Pradesh, by way of representation U/S 25(1) of the Patents Act at the Patent Office, relying on specific grounds of opposing the grant of patent to the instant application, while the first opposition was heard and was pending for disposal, relying on the grounds under Section 25(1)(b) of Patents Act - Novelty or anticipation by prior publication; Section 25(1)(e) of Patents Act - Lacks inventive step and Section 25(1)(f) of Patents Act - Not an invention.

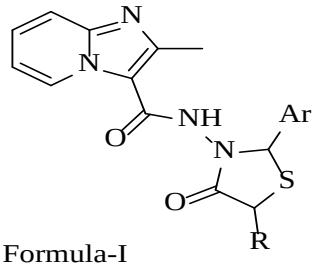
The representation of the opponent was forwarded to the applicant dated 02/08/2023 as per the provision U/R 55(3) of the Patents Rule, 2003, as amended to file statement and evidence if any U/R 55(4) of the Rule. The applicant then filed statement and evidence dated 28/09/2023 to meet the requirement U/R 55(4) of the Rule.

Both the 2nd opponent and the applicant were issued hearing notice dated 09/10/2023 to appear for the hearing, online, on 08/11/2023 at 2.30 PM by sharing the system generated VC link to hear both sides i.e. the grounds of pre-grant opposition relied upon by the 2nd opponent and the statement and the evidence submitted by the applicant to defend the 2nd representation.

Based on the grounds of the opposition relied upon by the 2nd opponent dated 10/07/2023, the statement and evidence filed by the applicant dated 28/09/2023, hearing only attended by the applicant and the explanation offered in the hearing dated 08/11/2023 and the amended claims filed by the applicant dated 21/11/2023 consequent to the discussion during the 2nd hearing, the followings are the observations.

Amended claims filed after the applicant in view of the second representation:

1. Thiazolidin-3-yl-imidazo-pyridine-3-carboxamide of formula I as an anti-malarial compound,



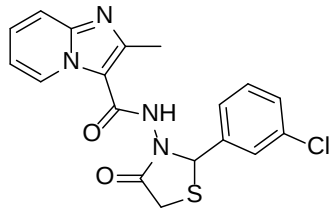
Formula-I

wherein R is -H or -CH3, -CH2-COOH;

Ar is aryl ring substituted by mono or di-substituents or tri substituents with nitro, –Cl, –F, –OH, –O-CH3, –NO-O –, cinnamyl at desired positions of the aryl ring.

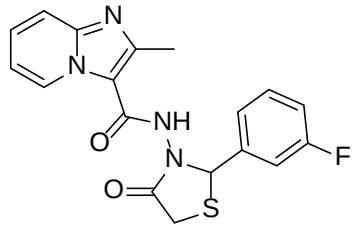
2. The anti-malarial compounds as claimed in claim 1 is selected from:

1a. *N*-(2-(3-chloropheny1)-4-oxothiazolidin-3-yl)-2-methylimidazo[1*,2-a*]pyridine-3-carboxamide;



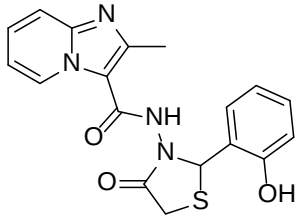
1a

1b. *N*-(2-(3-fluorophenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1,2-*a*]pyridine-3-carboxamide;



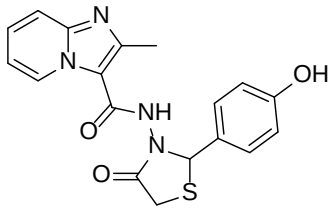
1b

1c. *N*-(2-(2-hydroxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1*,2-a*]pyridine-3-carboxamide;



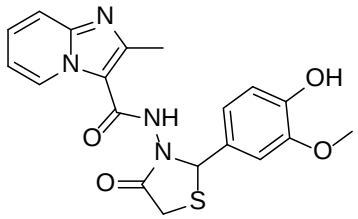
1c

1d. *N*-(2-(4-hydroxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1*,2-a*]pyridine-3-carboxamide;



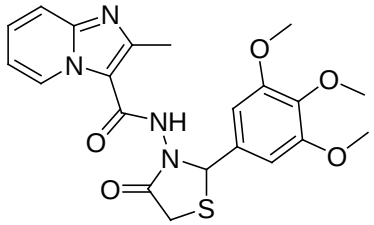
1d

1e. *N*-(2-(4-hydroxy-3-methoxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1,2-*a*]pyridine-3-carboxamide;



