TRAN & TRAN INTELLECTUAL PROPERTY CO. LTD

No.: 1112/2025/CVPD-SC

Re: Opposition to the Grant of a Patent for the application No. 1-2023-00319

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

Hanoi, January 12th, 2026

To: **INTELLECTUAL PROPERTY OFFICE OF VIETNAM**
384-386 Nguyen Trai, Thanh Xuan, Hanoi

We, Tran & Tran Co., Ltd., act as the industrial property agency representing the **Center for Action for People Living with HIV**, located at Group 18, Ngoc Thuy Ward, Long Bien District, Hanoi (*A copy of the Power of Attorney is attached, and the original was submitted with the request for cancellation of Patent No. ĐN1-2022-00080*). We hereby oppose the granting of the patent for the following application:

Application No.:	**1-2023-00319**
Title:	FORMULATIONS
Applicant:	VIIV HEALTHCARE COMPANY
Address:	251 Little Falls Drive, Wilmington, Delaware 19808, United States of America
PCT application No.:	PCT/IB2021/055535
PCT filing date:	23/06/2021
Priority Rights:	U.K. Patent Applications No. 2009685.5, filed on June 25, 2020.

Specifically, we oppose the grant of the patent for Application No. **1-2023-00319** because claims 1-11 of VIIV HEALTHCARE COMPANY (hereinafter referred to as "VIIV"), and claims 1-8 as amended on August 26, 2025, as they do not satisfy the patentability requirements; therefore, based on the following legal grounds and arguments:

Grounds for opposition:

1. Legal basis under current regulations

Pursuant to Article 112 of the Law on Intellectual Property, from the date of an industrial property registration application being published in the Industrial Property Gazette until the date of the decision to grant the protection certificate, any third party has the right to express their opinion to the State management agency on the industrial property rights concerning the granting or refusal of the protection certificate for such application.

The opinion must be in written form and accompanied by relevant documents or citations of information sources and is considered a source of reference information for the processing of industrial property registration application.

Based on the above provisions, we hereby exercise our right to file an opposition against invention application No. 1-2023-00319 based on the international No. PCT/IB2020/061582, filed on 23/06/2021.

2. Legal basis applicable at the time of opposing to grant

Patent application No. 1-2023-00319 based on the international No. PCT/IB2020/061582, filed on 23/06/2021, under the IP Law, is subject to the patentable requirements as set forth by the following provisions:

Article 58.1 of the IP Law:

« Article 58.1. An invention shall be protected by mode of grant of invention patent when it satisfies the following conditions :

a) Being novel

b) Involving an inventive step

c) Capable of industrial application. »

Article 60.1 of the IP Law:

« Article 60.1. An invention shall be deemed novel if it does not fall into one of the following cases:

a) It has been publicly disclosed by use or by means of a written description or in any other forms either inside or outside Vietnam before the filing date or the priority date, as applicable, of the invention registration application.

b) It has been disclosed in another inventory registration application with an earlier filing date or priority date but published on or after the filing date or priority date of such application.". »

Article 61.1 of the IP Law:

« Article 61.1. Inventive step of invention

An invention shall be considered involving an inventive step if, based on technical solutions already publicly disclosed through use or by means of a written description or any other form, inside or outside the country, prior to the filing date or the priority date, as applicable, of the invention registration application, it constitutes an inventive progress and cannot be easily created by a person with average knowledge in the art. »

Article 117a. The Law on Intellectual Property:

« Article 117a. Refusal to grant protection titles

...

1a. Apart from cases specified in Clause 1 of this Article, an application for registration of invention shall be refused to grant a protection title in the following cases:

a) The patent invention goes beyond the scope of disclosure of the initial description in the application for registration of the invention;

b) The invention has not been disclosed in a manner clear and complete in its description so that based on it persons with an average knowledge in technical sectors could conduct such invention; ... »

3. The Claims of the Vietnam patent application No. 1-2023-00319 do not meet the patentability criteria at the time of filing the application

