BEFORE THE CONTROLLER OF PATENTS, THE PATENT OFFICE,

KOLKATA

IN THE MATTER OF THE PATENTS ACT, 1970 and THE PATENTS RULES 2003.

IN THE MATTER OF a pre-grant representation under Section 25(1)

AND

IN THE MATTER OF:

Indian Patent Application **3865/KOLNP/2007** filed on 10th October, 2007.

AND

IN THE MATTER OF:

SANJEEV SHARMA,
S/o Shri. Lakhmi Chand,
R/o House No.57, Zamrudpur,
Greater Kailash-I, New Delhi-110048,
India …PETITIONER/OPPONENT

VS.

1) SMITHKLINE BEECHAM CORPORATION
   A United States Corporation
   One Franklin Plaza, P.O. Box 7929
   Philadelphia, PA 19101, United States of America.
2) SHIONOGI & CO. LTD.
   A Japanese Company,
   1-8 Doshomachi 3-Chome, Chuo-Ku,
   Osaka-Shi, Osaka 541-0045,
   Japan. …RESPONDENTS/APPLICANTS

STATEMENT OF CASE OF OPPONENT

1. Sanjeev Sharma herein is a person living with HIV. In the past he has suffered tremendously from lack of access to life saving anti-retrovirals. He is now receiving

treatment from the National AIDS Control Organization which procures low cost quality generic anti-retrovirals for nearly a million people living with HIV in India.

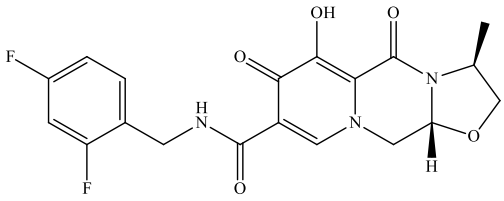
2. The Petitioner/Opponent believes in particular based on his own personal harrowing experience that instruments such as patents should not become a tool for creation of monopoly rights, which is then often abused by the patent holder as patients who desperately need access to new HIV medicines when they are faced with drug resistance are deprived of access. Opponent believes that this impugned patent application is an example of an attempt to obtain monopoly right, without any intention of actually marketing or allowing Indian generic companies to market the life saving integrase inhibitors for the benefit of people living with HIV in India and many other middle income developing countries.

3. The Petitioner/Opponent has learnt that the Applicant has filed an Indian National Phase Application No. 3865/KOLNP/2007 (being the impugned patent application), which is currently pending before the Patent Office. The impugned patent application claims inter-alia, a markush claim which has now been narrowed in scope by the Applicant to two substances (integrase inhibitors) capable of use in HIV treatment. The two substances are also called Dolutegravir and Cabotegravir. The Opponent believes that the one of the HIV drug - Dolutegravir - in question is not available in India and the applicants in fact have not applied for approval for marketing the drug not have they made it available under compassionate use to dying patients in India. The drug is already approved and available in the US, EU and other developed countries and has quickly become part of first line HIV treatment in the US recommended by the Department of Health and Human Services HIV treatment guidelines for treatment-naive adults and adolescents. The

applicants do not appear to have any intention of introducing the drug Dolutegravir in India and have effectively blocked the availability of the drug in the 'Indian market', limiting it only to public sector supply under a license with the Medicines Patent Pool and which has led to sub-licenses with Indian generic companies. This fundamentally undermines access for dying HIV patients who may need to procure the drug for salvage therapy in the absence of public sector procurement which happens after detailed consultations over several years. The second substance in question is a follow-on drug to Dolutegravir with a similar structure (called Cabotegravir) is in development by the Applicant as a long-acting injection.

4. The said Indian Patent Application is titled "Polycyclic carbamoylpyridone derivative having HIV integrase inhibitory activity" and is drawn to claims pertaining to a product known as Dolutegravir and Cabotegravir. The said Indian Application is drawn to two priorities being Japanese Patent Application No. 2005-131161 dated 28th April 2005 and JP 2005-1312076 dated 27th October 2005. The said Indian Application is the National Phase Entry of the PCT publication WO 2006/116764 filed on 28th April, 2006. The Indian Patent Application was filed on 10th October, 2007. The impugned patent application was published on 18th July, 2008. A request for examination vide Form 18 has been filed on 22nd April, 2009. The Application was initially filed with 56 claims, which apparently appear to have been amended by way of Form 13 filed on or about 30th August, 2012, after objections were raised in First Examination Report issued on 27th February, 2012 thereby amending the claims to 51 in number. Thereafter the claims were further amended and reduced to 9 in number. The final set of amended claims as filed on 13th February, 2013 are as below and annexed herewith as Annexure 1:

1) A compound which is (4R,9aS)-5-Hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid-2,4-difluoro-benzylamide or a pharmaceutically acceptable salt or solvate thereof.
2) A compound as claimed in claim 1, wherein the pharmaceutically acceptable salt is a sodium salt.
3) A pharmaceutical composition comprising a compound as defined in Claim 1 or 2 together with a pharmaceutically acceptable carrier.
4) A pharmaceutical composition as claimed in claim 3 wherein said composition comprises at least one additional therapeutic agent selected from reverse transcriptase inhibitors and protease inhibitors.
5) A compound of formula :



or a pharmaceutically acceptable salt or solvate thereof.

