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Date: 9th April 2020

1. The Central Government
   Health Secretary, New Delhi
   secyhfw@nic.in
2. Minister of Chemical and Pharmaceuticals
   New Delhi
   sadananda.gowda@sansad.nic.in and
   secy-pharma@nic.in

Re: **Revocation of Patent No. 332280 in Patent Application No. 201727012821 under sections 66 and 64 (1) of the Patents Act, 1970**

Dear Madam/ Sir,

We, the Cancer Patients Aid Association (CPAA), are charitable organization registered under the Societies Registration Act, 1860 in January 1970 and under the Bombay Public Trusts Act, 1940 in February 1970, having our main office and place of business at 5 Malhotra House, Opposite GPO, Mumbai – 400001, are sending this letter, through the Founder Member and Chairman, Mr. Y. K. Sapru. CPAA is concerned with cancer patients and has been providing for their treatment and rehabilitation. However, since the coronavirus - COVID-19 pandemic, their work has come to a halt, and some cancer patients may also face a gap in their treatment. Without treatment some cancers could obstruct and some could metastasise. In fact, about 20 per cent of patients in Italy who died of COVID-19 had active cancer. In fact, patients who are living with cancer, and are undergoing chemotherapy and/ or radical radiotherapy for lung cancer, and patients with blood and bone marrow cancer are particularly vulnerable to serious illness if they get COVID-19. The pandemic also poses several challenges to care-givers, and for patients to obtain treatment on time.

CPAA states that there is a high risk for patients with cancer to deteriorate into a worse state of health or die if they get COVID-19, especially if no treatment is available, accessible and affordable for them.

CPAA further states that for the treatment or possible treatment of coronavirus (COVID-19), a lot of drugs are in the clinical trial stage, and some combination

drugs of HIV – Lopinavir and Ritonavir (Kaletra) have worked on some or have failed on others. Drugs that are useful in the treatment of RNA (ribonucleic acid) viruses, like Hepatitis C (HCV), HIV, Ebola, etc. are being tested as treatment regimens for COVID-19.

We would like to bring to your notice a drug called Remdesvir that has not yet got approval for marketing, is in the trial stage, and is produced by Gilead Sciences Inc. This drug claims to be useful for "Filoviridae virus infections", particularly methods and nucleosides for treating Ebola virus, Marbug virus and Cueva virus. The coronavirus belongs to the same family of *filoviridae* virus. The drug, remdesvir, is undergoing clinical trials on COVID-19 patients, and may be an effective treatment.

Gilead Sciences Inc. filed **Patent Application No. 201727012821** (henceforth A.No.'821) for "compounds for treating filoviridae infections", on 11.04.2017 in India. The corresponding PCT Application No. is PCT/US2015/057933, which was filed on 29.10.2015, claiming a priority from 29.1.2014. Unfortunately the said application was granted a patent, bearing number **332280, on 18.02.2020**, by the Controller of Patents, Bhaskar Ghosh.

We state that the Patent No. 332280, granted to Gilead Sc. Inc. should be revoked immediately under Section 66, that is, in the interest of the public. It is imperative at a time like this that no monopoly rights be granted, so that more manufacturers can produce the drug to be made available to all the people who need it, at affordable costs. The government has the power to revoke the patent in public interest, may give an opportunity to hear the patent holder and, make a declaration to that effect in the Official Gazette and thereupon the patent can be deemed to be revoked.

We urge you to revoke the patent No. 332280 granted in A.No.'821 under section 66 of the Patents Act, 1970, in public interest, immediately.

In any event, we have cogent grounds to state that the said application No. 201727012821 (A.No.'821) ought not to have been granted a patent as it lacks novelty and inventive step, and that the Learned Controller erred in not taking cognizance of the prior art available in the public domain. The Controller though relied on prior art documents in the International Search Report (ISR) of the

corresponding PCT Application, grossly erred in not appreciating the disclosures made in those documents and in other documents that would make the application not patentable in India.