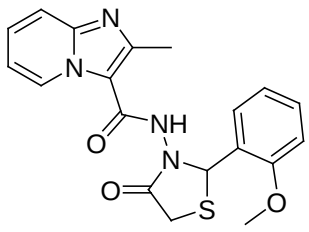
1e

1f. 2-Methyl-*N*-(4-oxo-2-(3,4,5-trimethoxyphenyl)thiazolidin-3-yl)imidazo[1,2-*a*]pyridine- 3-carboxamide;



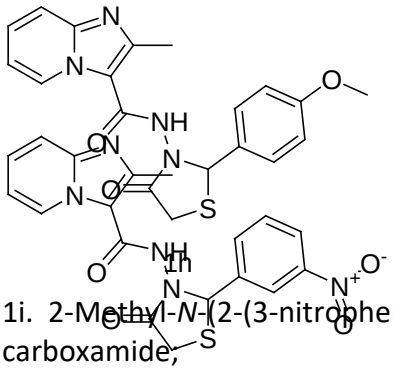
1f

1g. *N*-(2-(2-methoxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1*,2-a*]pyridine-3-carboxamide;



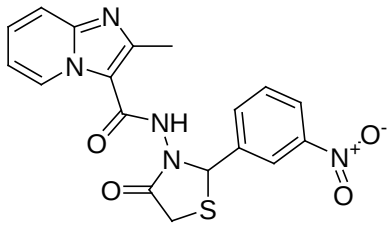
1g

1h. *N*-(2-(4-methoxyphenyl)-4-oxothiazolidin-3-yl)-2-methylimidazo[1,2-*a*]pyridine-3-carboxamide;



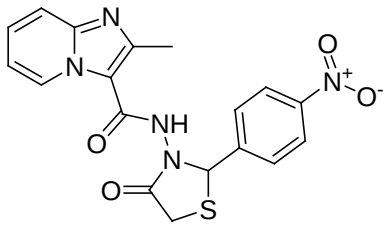
1h

1i. 2-Methyl-*N*-(2-(3-nitrophenyl)-4-oxothiazolidin-3-yl)imidazo[1,2-*a*]pyridine-3-carboxamide;



1i

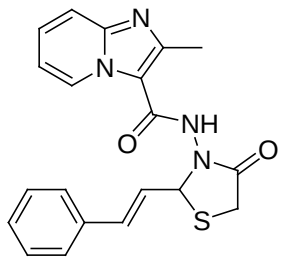
1j. 2-Methyl-*N*-(2-(4-nitrophenyl)-4-oxothiazolidin-3-yl)imidazo[1*,2-a*]pyridine-3-carboxamide;



1j

and

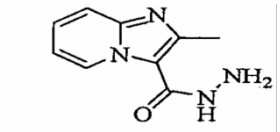
1k. 2-Methyl-*N*-(4-oxo-2-styrylthiazolidin-3-yl)imidazo[1*,2-a*]pyridine-3-carboxamide;



1k

3. Antimalarial compounds as claimed in claim 2 selected from the above-mentioned structure as 2-methyl-*N*-(4-oxo-2-(3,4,5-trimethoxyphenyl)thiazolidin-3-yl)imidazo[1,2-a]pyridine-3- carboxamide;

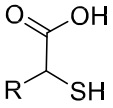
4. An one-pot synthesis of compound of formula I as claimed in claim 1, comprises of optimizing isolation of intermediate compounds of formulae IV, III and II in presence of ammonium persulphate as catalyst,



(Formula -IV)

Ar-CHO

Formula III;



Formula II.

5. The one-pot synthesis of compound of formula 1 as claimed in claim 3 wherein the catalyst is ammonium persulphate (APS).

For the sake of clarity, the opposition filed dated 09/01/2023, by the opponent, Mr. T. Iyer, be named as **Opponent–I** and the opposition filed dated 10/07/2023, by the opponent, Dr. Omprakash Singh Barkhamba be named as **Opponent–II** for all such interpretations hereinafter:

Observations on the oppositions filed, the Explanation and Amendments by the Applicant:

1). One preliminary issue the **Opponent - I** brought out while filing the pre-grant opposition is the lack of clarity about the applicant being declaring as an institute established by a Central, Provincial or State Act, which is owned or controlled by the Government and availing the facility to file expedited examination. The Opponent-II has relied that the document submitted by the applicant to support such a claim mentions Govt. of Gujarat, Gujarat Act No. 26 of 1978, as modified up to 31st December, 2017 and the application filed on 17/06/2022 can't be a valid application to avail expedited examination facility to which the Patent Office has allowed.

