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Ref. No. **0433-03/16**
of **March 16, 2016**

State Enterprise Ukrainian Intellectual Property Institute (Ukrpatent)

1 Hlazunova Str., Kyiv-42, 01601

Department for Examination of Applications for Inventions, Utility Models and Integrated Circuit Topographies

Expert N.M. Vakhovska

Acting under the Power of Attorney from the *All-Ukrainian Network of People Living with HIV/AIDS*, we file herewith the materials evidencing that the invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" according to Application No. a 2014 03617 of September 14, 2012 fails to meet the patentability criteria for "novelty" and "an inventive step" in according to Article 7 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" (hereinafter, the Law).

Bibliographic data of theApplication No. a 2014 03617 of September 14, 2012

Application No. a 2014 03617 of September 14, 2012 for the invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" was filed in Ukraine as a national phase of the International Application PCT/US2012/055621 published under WO2013040492 A2. The claims of the invention according to the Application No. a 2014 03617 are similar to the WO2013040492 A2 and in particular are related to:

- the composition comprising the compound 10 or a pharmaceutically acceptable salt thereof and the compound 6 or a pharmaceutically acceptable salt thereof (independent claim 1),

- the method of treatment of HCV infection in a human comprising administering the compound 10 or a pharmaceutically acceptable salt thereof and the compound 6 or a pharmaceutically acceptable salt thereof to a human (independent claim 10),

- the method of relieving one or more symptoms of HCV infection in a human comprising administering the compound 10 or a pharmaceutically acceptable salt thereof and the compound 6 or a pharmaceutically acceptable salt thereof to a human (independent claim 15),

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- the method of reducing viral load in a human with HCV comprising administering the compound 10 or a pharmaceutically acceptable salt thereof and the compound 6 or a pharmaceutically acceptable salt thereof to a human (independent claim 20),

- the method of reducing occurrence of HCV quasi-types resistant to oral antiviral agents administered together to a human comprising administering the compound 10 or a pharmaceutically acceptable salt thereof and the compound 6 or a pharmaceutically acceptable salt thereof to a human (independent claim 25),

- the composition according to claim 1 for the use in medical therapy (independent claim 33),

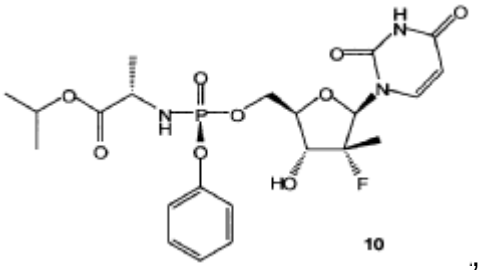
- the composition according to claim 1 for the use in the prevention or therapeutic treatment of HCV infection (independent claim 34),

- the use of the composition according to claim 1 for obtaining a medicinal product for the treatment of HCV infection in a human (independent claim 35),

- the use of the composition according to claim 1 for obtaining a medicinal product to alleviate one or more symptoms of HCV infection for a human (independent claim 36),

- the composition according to claim 1 for the use to reduce the viral load (independent claim 37).

Thus, all of the above listed objects of the invention are based on the combination of the compound 10 or a pharmaceutically acceptable salt thereof and the compound 6 or a pharmaceutically acceptable salt thereof, which must be suitable for the treatment of diseases caused by hepatitis C virus infection. The compound 10 is an S-isomer of the compound 9:



10

which is a hepatitis C virus (HCV) NS5B polymerase inhibitor developed by Gilead Pharmasset LLC (US), and administered for the treatment of chronic hepatitis C (CHC) as a component of the combination antiviral therapy in adults in combination with other medicines and is known as sofosbuvir (PSI-7977; GS-7977), http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf.