The patent was granted on the amended A.No.'821 that had three claims (6 claims were dropped), describing a scaffold of compounds that are primarily 1-substituted 4-aza 7,9-dideazaadenosine C-nucleosides. A.No.'821 claims specifically 16 compounds with the same core (heterocyclic base attached to a sugar moiety substituted at position 1' with cyno group) and minor modifications to the substituents attached to the phosphonate group substituted at 5' position of the sugar moiety (claim 1). It claims the specific structure of Remdesvir and its pharmaceutical acceptable salts (claim 2), and claims the composition comprising of a therapeutically effective amount of a compound, or pharmaceutically acceptable salt or carrier (claim 3).

The compounds claimed in A.No.'821 have already been disclosed earlier in prior art documents (**Exhibit A – WO'776, Exhibit B – Cho et al and Exhibit C – WO'127**), and some structures claimed are identical to and similar to compounds disclosed with anticipated, minor, routine modifications that are obvious to a person skilled in the art. We state that the said patent ought to be revoked also under Section 64 (1) (d), (e), (f), (k) of the Indian Patents Act, 1970 for the reasons stated hereinbelow:

(A) The invention so far claimed is not new, having regard to what was publicly known prior to the priority date (S.64 (1)(e)) of the Patents Act, 1970:

1. **WO2012/012776 A1** (hereinafter referred to as **WO'776**), is attached hereto as **Exhibit A**, is Gilead Sciences Inc. (the Applicant/ patent holder's) earlier application, which was also referred to in the ISR, that discloses markush structures and specific compounds. Some of the compounds disclosed in WO'776 are identical to those claimed in A.No.'821. In fact, WO'776 disclosed compounds in 2012, which the Applicant/ patent holder has made minor anticipated modifications, like incorporation of bulkier groups, addition of methyl branching, etc., that are not only anticipated, but are also obvious. Thus, compounds 1 to 16

claimed in claim 1 and, the compound claimed in claim 2 of A. No.'821 lack novelty.

2. WO'776, at **Exhibit A,** claims a scaffold for Formula I, wherein:-
   (i) A scaffold containing modified analogs of 4-aza-7,9-dideazaadenosine [when R1, R5, R10 are hydrogen atoms; R2 and R3 are both ORa wherein Ra is a hydrogen atom] are disclosed, in which
   (ii) the sugar moiety at position 1' is substituted with a nitrile group [CN; (R6)]; and
   (iii) at the 5' position instead of a OH may contain a monophosphate/substituted monophosphate group (R7) wherein Y=O, W1 is O-phenyl group (wherein the phenyl ring may be further substituted) and W2 is an amino acid ester functional group [pp. 56, 57, 146-150; wherein R of COOR(ester group) may be H, substituted C1-C8 alkyl group, substituted C2-C8 alkenyl, C2-C8 alkynyl, C6-C20 aryl, C2-C20 heterocyclyl groups among other functional groups];
   In certain instances, the substituents attached to the phosphorous atom may be interchanged i.e. W1 is an amino acid ester functional group and W2 is a O-phenyl group (pp.58, 59; 3rd scaffold on p.59 of WO'776 read left to right).
   (iv) Some compounds claimed in claims 13 and 25 of WO'776 (pp.152, 153 of WO'776) derived from the scaffold described above are of importance as they are identical or analogous or disclosed in the markush structures of WO'776 when compared to the compounds in claims 1, 2 of A.No.'821, as shown hereinbelow in Table1 and Note 1 and 2. A comparison of some of the compounds is as follows:-

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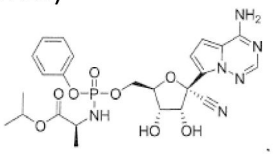
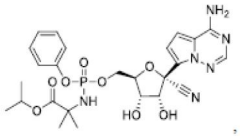
Table 1: Comparison of compounds between the prior art document WO'776 (Claims 13 & 25) and the A.No.'821 (claims 1, 2)