6) A compound as claimed in claim 5 or 6 which is (3S,11aR)-N-[(2,4-Difluorophenyl)methyl]-6-hydroxy-3-methyl-5,7-dioxo-2,3,5,7,11,11a-hexahydro[1,3]oxazolo[3,2-a]pyrido[1,2-d]pyrazine-8-carboxamide.
7) A compound as claimed in claim 5 or 6, wherein the pharmaceutically acceptable salt is a sodium salt.
8) A pharmaceutical composition comprising a compound as defined in anyone of Claims 5 or 6 together with a pharmaceutically acceptable carrier.
9) A pharmaceutical composition as claimed in claim 8 wherein said composition comprises atleast one additional therapeutic agent selected from reverse transcriptase inhibitors and protease inhibitors.

5. The impugned specification admits that the HIV integrase inhibitors were already known in prior art. The present impugned specification is also drawn to the compounds that are mere alternative to those in the prior art. The impugned specification claims compounds, depicted by an IUPAC name. The compound of claim 1 is disclosed in impugned specification at Example Y-3 at Page-116 (generically known as Dolutegravir) and the compound of claim 5 is disclosed in impugned specification at Example Z-9, Page-142 (generically known as Carbotegravir). It is submitted that all compounds including Dolutegravir and Cabotegravir are well known and well established by that of disclosure in prior art and ought to be rejected. The opponent further submit the claims as amended and currently on record are not patentable under this act on various grounds as below:

GROUND I

I) Section 25(1)(b)(c): Lack of Novelty

The invention as claimed in Claims 1 to 9 lacks novelty and are not patentable under Section 25(1)(b)(c) of the Patents Act, 1970 (as amended in 2005; hereinafter referred to as "the Act"). It is submitted that none of the claims of 3865/KOLNP/2007 are novel and they are all liable to be rejected on this ground alone.

It is submitted that all claims 1 to 9 of the impugned Patent application is anticipated by prior disclosure in US2005/0054645 (hereinafter referred as US'645 and annexed as Annexure-2) was published on March 10, 2005. It is submitted that the compound claimed in claim 1 and 5 are known and encompassed within the basic chemical structure of US'645 application.

Before discussing this ground of opposition, the various chemical parts of the compound claimed in claim 1 (purportedly known as Dolutegravir) and compound claimed in claim 5 (purportedly known as Cabotegravir) are discussed. Dolutegravir comprises of difluoro substituted phenyl methyl ring attached to a 1-oxa-diaza-antharcene ring via carboxamide group, wherein the 1-oxa-diaza-anthracene ring is further substituted with hydroxy at 5-position and dioxo group at 6 and 10-position. Whereas Cabotegravir comprises of difluoro substituted phenyl methyl ring attached to oxazolopyridopyrazine ring via carboxamide group, wherein the oxazolopyridopyrazine ring is further substituted with hydroxy at 6-position and dioxo group at 5- and 7-position. The structure of Dolutegravir is reproduced herein below at Figure 1 and 2.

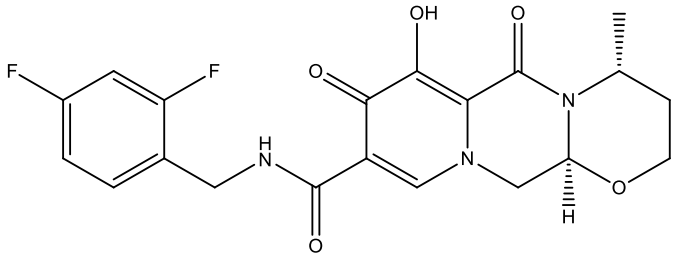


Figure 1: Structure of Dolutegravir

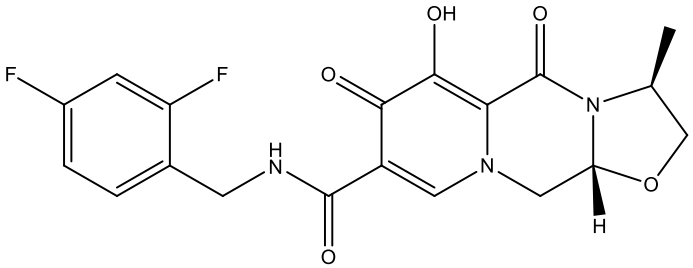


Figure 2: Structure of Cabotegravir

US'645 is drawn to nitrogen containing fused rings that are useful as inhibitor of HIV integrase and is used as an anti-HIV agent. US'645 disclose a group of compounds represented by general chemical structure known as the markush structure

encompassing several thousand of compounds. The markush structure is reproduced herein below at Figure 3.

