
No.: 824/2026/CVPD-SC

Hanoi, 24 August 2026

*Re: Opposition to the grant of an Invention
Patent; and submission of third-party
observations on Application No. 1-2024-03307*

To: INTELLECTUAL PROPERTY OFFICE OF VIETNAM (IPVN)

384-386 Nguyen Trai - Hanoi

We, Tran & Tran Intellectual Property Co., Ltd., an industrial property representation service organization, duly authorized by the **Action Center for People living with HIV** (address: Group 18, Ngoc Thuy Ward, Long Bien District, Hanoi City) (*a copy of the Power of Attorney is enclosed with this letter; the original was submitted together with the request for patent invalidation No. DN1-2022-00080*), hereby oppose the grant of a patent for the following invention application:

Item	Information
Vietnam application No.	1-2024-03307; entered national phase on 08/05/2024
International application	PCT/IB2022/059780; international filing date 12/10/2022; published as WO 2023/062559 A1 on 20/04/2023
Publication in Vietnam	VN 109864, published on 25/03/2025
Title of invention	Pharmaceutical composition containing an inhibitor of human immunodeficiency virus replication
Applicant	VIIV HEALTHCARE UK (NO.5) LIMITED
Applicant's address	GSK Medicines Research Centre, Gunnels Wood Road, Stevenage SG1 2NY, United Kingdom
Priority dates	US 63/255,056 dated 13/10/2021; US 63/257,212 dated 19/10/2021
Scope of opposition	All 58 claims currently maintained in Vietnam

Having studied the published application file and the amended set of claims filed upon entry into the Vietnam national phase, we submit that all 58 claims of Application No. 1-2024-03307 fail to satisfy the conditions for patent protection, in particular novelty and inventive step, and also present deficiencies in clarity, unity, and the degree of support from the description. The specific grounds and arguments are set out below.

I. LEGAL BASIS AND SCOPE OF REVIEW

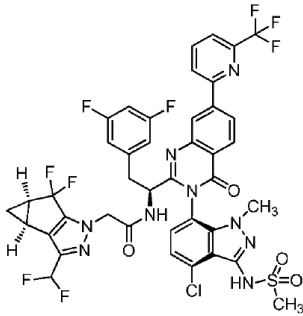
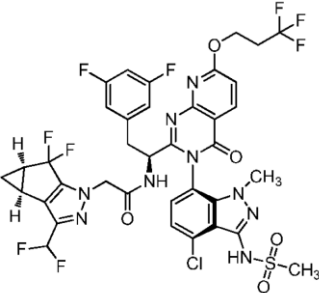
This document is filed to present third-party observations under Article 112 of the Intellectual Property Law. The term “opposition” used in this letter reflects our professional opinion and our request that the patent not be granted; it is not a request for handling under the opposition procedure set out in Article 112a. We respectfully request that Intellectual

Property Office of Vietnam (“IPVN”) accept all accompanying documents and evidence as reference information for use in examining the application before deciding whether to grant the patent.

Under Article 58.1 of the Intellectual Property Law, an invention may only be protected in the form of an Invention Patent where it is novel, involves an inventive step, and is capable of industrial application. Articles 60 and 61 set out the specific criteria for novelty and inventive step; Article 117.1(a) is the ground for refusing to grant a patent where the subject matter stated in the application does not fully satisfy the conditions for protection. Assessment of each essential technical feature and of whether a solution is obvious is carried out under Articles 20 and 21 of Consolidated Document No. 06/VBHN-BKHCN of 2026.

The claim set of the original PCT application comprised 68 claims. Upon entering the Vietnam national phase, the applicant deleted claims 59-65 (directed to methods of treatment) and claims 66-68 (directed to uses). Accordingly, this letter addresses only the 58 claims currently on file in Vietnam and does not rely on deleted claims 59-68.