Compounds disclosed in WO'776	**Compounds claimed in A.No.'821**	**Lack of novelty in A.No.'821**
(1) 2nd compound on p.155 (claim 25) 	(1) 1st compound claimed – claim 1 	(a) The compound disclosed in WO'776 and the one claimed in A.No.'821 are identical with respect to the heterocyclic base and sugar moiety and also their substitution patterns. . (b) They only differ in regard to the additional methyl branching on the carbon attached to the –NH- group. (c) However, provision for additional methyl branching at the identical position has already been disclosed by WO'776 (pg. 52 of WO'776) M12c of Rx includes 1, 2, or 3 substituents (R) on the carbon attached to –NH- group; and R is defined to include C1-C8 alkyl group (which includes methyl group) (p.49 of WO'776). In compound 1 of the granted patent, A.No.'821 the number of substituents is 2 i.e. 2 methyl groups, which is disclosed in WO'776.
(2) 1st compound on p.153 (claim 13)	(2) 2nd Compound claimed – Claim 1	(a) The compound disclosed in WO'776 and the one claimed in A.No.'821 are

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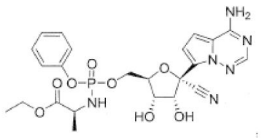
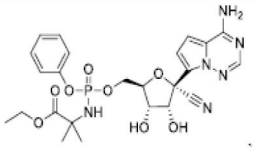
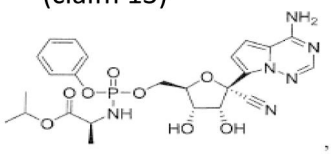
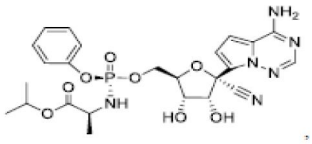
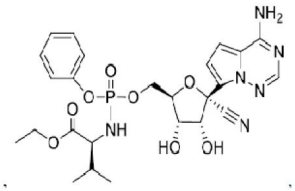
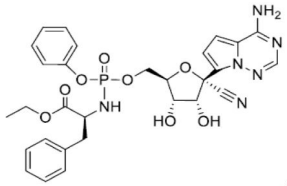
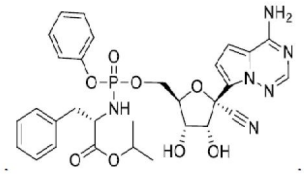
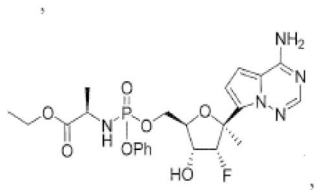
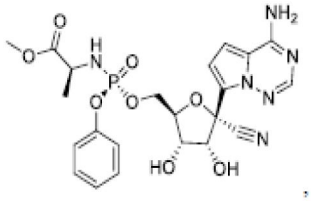
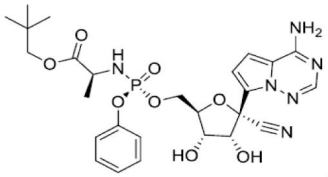
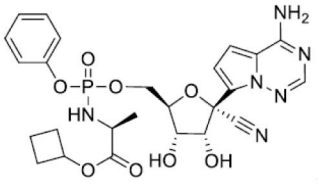
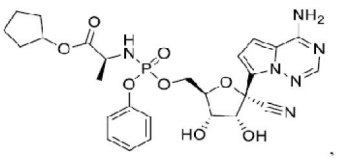
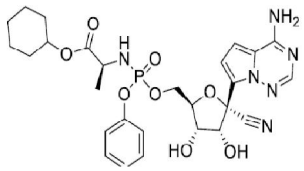
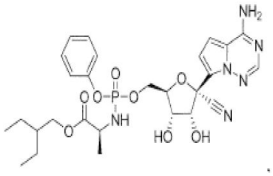
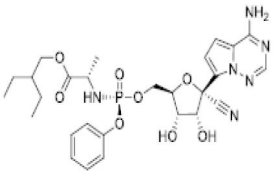
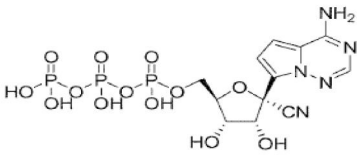
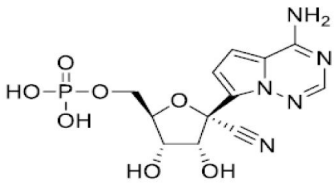
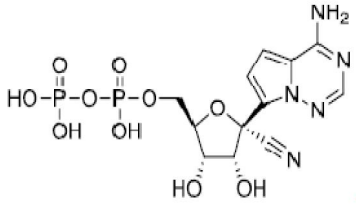
		identical with respect to the heterocyclic base and sugar moiety and also their substitution patterns . (b) They only differ in regard to the additional methyl branching on the carbon attached to the –NH- group. (c) However, provision for additional methyl branching at the identical position has already been disclosed by WO'776 (pg. 52) M12c of Rx includes 1, 2 or 3 substituents (R) attached on the carbon attached to –NH- group; and R is defined to include C1-C8 alkyl group (which includes methyl group) (p.49 of WO'776). In compound 2 of the granted patent, A.No.'821 the number of substituents is 2 i.e. 2 methyl groups which is prior disclosed by WO'776.
(3) 8th compound on p.152 (claim 13) 	(3) 7th compound claimed – claim 1 	(a)The compound in A.No.'821 is identical to the compound disclosed in WO'776.

