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No: 2506/2026/CVHB-SC

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Hanoi, August 07, 2026

***To*: INTELLECTUAL PROPERTY OFFICE OF VIETNAM (IPVN)**
384-386 Nguyen Trai - Hanoi
Re: Explanation of the reason for requesting invalidation of Patent No. 1-0057835

Dear Department:

We, Tran & Tran Intellectual Property Co., Ltd., are an industrial property representative service organization, authorized by the **Action Center for People living with HIV,** located at Group 18, Ngoc Thuy Ward., Hanoi city to proceed with filing a request for invalidation of a Patent in Vietnam.

In this writing, we respectfully request the IP Vietnam to consider and invalidate the Patent (hereinafter referred to as "**the Patent**") with the following details:

Patent No.:	**1-0057835**
Granted date:	April 22, 2026
Vietnamese application No:	1-2023-00361
Title of invention:	DISPERSIBLE TABLET FORMULATIONS COMPRISING DOLUTEGRAVIR AND PROCESS FOR PREPARING THE SAME
Owner:	**VIIV HEALTHCARE COMPANY (US)**
Address:	251 Little Falls Drive, Wilmington, Delaware 19808, United States of America
PCT application No.:	PCT/IB2021/055533
PCT filing date:	June 23, 2021
Priority data:	UK Patent Application No. 2009684.8, filed on 25/06/2020

Specifically, we request to invalidate all claims (hereinafter referred to as "Claims") of the Patent No. 1-0057835 **(**or Patent No. **57835**) of the Owner **VIIV HEALTHCARE COMPANY** (hereinafter referred to as "**VIIV"**) is based on the following legal grounds and arguments:

1. Legal basis applied according to current regulations

Clause 1, Article 58 of the Law on Intellectual Property provides that an invention shall only be protected in the form of an Invention Patent if it simultaneously satisfies the requirements of novelty, inventive step and industrial applicability.

Clause 1, Article 60 provides that an invention is considered novel if it has not been publicly disclosed prior to the filing date or the valid priority date, whether by use, written description, or in any other form, domestically or abroad.

Clause 1, Article 61 provides that an invention possesses an inventive step if, on the basis of technical solutions already publicly disclosed before the filing date or priority date, the invention represents an inventive advance and cannot be easily created by a person of ordinary skill in the relevant technical field.

Point b, Clause 2, Article 96 provides that a protection title shall be wholly or partially invalidated if the industrial property subject matter fails to satisfy the conditions for protection set out in Article 8 and Chapter VII of the Law on Intellectual Property. The invalidated portion shall be deemed to have no effect from the date the title was granted.

The procedure for considering a request for invalidation shall be carried out in accordance with Article 96 of the Law on Intellectual Property, Article 32 of Decree No. 65/2023/ND-CP, and the guiding provisions of Circular No. 23/2023/TT-BKHCN.

Both Law No. 07/2022/QH15 and Law No. 131/2025/QH15 establish the principle that the grounds for invalidating a protection title shall be determined in accordance with the law in effect at the time the title was examined and granted. Invention Patent No. 1-0057835 was granted on 22/04/2026. Although the applicable milestone may be determined by reference to each stage of examination, the provisions directly relevant to this case, namely Point b, Clause 2, Article 96, and the standards on novelty and inventive step under Articles 58, 60, and 61 - have not changed in a manner that would alter the assessment result set out in this document.

2. Scope of the claims of Invention Patent No. 1-0057835

The claims of Invention Patent No. 1-0057835, granted in Vietnam, had their scope of protection narrowed based on amendments made to the claims of the corresponding Chinese patent No. CN115697344B. Specifically, the granted patent contains nine claims, including tablet claims 1-8 and process claim 11 of the corresponding Chinese patent; claims 9-10, which are dependent claims relating to function/use, and claim 12, which relates to the subject of use in the corresponding Chinese patent, have been deleted. The amended claims have been renumbered, with claim 1 as the independent claim for the preparation, claim 9 as the independent claim for the process, and claims 2-8 as dependent claims.