The applicant submits that Maharaja KrishnakumarSinhji Bhavnagar University is a state-established government university. The name of this University was changed from "Bhavnagar University" to "Maharaja Krishnakumarsinhji Bhavnagar University" by the Government of Gujarat. The Gazette published by the Government of Gujarat for the establishment of Bhavnagar University under the Bhavnagar University Act, 1978 is well documented. The said Gazette was published on 17th April 1978 and the latest amendment

was brought in 2017. Therefore, the opponent's claim that the notification mentions it effective up to 2017 is not correct, rather the amendments were carried out up to December, 2017 is correct. The submission of the Opponent-I in this regard is not established based on the explanation and evidence filed by the applicant. Therefore, issue of an examination report on the expedited route based on the applicant's request is justified.

Opponent-II has raised some queries regarding allotment of cases and the reason of such changes in the allotment, and from one existing Controller to another new Controller. However, the **Opponent-II** view on such issues hardly matters, and need not require comments being administrative in nature.

The followings are the analysis and observation on each grounds of opposition:

1. **Ground of opposition under Section 25(1)(b) of Patents Act - Novelty or anticipation by prior publication;**

The **Opponent-I** in its submission in page 5 of the representation stated that the compound of Formula I as claimed in claim 1 is the combination of two moieties i.e. imidazo-pyridine and quinoline based 4-thiazolidinones using an amide linker. The two documents relied upon by the **Opponent-I** to establish such a ground of the opposition is:

Opponent–I (D1): Birgul Ozden Kasimogullari et al., Fused Heterocycles: Synthesis of Some New Imidazo (1,2-a)-pyridine derivatives, Molecules, 2004, Vol. 9, 894-901.

Opponent–I (D2): Sandeep Jain et al., Novel Arylidene derivatives of quinoline based thiazolidinones: Synthesis, in vitro, in vivo, and in silico study as antimalarials, Experimental Parasitology, 185, 2018, 107e114.

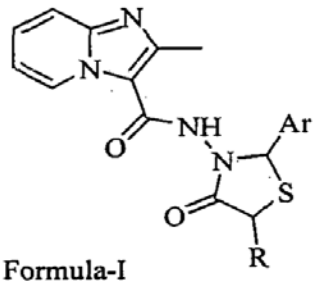
Documents relied upon by the **Opponent–II** under this ground of opposition is as follows:
Opponent – II (Exhibit 3) – J-Global ID: 200907080661487392 (year of publication 2009);
Opponent – II (Exhibit 4) – PubChem (year of publication 2006);

In page 7 of the representation the **Opponent-I** states that D1 discloses the imidazo-pyridine and D2 discloses quinoline based 4-thiazolidinones and both the prior art teach the amide linker. D2 is related to the anti-malarial. Since the impugned invention is related to the field of the medicinal chemistry, combination of moieties is the logical consideration for a skilled person. Hence claim 1 is not novel.

In page 9 of the representation the **Opponent-II** states that Exhibit 3 and Exhibit 4 although do not discloses any specific medicinal activity of the compound, but disclose the same structure and nomenclature. The inventors of the instant application just discovered the medicinal property (anti-malarial) of the same compound. The **Opponent–II** states that discovering a medicinal property of a structurally same compound is not patentable U/S

2(1)(j) of the Patents Act and hence the claimed compound of impugned application is not novel over Exhibit 3 or Exhibit 4.

The applicant in its statements and evidence as well as the hearing submission stated that the instant patent application disclosed a series of hybrid molecules of 2-methyl-N-(4-oxo-2-arylthiazolidin-3-yl)imidazo[1,2-a]pyridine-3-carboxamides containing imidazo-pyridine embedded with 4-thiazolidinones and amide linker present on the 3rd position of imidazo-pyridine heterocyclic motifs (Formula-I).