II. OVERVIEW OF THE CLAIMED SUBJECT MATTERS

Group	Claims	Main technical content
A1	1-16	Compound of Formula Ia  Formula Ia or  Formula Ib Formula Ib, including pharmaceutically acceptable salts, in a PEG/ethanol system; may additionally contain water, lecithin, propylene glycol, benzyl alcohol, or sesame oil; with limitations on PEG type and ratio.
A2	17-32	Same formulation platform as Group A1, but claiming the compound in free form only.
B1	33-45	Compound of Formula Ia or Ib, including pharmaceutically acceptable salts, in an aqueous system containing less than 1% PEG; may contain acetate buffer, mannitol/NaCl, and P338/P188; with limitations on particle size and a concentration of 300 mg/mL.
B2	46-58	Same formulation platform as Group B1, but claiming the compound in free form only.

The independent claims are claims 1, 2, 17, 18, 33, 34, 46, and 47. In terms of formulation, the claim set pursues two distinct approaches: (i) a PEG/ethanol co-solvent solution; and (ii) an aqueous nanosuspension containing poloxamer and mannitol. Claim pairs 1/17, 2/18, 33/46, and 34/47 have significantly overlapping scope: the first claim in each pair covers both the free-form compound and pharmaceutically acceptable salts, while the second claim in each pair is limited to the free-form compound only.

III. CONCLUSIONS OF THE INTERNATIONAL SEARCHING AUTHORITY

The European Patent Office (EPO), acting as the International Searching Authority, issued a Written Opinion of the International Searching Authority (WOSA). The subsequent International Preliminary Report on Patentability - Chapter I (IPRP) maintained the main findings of the WOSA. Mapping these findings onto the 58 claims currently maintained in Vietnam, the results can be summarized as follows:

Criterion	Vietnam claims	WOSA/IPRP conclusion
Novelty	2, 3, 8-14, 18, 19, 24-30, 33, 34, 45-47, and 58	Not novel
Novelty	1, 4-7, 15-17, 20-23, 31, 32, 35-44, and 48-57	Considered novel in the search results
Inventive step	1-58	Lacking inventive step
Industrial applicability	1-58	Satisfied

The WOSA and IPRP are not binding on the Office's examination. However, they constitute a valuable technical reference, as the EPO directly searched and assessed the corresponding international application. The EPO separately addressed the novelty and inventive-step criteria, identified the documents applicable to each group of claims, and found that the examples in the application do not demonstrate an unexpected technical effect attributable to PEG, ethanol, or conventional excipients. The IPRP of 16/04/2024 maintained these conclusions prior to the application's entry into the Vietnam national phase on 08/05/2024.

IV. KEY PRIOR ART DOCUMENTS

Code	Document	Publication date	Relevant content
D1	Vietnam Application No. 1-2022-07118; WO 2021/209900 A1; PCT/IB2021/0530 46; priority date 15/04/2020	21/10/2021	Earlier-filed application by the same applicant. Discloses Formula Ia and Formula Id (Formula Id being identical to Formula Ib of the application under review); a PEG/ethanol/water system, PEG200/300/400, P188/P338, NaCl, sodium acetate/acetate buffer, in solution or suspension form, at concentrations of 50-500 mg/mL.

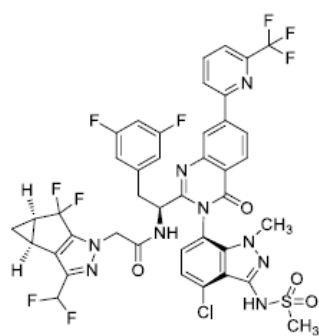
Code	Document	Publication date	Relevant content
D2	WO 2020/254985 A1	24/12/2020	Discloses exactly the compound of Formula Ib; examples include a 90% PEG400/10% ethanol solution and a 90% PEG400/5% ethanol solution; also discloses a subcutaneous injectable formulation of P188/PEG3350/mannitol/water.
D3	WO 2020/084492 A1	30/04/2020	Discloses exactly the compound of Formula Ia and an aqueous pharmaceutical preparation; used by the WOSA as a direct citation against claims 33 and 46.
D4	WO 2021/116872 A1	17/06/2021	Long-acting cabotegravir nanosuspension containing water, P338/P407, and mannitol, optionally free of PEG, with a particle size of approximately 0.2 μm , prepared by wet milling; also specifically identifies two capsid inhibitors (Ia/Ib) for combination use.
D5	Strickley, Pharmaceutical Research 21(2), 201-230	01/02/2004	General review of solvent systems used in injectable formulations: PEG300/400, ethanol, propylene glycol, sesame oil, benzyl alcohol, and lecithin/phosphatidylcholine.
N1	Trezza et al., Current Opinion in HIV and AIDS 10(4), 239-245	2015	Cabotegravir 200 mg/mL as an aqueous nanosuspension, approximately 200 nm in size, prepared by wet bead milling with mannitol/PEG3350/polysorbate 20, administered intramuscularly or subcutaneously.
N3	Rahnfeld & Luciani, Pharmaceutics 12, 567	2020	Review of lipid-based long-acting injectable formulations; confirms sesame oil and phospholipid/lecithin as known formulation platforms.
PCT	ISR, WOSA, and IPRP of PCT/IB2022/059780	2023-2024	Search results and direct assessment of the 68 claims of the PCT application, mapped to the 58 claims remaining in the Vietnam file.