Claim No.	Main Technical Content	Claim Type
1	A dispersible tablet comprising dolutegravir or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable calcium ion, wherein the calcium ion is present at 1.8-2.6% w/w in the tablet core.	Independent - formulation
2	The tablet according to claim 1, wherein the dolutegravir or pharmaceutically acceptable salt thereof is dolutegravir sodium.	Dependent
3	The tablet according to claim 1 or 2, containing 5 mg free acid equivalent of dolutegravir.	Dependent

4	The tablet according to claim 1, containing a flavoring agent.	Dependent
5	The tablet according to claim 4, wherein the flavoring agent is present up to 2% w/w in the tablet core.	Dependent
6	The tablet according to claim 1, containing sucralose.	Dependent
7	The tablet according to claim 6, wherein sucralose is present up to 2% w/w in the tablet core.	Dependent
8	The tablet according to claim 1, having a coating layer.	Dependent
9	A process for preparing the dispersible tablet according to claim 1, comprising mixing dolutegravir or a pharmaceutically acceptable salt thereof with a pharmaceutically acceptable ion.	Independent - process

The core of the granted invention does not lie in the discovery of the active ingredient dolutegravir, nor in the use of dolutegravir for HIV treatment, nor in the concept of a dispersible tablet for pediatric patients. What remains as the core is merely the selection of a dispersible dolutegravir tablet formulation containing a calcium ion source - in particular, the content range of 1.8-2.6% w/w calcium ion in the tablet core - together with certain organoleptic excipients and conventional formulation operations.

3. Reference documents, background references, and principles for assessing the invention

i) Reference documents:

Since the earliest priority date of the invention is 25/06/2020, documents D1–D4 and NPL-1-NPL-2, which constitute prior art publicly disclosed before the priority date, all serve as prior art for assessing novelty and inventive step. The Written Opinion and the IPRP are not used as independent cited references; they are merely international examination documents of reference value, showing how the cited references were assessed by the competent examining authority.

Code	Reference documents	Publication Date	Directly Relevant Content
D1	WO 2015/140569 A1 (Cipla) - Pharmaceutical formulation	24/09/2015	Dolutegravir is an active ingredient classified under Class II of the Biopharmaceutics Classification System, having low solubility; oral dolutegravir formulations may be prepared in the form of dispersible tablets, using excipients such as disintegrants, superdisintegrants, surfactants, sweetening agents, flavoring agents, and coating agents; the document also describes a preparation process comprising granulation, tablet compression, and film coating steps.
D2	WO 2014/184553 A1 (Cipla) -	20/11/2014	Antiretroviral formulations may contain dolutegravir or a salt/derivative thereof;

Code	Reference documents	Publication Date	Directly Relevant Content
	Antiviral pharmaceutical formulation		dispersible tablets/tablets for suspension, conventional preparation processes and excipients.
D3	CA2897137A1/WO 2014/125124/US2016/030353 -Solid dosage form of dolutegravir (Ratiopharm/Teva)	21/08/2014 / 04/02/2016	Solid dosage form containing dolutegravir or a salt thereof and a compound containing an alkaline earth/alkali ion; magnesium or calcium preferred; calcium sulfate listed; compound content 0.5–15% w/w; describes mixing/wet granulation/tablet compression.
D4	US 2018/0280401 A1 -general technical document on oral dispersible dosage forms	04/10/2018	Flavoring and sweetening agents, including sucralose, are conventional choices for improving the organoleptic properties of oral dispersible formulations.
NPL-1	FDA 2020 and NDA approval letter 213983 for TIVICAY PD dispersible tablets (dolutegravir); together with the ViiV press release dated 12/06/2020	12/06/2020, published before the priority date of 25/06/2020	TIVICAY PD is a 5 mg dolutegravir sodium tablet for oral suspension; the tablet has a strawberry cream flavor and a film coating; excipients include calcium sulfate dihydrate and sucralose.
NPL-2	Buchanan et al., Clinical Pharmacology in Drug Development 2017, 6(6), 577-583	2017 article	A 5 mg dispersible dolutegravir tablet for pediatric patients has been developed; the study directly investigated the effect of water with low/high mineral content.

