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GOVERNMENT OF INDIA
PATENT OFFICE
INTELLECTUAL PROPERTY BUILDING
G.S.T ROAD GUINDY
CHENNAI – 600 032

Date: 31/10/2019

Section 15

In the matter of Patents Act, and the Patents Rules

And

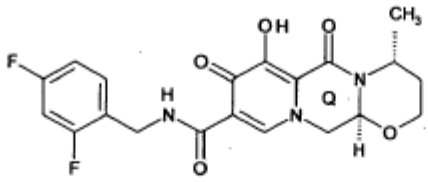
In the matter of Patent application number 1942/KOLNP/2011, filed on 16/03/2011

DECISION

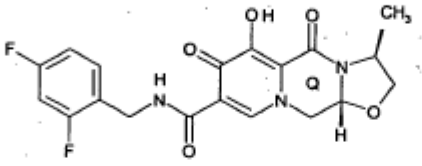
1. On 16/03/2011, the applicant 'VIIV HEALTHCARE COMPANY' of U.S.A. filed a National Phase patent application in India under Patent Cooperation Treaty in respect of an invention entitled 'SYNTHESIS OF CARBAMOYLPYRIDONE HIV INTEGRASE INHIBITORS AND INTERMEDIATES' through their attorney with the following claims;

What is Claimed is:

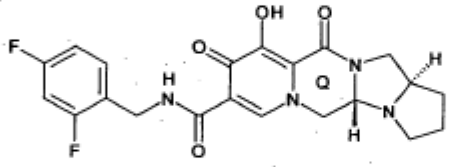
1. A process of for the preparation of a pyridone compound of formula (AA), (BB) or (CC):



AA



BB



CC

comprising the steps of:

P-1) brominating a compound of the following formula (I-I) to produe a bromine compound of the following formula (II-II):

I-I II-II

wherein

R is –CHO, –CH(OH)$_2$, –CH(OH)(OR^4), -CH(OH)-CH$_2$OH or –CH(OR^5)(OR^6);

P^1 is H or a hydroxyl protecting group;

P^3 is H or a carboxy protecting group;

R^4 is lower alkyl;

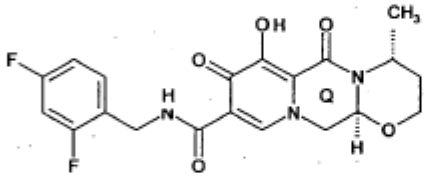
R^5 and R^6 are independently lower alkyl or R^5 and R^6 can be alkyl and joined to form a 5-, 6-, or 7-membered ring,

and

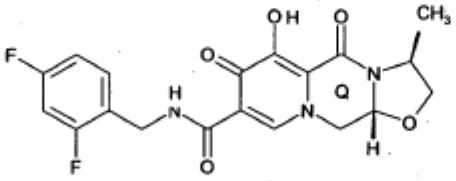
P-2) creating the 2,4-di-fluorophenyl-CH$_2$-NH-C(O)- sidechain with the reactants

2,4-di-fluorophenyl-CH$_2$-NH$_2$ and carbon monoxide.

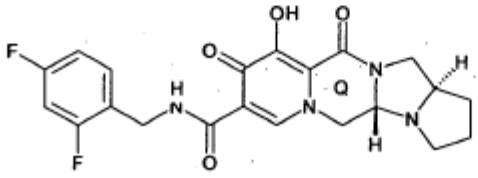
2. A process is provided for the preparation of a pyridone compound of the following formula (AA), (BB) or (CC):



AA

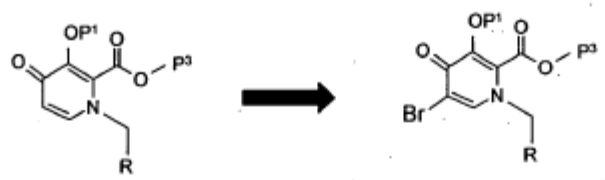


BB



CC

P-1) brominating a compound of the following formula (I-I) to produce a bromine compound of the following formula (II-II):



I-I II-II

wherein

R is –CHO, –$CH(OH)_2$, –CH(OH)(OR^4), -CH(OH)-CH_2OH or —CH(OR^5)(OR^6);