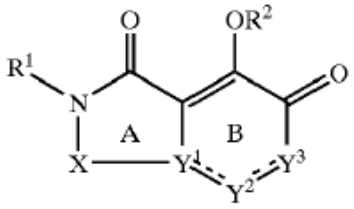
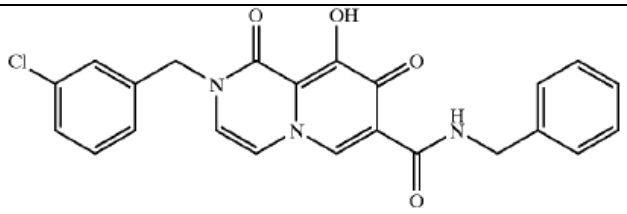
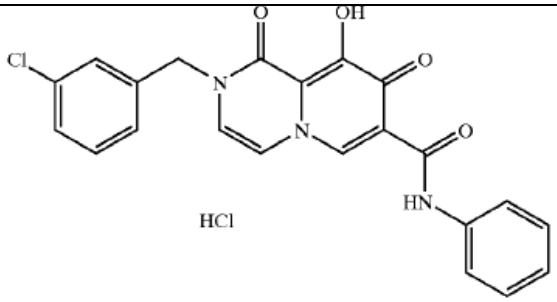
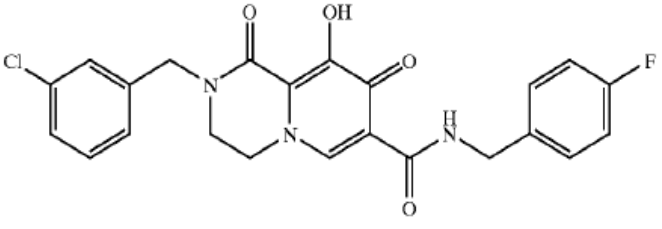
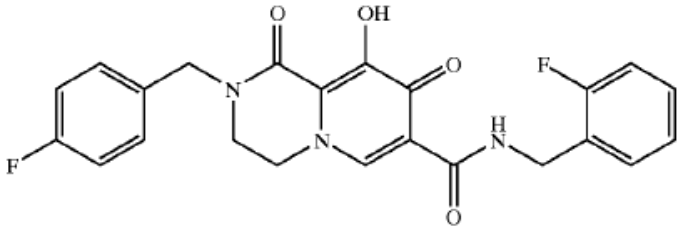
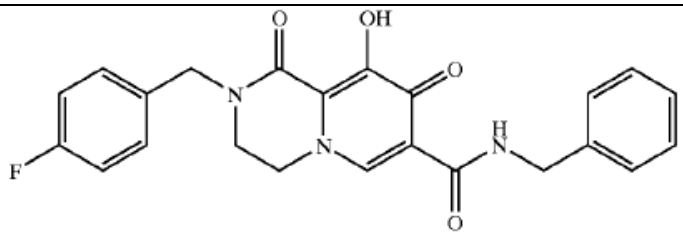


Figure 3

It is submitted that compound claimed in claims of Impugned Patent application are encompassed within the markush structure of US'645. US'645 exemplify several compounds with various substitutions which are similar to the compounds of the impugned patent application. Certain representative compounds of US'645 are represented herein below at Table 1.

Table 1: Representative Compounds of US'645

Example No.	Structure
Example 181	
Example 196	
Example 214	

Example 377	
Example 380	

It can be seen from the above Table 1, that all compounds exemplified by US'645 have a halogen substituted at 4-position of the phenyl methyl ring attached to pyridopyrimidine ring via carboxamide similar to the compounds of the impugned patent application. US'645 as described herein above clearly disclose compounds that are claimed within the markush structure of the impugned patent application. The disclosed compounds may be considered as the species compounds. It is well understood that a species will anticipate if the prior art discloses a species falling within the claimed genus. The species in that case will anticipate the genus. Further it is submitted that when the species is clearly named, the species claim is anticipated no matter how many species compounds are additionally named/claimed.

It is submitted that the US'645 teaches a generic formula embracing a certain number of compounds closely related to each other in structure and the properties possessed by the compounds and the structural semblance of the compound are the same as that of the impugned application. Moreover, such compounds were known as HIV integrase inhibitors for the treatment of AIDS. Hence, the compounds disclosed in US'645 anticipate the compounds claimed by the impugned application.

Thus it is submitted that all claims 1 to 9 of the impugned patent application are anticipated by US'645 and therefore ought to be rejected on this ground only.

GROUND II

II) Section 25(1)(e): Lack of Inventive Step

The invention so far claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regards to the matter published as mentioned in clause (b) or having regard to what was used in India before the date of priority.

The alleged invention disclosed in the impugned patent application, relates to two compounds, i.e., compound of claim 1 (generically known as Dolutegravir) compound of claim 5 (generically known as Cabotegravir) which are polycyclic carbamoyl pyridine derivatives and their use as HIV integrase inhibitors. As discussed in detail below, such compounds were already known before the priority date and the concept of developing such compounds for its intended anti-viral effect was well known before the priority date. Furthermore, the alleged invention relating to the polycyclic carbamoyl pyridine derivatives represents no more than routine modifications obtained by the application of generally known techniques available at the priority date. The impugned specification also professes that the alleged invention relates to compounds which are inhibitors of inhibitors of HIV integrase. The compound has a phenyl methyl ring, which is substituted at the 2- and 4- position with a fluoro group. The phenyl methyl ring is further substituted via a carboxamide group to the 1-oxa-diaza-anthracene ring (compound of claim 1) and oxazolopyridopyrazine ring (compound of claim 5). The 1-oxa-diaza-anthracene ring (compound of claim 1) is substituted at 6 and 10- position with dioxo group and at 5-position with a hydroxy

group, whereas the oxazolopyridopyrazine ring (compound of claim 5) is substituted at 5 and 7-position with a dioxo group and at 6-position with hydroxy group. It is well-known that phenylmethyl ring attached to bicyclic rings via carboxamide group are already known for their anti-viral activity.