ii) Professional references

- TĐQT-1: Written Opinion of the International Searching Authority dated 12/12/2021 in respect of PCT/IB2021/055533.
- TĐQT-2: International Preliminary Report on Patentability dated 13/12/2022 in respect of PCT/IB2021/055533.

Although it is not technical reference documents, these are professional references showing that the original set of claims of the same patent family was assessed unfavorably with respect to novelty/inventive step.

iii) Principles for assessing novelty

Novelty is assessed with respect to the entire combination of features of each claim on the basis of a single cited reference. Multiple independent references are not combined to conclude a lack of novelty. A feature is considered disclosed only where the cited reference discloses it directly, unambiguously, or inevitably; an inference that is merely probable but not inevitable is insufficient to negate novelty.

For a dependent claim, all features of the claim on which it depends continue to form part of the scope of protection. Accordingly, the fact that an additional feature - such as "dolutegravir sodium," "5 mg," "sucralose," or "having a coating layer" - is already known does not automatically deprive the entire dependent claim of novelty if the quantitative feature of claim 1 has not been fully disclosed by a single reference.

iv) Principles for assessing inventive step

For inventive step, the combination of multiple sources of information is permitted where there is technical justification indicating that a person of ordinary skill would consider those sources together. In this patent invalidation request, the analysis follows a four-step approach:

(a) identifying the closest prior art;

(b) identifying the distinguishing features;

(c) identifying the objective technical problem solved; and

(d) assessing whether a person of ordinary skill, based on the prior art and common general knowledge, could have arrived at the claimed solution without inventive effort.

The selection of a narrow quantitative range within a broader known range can give rise to an inventive step only where the selected range is critical or produces an unexpected technical effect, demonstrated by appropriate comparative data at or around the endpoints. Merely stating a preferred formulation and its organoleptic acceptance results is insufficient to demonstrate the criticality of the entire claimed range.

4. Grounds for Requesting Invalidation of the Entire Validity of Patent No. 1-0057835

i) NPL-1 is a Direct Anticipatory Reference to the Claimed Product

NPL-1 discloses almost the entire formulation of TIVICAY PD prior to the priority date. NPL-1 refers to TIVICAY PD as an "oral tablet," each tablet containing 5.26 mg of dolutegravir sodium equivalent to 5 mg of dolutegravir calculated as the free acid. The tablet is described as white, round, strawberry cream-flavored, and film-

coated. The inactive ingredients of the TIVICAY PD tablet include calcium sulfate dihydrate, crospovidone, mannitol, microcrystalline cellulose, povidone K29/32, silicified microcrystalline cellulose, sodium starch glycolate, strawberry cream flavor, and sodium stearyl fumarate; the coating layer contains hypromellose, polyethylene glycol, and titanium dioxide.

Thus, prior to the priority date, the public already knew of a dolutegravir sodium 5 mg tablet intended for dispersion or reconstitution into an oral suspension, containing calcium sulfate dihydrate as a source of calcium ions, a flavoring agent, sucralose, and a film coating. This is a technical starting point very close to the claimed subject matter - considerably closer than references that merely refer generically to dolutegravir or generically to dispersible tablet forms.

NPL-1 alone discloses most of the core technical features of Claims 1 through 8, including: a tablet for preparing an oral suspension or a dispersible tablet; dolutegravir sodium; a 5 mg content; calcium sulfate dihydrate as a source of calcium ions; strawberry cream flavoring; sucralose; and a film coating.