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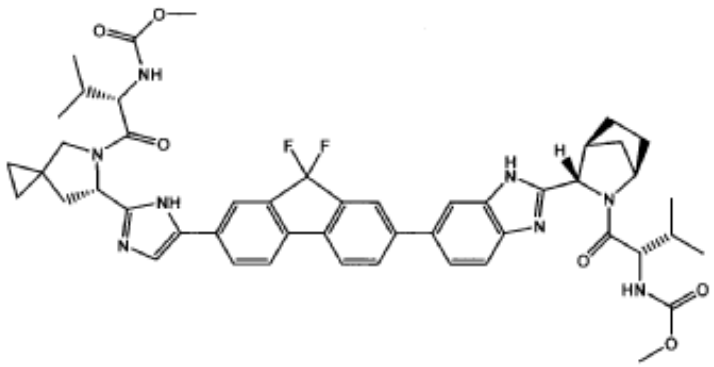
The compound 6 has the formula:



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and is a HCV NS5A protein inhibitor known as ledipasvir (GS-5885), which is also developed by the company Gilead Pharmasset LLC (US), and administered for the treatment of chronic hepatitis C (CHC) as a component of the combination antiviral therapy in adult subjects in combination with other medicines.

The combination of the abovementioned compound 10 and compound 6 is a composition for the treatment of hepatitis C, particularly in a tablet form, and is known as a medicinal product marketed as Harvoni, particularly described in: https://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf.

Regulations

According to Article 7 of the Law (the citations are italicized hereinbelow):

"3. An invention (utility model) shall be considered to be new provided if it does not form part of the state of the art.

4. The state of the art comprises all the facts made available to the public throughout the world before the date of filing of the application with the Office or, if the priority has been claimed, before the date of its priority.

…

7. An invention shall be considered as involving an inventive step provided if it is not obvious to a person skilled in the art, i.e. an invention does not proceed obviously from the state of the art."

According to Section 6.5.3.1 of the Rules of Examination of an Application for Invention and Application for Utility Model (hereinafter, the Rules of Examination):

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«An invention has an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. When assessing the inventive step, the claimed invention is compared not only with separate documents or their parts, but with combination of documents or their parts (so called composite prototype), when the possibility of combining the documents or their parts is obvious for a person skilled in the art.

When an inventive step is checked, it is established whether the influence of the combination of the features of the claimed invention on obtaining the technical result indicated by the applicant is known from the state of the art. If this fact is not established, the invention is considered to meet the criterion of inventive step. (Sec. 6.5.3.2 of the Rules).

The fact that influence of combination of features of the claimed invention on the technical result is known may be proved by combining two or more information sources or their parts, different excerpts from one and the same source or from any different information sources. Involvement of arguments based on knowledge well-known in a specific art without indication to any specific information sources is permissible. (Sec. 6.5.3.6 of the Rules).

If the claimed invention meets the criterion of inventive step with regard to the independent claim(s), the respective dependent claims are not further checked (Sec. 6.5.3.8 of the Rules)".

<u>The invention according to independent claim 1 fail to meet the patentability criterion for "novelty" and "an inventive step".</u>

As noted above, independent claim 1 relates to the composition comprising: 1) the compound 10 (sofosbuvir) or a pharmaceutically acceptable salt thereof, and 2) the compound 5 or a pharmaceutically acceptable salt thereof, or the compound 6 (ledipasvir) or a pharmaceutically acceptable salt thereof. The feature 2) described as an alternative, i.e. as a variant of the composition, is the combination of the compound 10 and the compound 6 or pharmaceutically acceptable salts of these compounds as described in one of the dependent claims (claim 3).

The prior art discloses the US 2011/306541 A1 (DELANEY IV WILLIAM [US] ET AL), published on December 15, 2015, which is also referred to as D2 in the International Preliminary Report on Patentability (IPRP). The said document relates to combinations of compounds for the treatment of hepatitis C. Table 1 on p. 54 thereof discloses the compound 6 (ledipasvir) with antiviral activity 0.0045 pM. Further, p. 7, 8 [0074] of this