V. CLAIMS LACKING NOVELTY

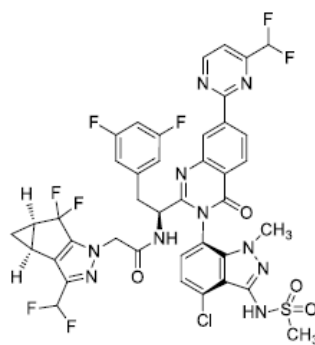
1. D1 / Vietnam Application No. 1-2022-07118 destroys novelty under Article 60.1(b)

D1 discloses not merely the same compound family. Claim 1 of D1 recites compounds of Formula Ia and Formula Id; on comparison of chemical structure, Formula Id of D1 is identical to Formula Ib of the application under review.

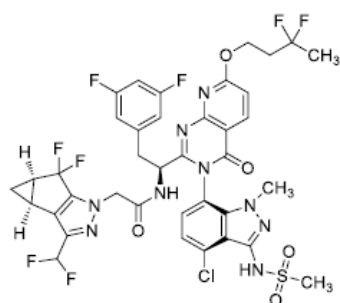
1. Dược phẩm bao gồm hợp chất có công thức Ia, công thức Ib, công thức Ic hoặc công thức Id:



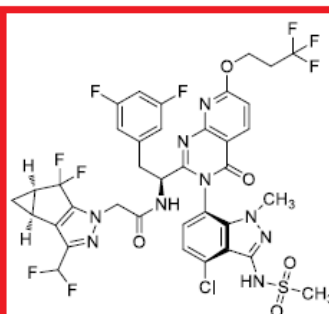
Công thức Ia



Công thức Ib



Công thức Ic



Công thức Id

hoặc muối được định của chúng và dung môi hoặc chất pha loãng được chọn từ nhóm bao gồm nước, rượu, polyetylen glycol (PEG), N-metyl-2-pyrrolidon (NMP), etyl lactat, propylen glycol, glycofurol và dimetylsulfoxit (DMSO).

Read together with its dependent claims, claims 1 and 5-8 of D1 disclose a formulation containing the above active ingredient together with water, PEG, and ethanol; claims 2-4 disclose P188/P338, NaCl, and both solution and suspension forms. The description of D1 further specifically discloses PEG200, PEG300, and PEG400; PEG3350 at a content below 1% by weight; sodium acetate and acetate buffer; and active-ingredient concentrations of approximately 300 mg/mL and approximately 280-320 mg/mL. D1 has therefore disclosed the core of both the PEG/ethanol branch and the aqueous suspension branch of the claim set under review.

Article 60.1(b) does not require that the earlier-filed application belong to a different applicant, nor that such document be published before the priority date of the application under review. Accordingly, the fact that D1 and Application No. 1-2024-03307 were both filed by ViiV Healthcare UK (No. 5) Limited, and the fact that WO 2021/209900 A1 was published after 13/10/2021, do not preclude reliance on this ground. Nevertheless, the assessment must be carried out separately for each claim: a claim is only unpatentable for lack of novelty where every technical feature of that claim is directly and unambiguously disclosed in D1 itself.