The feature not specifically disclosed in NPL-1, relative to the claims, is the calcium ion content or the amount of calcium sulfate in the tablet core corresponding to a range of 1.8% to 2.6% by weight as recited in Claim 1 and its dependent claims. However, the selection of a content range of 1.8% to 2.6% by weight is, in substance, merely an adjustment and optimization of excipient ratios within an already-known formulation to achieve a suitable balance of taste, disintegration, dissolution, and compressibility. This constitutes routine experimentation and optimization work performed by a person of ordinary skill in the field of pharmaceutical formulation.

Therefore, the issue of lack of inventive step should be considered as an independent ground and should be assessed first, irrespective of whether the claimed subject matter is found to lack novelty.

ii) Cipla's D1 and D2 Destroy the Novelty of the "Dolutegravir-Containing Dispersible Tablet" Platform and Strongly Reinforce the Lack of Inventive Step:

D1 (WO 2015/140569 A1) clearly states that dolutegravir is an active substance with very low water solubility, classified under Class II of the Biopharmaceutics Classification System (BCS). For poorly soluble active substances, the use of dispersible forms, superdisintegrants, surfactants, sweeteners, flavoring agents, and granulation/compression/film-coating techniques represents a conventional formulation

approach. D1 discloses oral dolutegravir preparations in various forms, including tablets, disintegrating tablets, dispersible tablets, granules, and reconstitutable powders; Claim 13 of D1 explicitly recites "disintegrating tablet" and "dispersible tablet" forms.

D1 further lists suitable excipient categories such as disintegrants or superdisintegrants, carriers or diluents, sweeteners, flavoring agents, surfactants, and coating agents. The examples in D1 describe processes for preparing a suspension or emulsion containing dolutegravir and excipients, followed by homogenization or milling to nanoscale particle size, spraying the mixture onto excipients in a fluidized bed apparatus, drying, final blending with disintegrants and lubricants, followed by tablet compression and film coating. These teachings demonstrate that the formulation process recited in Patent No. 1-0057835 does not extend beyond the conventional techniques and operations that a person of ordinary skill in the field of pharmaceutical formulation could carry out.

D2 (WO 2014/184553 A1) discloses antiretroviral preparations that may contain dolutegravir or a pharmaceutically acceptable salt or derivative thereof, while listing suitable dosage forms including disintegrating tablets, dissolving tablets, dispersible tablets, orally disintegrating tablets, and tablets for preparing an oral suspension. D2 is particularly significant in that it directly addresses the need for ease of use, improved treatment compliance, overcoming swallowing difficulties, and improved patient acceptability, including for pediatric and elderly patients. These are precisely the same problems that the dolutegravir-containing dispersible tablet form seeks to address.

Accordingly, although D1 and D2 should not be combined to conclude that Claim 1 as a whole lacks novelty, they clearly demonstrate that the idea of formulating dolutegravir as a dispersible tablet/disintegrating tablet/tablet for oral suspension was no longer new. The remaining features - such as the selection of organoleptic excipients, tablet compression, film coating, or formulation adjustments to improve disintegration, dissolution, and palatability - all fall within the scope of routine formulation optimization.

iii) D3 Discloses the Very Selection of Calcium Sulfate and an Encompassing Content Range

D3 discloses a solid dosage form containing dolutegravir or a pharmaceutically acceptable salt thereof, combined with a compound containing an alkaline earth metal ion and/or an alkalizing compound. Among the alkaline earth metal ions, D3 prefers

magnesium or calcium, and specifically identifies calcium sulfate as one of the suitable compounds. D3 also specifies that the amount of the ion-containing compound may be selected by a person of ordinary skill in the field depending on requirements for dissolution rate or compressibility. The disclosed content range is from 0.5% to 15% by weight of the dosage form, preferably from 1% to 8%, and more preferably from 3% to 5%.