3.1. Summary of the claims

Table 1: Summary of the type of claim protection

Type of protection	Claims	Details
Dispersible tablet formulation	1 (independent)	A dispersible tablet formulation comprising of **Dolutegravir + Abacavir + amivudine,** and at least one taste masking agent
Dispersible tablet formulation	2-5 (dependents)	wherein the dispersible tablet formulation is a multilayer dispersible tablet formulation
Dispersible tablet formulation	6-10 (dependents)	wherein the one taste masking agent comprises a sweetener, a flavouring agent, or a coating
Process for making a dispersible tablet formulation	11 (independent)	A process of making a dispersible tablet formulation comprising mixing **Dolutegravir + Abacavir + amivudine,** and at least one taste masking agent

According to the specification, Patent Application No. 1-2023-00319 relates to formulations comprising dolutegravir or a pharmaceutically acceptable salt thereof, abacavir or a pharmaceutically acceptable salt thereof and lamivudine, processes for making such formulations, and the use of such formulations in the treatment of HIV infection, in particular in the treatment of HIV infection in patients who have difficulty swallowing. Patent Application No. 1-2023-00319 claims protecion for a dispersible tablet formulation comprising mixing three HIV-active ingredients, namely dolutegravir, abacavir, and lamivudine, as mentioned above, for use of treatment or prevention of HIV infection in humans. The invention also claims protection for the process of making the above dispersible tablet formulation.

However, on May 27, 2025, the National Office of Intellectual Property issued a Notification on the result of substantive examination refusal to grant for the application on the grounds that claims 1 and 6-11 did not meet the requirement of novelty; claims 1-11 did not meet the requirement of inventive step, for the reasons set out in Box No. V of the International

Preliminary Report on Patentability – IPRP for the International Application No. PCT/IB2021/055535.

On August 26, 2025, the applicant filed an official response with a narrowed claim set, in which the feature *"multilayer dispersible tablet formulation"* of claim 2, and the feature *"dolutegravir or a pharmaceutically acceptable salt thereof is present within a separate layer to the abacavir or a pharmaceutically acceptable salt thereof"* was added to independent claim 1; and the originally filed claims directed to the dispersible tablet formulation of claims 2; 4; 11 were deleted. Specifically:

Table 2: Summary of the amended claims of the invention

Amended claim	**Original claim supporting the amendment**
Claim 1 (independent)	Original claim 1 + claim 2 + claim 4
Claim 2 (dependent)	Original claim 3
Claim 3 (dependent)	Original claim 5
Claim 4 (dependent)	Original claim 6
Claim 5 (dependent)	Original claim 7
Claim 6 (dependent)	Original claim 8
Claim 7 (dependent)	Original claim 9
Claim 8 (dependent)	Original claim 10

3.2. Relevant technical documents

In order to access the novelty and inventive step of the invention, we have reviewed the technical documents disclosed prior to the filing date. The following are three representative prior art documents (designated as D1, D2, and D3) used as evidence:

D1: (Rajendra 2018): Document D1 is a medical research article published in 2018, which dicusses the efficacy and safety of a combination regimen comprising dolutegravir, abacavir, and lamivudine in the treatment of HIV-1. This article shows that the combination of the above three active ingredients in a single treatment regimen was already known and had been applied in clinical practice as of 2018. In other words, the three-drug regimen as claimed in the present patent application represents an effective treatment option that had been publicly disclosed prior to the filing date of the present application.

D2: (McDermott – US20140234415A1): Document D2 is a patent application published in 2014 (United States) relating to a dispersible tablet formulation compriing of "two or more or more different active digredients." Specifically, D2 discloses techniques for formulating multilayer tablets or combination tablets comprising multiple active ingredients, particularly for use in anti-HIV medicines. D2 provides examples of combinations of anti-HIV drugs that may be incorporated into a single tablet, including drugs belonging to the integrase inhibitor class, the nucleoside reverse transciptase inhibitor class, etc. In particular, D2 discloses that specific active ingredients such as lamivudin, zidovudin, abacavir, as well as

integrase inhibitors (for instance, raltegravir or dolutegravir), may be combined in a single pharmaceutical composition.

D3 (Malhotra – WO2015/140569): Document D3 is a PCT application published in 2015, which describes pharmaceutical compositions comprising dolutegravir together with pharmaceutically acceptable excipients. In particular, D3 focuses on addressing the poor solubility of dolutegravir by reducing the particle size to the nanoscale and/or using absorption enhancers. D3 shows that dolutegravir can be formulated in the form of nanoparticles and admixed with excipients such as surfactants, polymers, solvents, and solubility enhancers. In addition, D3 discloses the capability of combining dolutegravir with other antiretroviral agents, (including other ARV drugs or potentiators), in a single pharmaceutical composition. This document demonstrates that dolutegravir itself had been specifically studied in formulation research, and that combining dolutegravir with other ARV drugs had already been contemplated in the state of the art.