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document discloses that the compounds according to the invention, in particular the compound 6, may be used for the treatment of hepatitis C together with one or more additional therapeutic agents, in particular nucleosides or nucleoside HCV NS5B polymerase inhibitors, namely PSI-7977 (sofosbuvir). Thus, p. 4 [0036] discloses that the said compounds may exist as stereoisomers, in particular S-isomer, which is used as the compound 10 in claim 1. Further, the description to the said document also discloses possible use of pharmaceutically acceptable salts of the said compounds, in particular compound 10 and compound 6. Thus, independent claim 1 according to Application No. a 2014 03 617, i.e. the composition comprising the compound 10 (sofosbuvir) or a pharmaceutically acceptable salt thereof and the compound 6 (ledipasvir) or a pharmaceutically acceptable salt thereof are known from US 2011/306541 A1. Therefore, **the invention according to independent claim 1 is the prior art and therefore does not meet the patentability criterion for "novelty" in according to Part 3 of Article 7 of the Law.**

As stated above, the application of the combination of the compound 10 and compound 6 is known from the prior art, in particular from the US 2011/306541 A1. Further, the applicant in the description of the claimed invention states that obtaining and purification of the compound 10 are known from the Documents US 2010/0298257 A1 and US7964580 B2 (p. 10 and 113 of the description), and obtaining of the compound 6 is known from the Document US 12/779,023 (US 20100310512 A1), p. 94 of the description, and is also disclosed in the US 2011/306541 A1, in particular on the diagram 16, pp. 46-48. Herewith, the description of the claimed invention provides no data on the new antiviral activity of the combination of compounds 10 and 6.But the description contains separately the results with regard to biological activity of the compound 6 (p. 147-150) and a biological example of cross-resistance of the compound 10 and compound 6 (p. 150-155). According to the presented data, resistance mutations of compound 10 and compound 6 do not exhibit cross-resistance, suggesting the possibility of their use in combination with HCV treatment, but the description provides no facts on the new activity of the combination of these compounds. According to the description, the object of the invention is to provide compositions and therapeutic methods for treatment of viral infections (e.g. HCV), p. 3 of the description. Thus, whereas the compound 10 is used exactly as a HCV NS5B polymerase inhibitor and the compound 6 is used for the treatment of hepatitis C exactly as a HCV NS5A protein inhibitor, i.e. the said compounds are used according to the prior art, and new antiviral activity of the combination of the compounds is not given by the applicant, then the use of the compound 10 and the compound 6 for the treatment of hepatitis C in combination are obvious to a person skilled in the art. Therefore, **the invention according to claim 1 has no inventive step in according to Part 7 of Article 7 of the Law**.

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Claims 3, 5-8, which depend on claim 1, relate to the additional substances in the composition of the compounds 10 and 6 as well as certain forms of making such compositions, and contain no other features that would be unobvious to a person skilled in the art. Thus, **the features of dependent claims 3, 5-8 have no inventive step in according to Part 7 of Article 7 of the Law, even when combined with the features of independent claim 1.**

The invention according to independent claims 10, 15, 20, 25, 33-41 does not meet the patentability criterion for an "inventive step".

As noted above, independent claims 10, 15, 20, 25, 33-41 relate to methods of using compositions of compounds 10 and 6 according to claim 1 of the invention based on their known antiviral activity, in particular for the treatment of HCV infection in humans, relieving symptoms of HCV infection in humans, reducing viral load in humans with HCV etc., and the use of the said composition in medical therapy, for the prevention and therapeutic treatment of HCV infection etc. All of the said features of these claims associate with antiviral activity of the compound 10 and the compound 6 and do not contain any additional essential features. Therefore, the independent claims 10, 15, 20, 25, 33-41, which are completely based on the composition of Claim 1, are obvious to a person skilled in the art and fail to meet the patentability criteria for "novelty" and "an inventive step"..

Also claims 12, 14, 17, 19, 22, 24, 27, 29, 30, 44, which are depend on independent claims 10, 15, 20, 25, 33-41, relate to the presence of additional substances in the composition of compound 10 and 6, in particular such as ribavirin, or relate to the absence of interferon when the composition according to claim 1 is administered for the treatment of HCV as well as certain forms of making such compositions, and do not contain other features that would be unobvious for a person skilled in the art. Thus, **the features of dependent claims 12, 14, 17, 19, 22, 24, 27, 29, 30, 44 do not involve an inventive step within the meaning of Part 7 of Article 7 of the Law, even when combined with the features of respective independent claims of the invention**.