Where the calcium ion source is calcium sulfate dihydrate, calcium constitutes approximately 23.28% by weight of this salt. Accordingly, a calcium ion content of 1.8% to 2.6% by weight corresponds to approximately 7.73% to 11.17% by weight of calcium sulfate dihydrate in the tablet core. This entire converted range falls within the 0.5% to 15% by weight range for the ion-containing compound already disclosed in D3. D3 further specifies that the weight of the dosage form is calculated on the basis of the uncoated tablet, which in substance corresponds to the weight of the tablet core as recited in Claim 1 of Patent No. 1-0057835.

D3 also specifies that the amount of the ion-containing compound is not specifically limited and may be selected by the formulator according to product requirements. Meanwhile, NPL-1 explicitly names calcium sulfate dihydrate as an ingredient present in the TIVICAY PD 5 mg tablet. Therefore, testing several different content levels to determine a suitable ratio balancing dissolution, taste, disintegration, and compressibility requirements constitutes merely routine experimentation and optimization work by a person of ordinary skill in the field of pharmaceutical formulation.

iv) NPL-2 Demonstrates that the 5 mg Dispersible Tablet and the Issue of Water Mineral Content Were Already Known

NPL-2 is an article authored by the ViiV/GSK group itself prior to the priority date, studying the relative bioavailability of dolutegravir dispersible tablets and the effect of low-mineral/high-mineral water. NPL-2 uses a 20 mg dose in the form of four 5 mg dispersible tablets, directly evaluating dispersion in low-mineral/high-mineral water and a 30-minute waiting period after dispersion. Thus, a person of ordinary skill prior to the priority date already knew that: (i) dolutegravir dispersible tablets for pediatric patients had been developed; (ii) the 5 mg tablet unit was an actual dosage unit; and (iii) the effect of ions/minerals in the dispersion medium was an already-recognized technical issue.

5. The Patent's 9 Claims Do Not Meet the Patentability Requirements

i) Claim 1 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-1 discloses most of the features of Claim 1 within the same TIVICAY PD product, including a tablet for preparing an oral suspension, dolutegravir sodium, calcium sulfate dihydrate, a flavoring agent, sucralose, and a coating layer. D1 and D2 also directly disclose a dispersible tablet form containing dolutegravir. However, based solely on the content set forth in NPL-1, the calcium ion content of 1.8% to 2.6% by weight in the tablet core is not specifically stated in numerical terms. Therefore, Claim 1 can only be found to lack novelty if evidence establishes that the TIVICAY PD product disclosed prior to the priority date necessarily contained calcium ions within this range, or if it is determined that the above quantitative feature is an inherent characteristic of the already-disclosed product.

Regarding inventive step: Even assuming that Claim 1 retains formal novelty because the calcium ion content range of 1.8% to 2.6% is not directly stated in NPL-1, Claim 1 still fails to meet the requirement of inventive step. NPL-1 may be regarded as the closest prior art reference, as it discloses almost the entire basic structure and composition of the product. The sole remaining distinguishing feature is, in substance, merely the determination of the calcium ion content in the tablet core.

In this case, the technical problem to be solved is simply the selection of a suitable amount of a calcium-ion-providing compound within an already-known dolutegravir-containing dispersible tablet, in order to adjust dissolution, taste acceptability, and other properties required during formulation. D3 clearly discloses the use of a compound containing an alkaline earth metal ion, including calcium sulfate, in a solid dosage form containing dolutegravir, and discloses a content range encompassing the range corresponding to Claim 1 after conversion. D1 and D2 further provide the technical basis for the dolutegravir-containing dispersible tablet form, while NPL-2 shows that the 5 mg dolutegravir dispersible tablet, as well as the effect of minerals or ions present in water on this product, were already known prior to the priority date.