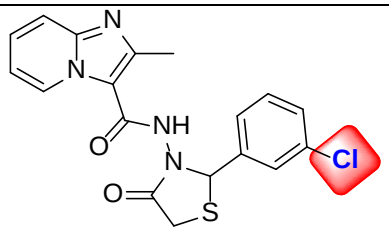
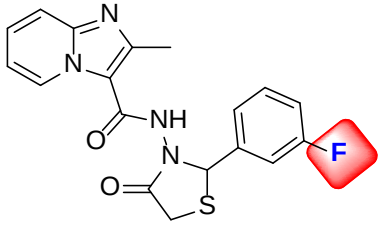
Formula-I

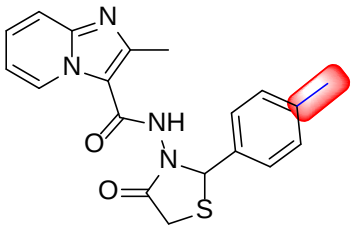
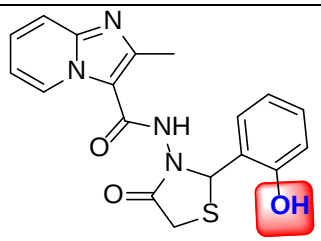
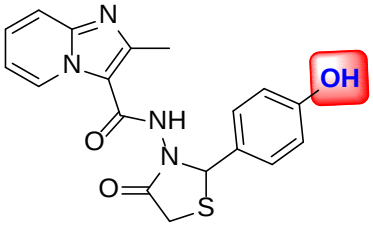
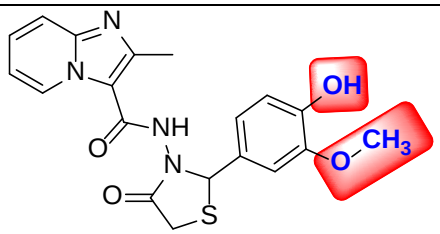
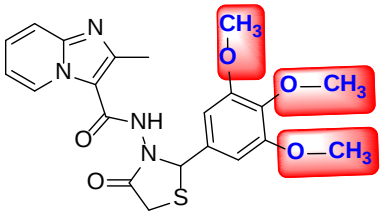
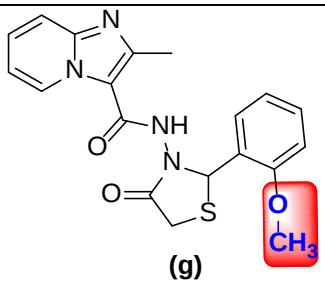
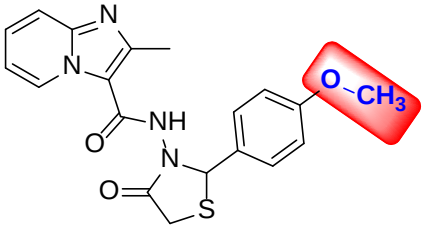
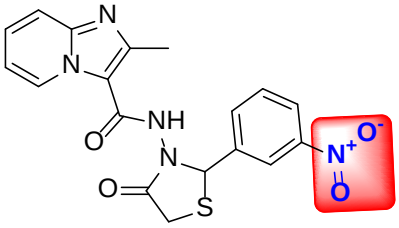
wherein R is -H or -CH3, -CH2-COOH;

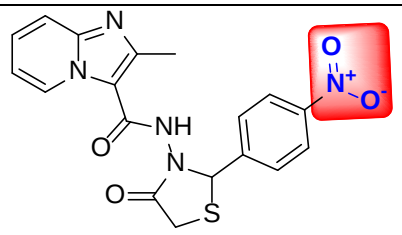
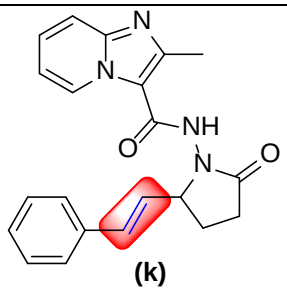
Ar is aryl ring substituted by mono or di-substituents or tri substituents with nitro, –Cl, –F, –OH, –O-CH3, –NO-O –, cinnamyl at desired positions of the aryl ring.

The synthetic procedure was performed via one pot reaction and process for preparation and formulas (IV), (III), and (II) are condensed together, optimizing the in-process isolation of intermediate compounds thereof.