It is submitted that from as early as 1990's, phenylmethyl ring attached to bicyclic rings via carboxamide group as disclosed in the impugned patent application have been used for HIV integrase inhibitory activity.

It is well established that such compounds comprising phenylmethyl ring attached to bicyclic rings via carboxamide group were reported to be active as anti-viral agents as evident by WO1999/032450 (hereinafter referred as WO'450 and annexed as Annexure-3) titled "4-hydroxyquinoline-3-carboxamides and hydrazides as antiviral agents" published on January 01, 1999. WO'450 discloses 4-hydroxyquinoline-3-carboxamide derivatives and the use of such derivatives as antiviral agents against viruses of the herpes family. The compound of WO'450 is represented by a general chemical structure known as the markush structure and is reproduced herein below at Figure 4.

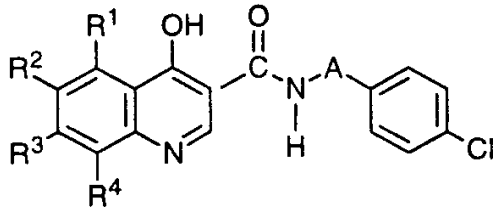
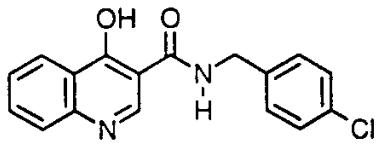
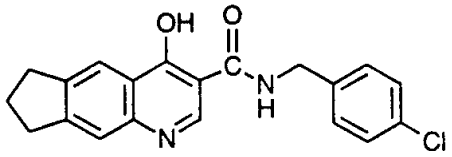
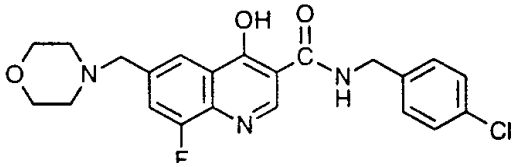


Figure 4

It is submitted that WO'450 discloses compounds with substitutions pertaining to phenylmethyl pyridine carboxamide wherein the pyridine is further attached to phenyl ring together forming a benzopyridine ring. Certain compounds that are embraced

within the markush formula of WO'450 are also exemplified. Certain representative compounds of WO'450 are represented herein below at Table 2.

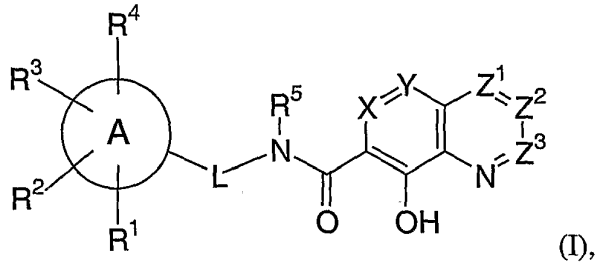
Table 2: Representative Compound's of WO'450

S.No.	Example No.	Structure
1	Example 6	
2	Example 64	
3	Example 158	

It can be seen from the above Table 2, that all compounds exemplified by WO'450 have a halogen substituted phenyl methyl ring which is substituted with a benzopyridine ring via a carboxamide group. Therefore, it can be clearly seen that phenylmethyl ring attached to benzopyridine, wherein the phenyl ring is further substituted with a halogen group are already known and well established in prior art.

WO2002/030426 (hereinafter referred as WO'426 and annexed herewith as Annexure-4) titled "Aza- and Polyaza- Naphthalenyl- Carboxamides useful as HIV Integrase Inhibitors", was published on April 18, 2002. WO'426 discloses aza- and polyaza-naphthalenyl carboxamides derivatives and the use of such derivatives in the inhibition of HIV integrase. The compounds of WO'426 are represented by a general chemical

structure known as the markush structure. The general chemical structure of WO'426 is represented herebelow at Figure 5.

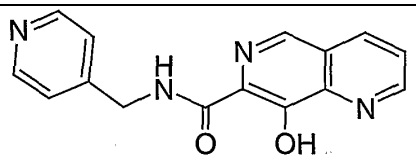
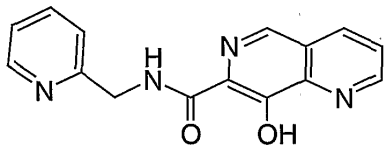


(I),

Figure 5

WO'426 provides compounds with substitutions pertaining to the presence of diaza-naphthyridine carboxamide compounds that are useful as HIV Integrase Inhibitors. Certain compounds that are embraced within the Markush of WO'426 are exemplified and it is notable that these compounds comprise a methyl pyridine ring attached to diaza-naphthyridine ring via a carboxamide group. Certain representative compounds of WO'426 are represented herebelow at Table 3.