Accordingly, the selection of the calcium ion content range set forth in Claim 1 is merely the result of applying guidance already present in the prior art, combined with routine formulation experimentation and optimization. This selection does not

constitute an inventive technical advance, and therefore Claim 1 fails to meet the requirement of inventive step.

ii) Claim 2 Does Not Meet the Patentability Requirements

Regarding novelty: The feature of dolutegravir sodium is directly disclosed by NPL-1 in the TIVICAY PD product itself. D1 and D3 also refer to dolutegravir in the form of a pharmaceutically acceptable salt, including the sodium salt. Therefore, the additional feature of Claim 2 does not create a new technical feature relative to the known prior art.

Regarding inventive step: The sodium salt of dolutegravir is an already-known salt form that has been used in a commercial pharmaceutical product. The selection of dolutegravir sodium for use in the dispersible tablet does not produce any unexpected technical effect or particular technical advantage, but is merely the use of a conventional salt form of an already-known active substance. Since Claim 2 is dependent on Claim 1, and the additional feature of Claim 2 was also disclosed prior to the priority date, Claim 2 fails to meet the requirement of inventive step.

iii) Claim 3 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-1 discloses that each TIVICAY PD tablet contains 5.26 mg of dolutegravir sodium, equivalent to 5 mg of dolutegravir calculated as the free acid form. NPL-2 also refers to a 20 mg dose administered as four dispersible tablets, each containing 5 mg of dolutegravir. Thus, the feature of a 5 mg content set forth in Claim 3 was disclosed prior to the priority date and does not create a new technical feature relative to the known prior art.

Regarding inventive step: The patent specification does not demonstrate that the selection of a 5 mg content per tablet produces any unexpected technical effect or particular technical advantage. This is a dosage level for pediatric patients that was disclosed prior to the priority date both in the TIVICAY PD product and in studies related to dosage forms and the use of dolutegravir. Therefore, the additional feature regarding the 5 mg content is merely the application of an already-known dosage unit and cannot render the subject matter of Claim 3 inventive, given that Claim 1, upon which it depends, already fails to meet the requirement of inventive step.

iv) Claim 4 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-1 discloses that the TIVICAY PD tablet contains a strawberry cream flavoring agent. D1 and D2 also list flavoring agents as a conventional

class of excipients used in oral preparations. D4 further shows that the use of flavoring agents is a conventional option for oral dosage forms, particularly dispersible tablet forms. Therefore, the additional feature of Claim 4 was already known prior to the priority date and does not create a new technical feature relative to the prior art.

Regarding inventive step: Dolutegravir has an unpleasant taste, which is particularly disadvantageous for dosage forms intended for children. Adding a flavoring agent to mask taste and improve patient acceptability is a conventional formulation measure that has been widely applied to oral preparations, especially dispersible tablets. The selection of a flavoring agent in this case does not produce any unexpected technical effect or particular technical advantage. Therefore, the additional feature of Claim 4 does not give rise to an inventive step, and Claim 4 fails to meet the requirement of inventive step.

v) Claim 5 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-10 discloses that the TIVICAY PD tablet contains a strawberry cream flavoring agent but does not specify the content of the flavoring agent in the tablet core. Therefore, absent documentation or evidence establishing the flavoring agent content in the TIVICAY PD product as disclosed prior to the priority date, there is insufficient basis to conclude that the quantitative feature of Claim 5 lacks novelty. Accordingly, Claim 5 is more appropriately assessed primarily from the standpoint of inventive step.

Regarding inventive step: The limitation "up to 2% by weight" is a broad range, encompassing any amount of flavoring agent not exceeding 2% by weight of the tablet core. For an already-known oral preparation containing a flavoring agent, adjusting the amount of flavor within a suitable range to achieve the desired taste-masking and organoleptic properties is merely routine experimentation and optimization work performed by a person of ordinary skill in the field of pharmaceutical formulation. The patent specification also fails to demonstrate that the 2% limit produces any critical, unexpected, or superior technical effect compared to other content levels. Therefore, the additional feature of Claim 5 does not give rise to an inventive step, and Claim 5 fails to meet the requirement of inventive step.

vi) Claim 6 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-1 discloses that sucralose is a pharmacologically inactive ingredient in the TIVICAY PD tablet. D4 also discloses sucralose as a suitable

sweetening agent for use in oral preparations, particularly dispersible forms. Therefore, the feature of using sucralose in this claim was already known prior to the priority date and does not create a new technical feature relative to the prior art.