The following table directly compares D1 against the claims of Vietnam Invention Application No. 1-2024-03307:

Claim(s)	Feature at issue	Disclosed in D1	Proposed conclusion
1, 2, 17, 18	Ia/Ib + PEG + ethanol	D1: Formula Ia/Id; claim chain 1, 6, and 8.	Directly disclosed; refusal for lack of novelty is proposed.
3, 19	Addition of one or more excipients, including water	D1: claim chain 1, 5, 6, and 8 discloses water, PEG, and ethanol.	Directly disclosed under the aqueous embodiment.
8-10, 24-26	PEG200/300/400	D1 specifically names PEG200, PEG300, and PEG400; claim 7 separately names PEG300.	Directly disclosed; PEG300 is also recited in a dependent claim chain.
14, 30	Homogeneous solution	Claim 3 of D1 discloses solution form; read together with claims 1, 6, and 8.	A solution is a single-phase homogeneous system; not novel.
33, 34, 46, 47	Ia/Ib + water + less than 1% PEG	D1 discloses Ia/Id, water, and PEG3350 at a content below 1% in the description.	Directly disclosed in the description; consistent with the WOSA's finding.
35, 36, 48, 49	P338/P188, NaCl, or sodium acetate	Claim 2 and the description of D1 disclose P188, P338, NaCl, and sodium acetate/acetate buffer.	Each claim requires only one option from a list of alternatives to be disclosed; the corresponding portion lacks novelty.
37, 38, 50, 51	Sodium acetate + acetic acid; addition of mannitol/NaCl	D1 discloses sodium acetate, acetate buffer, and NaCl, but does not disclose mannitol; the acetic-acid component must be compared directly against the buffer system.	Fallback ground: a finding of lack of novelty requires that D1 directly disclose the complete acid/buffer system together with the corresponding dependent chain.
45, 58	Heterogeneous suspension	Claim 4 and the description of D1 disclose a suspension of Ia/Id.	Directly disclosed under the suspension embodiment.
Remaining claims	Ethanol/PEG ratios, lecithin, particle size, 5.4% P338, 3.5% mannitol	D1 does not fully disclose every quantitative feature in the same combination.	D1 alone is not relied upon to challenge novelty; D2-D5, N1, and N3 are used in the inventive-step assessment.

Based on the foregoing analysis and comparison table, we submit that claims 1-3, 8-10, 14, 17-19, 24-26, 30, 33-36, 45-49, and 58 fail to satisfy the novelty requirement under Article 60.1(b) of the Intellectual Property Law.

2. D2 directly discloses Formula Ib in a PEG400/ethanol system

D2 discloses exactly the compound of Formula Ib in Example 1. At page 41, lines 4-5, D2 describes an intravenous solution comprising 90% PEG400 and 10% ethanol, and an oral solution comprising 90% PEG400 and 5% ethanol. Accordingly, at least claims 2 and 18 are fully disclosed. Through the dependent chains from claims 2 and 18, D2 also discloses PEG400, an ethanol content within the range of 5-25%, and a homogeneous solution formulation. Claims 10, 11, 14, 26, 27, and 30 therefore also lack novelty within the corresponding scope.

D2 further describes, at page 43, lines 24-25, a subcutaneous injectable formulation comprising 1% Kolliphor P188, 1% PEG3350, 3.5% mannitol, and 94.5% water. This formulation is very close to the aqueous suspension group of the application under review. However, D2 states a PEG content of 1%, whereas claims 34 and 47 require “less than 1%.” We therefore do not rely on this example alone to conclude that claims 34 and 47 lack novelty, but rather use it as important evidence in the inventive-step assessment in Section VI.

3. D3 directly discloses Formula Ia in an aqueous formulation

D3 discloses exactly the compound of Formula Ia and an aqueous pharmaceutical preparation. Claims 33 and 46 recite a PEG content of “less than 1% by weight” without specifying a lower limit greater than zero. As currently drafted, a formulation containing no PEG (0%) would still fall within this scope. The WOSA reached a similar conclusion for at least claims 33 and 46. If the applicant intends for PEG to be mandatorily present, the current claim language does not reflect that limitation and could only be clarified by an amendment that does not go beyond the content originally disclosed.