3.3. Grounds to oppose

Based on the abovementioned prior art documents, we find that the claims of Patent Application No. 1-2023-00319 do not satisfy the requirements of novelty and inventive step, as follows:

3.3.1. The invention lacks novelty

As presented above, the core subject matter of the invention - the combination of the active ingredients dolutegravir, abacavir, and lamivudine - was widely known prior to the priority date, in particular through the commercial product TRIUMEQ®, which has been authorized for marketing and widely used in HIV treatment since 2014. In addition, D1 (2018) shows that this three-drug combination regimen had been publicly disclosed and implemented. Therefore, the dispersible tablet forumulation as recited in claims 1–10, as well as the process for making the dispersible tablet as recited in claim 11, as set forth in the present invention, is not novel.

With respect to the dispersible tablet, this is a conventional dosage form that has been widely used in the pharmaceutical field, particularly for pediatric patients. Document D2 (2014) discloses, in principle and by way of examples, multi-component tablets for ARV drugs; moreover, the fixed-dose combination product ABC/3TC (Epzicom™ or Kivexa™), comprising two active ingredients (ABC+3TC), had already existed. The addition of dolutegravir to the ABC/3TC pair to create a three-in-one tablet is clearly a natural extension of existing two-in-one tablets, with the objective of reducing the number of tablets taken daily by patients. Therefore, the dispersible tablet formulation according to claims 2-5 do not create a new technical feature.

Regarding the addition of taste-masking agents (flavoring agents, sweeteners) as defined in claims 6-10, such additives are conventional excipients that are commonly used to impove patient compliance and do not create any new technical characteristics for the active ingredients. Accordingly, it can be concluded that all technical features set forth in claims 1-11 had been publicly disclosed prior to the priority date; therefore, do not satisfy the "novelty" requirement under Article 60 of the IP Law.

3.3.2. The invention lacks inventive step (Aritcle 61)

In the context of formulating HIV medicines, particularly for the pediatric patients, a person skilled in the art would naturally make the following selections:

- Selecting a dispersible tablet dosage form suitable for patients who have difficulty swallowing (especially children);
- adding taste-masking agents to improve drug acceptability;
- adjusting the amounts of active ingredients in accordance with therapeutic dosages established in medical literature and treatment guidelines.

The above-mentioned selections do not constitute inventive activity, but rather represent routine practices that had been widely applied and stabilized in the pharmaceutical field prior to the filing date.

Before 2020, the trend of combining multiple antiviral active ingredients into a single tablet in order to improve treatment compliance had become a primary and widely accepted therapeutic strategy in HIV treatment. A person having ordinary skill in the art would naturally recognize that:

- Dolutegravir (DTG) is a newer active ingredient with high efficacy;
- Abacavir/lamivudine (ABC/3TC) constitutes a classical "backbone" regimen that has been widely used.

The incorporation of DTG into the ABC/3TC combination to form a stronger and more convenient regimen therefore represents an inevitable step from a therapeutic perspective, and does not involve any hidden or unexpected technical features. In fact, since 2018, the World Health Organization (WHO) has recommended the DTG + ABC/3TC regimen as one of the preferred treatment options. Accordingly, the technical problem addressed (formulating a combined DTG/ABC/3TC pharmaceutical composition) has a clear and obvious technical motivation, and is not the result of an inventive contribution.