Table 3: Representative Compounds of WO'426

S.No.	Example No.	Structure
1	Example 13	
2	Example 14	

It can be seen from the above Table 3, that most of the compounds exemplified by WO'426 have a methyl pyridine ring attached to diaza-naphthyridine ring via a carboxamide group and thus such compounds were already known and well established in prior art. Further, it can be clearly seen that compounds of WO'426 were known for

their HIV integrase inhibitory activity. Thus compounds having structure similar to that of the compounds claimed in the impugned patent application are already well-established and known in prior art.

WO2003/035076 (hereinafter referred as WO'076 and annexed as Annexure-5) titled "Dihydroxypyrimidine carboxamide inhibitors of HIV Integrase", was published on May 01, 2003 by Istituto Di Ricerche Di Biologia Molecolare P. Angeletti Spa. WO'076 discloses dihydroxypyrimidine carboxamides derivatives and the use of such compounds as HIV integrase inhibitors. The compound of WO'076 is represented by a general chemical structure known as the markush structure and is reproduced hereinbelow in Figure 6.

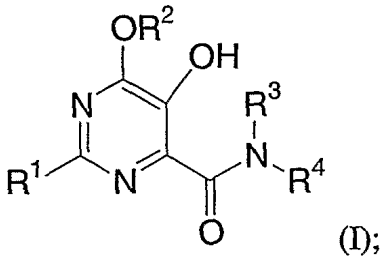


Figure 6

WO'076 provides compounds with substitutions pertaining to difluoro substituted phenyl methyl ring which is further attached to a pyrimidine ring via carboxamide group. WO'076 lists several compounds which were presented in various tables in the specification such as Table 1-24, 15B, 17B, 21B, 22B and 23B. On examining few representative structures of WO'076, it may be noted that all the compounds possess a basic moiety of N-benzyl-5,6-dihyroxypyrimidine-4-carboxamide (as represented herebelow in Figure 7).

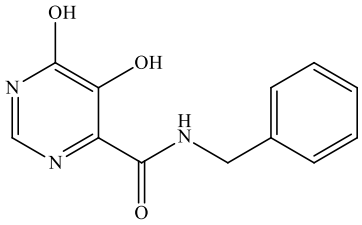


Figure 7

Certain compounds that are embraced within the Markush formula of WO'076 are also exemplified. Certain representative compounds of WO'076 are represented herebelow at Table 4.

Table 4: Representative Compounds of WO'076

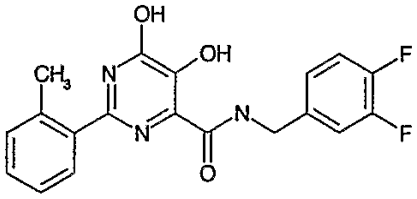
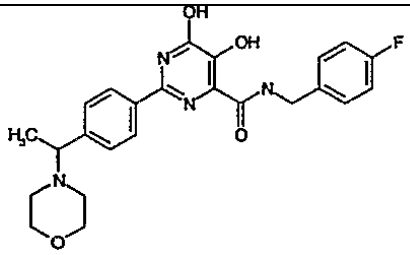
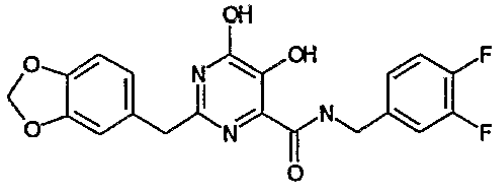
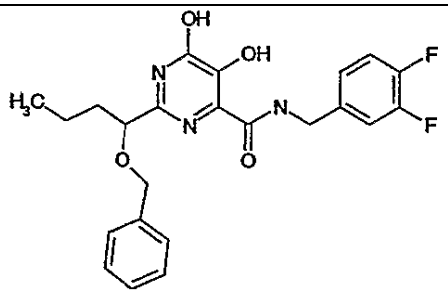
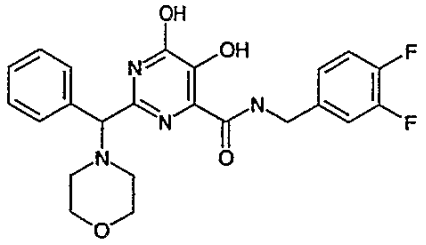
Example No.	Structure
Table 5, Example 8	
Table 7, Example 31	
Table 10, Example 10	
Table 11, Example 6	

Table 14, Example 1	

It can be seen from the above Table 4, that compounds disclosed by the impugned patent application falls within the markush of WO'076. In addition, it is also to be noted that the markush structure of WO'076 is same as the markush structure disclosed in the impugned specification. WO'076 also discloses that the compounds of the present invention are used as HIV integrase inhibitors. Thus, the compounds claimed in the impugned patent application are already known and well established in prior art.

WO2003/0602204 (hereinafter referred as WO'204 and annexed herewith as Annexure-6) titled "Hydroxynaphthyridinone Carboxamides useful as HIV Integrase Inhibitors", was published on July 31, 2003 by Merck & Co., Inc. WO'204 discloses Hydroxynaphthyridinone Carboxamides and the use of such compounds in the inhibition of HIV integrase. The compounds of WO'204 are represented by way of general chemical structure known as the markush structure encompassing several compounds. The general chemical structure disclosed in WO'204 is represented hereinbelow at Figure 8.