	(3a) 4th compound claimed-claim 1  (3b) 3rd compound claimed-claim 1  (3c) 6th compound claimed-claim 1 	(a) The compound disclosed in WO'776 and the one claimed in A.No.'821 are identical with respect to the heterocyclic base and sugar moiety and substitution pattern of these compounds. (b) The difference between compounds of the granted patent, A.No'821 and WO'776 is the replacement of a lower alkyl group (as shown in the compound of WO'776) with a substituted higher alkyl group on the carbon attached to –NH-group (in A.No.'821). (c) However, provision for a substituted higher alkyl group at the identical position has already been disclosed by WO'776 (p.52) M12c of Rx includes only 1 substituent (R) attached on the carbon attached to –NH- group; and R is disclosed to be substituted C1-C8 alkyl group (pp.49 WO'776). (d) Also the terminal substituent of the amino acid ester as claimed in A.No.'821 has already been disclosed to contain C1-C8 alkyl group in WO'776 (p.41

		of WO'776).
(4) 5th compound claimed on p.152 (claim 13) 	(4) 8th Compound claimed - claim 1  (4a) 9th compound claimed- claim 1  (4b) 5th compound claimed- claim 1  (4c) 10th compound claimed- claim 1 	(a) The compound disclosed in WO'776 and the one claimed in A.No.'821 mainly differ in terms of substitution at 1' and 2' position of the sugar moiety. However, it is to be noted both these functional groups i.e. CN (R6 in WO'776) and OH [R2 in WO'776 is disclosed to be either ORa (Ra is a hydrogen atom) or halogen] have already been disclosed to be substituted at these identical positions (1' and 2') in WO'776 (p.9 of WO'776). (b) A lower alkyl amino acid ester derivative (terminal substituent as methyl in compound 8 of claim 1 in A.No.'821, instead of ethyl group as shown in the corresponding compound of WO'776, claim 13 compound 5) (pg.152). Similarly, in compound 9 of A.No.'821, a higher and branched alkyl amino acid ester (2,2-dimethyl propyl group instead of methyl group of WO'776) is seen

	(4d) 11th compound claimed-claim 1 	substituted as the terminal group. In compounds 5, 10 and 11 of A.No.'821, cycloalkyl groups (containing 4, 5 and 6 carbon atoms respectively) have been claimed as the terminal substituent. However in WO'776, it has already been disclosed that the terminal substituent is an optionally substituted C1-C8 alkyl group (R) (p.41 of WO'776), which include ethyl, 2,2-dimethyl propyl group, and cycloalkyl groups, as all these groups contain 1-8 carbon atoms.
5) 9th compound claimed on p.152 (claim 13) 	5) Compound claimed in claim 2 and 16th compound of claim 1 	(a) The compound disclosed in WO'776 and the one claimed in A.No.'821 are identical and have the same core attached to an identical sugar moiety which at the 5' position is attached to a monophosphate group which is substituted with identical functional groups. (b) The only difference is the defining the stereochemical orientation which has not been specified in the structure of the compound disclosed in