3.3.2.i) Document D1 is the closes prior art and deprives the inventiveness of solution

Document D1 discloses a multi-component dispersible tablet comprising Dolutegravir in combination with Abacavir and Lamivudine, together with in vivo clinical data, and is therefore considered the closest prior art to the solution in WO2021260569. The technical problem addressed in D1 is: *"How to provide dolutegravir in the form of a dispersible tablet with high bioavailability, stability, and suitability for patients who have difficulty swallowing?"*

Table 3: Comparision of the formulations of D1 and WO2021260569

Criteria	**Formulation D1**	**Formulation WO2021260569**
Dosage form	Dispersible tablet	Multilayer dispersible tablet
Active ingredients	DTG + ABC + 3TC	DTG + ABC (± 3TC)
Objective	Suitable for pediatric use; improvement of absorption	Improvement of DTG bioavailability
Principle	DTG is dispersed within a multi-component system	DTG is located in a separate layer

D1 demonstrates that the bioavailability of Dolutegravir in a dispersible tablet is significantly increased (~53–59%), independently of the mineral content of water or the

residence time prior to administration. The increase in DTG bioavailability cited by the applicant of WO2021260569 (~1.6-times) is neither superior to nor unexpected in comparison with the level disclosed in D1. Accordingly, this effect cannot be regarded as an "unexpected technical effect" under patent examination standards.

The measure of "separating Dolutegravir into an independent layer" in the dispersible tablet of WO2021260569 merely represents an obvious formulation optimization derived directly from the known multi-component dispersible tablet system, and therefore does not satisfy the requirement of inventive step under Article 61 of the IP Law.

3.3.2.ii) Document D2 fully discloses the layer-seperation solution and its technical purpose

Document D2 provides detailed guidance on multilayer tablet technology in the treatment of HIV/AIDS in order to address pharmaceutical issues such as drug–drug interactions, stability, and controlled release.

Table 4: Comparision of the formulations of D2 and WO2021260569

Criteria	**Formulation D1**	**Formulation WO2021260569**
Dosage form	Two-layer tablet for HIV/AIDS treatment	Multilayer tablet for HIV treatment
Composition of each layer	Each layer contains one or more different ARV agents (including DTG, ABC, etc.)	Each layer contains one or more active ingredients
Technical motivation	Avoid incompatible drug–drug interactions; control drug release	Separation of active ingredients to avoid interactions
Principle	DTG is dispersed within a multi-component system	DTG is located in an independent layer
Effect	Controlled release and improved stability through layer separation and solid dispersion	Improved bioavailability and/or stability
Optimization measures	Reduction of particle size to ≤ 200μm; layer separation	Adjustment of particle size and excipients to ensure tablet integrity

The main technical features of the claims under examination — namely, the multilayer tablet, separation of active ingredients, and the objective of improving stability and/or bioavailability — have all been fully disclosed in Document D2. Any improvement in bioavailability (if any) is an inevitable and predictable result of applying the layer-separation solution disclosed in the prior art in order to avoid incompatibility and optimize the pharmaceutical system, and therefore does not constitute an unexpected technical effect.

Accordingly, the application or adjustment of the solutions disclosed in D2 merely represents routine formulation optimization and does not satisfy the requirement of inventive step under Article 61 of the IP Law.

3.3.2.iii) Document D3 demonstrates the obviousnes of the solution

Document D3 (WO2015/140569 A1) also provides a solution for addressing the poor solubility of Dolutegravir through nanotechnology and suitable excipients, thereby confirming that the bioavailability of DTG is highly dependent on formulation design and structural configuration. Below is a technical comparison table between D3 (WO2015/140569 A1) and WO2021260569.

Table 5: Technical comparison table between D3 (WO2015/140569 A1) and WO2021260569.

Criteria	**D3**	**WO2021260569**	**Comments**
Technical field	Pharmaceutical formulations for HIV treatment	Pharmaceutical formulations for HIV treatment	Same technical field
Core active ingredient	Dolutegravir (DTG)	Dolutegravir (DTG) in combination with abacavir (ABC) and lamivudine (3TC)	DTG is the core technical focus
Technical problem	Poor solubility, low dissolution, dependent on food intake	DTG bioavailability is affected by formulation structure	Same underlying problem
Technical objective	Improve DTG bioavailability	Improve DTG bioavailability	Identical technical objectives
Nature of the solution	Modify the physical state of DTG (nano-formulation, excipients)	Separate DTG from ABC by means of a multilayer tablet structure	Both are conventional formulation solutions
Technical approach	Increase surface area → improve solubility → improve bioavailability	Reduce interactions → Increase stability → improve bioavailability	Classical formulation logic
New active ingredient	None	None	No chemical contribution
New pharmacological mechanism	None	None	No new mechanism
Achieved effect	DTG bioavailability improved	DTG bioavailability increased (~1.6-times)	Comparable effect
Predictability	Predictable based on D3	Claimed by the applicant as "unexpected"	Contradicts D3
Formulation scope	Tablets, dispersible tablets, pellets, MUPS, etc.	Multilayer dispersible tablet	Merely an obvious option

Improving the bioavailability of DTG by changing the formulation structure (including layer separation) is a predictable outcome and does not represent an inventive leap.