Further the compound of Exhibit 3 or Exhibit 4 vis-a-vis the compounds claimed in the instant set of claims given in a tabular form is as follows:

Compound in the Exhibit 3 or 4 of the Opponent-II	Compounds of the Present invention
	 **(a)**
	 **(b)**

	 (c)
	 (d)
	 (e)
	 (f)
	 (g)
	 (h)
	 (i)

	 (j)  (k)

The synthesized hybrids as stated by the applicant were evaluated for antimalarial activity against P. falciparum by utilizing quinine as a standard drug. A tri-substituted derivative (2,3,4- (OCH3)3) was found to be higher potency than the standard drug.

The applicant elaborated that D1 of the **Opponent-I** is a research article relates to some new thiazolidines and spirothiazolidines derived from hydrazones of 2-methylimidazo[1,2-a]pyridine3-carboxylic acid hydrazide, a bioisosteric derivative of isoniazid, were synthesized and characterized by analytical, IR, 1H- and 13C-NMR and mass spectral data. Some of the newly synthesized compounds were screened for their antimycobacterial activities. None of the tested compounds showed significant in vitro antituberculous activity at 6.25 µg/mL (MIC rifampin 0.031 µg/mL). Therefore, the document D1 is not relevant prior art as relied upon by the opponent. D2 of the **Opponent-I** discloses quinoline based 4-thiazolidinones with an amide linker which is completely different from the class of compounds claimed in the instant application.

Replying to the comments of the **Opponent–II**, on lack of novelty, the applicant states that the cited prior art i.e. Exhibit 3 and Exhibit 4 cover a compound different from all the eleven compounds a, b, c, d, e, f, g, h, i, j and k as shown in the table given above in page 11-12 which are claimed in the application.

The applicant submitted that in order to allege lack of novelty, a prior document objecting to the novelty of a patent application was required. The opponents lack in this respect and brought two documents before the Controller to establish such aspect which should be denied and required complete dismissal.

From the above analysis considering the points of the **Opponent–I** and **Opponent–II**, as well as the applicant it is observed that document D1 and D2 of the **Opponent–I** fails to establish such a ground of opposition with regard to not bringing before the Controller any relevant prior art. Neither D1 nor D2 are relevant prior art relied upon by the opponent to challenge the compound of formula 1 as not novel.

As far as the Exhibit 3 and Exhibit 4 of the **Opponent–II** is concerned, although the structural framework of the claimed compounds and the compounds in Exhibit 3 and Exhibit 4 same, there is a difference in the nature of substituent in the attached aryl ring as well as in the position also (as evident from the above table). Therefore, the compound of Exhibit 3 and Exhibit 4 are not same as that of the compounds claimed and fails to establish the ground of opposition U/S 25(1)(b) of the Patents Act.

2. Ground of opposition under Section 25(1)(e) of Patents Act - Lacks inventive step;

The **Opponent-I** has drawn the attention of the Controller stating that the findings of the grounds of novelty as offered by them could be applied for assessment of inventive step in the present context. The **Opponent-I** emphasised that D1 suggested imidazo-pyridine ring and D2 suggested quinoline based 4-thiazolidinone for antimalarial activity, therefore, it is obvious for a skilled person to combine the teaching of D1 and D2 in order to reach the compound as claimed in claim 1 of the impugned application. No unexpected effect/surprising feature is observed in the impugned claims of the application filed.

The applicant's submission is that the inventors of the present patent application are involved actively in research in the field of medicinal chemistry for a long time. Any person skilled in the art of research must appreciate that it is not an easy task to synthesize a novel and innovative compound that too, merely based on the knowledge of the formation of amide bonds between Imidazo-pyridine motif and 4-thiazolidinone derivative. The point and the argument of the applicant were appreciated at this point.

The **Opponent–II** is of the view that the applicant has self admitted in the specification itself (page 5), that the compound (Formula I) of the impugned application is an effect of the inspiration/motivation of Formula 2-6, the alleged invention is obvious and liable to be refused on this ground alone. Further, the **Opponent–II** states that the argument in view of Exhibit 3 or Exhibit 4 for novelty can be considered for the inventive assessment. The **Opponent–II** also states that Exhibit 5 (CESUR N, 1994) teaches the compounds where thiazolidinone is being inserted at 3rd position of imidazole-pyridine ring in order to achieve a medicinal activity (anti-fungal). Since the concept of insertion of thiazolidinone into imidazole-pyridine ring is already known for achieving a medicinal activity, it is obvious to a skilled person to use the same concept for another medicinal activity (anti-malaria).