		WO'776, indicating that it is racemic while compound 16 of claim 1 and the compound in claim 2 of the granted Application, A.No.'821 defines stereochemistry at the chiral centres of these functional groups substituted on the phosphonate. The compounds are identical.
(6) 3rd compound claimed on p.156 (claim 25) 	6) 13th compound claimed-claim 1  (6a) 14th compound claimed-claim 1 	(a) Triphosphate group attached to the sugar moiety at the 5' end has been claimed in a compound of WO'776. Exploring mono and bi phosphate groups attached at the same position when a triphosphate group has been claimed in A.No.'821 cannot be considered novel and is not only anticipated but also obvious to a person skilled in the art.

NOTE: (1) For compound 15 of claim 1 of A.No.'821: Compound claimed contains a heterocyclic base attached to a sugar moiety with a substitution pattern which is identical to the scaffold disclosed in WO'776 (p.8 and 9 of WO'776). In the compound of A.No.'821, a modified form of monophosphate group is attached to the sugar moiety wherein one of the OH groups is replaced by an amino acid derivative. Further, the molecule is ionized by removal of the acidic proton of carboxylic acid and the OH of the phosphonate group. Ionization is a pH dependent

process and thus an ionized compound cannot be claimed as a novel form. Ionized compounds are commonly used in the process of salt formation.

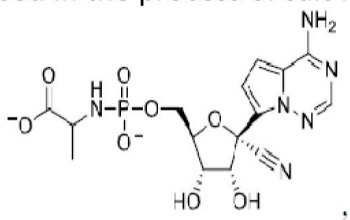


Fig 1: Compound 15 in claim 1 of A.No.'821

NOTE : (2) For compound 12 of A.No'821: WO'776 also discloses that the central phosphonate is attached to a substituted hydroxy group (Rx) wherein Rx is C6-C20 aryl group (p.58 of WO'776). This is similar to compound 12 of claim 1 where one of the hydroxy group of the central phosphonate remains unsubstituted but the other hydroxy group is substituted with a phenyl ring which has already been disclosed in WO'776 (Rx is a C6-C20 aryl group; phenyl group is considered as a C6 aryl ring).Thus substitution of the phosphonate group with an O-phenyl group has already been disclosed in WO'776.

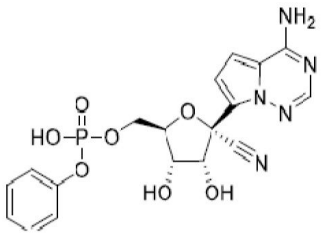


Fig 2: Compound 12 in claim 1 of A.No.'821

(v) WO'776, **Exhibit A** hereto, claims a compound used for the treatment of mRNA virus, *paramyxoviridae* infections, like pneumonia, parainfluenza, measles, mumps, rubella, etc. A.No.'821 is for treatment of RNA viruses too.

(vi) WO'776, **Exhibit A** hereto, also claims the salt forms and pharmaceutically acceptable carriers of the compounds disclosed (Claims, 1, 13, 14, 25, 26 and 31 and disclosed on pp. 80-81, 85-96 of WO'776). The same is claimed in claim 3 of A.No'821, which thus lacks novelty.

(vii) Thus, in light of the disclosures in WO'776, claims 1 (all the compounds 1 to 16), claim 2 and claim 3 of A.No.'821 lack novelty.

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(B) **The invention so far claimed is obvious or does not involve an inventive step (S.64 (1)(f)) of the Patents Act, 1970**:

1. **Cho, et al., 2012**, attached hereto as **Exhibit B**, disclose the identical core structure as the one claimed in the A. No.'821. They disclose the substitution of the cyano group (p.2706, LHC, Scheme 1, 3(a) – R = CN), at the same 1' position in the core as claimed by the Applicant in A.No.'821. Further, Cho, et al. also reports the stereochemistry of these compounds.