Regarding inventive step: Sucralose is a high-intensity sweetener commonly used in oral preparations to mask the unpleasant taste of active substances and improve patient acceptability, particularly for pediatric medicines. Accordingly, selecting sucralose as the sweetening agent in a dolutegravir-containing dispersible tablet is merely a conventional excipient selection that a person of ordinary skill in the field of pharmaceutical formulation could readily make. The specification also fails to show that the use of sucralose produces any unexpected technical effect or particular technical advantage. Therefore, this additional feature does not give rise to an inventive step and cannot render the claimed subject matter inventive.

vii) Claim 7 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-1 discloses that the TIVICAY PD tablet contains sucralose but does not specify the sucralose content in the tablet core. Therefore, absent further documentation or evidence establishing the sucralose content in the product as disclosed prior to the priority date, there is insufficient basis to conclude that the quantitative feature of Claim 7 lacks novelty. Accordingly, Claim 7 is more appropriately assessed primarily from the standpoint of inventive step.

Regarding inventive step: The limitation "up to 2% by weight" encompasses any amount of sucralose not exceeding 2% by weight of the tablet core. For an already-known oral preparation containing sucralose, adjusting the content of this sweetening agent to achieve a suitable balance of sweetness, aftertaste, powder blend flowability, compressibility, and tablet disintegration is merely routine experimentation and optimization work performed by a person of ordinary skill in the field of pharmaceutical formulation. The patent specification also provides no data demonstrating that the 2% limit is a threshold of particular technical significance or produces an unexpected effect. Therefore, the additional feature of Claim 7 is, in substance, merely the optimization of the content of an already-known excipient and does not give rise to an inventive step.

viii) Claim 8 Does Not Meet the Patentability Requirements

Regarding novelty: NPL-1 discloses TIVICAY PD in the form of a film-coated tablet; the coating layer composition includes hypromellose, polyethylene glycol, and

titanium dioxide. D1 also clearly states that dolutegravir-containing tablets may be film-coated. Thus, the feature of having a coating layer in Claim 8 was clearly disclosed prior to the priority date and does not create a new technical feature relative to the known prior art.

Regarding inventive step: Film coating is a conventional formulation technique, commonly used to improve organoleptic properties, increase stability, aid tablet identification, and provide greater convenience in manufacturing, storage, and use. Applying a film coating to the dolutegravir-containing dispersible tablet is merely a conventional technical measure that a person of ordinary skill in the field of pharmaceutical formulation could readily select. The patent specification also fails to show that this coating layer produces any unexpected technical effect or particular technical advantage relative to the known prior art. Therefore, the additional feature of Claim 8 does not give rise to an inventive step, and Claim 8 fails to meet the requirement of inventive step.

ix) Claim 9 Does Not Meet the Patentability Requirements

Regarding novelty: Claim 9 has a very broad scope of protection, essentially requiring only the step of mixing dolutegravir or a pharmaceutically acceptable salt of dolutegravir with a suitable pharmaceutical ion source. D3 discloses a method for preparing a solid dosage form containing dolutegravir, in which dolutegravir or a pharmaceutically acceptable salt or solvate form thereof is mixed with a compound containing an alkaline earth metal ion and/or an alkalizing compound, after which the mixture may be wet-granulated and compressed into tablets. D1 also describes formulation steps including preparing a suspension, spraying, drying, final blending, adding a lubricant, tablet compression, and coating. Therefore, in view of the broad scope of Claim 9 as granted, the principal technical steps of this process were disclosed in the prior art before the priority date. Accordingly, Claim 9 fails to meet the requirement of novelty, or at minimum contains no technical feature that differs in any meaningful way from D3.