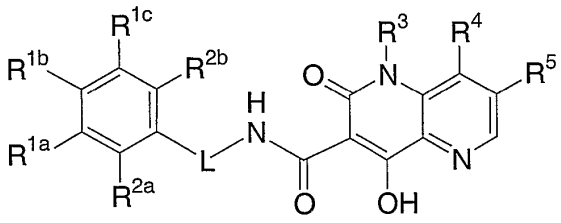
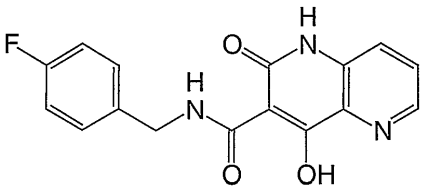
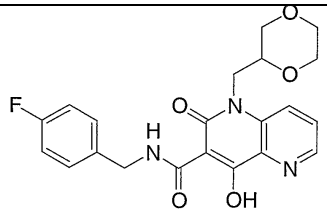


Figure 8

WO'204 provides compounds with halogen substitution at the phenylmethyl ring which is attached to diaza-naphthyridine ring via a carboxamide group. Certain compounds that are embraced within the Markush formula of WO'204 are also exemplified. Certain representative compounds of WO'204 are represented herebelow at Table 5.

Table 5: Representative Compounds of WO'204

Example No.	Structure
Example 1	
Example 4	

It can be seen from the above Table 5, that all the compounds exemplified by WO'204 have a halogen group substituted at the phenyl methyl ring at 4-position. The phenyl methyl ring is further attached to diaza-naphthyridine ring via carboxamide group. The diaza-naphthyridine ring is substituted at 4-position with a hydroxy group and 2-position with an oxo group. Moreover such compounds were known for their HIV integrase inhibitory activity. Therefore, it can be clearly seen that halogen substituted phenyl methyl ring attached to a diaza-bicyclic ring via a carboxamide group are already known and well established in prior art.

WO2004/058756 (hereinafter referred as WO'756 and annexed as Annexure-7) titled "Tetrahydro-4h-pyrido[1,2-a]pyrimidines and related compounds useful as HIV Integrase Inhibitors", was published on July 15, 2004 by Angeletti P Ist Richerche

Bio. WO'756 discloses hydroxy pyrimidine containing compounds for HIV integrase inhibitory activity. The compounds of WO'756 are represented by way of general chemical structure known as the markush structure. The chemical compound disclosed in this application comprises of phenyl methyl ring attached to a diaza-bicyclic ring via a carboxamide group. The same is represented hereinbelow at Figure 9.

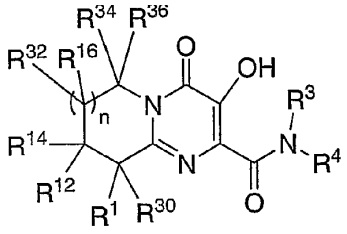
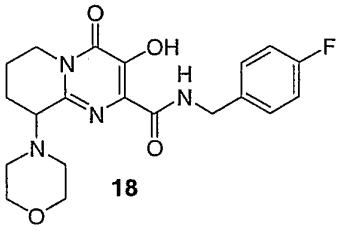
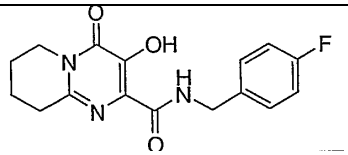
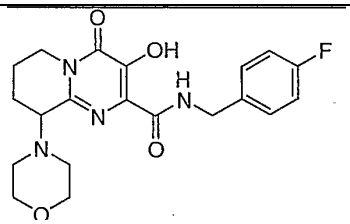
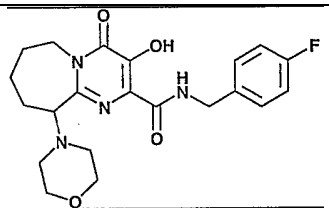


Figure 9

WO'756 provides compounds with substitutions pertaining to the presence of halogen substitution at 4-posiiton of phenyl methyl ring which is further attached to the pyridopyridimine ring. The pyridopyrimidine ring is substituted at 3-position with a hydroxy group and an oxo group at 4-position. Certain compounds that are embraced within the Markush formula of WO'756 are also exemplified. Certain representative compounds of WO'756 are represented herebelow at Table 6.

Table 6: Representative Compounds of WO'756

Example No.	Structure
Example 2	 **18**
M+318	

M+403	
M+417	

It can be seen from the above Table 6, that all compounds exemplified by WO'756 discloses a 4-fluoro substituted phenylmethyl ring which is attached to a pyridopyrimidine ring via a carboxamide group. In addition, it can also be noted from the exemplified compounds of WO'756 that the pyridopyrimidine ring is also further substituted with a morpholine ring. Moreover, such compounds were known as HIV integrase inhibitors. Therefore, it can be clearly seen that morpholine substituted pyridopyrimidine ring attached to fluoro substituted phenyl methyl ring via carboxamide are already known and well-established in prior art prior to the priority date of the impugned patent application.