Taking into account the above considerations, the claimed invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" according to Application No. a 2014 03617 according to independent claim 1 does not meet the patentability criteria for "novelty" and "an inventive step" within the meaning of parts 3 and 7 of Article 7 of the Law, and claims 3, 5-8, 10, 15, 20, 25, 33-41, 12, 14, 17, 19, 22, 24, 27, 29, 30, 44 do not involve an inventive step within the meaning of Part 7 of Article 7 of the Law.

Furthermore, on behalf of the principal, we would like to provide below additional information, which is not related to the invention, but rather intended to explain the motivation of the objection filed by a legal entity, which is a charitable non-for-profit

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organization and, as such, may neither manufacture nor distribute medicinal products and, hence, cannot compete with the applicant in Ukraine.

Hepatitis C virus (HCV) is a major global problem for public health. The virus is transmitted by direct contact with blood of an infected person. People with injuries from needles, healthcare professionals working with blood/blood products, recipients of transfusions/blood products, organ transplant recipients and injection drug users are among the risk groups for HCV infection. According to the World Health Organization, 170+ million people are chronic carriers of hepatitis B virus, which can cause cancer and/or cirrhosis. Ukraine has about 1.2 million people who are chronically infected with HCV[1]. Today, about 66 thousand patients with HCV[2] require therapy, while the National Targeted Programme for Prevention, Diagnosis and Treatment of Viral Hepatitis for the Period until 2016 provide treatment to about 1,300 patients only due to high treatment costs.

In addition, there are about 231,409 people living with HIV (PLHIV) in Ukraine[3]. Given global co-infection rate is 15%, which means that about 34,000 people living with HIV are also infected with HCV. HIV affects the progression of HCV, which leads to higher rates of HCV progression in a chronic form, accelerates progression of HCV infection and contributes to high mortality. In the era of antiretroviral therapy, patients co-infected with HIV/HCV are at higher risk of morbidity and mortality compared to patients with HIV infection only and those with chronic hepatitis C alone.

HIV-infected patients still demonstrate a five times greater mortality rate compared to non-HIV-infected people, and chronic hepatitis C is associated with a 50% increase in mortality rate among patients diagnosed with AIDS.[4]

Taking into consideration the crisis related to HCV and HIV/AIDS in Ukraine's public health, it is important that people living with HCV and HIV can get access to the latest and most effective treatment methods without "evergreen" patents, which stand on their way. "Evergreen" patents allow a company to obtain "artificial" exclusive rights. This allows the company to set extremely high prices for medicines making them absolutely unaffordable

[1] Уніфікований клінічний протокол: вірусний гепатит С, затверджений наказом МОЗ № 233, від 02 березня 2014, стор. 7 [Unified Clinical Protocol: Viral Hepatitis C approved by MoH Order No. 233 dd. March 02, 2014, p. 7, *in Ukrainian*]
http://www.dec.gov.ua/mtd/dodatki/2014_233VirysGepatitC/2014_233_YKPMD.doc
[2] http://hvstop.org/news.php?id_news=168
[3] Український центр контролю за соціально небезпечними хворобами, Інститут епідеміології та інфекційних хвороб імені Л. В. Громашевського, Інформаційний бюлетень № 40, Київ, 2013, стор. 14. http://ucdc.gov.ua/uk/statystyka/informatsijni-byuleteni/vil-infektsiya [Ukrainian Center for Control over Socially Dangerous Diseases, L.V. Gromashevsky Institute for Epidemiology and Infectious Diseases, Information Bulletin No. 40, Kyiv, 2013, p. 14 *in Ukrainian*]
[4] Branch AD, Van Natta ML, Vachin ML, et al. Mortality in HCV-infected patients with a diagnosis of AIDS in the era of combination anti-retroviral therapy. Clin Infect Dis 2012;55:137-144

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for Ukrainian patients. For example, Gilead set the price for a treatment course with HARVONI as high as USD 94,500 and CAD 80,000 in the USA and in Canada, respectively.