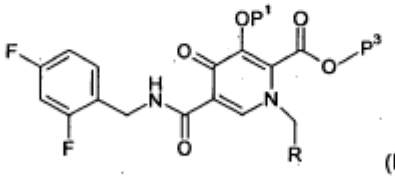
P^1 is H or a hydroxyl protecting group;

P^3 is H or a carboxy protecting group;

R^4 is lower alkyl;

R^5 and R^6 are independently lower alkyl or R^5 and R^6 can be lower alkyl and joined to form a 5-, 6-, or 7-membered ring,

P-2) creating the 2,4-di-fluorophenyl-CH_2-NH-C(O)- sidechain with the reactants 2,4-di-fluorophenyl-CH_2-NH_2 and carbon monoxide to form a compound of formula III-III:



(III-III)

P-3) condensing and debenzylating a compound of formula III-III to form a compound of formula AA, BB, or CC.

3. The process according to claim 1, wherein said step P-2) is carried out before creation of the Q ring.

4. The process according to claim 1 or 2, wherein said pyridone compound is of the formula AA.

5. The process according to claim 1 or 2, wherein said pyridone compound is of the formula BB.

6. The process according to claim 1 or 2, wherein said pyridone compound is of the formula CC.

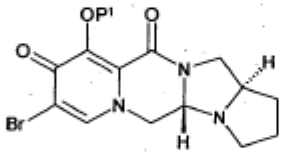
7. The process according to claim 1, wherein said step P-2) is carried out after creation of the Q ring.

8. The process according to claim 7, wherein said pyridone compound is of the formula AA.

9. The process of Claim 7, wherein said pyridone compound is of the formula BB.

10. The process of Claim 7, wherein said pyridone compound is of the formula CC.

11. A compound of the following formula (DD):



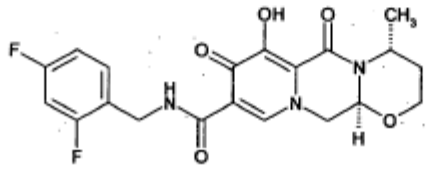
DD

wherein P^1 is H or a carboxy protecting group.

12. The compound of claim 11, wherein P^1 is benzyl.

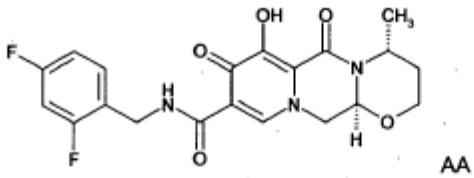
13. A process according to any of claims 1-10 wherein P^1 is benzyl; P^3 is methyl; and R is –CHO, –CH(OH)(OR^4), -CH(OR^5)(OR^5) wherein R^4 and R^5 are lower alkyl.

14. A salt or a hydrate thereof of a compound of formula AA



AA

15. A crystal form of a sodium salt or a hydrate thereof of a compound of formula AA



AA

16. A crystal form according to claim 15 having one or more physical properties selected from the group consisting of (i) and (ii):
(i) having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 19.2° ± 0.2° and 21.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern; and
(ii) having characteristic infrared absorption spectra at 1641cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1503cm^{-1} ± 2cm^{-1} and 1424cm^{-1} ± 2cm^{-1}.

17. A crystal form according to claim 15 having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 19.2° ± 0.2° and 21.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

18. A crystal form according to claim 15 having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 14.6° ± 0.2°, 15.2° ± 0.2°, 17.6° ± 0.2°, 19.2° ± 0.2°, 21.8° ± 0.2°, 24.1° ± 0.2° and 28.7° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

19. A crystal form form according to claim 15 having characteristic infrared absorption spectra at 1641cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1503cm^{-1} ± 2cm^{-1} and 1424cm^{-1} ± 2cm^{-1}.

20. A crystal form according to claim 15 having characteristic infrared absorption spectra at 1641cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1503cm^{-1} ± 2cm^{-1}, 1424cm^{-1} ± 2cm^{-1}, 1282cm^{-1} ± 2cm^{-1}, 1258cm^{-1} ± 2cm^{-1}, 1093cm^{-1} ± 2cm^{-1} and 1069cm^{-1} ± 2cm^{-1}.