US2005/0054645 (hereinafter referred as US'645 and annexed as Annexure-2) titled "Nitrogen-containing fused ring compound and use thereof as HIV integrase inhibitor" published on March 10, 2005, discloses nitrogen containing fused rings as an inhibitor of HIV integrase and is used as an anti-HIV agent. US'645 disclose a general chemical structure known as the markush structure encompassing several thousand of compounds and the same is reproduced herein below at Figure 10.

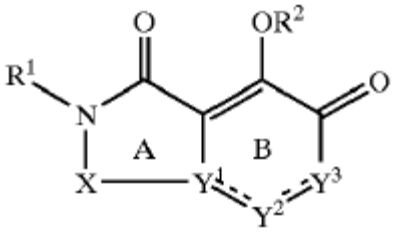
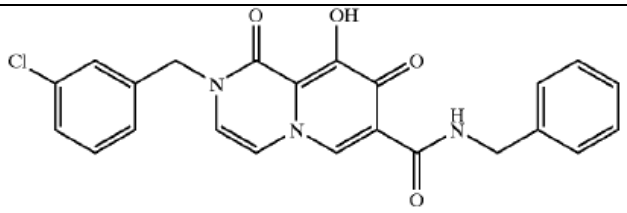
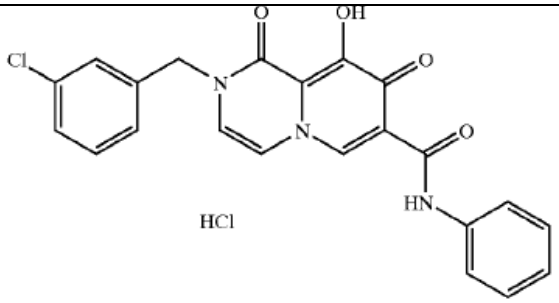
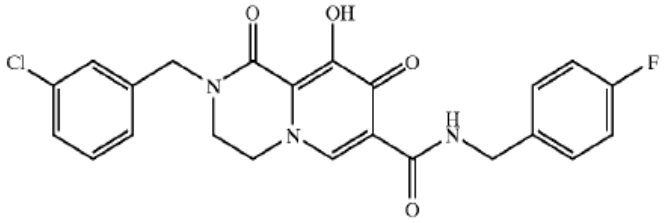
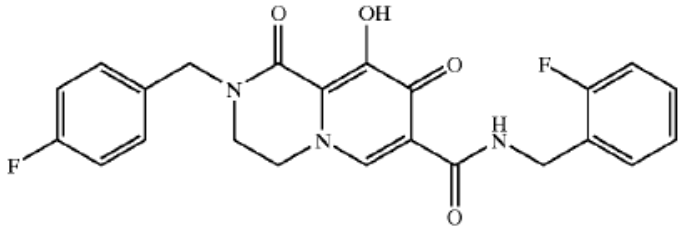
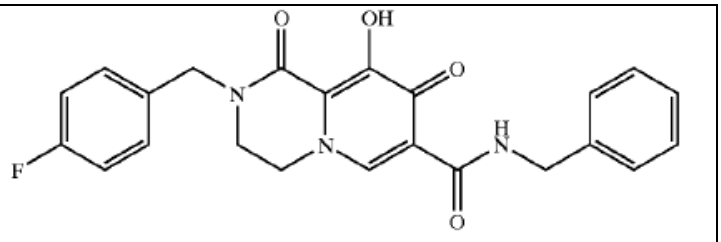


Figure 10

US'645 exemplify several compounds with various substitutions which are similar to the compounds of the impugned patent application. Certain representative compounds of US'645 are represented herein below at Table 7.

Table 7: Representative Compounds of US'645

Example No.	Structure
Example 181	
Example 196	
Example 214	
Example 377	

Example 380	

It can be seen from the above Table 7, that all compounds exemplified by US'645 have a halogen substituted at 4-position of the phenyl methyl ring attached to pyridopyrimidine ring via carboxamide similar to the compounds of the impugned patent application. Moreover, such compounds were known as HIV integrase inhibitors for the treatment of AIDS. Therefore, it can be clearly seen that the compounds similar to the compounds claimed in the claims of impugned patent application are already known and well-established in prior art.

From the art, it may be noted that there is sufficient motivation and suggestion to a person skilled in the art to choose halogen substituted phenyl methyl ring attached to bicyclic rings via carboxamide group as a start point to improvise the structure and develop new derivatives by attaching another ring to the bicyclic ring to form tricyclic ring which is attached to halogen substituted phenylmethyl ring via carboxamide group and the use of such compounds as HIV integrase inhibitors. This suggestion is drawn from the above discussed prior art.

Thus, it is well established that the compounds having halogen substituted phenyl methyl ring attached to bicyclic or tricyclic rings via carboxamide group are already known for their HIV integrase inhibitory activity.

Hence, all aspects of the compounds of the impugned patent application as claimed in claim 1 and claim 5 are obvious by disclosure in prior art and do not have any inventive merit.