We kindly ask the expert to review the materials submitted and the information about lack of patentability criteria for said claims of the invention “METHODS OF TREATMENT OF HEPATITIS C VIRUS” and to take them into account under examination.

Enclosure:

- Power of Attorney issued by *All-Ukrainian Network of People Living with HIV/AIDS*, 1 page 1 copy

Sincerely,

Patent Attorney

Borovyk Petro

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Ref. No. 1401-09/16 of September 12, 2016

State Enterprise Ukrainian Intellectual Property Institute (Ukrpatent)

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Department for Examination of Applications for Inventions, Utility Models and Integrated Circuit Topographies

Chief Expert I.A. Karpets

RE: *Preliminary Report of Substantive Examination of April 25, 2015*

Application No. a201403617

Title of the invention: Methods of treatment of Hepatitis C Virus

Applicant: GILEAD PHARMASSET LLC (US)

Date of filing: September 14, 2012

Acting under the Power of Attorney from the *All-Ukrainian Network of People Living with HIV/AIDS*, we file herewith for your kind attention additional materials to those sent on March 16, 2016 evidencing that the invention “Methods of Treatment of Hepatitis C Virus” according to Application No. a201403617 of September 14, 2012 fails to meet the patentability criteria in according to Article 7 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" (hereinafter, the Law).

The additional materials take into account the applicant’s reply to the Preliminary Report of Substantive Examination of April 25, 2016, Ref. No. 9046/3A/16.

The said reply contains the amended claims of the claimed invention and explanations with regard to compliance of the invention with the patentability criterion for “an inventive step” according to the amended claims. The amended claims of the invention concern a composition containing a therapeutically effective amount of the compound 10 (known as sofosbuvir) or a pharmaceutically acceptable salt thereof and the compound 6 (known as ledipasvir) or a pharmaceutically acceptable salt thereof, and also pharmaceutically acceptable excipients, carriers or diluents (independent claim 1). All other amended dependent claims are based on independent claim 1. Besides the amended claims, the reply was filed with arguments in favor of compliance of the invention according to independent claim 1 with the patentability criterion for "an inventive step". All arguments

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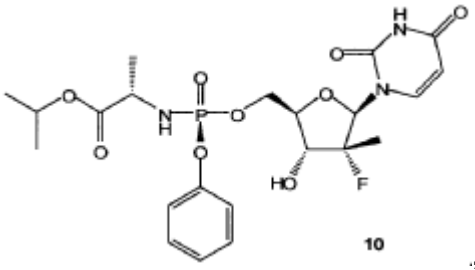
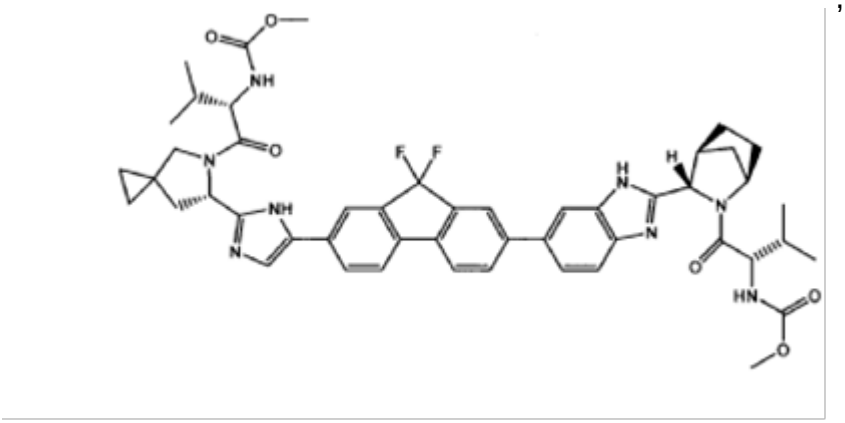
are based on the article by Kris V. Kowdley at al. “Ledipasvir and Sofosbuvir for 8 to 12 Weeks for Chronic HCV without Cirrhosis” (a copy thereof is attached to the reply).