21. A crystal form according to claim 15 having one or more spectra selected from the group consisting of (a) to (c):
(a) X-ray powder diffraction pattern substantially as shown in Figure 1;
(b) Infrared absorption spectra substantially as shown in Figure 2; and
(c) Solid state ^{13}C-NMR spectra substantially as shown in Figure 3.

22. A crystal form according to claim 15 having one or more physical properties selected from the group consisting of (iii) and (iv):

(iii) having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 16.0° ± 0.2°, and 22.8° ± 0.2°degrees two-theta in an X-ray powder diffraction pattern; and
(iv) having characteristic infrared absorption spectra at 1637cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1501cm^{-1} ± 2cm^{-1} and 1422cm^{-1} ± 2cm^{-1}.

23. A crystal form according to claim 15 having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 16.0° ± 0.2°and 22.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

24. A crystal form according to claim 15 having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 15.4° ± 0.2°, 16.0° ± 0.2°, 18.7° ± 0.2°, 19.1° ± 0.2°, 19.8° ± 0.2°, 22.8° ± 0.2° and 26.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

25. A crystal form according to claim 15 having characteristic infrared absorption spectra at 1637cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1501cm^{-1} ± 2cm^{-1} and 1422cm^{-1} ± 2cm^{-1}.

26. A crystal form according to claim 15 having characteristic infrared absorption spectra at 1637cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1501cm^{-1} ± 2cm^{-1}, 1422cm^{-1} ± 2cm^{-1}, 1277cm^{-1} ± 2cm^{-1}, 1258cm^{-1} ± 2cm^{-1}, 1093cm^{-1} ± 2cm^{-1} and 1069cm^{-1} ± 2cm^{-1}.

27. A crystal form according to claim 15 having one or more spectra selected from the group consisting of (d) and (e):
(d) X-ray powder diffraction pattern substantially as shown in Figure 4; and
(e) Infrared absorption spectra substantially as shown in Figure 5.

28. A pharmaceutical composition comprising a crystal form as defined in any one of the claims 15 to 27.

29. A process for preparation of a crystal form as defined in any one of the claims 15 to 27.

2. The PCT International application number for the above national phase application 1942/KOLNP/2011 was PCT/US2009/006422 dated 08/12/2009.

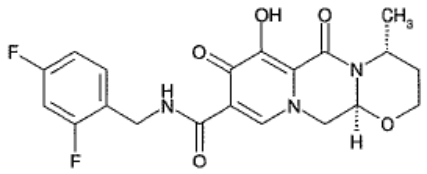
3. With reference to the RQ No. 5229/RQ-KOL/2012 dated 15/11/2012, Examination has been conducted under Section 12 and 13 of the Patents Act 1970 and First Examination Report (FER) was issued.

4. The applicant has filed their reply to the First Examination Report with the following amended claims;

AMENDED 1

WE CLAIM :

1. A sodium salt of a compound of formula AA



AA

or a hydrate thereof.

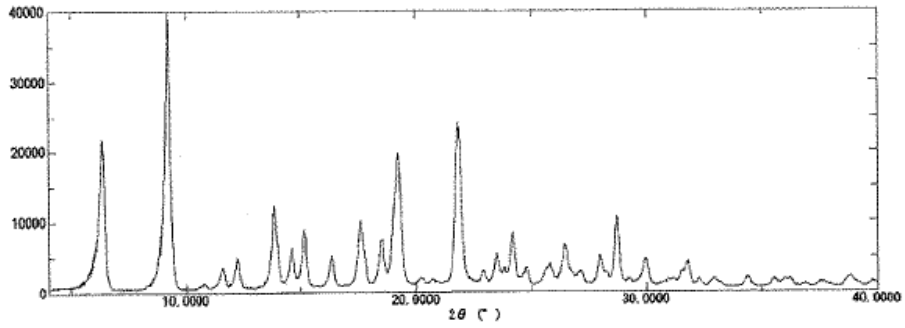
2. A crystal form of the sodium salt of a compound or a hydrate as claimed in claim 1 having one or more physical properties selected from the group consisting of (i) and (ii): (i) having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 19.2° ± 0.2° and 21.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern; and (ii) having characteristic infrared absorption spectra at 1641cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1503cm^{-1} ± 2cm^{-1} and 1424cm^{-1} ± 2cm^{-1}.

3. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 19.2° ± 0.2° and 21.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

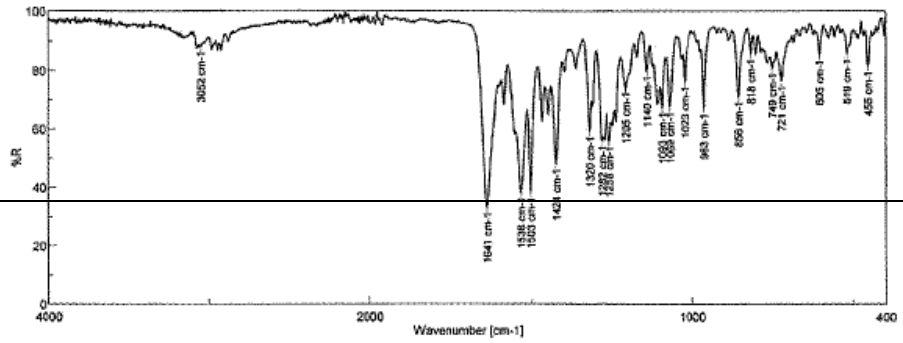
4. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 14.6° ± 0.2°, 15.2° ± 0.2°, 17.6° ± 0.2°, 19.2° ± 0.2°, 21.8° ± 0.2°, 24.1° ± 0.2° and 28.7° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

5. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having one or more spectra selected from the group consisting of (a) to (c):

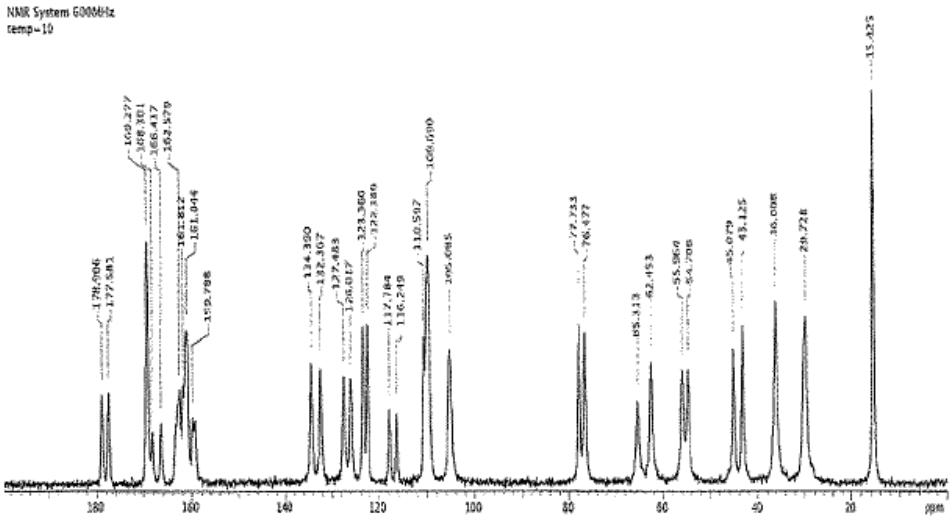
(a) X-ray powder diffraction pattern substantially as shown in Figure 1 below;



(b) Infrared absorption spectra substantially as shown in Figure 2 below; and



(c) Solid state ^{13}C-NMR spectra substantially as shown in Figure 3 below.



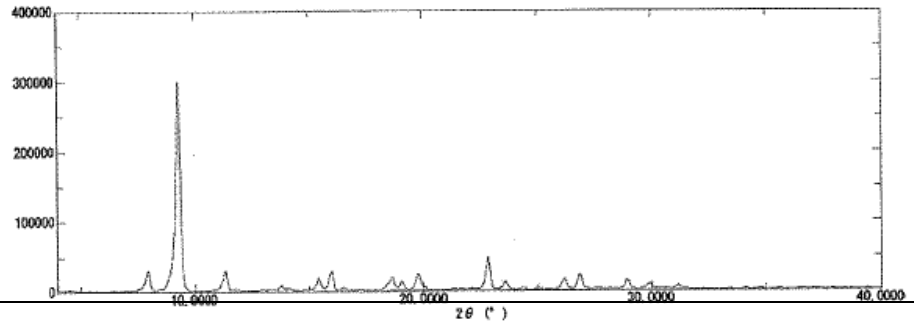
6. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having one or more physical properties selected from the group consisting of (iii) and (iv):
(iii) having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 16.0° ± 0.2°, and 22.8° ± 0.2°degrees two-theta in an X-ray powder diffraction pattern; and
(iv) having characteristic infrared absorption spectra at 1637cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1501cm^{-1} ± 2cm^{-1} and 1422cm^{-1} ± 2cm^{-1}.

7. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 16.0° ± 0.2°and 22.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

8. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 15.4° ± 0.2°, 16.0° ± 0.2°, 18.7° ± 0.2°, 19.1° ± 0.2°, 19.8° ± 0.2°, 22.8° ± 0.2° and 26.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

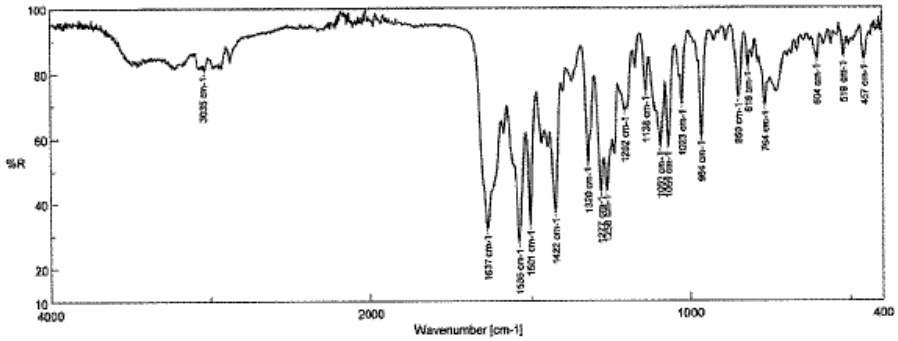
9. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having one or more spectra selected from the group consisting of (d) and (e):

(d) X-ray powder diffraction pattern substantially as shown in Figure 4 below;



and

(e) Infrared absorption spectra substantially as shown in Figure 5 below.



AMENDED 1

10. A pharmaceutical composition comprising a crystal form as claimed in any one of the claims 2 to 9.

5

Dated this 9th day of May, 2011

10

(RUPSA GUPTA)
(Regn. No.: IN/PA-1613)
OF D. P. AHUJA & CO.
APPLICANT'S AGENT

5. But the reply was not satisfactory therefore hearing was offered, later adjourned and held. The following objections were communicated in the hearing notice;

INTELLECTUAL PROPERTY INDIA

THE PATENT OFFICE

Date-18-07-2019

Objections

Formal Requirement(s)

1. Amended set of claims has been submitted to the patent office along with marked-up copy of claims, while the new amended set of claims has used the drawing in between the claims. This insertion of figures or drawings in between the claims is not allowed in the claims. Therefore the applicant should submit a fresh set of amended claims and a fresh set of drawings separately in the prescribed manner as per the PatentsAct.

Invention u/s 2(1)(j)

1. The subject-matter of claims of the alleged invention explains the crystal form of sodium salt of compound AA or a hydrate and process of its preparation. While the prior art cited in the FER teaches compounds (polycyclic carbamoylpyridone derivative, Aza- and polyaza-naphthalenyl carboxamide derivatives, quinoline carboxamide and naphthyridine carboxamide derivatives, hydrate of AA) which show HIV integrase inhibitory activity. para 17, of D1 discloses a salt or hydrate of compound AA. The crystal form of compound AA has been disclosed in page 80 of D1. On reply applicant has submitted that it is impossible to predict which pharmaceutical solids or salt forms of D1 will organize into crystals, which will remain amorphous or will form a hydrate. While several form of AA has been made very clear from disclosure of D1 (page 10, para 17).

   The present invention discloses sodium salt or hydrate of compound AA. The compound AA is well known from the cited document D1, where substituent for the compound of para 12; R is halogen, m is 0 to 3, R1 is H, R3 is H, R14 & Rx is H and ring A according to para 17; A-1 where z is Oxygen, R20 to R25 are substituent S2 and S2 is optionally substituted lower alkyl. Therefore it is obvious for the person skilled in the art to prepare any salt or hydrate. There is no inventive step.

   Moreover the cited document D1 in example Z-9 (page 142) discloses a sodium salt of a compound wherein side ring A is a five membered ring, where as in the present invention it is six membered ring. Therefore it is obvious to the person skilled in the art to prepare the sodium salt.