Reducing the number of tablets from multiple separate tablets to a single fixed-dose combination tablet is an inevitable therapeutic benefit, rather than a technical effect arising from an invention. The invention also does not demonstrate any unexpected synergistic effect or any particular improvement among the three active ingredients.

A synthesis of documents D1, D2, and D3 shows that the solution in WO2021260569 is merely a logical and obvious result of applying conventional formulation techniques and does not produce any unexpected technical effect, nor does it go beyond the ordinary reasoning ability of a person skilled in the art. Therefore, the invention does not satisfy the inventive step requirement under Article 61 of the IP Law.

In summary, whether claims 1–11 as originally filed or claims 1–8 as amended, they merely constitute routine optimization, do not produce any unexpected technical effect, and do not go beyond the ordinary reasoning ability of a person having ordinary skill in the art.

3.3.3. The patent specification lacks clarity and sufficient disclosure

We further note that the specification of Application No. 1-2023-00319 does not disclose any additional or specific technical features beyond the mere combination of known components. The description (as publicly available) only provides general information regarding dosage ranges of each active ingredient and mentions that the formulation may be prepared in the form of a dispersible tablet or suspension, but does not provide detailed guidance on any specific method for preparing a three-component tablet formulation. Such general guidance merely falls within the common general knowledge of pharmaceutical formulation technology. Therefore, the scope of the claims is very broad (covering all pharmaceutical forms comprising three active ingredients) and is not sufficiently supported by the specification. Accordingly, the patent application does not sufficiently and clearly disclose the invention in order to carry out the invention, and the scope of the claims may extend beyond the content originally disclosed.

In practice, the International Search Report (WOISA) and the International Preliminary Report on Patentability (IPRP) for the corresponding PCT application have concluded that the invention does not meet the requirements for patent grant. We are aware that, during the international phase, the search authority raised objections regarding the novelty and inventive step of the claims. Furthermore, in the United States, the corresponding patent application was also rejected through Office Actions issued by the USPTO. In particular, the Final Rejection issued by the USPTO determined that the claims were not novel and/or were obvious in view of the cited prior art documents in the field. These conclusions from the above competent authorities further confirm that the solution disclosed in the present application lacks novelty and inventive step and is therefore not eligible for the grant of a patent right.

4. Requests of the opponent

Based on the legal grounds and the aforementioned arguments and evidence, we firmly assert that the Patent Application No. 1-2023-00319 does not meet the patent protection criteria in Vietnam, in particular the requirements of novelty and inventive step under Articles 58, 60, and 61 of the Law on Intellectual Property.

Granting an invention patent for a technical solution that does not meet the above patentability criteria would be inconsistent with the objectives of the patent protection system, which is intended to confer exclusive rights only on truly novel and inventive technical

solutions. Such grant would also risk narrowing the public domain and restricting legitimate exploitation of technical solutions that should remain available to the public.

In the pharmaceutical field, ensuring a reasonable balance between patent exclusive rights and the public interest is a fundamental principle of intellectual property law. Therefore, refusing protection for technical solutions that do not meet the patentability requirements is necessary in order to prevent the unjustified expansion or prolongation of exclusive protection, while ensuring the transparency and stability of the patent protection system.

Based on the foregoing analyses, we respectfully request that the Patent Office consider and refuse the grant of a patent for the application No. 1-2023-00319, in accordance with the applicable laws and regulations.

We sincerely thank the Patent Office.

Recipients:
- As above;
- Archives.

Attached documents:

- Copies of cited documents D1 to D3;
- Copy of the Power of Attorney.

TRAN & TRAN INTELLECTUAL PROPERTY CO., LTD
DIRECTOR

M.S.D.N: 0106307457 - C.T.T.N.H.H - CÔNG TY TNHH SỞ HỮU TRÍ TUỆ TRẦN & TRẦN - THÀNH PHỐ HÀ NỘI

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