2. Cho, et al. states that structural modifications of natural N-nucleosides on either the sugar or the base has led to a variety of therapeutic agents, including antiviral agents (p.2705, LHC). Cho et al., conceived modifications on the sugar moiety (substitution at position 1') and substituents attached to the sugar moiety at 5' position. They investigated 1'-substituted nucleosides as inhibitors of viral RNA-dependent RNA polymerases (p.2705, LHC).

3. Cho et al. chose C-nucleoside analog of 1, 4-aza-7,9 dideazaadenosine and 1'-substituted analogs of this compound to investigate the antiviral activities and selectivity against a panel of RNA viruses and its correlation to anti-HCV potency (p.2705, RHC, Fig.2). The RNA viruses selected included Paramyxoviridae, Flaviviridae, **Coronaviridae (SARS-CoV)**, etc. (p.2706 LHC and Table 1).

4. Cho, et al. also disclose the method of preparation of the compound (p.2706 Scheme 1) and disclose the tri-phsophate and the bis-(SATE) mono-phosphate prodrugs of the compound (p.2706 – 8a - 8d and 9a – 9d respectively). The Applicant in A.No.'821 has claimed the monophsophate and bi-phosphate prodrugs of the compound, and disclosed the tri-phosphate prodrug, which were disclosed by Cho, et al. and are obvious to a person skilled in the art.

5. Further, Cho, et al. observed that the monophosphate prodrugs as compared to the parent nucleosides showed a marked enhanced replicon activity. Greater potency and selectivity was observed for the

compounds with cyano substituent on the sugar moiety (3a and 9a), that warranted structural modifications to improve selectivity (p.2706, RHC). Thus, Cho, et al. established 1'-substituted nucleosides as antiviral agents (p.2027, LHC).

6. The Learned Controller erred in not taking cognizance of the prior art cited at **Exhibit B**, that clearly disclosed not only the core of the compound claimed in A.No.'821, but also the monophosphate and tri-phosphate prodrugs of the compound, their stereochemistry; the use of the compound as antiviral agents, useful against Coronavirus, and envisaged modifications to improve selectivity. Thus, all the claims in A.No.'821 lack inventive step, and in particular (as shown above in Table 1) compounds 13 and 14 of claim 1 of A. No.'821 lack not only inventive step but also novelty.

7. Further, WO'776, at **Exhibit A** hereto also discloses compounds that would make it obvious to a person skilled in the art to arrive at some of the compounds claimed in claim 1 of A.No.'821.
   (a) WO'776 defines and claims and a broad markush scaffold in formula I and claims specific (claims 13, 25) which are derived from this scaffold. The substitution patterns as disclosed in WO'776 are identical in A.No.'821 (as shown above), and minor modifications have been carried out at the 5' position namely with respect to the substituents attached to the central phosphonate group to derive various forms of prodrugs in A.No.'821.
   (b) In A.No.'821, compounds 6 to 10 of claim 1 contain substituents on the phosphonate group, which is attached at the 5' end of the sugar moiety. One such substituent is an amino acid ester group. Further, the terminal group attached to oxygen atom of the ester group differs in each of these compounds claimed in claim 1, wherein the terminal group attached is a linear alkyl chain r a cycloalkyl group (containing 4 to 6 carbon atoms). However, WO'776 discloses a broad range of such functional groups including C1-C8 alkyl group [see pp. 50, 56 (functional groups claimed for R)] for substitution at the same position, thus displaying the possibility of same or similar substitutions as claimed in the compounds in claim 1 of A.No.'821.

(c) One of the other strategies employed by the Applicant/ Patent holder of A.No.'821 has been to change the position of the substituents attached to the central phosphorous atom. For example, the position of the O-phenyl substituent and the amino acid ester substituent as disclosed in WO'776 have been interchanged in A.No.'821. For example compound 16 claimed in claim 1 of A.No.'821 is identical to the 9th compound claimed in claim 13 of WO'776 (p.152) in all respects, except for the above disclosed substituents being interchanged in the compound claimed in the granted patent A.No.'821.