   Therefore the subject-matter of the claims lacks inventive step u/s 2(j)(ja) of the Patents Act.

Non-Patentability u/s 3

1. The subject matter of the claimsfallwithin the scope of section 3(d) of the Patents Act, The present invention discloses sodium salt or hydrate of compound AA. The compound AA is well known from the cited document D1, where the substituent for the compound of para 12; R is halogen, m is 0 to 3, R1 is H, R3 is H, R14 & Rx is H and ring A according to para 17; A-1 where z is Oxygen, R20 to R25 are substituent S2 and S2 is optionally substituted lower alkyl. Therefore the present invention is a new form of known substance without any supportive data for the enhancement in efficacy.

   Also the cited document D1 in example Z-9 (page 142) discloses a sodium salt of a compound wherein side ring A is a five membered ring, whereas in the present invention it is six membered ring. But the present invention did not provide any comparative study for the closest prior art compound in order to prove the enhancement in efficacy.

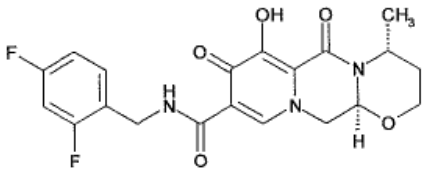
   Moreover applicant of the present invention and the D1 are same, therefore it is well known to the applicant. The applicant is trying for evergreening of the patent which cannot be allowed unless the requirement under section 3(d) of the Patents Act is met.

6. The applicant has filed their written submission along with the following amended claims;

AMENDED 2

WE CLAIM :

1. A sodium salt of a compound of formula AA



AA

or a hydrate thereof.

2. A crystal form of the sodium salt of a compound or a hydrate as claimed in claim 1 having one or more physical properties selected from the group consisting of (i) and (ii): (i) having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 19.2° ± 0.2° and 21.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern; and (ii) having characteristic infrared absorption spectra at 1641cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1503cm^{-1} ± 2cm^{-1} and 1424cm^{-1} ± 2cm^{-1}.

3. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 19.2° ± 0.2° and 21.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

4. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 6.4° ± 0.2°, 9.2° ± 0.2°, 13.8° ± 0.2°, 14.6° ± 0.2°, 15.2° ± 0.2°, 17.6° ± 0.2°, 19.2° ± 0.2°, 21.8° ± 0.2°, 24.1° ± 0.2° and 28.7° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

5. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having one or more physical properties selected from the group consisting of (iii) and (iv): (iii) having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 16.0° ± 0.2°, and 22.8° ± 0.2°degrees two-theta in an X-ray powder diffraction pattern; and (iv) having characteristic infrared absorption spectra at 1637cm^{-1} ± 2cm^{-1}, 1536cm^{-1} ± 2cm^{-1}, 1501cm^{-1} ± 2cm^{-1} and 1422cm^{-1} ± 2cm^{-1}.

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AMENDED 2

6. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 16.0° ± 0.2°and 22.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

7. A crystal form of the sodium salt of a compound or hydrate as claimed in claim 1 having characteristic diffraction peaks at 8.0° ± 0.2°, 9.3° ± 0.2°, 11.3° ± 0.2°, 15.4° ± 0.2°, 16.0° ± 0.2°, 18.7° ± 0.2°, 19.1° ± 0.2°, 19.8° ± 0.2°, 22.8° ± 0.2° and 26.8° ± 0.2° degrees two-theta in an X-ray powder diffraction pattern.

8. A pharmaceutical composition comprising a crystal form as claimed in any one of the claims 2 to 7.

Dated this 9th May, 2011

(RUPSA GUPTA)
of D.P. AHUJA & CO.
Registration No.: IN/PA-1613
APPLICANT'S AGENT
E-mail: patents@dpahuja.com
Mobile Phone: +919831360050

7. The applicant submitted a common reply for both inventive step and Non-Patentability as follows;

   "The crystal claims are directed to a specific well characterized crystal of a sodium salt of a compound AA. D1 fails to teach how to make the crystalline form. It is impossible to predict which pharmaceutical solids or salt forms of D1 will organize into crystals, which will remain amorphous or will form a hydrate. Even if one skilled in the art would have thought that some of the D1 compounds would form a crystal, the skilled person would not have been able to predict the particular claimed crystal forms of the claimed sodium salts of compound AA. Also crystalline salt forms are in general preferred over the base form as they often have increased stability, bioavailability, water solubility etc. as discussed on page 16, lines 2-7 of the specification, the crystals of the present invention demonstrate high solubility in water or saline, high bioavailability (BA), high maximum drug concentration (Cmax), short minimum drug concentration time (Tmax), high stability against heat or light, and/or good handling properties".