The **Opponent-II** also relied on Exhibit 6 (Birgul Ozden Kasimogullari and Zafer Cesur, 2004) related to synthesis of some new imidazo[1,2-a]-pyridine derivatives. The said document teaches basic moiety but does not suggest peripheral moiety. Exhibit 7 (Khalid Karrouchi et al, 2018) teaches peripheral moiety which can impart antimalarial activity. A skilled person would combine the teaching of Exhibit 6 and Exhibit 7 in order to get the compound (Formula I) of the impugned application. Based on the **Opponent–II**'s analysis in the instant circumstances and the documents relied upon, also cited the decision of Hon'ble

Supreme Court on the test of inventive step in the Biswanath Prasad Radhey Shyam Vs Hindustan Metal Industries, AIR 1982 SC 144.

The submission of both the opponents as well as the applicant in the hearing and the submission made thereafter, were considered. The contention of the **Opponent–I**, both on the teachings of D1 and D2 as discussed above to consider the instant invention claimed as lacking inventive step has not been appreciated. The combined teachings of D1 and D2 can't suggest a person skilled in the art to arrive at the present invention with the functional objective of the invention i.e. to act as an antimalarial compound. The applicant's submission that it is not an easy task to synthesize a novel and innovative compound that too, merely based on the knowledge of the formation of amide bonds between Imidazo-pyridine motif and 4-thiazolidinone derivative by a person skilled in the art to address the antimalarial property of the claimed compound is considered. "

It is observed that the opponent's submission has been inadequate to convince the Controller that he relied upon few documents that would have been thought by a person skilled in the art to arrive to the instant invention going through the relied prior art. The opponent therefore, has failed to establish such a ground of opposition. The combined teachings of D1 and D2 would not establish that the invention claimed in any of the claims is obvious to a person skilled in the art and lack inventive step. Therefore, the opponent-I has failed to establish this ground of opposition.

The statement of **Opponent–II** in the representation that the applicant has self admitted in the specification itself (page 5), that the compound (Formula I) of the impugned application is an effect of the inspiration/motivation of Formula 2-6, with no elaboration and discussion as well, that the alleged invention is obvious and liable to be refused on this ground alone does not hold good. To counter the submission of the applicant in this regard, the Controller could have been given enough evidence to take a decision on this matter with respect to the statement of the **Opponent-II**.

Further, the **Opponent–II** relied on the Exhibit 3 or Exhibit 4 which were discussed above to establish lack of novelty, Exhibit 5 (CESUR N, 1994) - teaching about thiazolidinone is being inserted at 3rd position of imidazole-pyridine ring in order to achieve a medicinal activity (anti-fungal), Exhibit 6 (Birgul Ozden Kasimogullari and Zafer Cesur, 2004) - teaching about synthesis of some new imidazo[1,2-a]-pyridine derivatives with no suggestion on peripheral moiety and Exhibit 7 (Khalid Karrouchi et al, 2018) - teaching about peripheral moiety which can impart antimalarial activity.

Exhibit 3 or 4 although discusses about the structural framework of the molecule to be same as claimed in the invention, but not the same as far as the substituents to the aryl ring as well as their position in multiple numbers in few instances of the applicant's invention. Therefore, all the molecules claimed are novel. Further, the objective of the prior art i.e. in terms of the therapeutic activity is not at all disclosed. The applicant herein claims

a novel set of compounds and with an objective to that, such compounds are potent antimalarial agent with experimental data in the specification to show their activity. Therefore, it will not be obvious to a person skilled in the art to think of such novel compounds and its purpose to act as antimalarial agents. The submitted prior art in this regard are silent on the purpose of the invention in the prior art which is an essential requirement to obtain a patent.

From the teachings of Exhibit 5, 6 and 7 of the **Opponent–II** as stated above, it will also not be obvious to a person skilled in the art to imagine insertion of thiazolidinone at 3rd position of imidazole-pyridine ring with the objective to obtain an antimalarial drug (Exhibit 5) since it is all about anti-fungal, to utilize the teachings of Exhibit 6 which synthesises some new imidazo[1,2-a]-pyridine derivatives and no mention on peripheral moiety as in the instant invention and teaching of Exhibit 7 about peripheral moiety that can impart antimalarial activity. The combination of the teachings of Exhibit 3 and 4, Exhibit 5, 6 and 7 also will not be obvious to a person skilled in the art to invent a novel set of compounds and all such compounds are having antimalarial activity. Therefore, the documents cited by the **Opponent–II** on the ground of lack of inventive step has not been established in view of the discussion and observation drawn above.