4. Conclusion on novelty

The WOSA concluded that PCT claims 2, 3, 8-14, 18, 19, 24-30, 33, 34, 45-47, and 58-68 lack novelty. After deletion of claims 59-68 upon entry into the Vietnam national phase, the corresponding remaining claims are 2, 3, 8-14, 18, 19, 24-30, 33, 34, 45-47, and 58. Based on the file currently available, the clearest direct disclosures are: D2 in relation to claims 2, 10, 11, 14, 18, 26, 27, and 30; and D3 in relation to claims 33 and 46.

VI. ALL 58 CLAIMS LACK INVENTIVE STEP

1. Group A: PEG/ethanol co-solvent solutions (claims 1-32)

For the compound of Formula Ia, D3 is a suitable closest prior art; for the compound of Formula Ib, D2 is a suitable closest prior art. Both documents disclose exactly the active ingredient and a pharmaceutical preparation for use in HIV treatment. The main difference in the broadest claims lies in the PEG/ethanol co-solvent system. Within the limits of the experimental data in the application, the objective technical problem can only be defined as providing an alternative pharmaceutical formulation for a known capsid inhibitor. There is no basis to elevate the technical problem to “improved long-acting effect,” because the application contains no properly matched comparative test showing that such improvement stems specifically from the distinguishing feature.

- D2 directly shows that the compound of Formula Ib is soluble in a PEG400/ethanol system. Selecting among PEG200, PEG300, and PEG400 - members of the same polymer series differing only in molecular weight - is routine formulation work based on solubility, viscosity, injectability, and tolerability.

- D5 compiles numerous commercial injectable formulations, including systems containing up to 50% PEG300 and 20% ethanol; PEG300/PEG400, ethanol, and propylene glycol are all well-known co-solvents for injectable formulations. The application's ranges of 40-50% PEG and 5-25% ethanol therefore fall within a known formulation region.
- Optional excipients such as water, propylene glycol, benzyl alcohol, sesame oil, and lecithin/phosphatidylcholine are all common formulation ingredients. The file does not demonstrate any unexpected technical effect specifically attributable to the addition of each of these components.
- D5 further describes sesame oil and benzyl alcohol in intramuscular formulations, as well as typical injectable emulsions containing approximately 1% egg lecithin. N3 further confirms sesame oil and phospholipid/lecithin as known formulation platforms. The options recited in claims 3-7 and 19-23 therefore do not represent an inventive step.
- The specific ratios of 20/45/20/15 in claims 15, 16, 31, and 32 are merely selections within a finite formulation space. The application provides no evidence that these ratios produce a critical threshold or a synergistic effect.

2. Group B: aqueous nanosuspensions containing P338/mannitol (claims 33-58)

For this group, D3 and D2 respectively provide exactly the active ingredients of Formula Ia and Formula Ib, while D4 directly discloses a long-acting aqueous nanosuspension formulation platform for HIV treatment. The objective technical problem is to provide a stable, high-concentration, long-acting injectable aqueous suspension. D4 addresses precisely this problem; notably, D4 also specifically identifies “Compound 1” of WO 2020/084492 (Formula Ia) and “Compound 2” of PCT/IB2020/055653 (Formula Ib) as capsid inhibitors suitable for combination use. A formulator therefore has a clear technical basis and a reasonable expectation of success in applying this known formulation platform to the two active ingredients of the application under review

- D4 discloses a cabotegravir suspension at 350-600 mg/mL, P338/P407 at 4-50 mg/mL, mannitol at 15-40 mg/mL, PEG optionally at 0 mg/mL, a median particle size of 0.15-0.25 μm , and a wet bead milling process.
- Example 9 of D4 produces a suspension of approximately 500 mg/mL containing 35 mg/mL P338, 40 mg/mL mannitol, 0-40 mg/mL PEG3350, with a particle size of approximately 0.2 μm . This document also directly records the stability of particle size over storage time.
- N1, published in 2015, already described cabotegravir at 200 mg/mL as an aqueous nanosuspension with a particle size of approximately 200 nm, produced by wet bead milling in a system of mannitol, polysorbate 20, PEG3350, and water for injection, administered intramuscularly or subcutaneously.
- D2 additionally provides a subcutaneous formulation of P188/PEG3350/mannitol/water for the very compound of Formula Ib. On this basis, substituting P338 for P188, or adjusting the poloxamer, mannitol, and PEG content, is merely routine optimization among a finite set of already-indicated options.
- The values of 300 mg/mL, 5.4% P338, 3.5% mannitol, particle sizes of 0.2-0.5 μm or below 0.2 μm , and acetate buffer all lie within or very close to the known technical field. The file does not demonstrate a critical threshold or synergistic effect at these specific values.