8. From the above it is very clear that there is no dispute that compound AA is known i.e. The compound AA is well known from the cited document D1, where substituent for the compound of para 12; R is halogen, m is 0 to 3, R1 is H, R3 is H, R14 & Rx is H and ring A according to para 17; A-1 where z is Oxygen, R20 to R25 are substituent S2 and S2 is optionally substituted lower alkyl. Moreover the cited document D1 in example Z-1 (page 128) and Z-9 (page 142) discloses a sodium salt of a compound wherein side ring A is a five membered ring, where as in the present invention it is six membered ring. Because in the definition of ring "A" it was given that that the "A" ring is an optionally substituted and optionally condensed 5- to 7- membered heterocycle containing 1 to 2 atom(s). Therefore it is obvious to the person skilled in the art to prepare the compound AA and its sodium salt or hydrate.

9. The applicant reference to the page 16, lines 2-7 of the specification that the "the crystals of the present invention demonstrate high solubility in water or saline, high bioavailability (BA), high maximum drug concentration (Cmax), short minimum drug concentration time

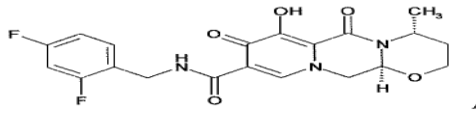
(Tmax), high stability against heat or light, and/or good handling properties" is mere statement, there is no data provided in support of the same.

10. The present invention fall within the scope of section 3(d) of the Patents Act, since they are the new form of known compound from D1 (as above) i.e. sodium salt and crystalline form i.e. i.e. The compound AA is well known from the cited document D1, where substituent for the compound of para 12; R is halogen, m is 2 (0 to 3), R1 is H, R3 is H, R14 & Rx is H and ring A according to para 17; A-1 where z is Oxygen, R20 to R25 are substituent S2 and S2 is optionally substituted lower alkyl (methyl).

11. In addition the present invention also a derivative of a known compound (under section 3(d) of the Patents Act) from the cited document D1 in example Z-1 (page 128) and Z-9 (page 142) discloses a sodium salt of a compound wherein side ring A is a five membered ring, where as in the present invention it is six membered ring. Because in the definition of ring "A" it was given that that the "A" ring is an optionally substituted and optionally condensed 5- to 7- membered heterocycle containing 1 to 2 atom(s). In the present invention the ring "A" is six membered ring.

    Present invention:

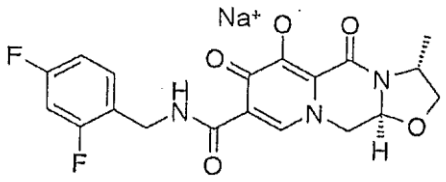
    A sodium salt of a compound of formula AA

    AA

    or a hydrate thereof.

    Example Z-1 (page 128) of D1:

12. From the above it is very clear that the compound of the present invention fall within the scope of section 3(d) of the Patents Act, but there is no therapeutic efficacy data to show

enhancement in therapeutic efficacy as required under section 3(d) of the Patents Act, which is very much essential and important parameter to decide the patentability of the present invention.

13. The Honorable Supreme Court of India in Novartis Vs Union of India & others, stated as follows;

"180. What is "efficacy"? Efficacy means[1] "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy….".

"187. In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy".

14. The above principle laid down by the Honorable Supreme Court of India in Novartis Vs Union of India & others is squarely applicable to the present invention. The present invention is not patentable under section 3(d) of the Patents Act, since there is no therapeutic efficacy data.

15. After considering all the documents referred by the applicant and their submission and in view of my finding above I refuse to proceed with this application under section 15 of the Patents Act.

B. AHILAN

Deputy Controller of Patents & Designs

To

D. P. AHUJA & CO.,