Hence, all the claims 1 to 9 of the impugned patent application ought to be refused on this ground only.

GROUND III

6. **Section 25 (1)(f) Subject of claims 1 to 9 is not an invention within the meaning of this Act or is not patentable under this Act**

a) The Subject matter of the claims 1-9 do not constitute an invention as understood under Section 2(1)(j) of the Act:

It is submitted that since the Claims 1-9 are not inventive and lack industrial application, they do not constitute an 'invention' under the Act.

b) The subject matter of Claims 1 and 5 are not an invention under Section 3(d) of the Act:

The compounds of the impugned specification are nothing but derivatives of compounds known in prior art. The compounds claimed in the impugned patent application appear to be derivatives of phenylmethyl-3-carboxamide substituted pyridopyrimidine compounds. This is an admitted position by the Applicants in background that carbamoyl pyridine derivatives and N-containing condensed cyclic compounds having HIV integrase inhibitory activity are already known in prior art. The derivatives as disclosed in the impugned patent application are not compared with the closest compounds for therapeutic efficacy. Activities of compounds claimed in Claim 1 and 5 are not specifically disclosed. In order to discharge the burden of section 3(d), the

Applicant ought to have compared therapeutic efficacy with the closest compounds disclosed in prior art. The applicant has failed to discharge this burden.

c) The subject matter of Claims 3,4,8 and 9 are not patentable under Section 3(e) of the Act:

These claims are drawn towards to a composition**.** The composition reflects only the qualities of the individual components and does the functions only of its individual components and has no enhanced effect or does a new function different from that of its constituents. Therefore the composition as a whole results only in the aggregation of the properties of its components without any synergistic/enhanced effect and hence is not patentable under section 3(e) of the Act. Therefore these claims ought to be rejected on this ground.

In regard, the Opponent craves leave to refer and rely on submission made in Grounds I-III above and the same are not being reiterated for the sake of brevity.

GROUND IV

7. **Section 25 (1)(g): The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed.**

A. The claims of the alleged invention are not appropriately supported by the impugned specification

1. The Claims 2, and 7 are drawn to the pharmaceutically acceptable salt of compound claimed in claim 1 and 5. However, no such salt/ sodium salt of compound of claim 1 and 5 are disclosed in the impugned specification.

2. The Claims 3, 4, 8 and 9 relates to a pharmaceutical composition of the compound which is claimed in Claims 1 and 5. However, such claims are not supported by the description in the specification. The specification gives a mere disclosure about the pharmaceutically acceptable carrier which broadly covers excipients, carrier and diluent. However there is no suggestion in the impugned patent application regarding the manner in which the specific excipients, carrier and diluent are to be used for the specific compounds claimed in Claims 1 and 5. Further, Claims 3, 4, 8 and 9 lacks sufficient disclosure for obtaining the composition of compounds claimed in claims 1 and 5. Further, the specification does not disclose the best form of administration of the drug. Further, specific excipients for the preparation of best mode of administration are not disclosed. Therefore, a person skilled in the art will not be able to make the specific composition of compounds claimed in claims 3, 4, 8 and 9.

In view of the above, the complete specification of the impugned patent application is insufficient and does not describe the best of mode of performing the invention.

GROUND V

8. **Section 25 (1)(h): The Applicant has failed to disclose to the Controller the information required under Section 8.**

It is submitted that the Applicant/Respondent has failed to disclose the details of corresponding foreign applications filed, and on this ground alone the patent application should be rejected.

9. **HEARING REQUESTED**

The Opponent hereby requests a hearing under section 25(1) of the Patents Act, 1970 (hereinafter referred to as "the Patents Act") and Rule 55 of the Patents Rules (hereinafter referred to as "the Rules").

10. The Opponent craves leave to amend the opposition and add further grounds and documents as when required.

11. Further the Opponent craves leave to adduce evidence in support of the Opposition.

12. The Applicant has not followed the set procedure prescribed by the Act to amendment the claims. Hence the amended claims ought to be rejected *in limine*.

PRAYER

In the fact and circumstances of the case, the Opponent prays as follows:

i. that the Indian Patent Application No. 3865/KOLNP/2007 made by SMITHKLINE BEECHAM CORPORATION, A United States Corporation, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101, United States of America and SHIONOGI & CO. LTD. A Japanese Company, 1-8 Doshomachi 3-Chome, Chuo-Ku, Osaka-Shi, Osaka 541-0045, Japan be rejected under Section 25(1) of the Patents (Amendment) Act, 2005;

ii. the Opponent may be allowed to file further documents as evidence if necessary to support their averments;

iii. the Opponent may be allowed to amend the opposition, add additional grounds and documents if required;

iv. the Opponent may be granted leave to adduce evidence in support of the opposition;

v. the Opponent may be granted an opportunity of being heard in the matter before any intention final orders are passed;

vi. the Opponent may be allowed to make further submissions and file rejoinder or other appropriate evidence in case the applicant makes any amendments in the claims;

vii. any other reliefs considering the facts and circumstances may be granted in favour of the Opponent in the interest of justice.

Dated this 3rd day of February 2016

MEGHNA MISHRA
Agent for the Opponent