(d) Also, removal of phosphate groups (triphosphate prodrug has been claimed in WO'776), to explore activity of mono and biphosphate prodrugs has also been done by the present Applicant in A.No.'821.

(e) These strategies employed by the Applicant are not in anyways novel and are known to a person skilled in the art. In the process of lead optimization, a medicinal chemist might use any of the above disclosed strategies to modify physico-chemical properties of compounds derived from an identical scaffold. Thus, as seen from the table and notes 1 and 2, and from the above, claim 1 and claim 2 of the granted patent A.No.'821 lack inventive step also.

8. **WO2012040127 A1** (hereinafter referred **WO'127**), annexed hereto as **Exhibit C**, discloses compounds and their pharmaceutical acceptable salts, in which the core i.e. the heterocyclic base is an bioisosteric replacement of the one claimed in A.No.'821. WO'127 discloses a core that though is a bi-cyclic ring, the nitrogen atom of the 5-membered ring is not shared with the 6-membered ring. But, the number of nitrogen atoms in the bi-cyclic ring system, the position of the nitrogen atoms in the 6-membered ring, and the placement of the amino group is the same in WO'127 and in A. No.'821. Further, exploring of nitrogen atoms at different positions of the bicyclic ring (bioisosteric modification) is routinely done in the process of lead discovery and development.

9. WO' 127 discloses compounds wherein:-

(a) An optionally substituted heterocyclic base (B1) is attached to a sugar moiety. This heterocyclic base is a pyrrolopyrimidine bicyclic

ring (provided Y2 is CR I2 wherein RI2 is a hydrogen atom; RA2 is a hydrogen atom) substituted with an amine group (RB2 is NH2 provided RW2 is a hydrogen atom) (pp. 190, 195, 196 claims 1, 46 of WO'127);

(b) The sugar moiety to which this heterocyclic base is attached is substituted at position 1' with a cyano group (R9) and at 2' and 3' is substituted with OH group (when R6 and R7 are OR12 and OR14 groups; wherein R12 and R14 are both hydrogen atoms respectively) (pp.190, 191 of WO'127);

(c) The sugar moeity at the 5' position is substituted with a monothiophosphate group wherein the phosphorous atom is attached to O^-, OH or an optionally substituted amino acid ester derivative (R1). The structure is revealed in claim 17, wherein an NH group is attached to a carbon atom which is substituted with R23 [wherein R23 is a hydrogen, optionally substituted C1-C6 alkyl, C1-6 haloalkyl, C3-6 cycloalkyl, C6 aryl, C10 aryl, aryl (C1-6 alkyl) functional groups], R24 (wherein R24 is a hydrogen atom, substituted C1-C4 alkyl group) and is further substituted with -C(=O)O- which is terminally substituted with R22 (wherein R22 is a hydrogen atom, optionally substituted C1-C6 alkyl, C3-C6 cycloalkyl, aryl, haloalkyl, aryl (C1-6 alkyl group) (pp. 190, 192-194, claims 1, 15-25, 28, 29). Some examples of the above described amino acid ester derivatives have been specifically shown in claims 26, 27 (pp.193, 194 of WO'127);

(d) The phosphorous atom of the monothiophosphate group is also attached to O-R2 (wherein R2 may be optionally substituted aryl, heteroaryl, heterocyclic group).

(e) Compounds claimed in the granted patent A.No.'821 claims structural features very similar to those disclosed by scaffold of formula I and compounds derived as disclosed in WO'127;

(f) In A.No.'821, the sugar moiety itself is substituted at 1' position with a cyano group (which is analogous to R9 of WO'127) and at 2' and 3' positions with OH group (which analogous to R6 and R7 of WO'127), respectively, which is seen in all the compounds claimed in A.No.'821;

(g) The sugar moeity at 5' position is substituted with a monophosphate group (contains P=O instead of P=S seen in WO'127). However, oxygen and sulphur are known to be bioisosteres and thus can be used and are used as replacements of each other;