The compound 10 is known to be an S-isomer of the compound 9:



which is a hepatitis C virus (HCV) NS5B polymerase inhibitor developed by the Gilead Pharmasset LLC (US) and administered for the treatment of chronic hepatitis C (CHC) as a component of the combination antiviral therapy in adult subjects in combination with other medicines, and is known as sofosbuvir (PSI-7977; GS-7977), http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf.

The compound 6 has the formula:



and is a HCV NS5A protein inhibitor known as ledipasvir (GS-5885), also developed by the Gilead Pharmasset LLC (US), and administered for the treatment of chronic hepatitis C (CHC) as a component of the combination antiviral therapy in adult subjects in combination with other medicines.

The combination of the said compound 10 and compound 6 is a composition for the treatment of hepatitis C, particularly in a tablet form, and is known as a medicinal product marketed as Harvoni, particularly described in: https://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf.

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According to Parts 4 and 7 of Article 7 of the Law (the citations are italicized hereinbelow): *an invention shall be considered as involving an inventive step provided if it is not obvious to a person skilled in the art, i.e. an invention does not proceed obviously from the state of the art. The state of the art comprises all the facts made available to the public throughout the world before the date of filing of the application with the Office or, if the priority has been claimed, before the date of its priority.*

According to Section 6.5.3.1 of the Rules of Examination of the Application for Invention and Application for Utility Model (hereinafter, Rules):

«An invention has an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. When assessing the inventive step, the claimed invention is compared not only with separate documents or their parts, but with combination of documents or their parts (so called composite prototype), when the possibility of combining the documents or their parts is obvious for a person skilled in the art.

When an inventive step is checked, it is established whether the influence of the combination of the features of the claimed invention on obtaining the technical result indicated by the applicant is known from the state of the art. If this fact is not established, the invention is considered to meet the criterion of inventive step. (Sec. 6.5.3.2 of the Rules).

The fact that influence of combination of features of the claimed invention on the technical result is known may be proved by combining two or more information sources or their parts, different excerpts from one and the same source or from any different information sources. Involvement of arguments based on knowledge well-known in a specific art without indication to any specific information sources is permissible. (Sec. 6.5.3.6 of the Rules).

If the claimed invention meets the criterion of inventive step with regard to the independent claim(s), the respective dependent claims are not further checked (Sec. 6.5.3.8. of the Rules)".

<u>The invention according to independent claim 1 does not meet the patentability criterion for "an inventive step" based on the following considerations.</u>

The combination of sofosbuvir and ledipasvir, as disclosed in independent claim 1 of the amended claims, is known in the art, i.e. in the known document US 2011/306541 A1 (DELANEY IV WILLIAM [US] ET AL), published on December 15, 2015, which is also referred to as D2 in the International Preliminary Report on Patentability (IPRP). The said document relates to combinations of compounds for the treatment of hepatitis C. Table 1

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on p. 54 thereof discloses the **compound 6 (ledipasvir)** with antiviral activity 0.0045 pM according to the invention. Further, p. 7, 8 [0074] of this document discloses that the compounds according to the invention, in particular the compound 6, may be used for the treatment of hepatitis C together with one or more additional therapeutic agents, in particular nucleosides or nucleoside HCV NS5B polymerase inhibitors, namely **PSI-7977 (sofosbuvir)**. Thus, D2 on p. 4 [0036] discloses that the said compounds may exist as stereoisomers used as the compound 10 in claim 1 of the invention. Further, the description of D2 discloses possible use of pharmaceutically acceptable salts of the said compounds, in particular compounds 10 and 6. The said pages of D2 are attached hereto.

The fact that S-isomer of the compound 10 can be used is obvious for a person skilled in the art of pharmaceutics, and besides the description of the invention according to Application No. a201403617 does not explain the choice of this isomer and its impact on the technical result.

Thus, the composition comprising the compound 10 (sofosbuvir) or a pharmaceutically acceptable salt thereof and the compound 6 (ledipasvir) or a pharmaceutically acceptable salt thereof is obvious for a person skilled in the art from D2 , i.e. clearly follows from the prior art.