Regarding inventive step: In any event, the process of Claim 9 consists, in substance, merely of blending the active substance with an ion-providing compound and suitable excipients during the tablet manufacturing process. These are basic and conventional operations in tablet formulation technique. D3 clearly discloses blending dolutegravir with a compound containing an alkaline earth metal ion, while D1 discloses

the subsequent steps of granulation, drying, blending, addition of a lubricant, tablet compression, and coating. Based on this guidance, a person of ordinary skill in the field of pharmaceutical formulation could construct and carry out the process of Claim 9 using conventional technical operations without requiring any inventive contribution. Therefore, Claim 9 fails to meet the requirement of inventive step.

6. Reference Value of the International Examination Documents

The Written Opinion dated December 12, 2021, and the IPRP dated December 13, 2022, issued with respect to application PCT/IB2021/055533, do not constitute prior art references in the technical sense, and they have no binding effect on the Intellectual Property Office of Vietnam. Nevertheless, they serve as directly relevant professional reference material concerning the same patent family, showing that during the international phase, the original set of claims was previously assessed unfavorably with respect to novelty and/or inventive step.

The fact that the applicant narrowed the scope of the claims in certain countries - including a narrowing direction corresponding to Chinese Patent No. CN115697344B - does not automatically give rise to inventive step. The remaining scope after narrowing centers principally on the selection of the calcium ion source, the calcium ion content, the 5 mg dosage unit, sucralose, the flavoring agent, and the coating layer. However, these features were either directly disclosed or were clearly indicated by the prior art before the priority date. Accordingly, such narrowing of claim scope is not, by itself, sufficient to demonstrate that the remaining subject matter possesses an inventive step.

7. Conclusion and Recommendation

On the basis of the legal grounds, technical analysis, and evidence set forth above, it can be seen that Patent No. 1-0057835 does not represent a genuine technical contribution beyond what was already known in the prior art before the priority date. Specifically, the TIVICAY PD product had already disclosed nearly the entire actual composition of a tablet containing 5 mg of dolutegravir sodium for preparing an oral suspension; D1 and D2 had disclosed the technical foundation for dispersible tablet, disintegrating tablet, and tablet-for-oral-suspension forms containing dolutegravir; D3 had disclosed combining dolutegravir with a compound containing an alkaline earth metal ion, including calcium sulfate, with a content range encompassing the range corresponding to the claimed calcium ion content; and NPL-2 had disclosed a

dispersible tablet containing 5 mg of dolutegravir, as well as the effect of minerals or ions present in water on the use of this dosage form.

The calcium ion content range of 1.8% to 2.6% by weight in the tablet core has not been shown to be a range of critical technical significance, nor has it been shown to produce an unexpected technical effect relative to already-known content ranges. The remaining features - including dolutegravir sodium, the 5 mg dosage unit, the flavoring agent, sucralose, the content limits of the taste-related excipients, the coating layer, and the blending step - are all ingredients, parameters, or formulation operations that were already known or that fall within the scope of routine selection and optimization by a person of ordinary skill in the field of pharmaceutical formulation.

Accordingly, we respectfully request that the Intellectual Property Office review and re-examine the content of Patent No. 1-0057835, and issue a decision invalidating the Patent in its entirety pursuant to Point b, Clause 2, Article 96 of the current Law on Intellectual Property, on the grounds that Claims 1 through 9 fail to meet the conditions for patentability at the time the Patent was granted.

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

Tran & Tran Intellectual Property Co., Ltd
Director

Recipients:
- *As above;*
- *Archives*

Attached documents:
- Copies of Documents D1–D4;
- Copies of Non-Patent Literature NPL-1 and NPL-2.

TRAN QUANG PHUONG