3. Ground of opposition under Section 25(1)(f) of Patents Act - Not an invention;

The **Opponent-I** has relied upon Section 3(d) of the Act to believe that invention claimed in any claims of the specification is not an invention with the statement: "Impugned application talked about the antimalarial activity of the compound (Table 2, 1a-1l) in view of 'potency'. The 'potency' is different from the "therapeutic efficacy" as the compound patent as India is concerned. The requirement for Section 3(d) is that there must be a study & data thereof which could establish the claimed compound (Formula I) will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with imidazo-pyridine or quinoline based 4-thiazolidinones individually. The impugned application is absolutely failed to disclose such study/data. Hence, section 3(d) attracts the instant claims".

The applicant while relying on the order of the IPAB in case of Fresenius Kabi Oncology Limited Vs. Glaxo Group Limited, Order No. 162 of 2013, expressed that to raise a challenge or on the objection under Section 3(d), one has to specifically allege and identify at least following three questions: a) What is the specific "known" substance? b) How and why the claimed molecule(s) or substance(s) is a derivative or is otherwise a new form of known substance? c) What is the basis to asset that the alleged "known" substance and the claimed molecule or substance has the same "known" efficacy? The **Opponent-I** has categorically failed to provide any evidence which possibly indicates that the Formula I of the instant application is known.

Opponent–II has also opposed grant of the patent on the ground of not an invention U/S 3(d) of the Patents Act. Documents of particular relevance giving are exhibit 3 or exhibit 4 arguing mere discovery of any new property or new use of a known substance is not patentable. However, the claimed compounds are not known substance and therefore these compounds so all together a new property i.e. antimalarial activity not disclosed in any prior art.

It is observed from the ongoing analysis that both the opponents failed to establish the claimed compound of the applicant to be **a new form of a known substance**. In absence of such submission it is established that the compound claimed is new and involves inventive step, therefore the provision of requirements as per Section 3(d) of the Act, as raised by both the opponents may not be applicable in the present case. This ground of opposition has not been established by the opponents.

Opponent–II has also opposed grant of the patent on the ground of not an invention U/S 3(e) of the Patents Act. However, the limitation of document relied upon has already been described above in the ground of opposition U/S 25(e) of the Act. Without having substantial evidence on this aspect and with a narrow interpretation it cannot be asserted that the admittance of the applicant in page 5 of the specification can be considered as not an invention U/S 3(e) of the Act.

4. Ground of opposition under Section 25(1)(g) of Patents Act - Clarity and insufficiency.

While relying on this ground the **Opponent-I** states that the applicant has not disclosed "How to synthesize the compound Thiazolidin-3-yl-Imidazo-pyridine-3- carboxamide of formula I is not clear from the claim as there is no process steps."

The applicant while defending this ground states that "The applicant has claimed a new and innovative chemical compound, Formula I in the instant application. The complete specification of the instant application clearly provides complete details pertaining to the synthesis of the compound of Formula I through Example 1 to 15 provided in detail on Page Nos. 16 to 19 of the specification.

It is also opined that the statement of the applicant is correct as verified from the specification filed in this office. The examples and the scheme of the reaction given thereof gives enough clarity and sufficiency of disclosure. The **Opponent-I** fails to establish such a ground of opposition.

Based on the matter submitted by both the opponents (**Opponent–I** and **Opponent-II**) (*ex-parte*) through the pre-grant opposition, the submission and the argument of the applicant in the hearing proceedings and the amendment carried out in the claims and the findings from the investigation as presented above, it is concluded that both the opponents have failed to establish none of the grounds of the opposition relied upon i.e. Section 25(1)(b); Section 25(1)(e); Section 25(1)(f) and Section 25(1)(g) of the Patents Act.

Therefore, it is hereby ordered that the invention disclosed and claimed in the instant application No. 202221034803 entitled “THIAZOLIDIN-3-YL-IMIDAZO-PYRIDINE-3-CARBOXAMIDE AS ANTIMALARIAL AGENTS” has been proceeded to grant with the amended claims 1-5 and simultaneously, the pre-grant oppositions filed as per the provision under Section 25(1) of the Act and corresponding Rules made there under is disposed of.

Dated this 21/12/2023

Dr. Amarendra Samal
Joint Controller of Patents & Designs
Patent Office, Chennai