3. The description does not demonstrate an unexpected effect

Examples A-K show that certain formulations can be prepared and were subjected to pharmacokinetic evaluation in mice. However, these results do not establish a causal relationship between any individual distinguishing feature and an unexpected technical effect relative to the closest prior art. Specifically:

- Multiple variables are changed simultaneously between formulations, so the results obtained cannot be attributed specifically to PEG type, ethanol ratio, P338, mannitol, or particle size.
- The pharmacokinetic studies primarily use a sample size of $n = 3$ and lack a properly matched comparative formulation - matched in active ingredient, content, route, and dose - representative of D2, D3, or D4.
- The application contains no excipient-by-excipient exclusion experiments, no comparative stability data, no data on plunger force or syringeability, and no statistical analysis sufficient to demonstrate the criticality of 40-50% PEG, 20% ethanol, 5.4% P338, 3.5% mannitol, or the claimed particle-size ranges.
- Data obtained from a limited number of individual formulations cannot reasonably be extrapolated to both active ingredients, all pharmaceutically acceptable salts, numerous optional excipients, and both physical states covered by the full scope of all 58 claims.

Accordingly, even the claims that the WOSA considered novel differ from the prior art only in the selection or quantitative adjustment of components. Such differences would be obvious to a person of ordinary skill in the field of pharmaceutical formulation, or amount merely to a simple combination of known technical solutions, falling within Article 21.3(c) of Consolidated Document No. 06/VBHN-BKHCHN of 2026.

Based on the foregoing analysis, we respectfully request that the Office conclude that all 58 claims fail to satisfy the inventive-step requirement under Article 61 of the Intellectual Property Law.

VII. DEFICIENCIES IN CLARITY, UNITY, AND SUPPORT

1. Claims with overlapping scope

Claim pairs 1/17, 2/18, 33/46, and 34/47 are not fully identical: the first claim in each pair covers both the free-form compound and pharmaceutically acceptable salts, while the second covers only the free-form compound. However, the entire scope of the second claim already falls within the scope of the first. Structuring eight independent claims around four overlapping subject matters makes the boundary of protection difficult to determine and fails to meet the requirement of concise, clear presentation consistent with the description under Article 12.8 of Consolidated Document No. 06/VBHN-BKHCHN of 2026. The WOSA also noted this deficiency.

2. The two formulation approaches do not share a single general inventive concept

The PEG/ethanol solution group and the aqueous nanosuspension group solve the formulation problem by two different mechanisms: one dissolves the active ingredient using a co-solvent system, while the other controls the solid phase and particle size using a surfactant. Formula Ia and Formula Ib are also two distinct compounds. The only remaining common element is the broad goal of creating a pharmaceutical product containing an HIV capsid inhibitor, while both the active ingredients and the two formulation platforms are already known. The WOSA concluded that the eight independent claims do not share a single special technical feature defining a general inventive concept. Accordingly, the application fails to satisfy the unity of invention requirement under Article 100.4 of the Intellectual Property Law.

VIII. CONCLUSION AND RECOMMENDATION

On the basis of all the legal and technical grounds set out above, we respectfully request that the Intellectual Property Office of Vietnam accept and consider this letter, and refuse all of claims 1-58 for failure to meet the standards for patent protection. Should the applicant be permitted to amend the application, we request that the applicant be required to

eliminate the overlapping scope, clarify the boundaries of protection, and demonstrate unity and adequate support across the entire scope of the claims.

We respectfully thank the Office for its consideration of this request.

Recipients:

- *As above;*
- *Archives*

Tran & Tran Intellectual Property Co., Ltd.
Director

Attached documents:

- *Copies of the cited prior-art documents*
- *Copy of the Power of Attorney*

TRAN QUANG PHUONG