(h) The monophosphate group in A.No.'821 for many of the compounds is attached to a substituted amino acid ester derivative (compounds 1 to 11, 15, 16 of claim 1 and claim 2). The various types of derivatives of the compounds claimed in A.No.'821 have previously been disclosed and extensively covered by WO'127 (see point c of WO'127; analogous to R1 of WO'127);

(i) The phosphorous atom of the compounds in A.No'821 is also attached to O-phenyl ring, which also has already been disclosed in WO'127 (R2 of WO'127);

(j) Thus, compounds 1 to 11, 15, 16 in claim 1, and claim 2 of the granted patent A.No.'821 lack inventive step.

(k) Compounds claimed in claim 52 of WO'127 [compounds 5, 6 (p.198), compound 3 (p.199), compounds 4, 6, 7, 9 to 11 (p.200), compound 6 (p.201) bear similarity to many of the compounds claimed in the granted patent A.No.'821.

(l) Pharmaceutical compositions containing similar prodrugs, their salt forms for the treatment of viral diseases (coronaviridae, filoviradae, etc. mentioned on p.62 of WO'127) have already been disclosed in WO'127 (pp.58-74 WO'127). Thus, claim 3 of A.No'821 also lacks inventive step.

(C) Thus, it is submitted that in the above mentioned prior art documents, annexed hereto as **"Exhibits A, B and C"**, the claims in the granted patent A.No.'821 lack novelty and inventive step. The information in the prior art documents disclose the essential elements of the alleged invention in the patent granted to A.No.'821. Novelty is destroyed when the essential elements are disclosed, even if the details of executing the invention, or clear description of its properties or method of making it were not disclosed. The above mentioned prior art documents show identical structures, that were claimed in the granted patent A.No.'821, that ought not to have been granted.

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(D) Further inventive step claims in the patent granted in A.No.'821 are destroyed as what is claimed is obvious to a person skilled in the art, i.e. there is reasonable expectation of success embedded in the prior art that motivates a skilled person to arrive at the alleged invention, as claimed in A.No.'821. Obviousness does not require absolute predictability of success. All that is required is reasonable expectation of success in the matter of pharmaceutical drugs. All the prior art documents annexed hereto provide reasonable predictability of success, and the patent ought not to have been granted to A.No.'821.

(E) The claims are not an invention within the meaning of the Act (64(1)(d)) and are not patentable under the Patents Act (S.64(1)(k)). It is submitted that the claims in A.No'821 fall within the category of not patentable and not an invention as described under section 3(d) of the Patents Act, and do not meet the requirements of the definitions of "invention" and "inventive step" as set out under sections 2(1)(j) and 2(1)(ja) of the Patents Act, 1970. The patent in A.No'821 ought to be revoked *in toto*.

(F) It is submitted that the salt forms of known compounds are not patentable in India under the law, and the Learned Patent Controller erred in granting a patent to the Applicant in A.No'821.

(G) Further, it is important to state that the right to health as guaranteed under Article 21 of the Constitution of India is paramount, and includes the right to health. Medicines required for the treatment of COVID-19 and similar infectious viral diseases ought to be made available at affordable prices to all people in need of it. The wrongful grant of the patent breaches the right to life of many patients with COVID-19, and those who are vulnerable to it, or those with co-morbidities (like cancer, diabetes, etc.) in whom the infection with coronovirus could prove to be fatal. The wrongful grant of the patent to the Applicant, Gilead Sciences Inc. for the drug remdesvir, and similar compounds as claimed in A.No.'821, will lead to monopolistic prices of these life saving drugs and will adversely affect the right to life and good health of the people in India.

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We therefore urge you to take urgent action and revoke the patent granted, being Patent No. 332280 granted in Patent Application No. 201727012821 on 18.2.2020, in public interest and on grounds of the lack of novelty, lack of inventive step, and because the Application No.'821 is not an invention and is not patentable under the Patents Act, as stated in the prior art and the reasons stated hereinabove.

We shall remain grateful and obliged.

Thanking you,

Yours truly,

Mr. Y. K. Sapru
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