Further, the applicant in the description of the invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" according to Application No. a 2014 03617 states that obtaining and purification of the compound 10 are known from the Documents US 2010/0298257 A1 and US7964580 B2 (p. 10 and 113 of the description), and obtaining of the compound 6 is known from the Document US 12/779,023 (US 20100310512 A1), p. 94 of the description, and is disclosed in the US 2011/306541 A1, in particular on diagram 16, pp. 46-48. Herewith, the description of the invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" according to Application No. a 2014 03617 provides no data on the new antiviral activity of the combination of compounds 10 and 6, but states separately the results with regard to biological activity of the compound 6 (p. 147-150 of the description) and gives a biological example of cross-resistance of the compound 10 and compound 6 (p. 150-155 of the description). According to the presented data, resistance mutations of compound 10 and compound 6 do not exhibit cross-resistance, suggesting their possible use in combination with HCV treatment, but the description provides no details on the new activity of the combination of these compounds. According to the description, the object of the invention is to provide compositions and therapeutic methods for treatment of viral infections (e.g. HCV), p. 3 of the description. Thus, whereas in accordance with the invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" according to Application No. a 2014 03617 the compound 10 is used exactly as a HCV NS5B polymerase inhibitor and the compound 6 is used for the treatment of hepatitis C exactly

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as a HCV NS5A protein inhibitor, i.e. the said compounds are used according to the purpose known in the prior art, and taking into account the fact that the new antiviral activity of the combination of compounds is not given by the applicant, then the use of the compound 10 and the compound 6 for the treatment of hepatitis C in combination are obvious to a person skilled in the art. This further indicates that **the invention according to claim 1 has no inventive step in according to Part 7 of Article 7 of the Law**.

In this case, the article filed by the applicant in support of compliance of the invention with inventive step criterion, in particular the information in Table 2 of the article, compares the effect of using the combination of ledipasvir and sofosbuvir with the effect of using this combination with ribavirin, and compares the effect of using the combination of ledipasvir and sofosbuvir for different duration (8 weeks vs. 12 weeks). In particular, on p. 1887, para. 3 above, the article states that the use of ribavirin worsens external influence in the treatment of hepatitis C with the said combination, with no treatment effect achieved. Therefore, the said article provides no information about unexpected (synergistic) effect of using ledipasvir and sofosbuvir compared with the use of each ingredient of the combination separately.

It should be noted that the information in this article also goes beyond the primary filed application, and the authors of this article are not listed as inventors of the claimed invention, so there is every reason not to take this article into account as an argument for the presence of unobvious effect of using the invention.

Claims 2-5, which depend on claim 1, relate to the absence or presence of additional substances in the compositions of compounds 10 and 6, and the use of such composition for the treatment of hepatitis C, i.e. do not contain other features that would be unobvious for a person skilled in the art. Thus, **the features of dependent claims 2-5 do not involve an inventive step in according to Part 7 of Article 7 of the Law, even when combined with the features of independent claim 1.**

For these reasons, the claimed invention "METHODS OF TREATMENT OF HEPATITIS C VIRUS" according to Application No. a 2014 03617 (independent claim 1 and dependent claims 2-5) does not meet the patentability criterion for "an inventive step" in according to Part 7 of Article 7 of the Law.

Please also take into account additional information from *All-Ukrainian Network of People Living with HIV/AIDS,* which was presented in the previous opposition of March 16, 2016 with regard to the general situation of treatment hepatitis C virus (HCV) and attempts of pharmaceutical companies to get "evergreen" patents on pharmaceutical combinations known in the prior art.

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We kindly ask the expert to review the filed materials and the information on incompliance of the said claims of the invention “METHODS OF TREATMENT OF HEPATITIS C VIRUS” according to Application No. a 2014 03617 of September 14, 2012 with the patentability criteria and to take them into account under examination.

Enclosure:

- Power of Attorney issued by *All-Ukrainian Network of People Living with HIV/AIDS*, 1 page 1 copy
- photocopies of pages 1, 4, 8, 54 of the Document US 2011/306541 A1, 4 pages 1 copy

Sincerely,

Patent Attorney

Borovyk Petro