

Notes on April 23, 2024 Decision by Colombia Superintendence of Industry and Commerce regarding the Compulsory License on Dolutegravir

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Draft, April 25, 2024

These notes concern the document:

[REPÚBLICA DE COLOMBIA SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Resolución N° 20049 Ref. Expediente N° NC2024/0001417](#)

Table of contents

Brief Overview	1
Full Summary of Resolution No. 20049	2
Summary of Decision	2
I. Competence of the Superintendence of Industry and Commerce	3
II. Applicable Regulations	3
III. Statement of the Owners of the Patented Invention	4
1. Government Use Modality	4
2. The Notice	6
3. Methodology for Calculating Compulsory License Compensation	6
3. [sic] Ministry of Health Capacity	8
IV. Documentary Evidence Provided by the Owners of the Patented Invention	8
V. Final Arguments or Statements	9
VI. Conclusions of the Superintendency of Industry and Commerce	10
RESOLVES	10

Brief Overview

The resolution, numbered 20049, outlines the decision made by the Superintendence of Industry and Commerce regarding the compulsory license for a patent involving the medication dolutegravir. This decision follows a declaration by the Ministry of Health and Social Protection, citing public interest reasons. The license permits governmental use of the medication to address health concerns, particularly regarding HIV/AIDS treatment, through the provision of generic medication to affected populations.

Quick overview:

- **Competence of the Superintendence:** The Superintendence's authority to grant compulsory licenses is established by relevant statutes, including Andean Community regulations and domestic laws. The Superintendence has the autonomy to define the scope, duration, compensation, and other conditions of the license based on arguments presented by both the applicant and patent holders.
- **Applicable Regulations:** The application for a compulsory license is based on Andean Community regulations allowing licenses for public interest reasons. The Ministry's declaration of public interest is supported by existing legal provisions, and the Superintendence's decision adheres to these regulations.
- **Statement of the Owners of the Patented Invention:** The patent holders' representative raises objections regarding the legality of the governmental use modality and procedural errors. However, the Superintendence defends the use of public interest reasons and clarifies that the process follows Andean Community law.
- **Methodology for Calculating Compensation:** The patent holders' representative challenges the proposed methodology for compensation, arguing that it lacks consideration of crucial factors and may underestimate the patent's value. The Superintendence defends the chosen methodology, asserting its adherence to international standards and is specific to the Colombian context.
- **Ministry of Health Capacity:** The patent holders raised concerns about the Ministry's capacity to comply with the license conditions. However, the Superintendence clarifies that the Ministry has the legal authorization for medication acquisition and importation, aligning with Colombia's healthcare objectives.
- **Documentary Evidence Provided by Owners of the Patented Invention:** The evidence provided by the patent holders' representative is deemed admissible but does not decisively affect the license conditions. The Superintendence emphasizes that the license issuance is driven by public interest, and compensation determination considers relevant factors.
- **Conclusions of the Superintendency:** The resolution grants the compulsory license to the Ministry of Health and Social Protection for governmental use, outlining the conditions, term, and compensation details. The decision is made in accordance with relevant regulations and becomes effective upon enforceability.

Full Summary of Resolution No. 20049

The following summary follows the same format used in the Resolution.

Summary of Decision

The Superintendence of Industry and Commerce, exercising legal authority under relevant statutes, grants a compulsory license for a patent involving dolutegravir for public interest reasons, following a declaration by the Ministry of Health and Social Protection. The license is intended for governmental use to address health concerns, including providing generic medication for various affected populations. The Superintendence, following established procedures, accepted and processed the Ministry's request, allowing both parties to present arguments and evidence. After due consideration, a decision was made to grant the compulsory license, taking into account all relevant factors and submissions.

I. Competence of the Superintendence of Industry and Commerce

The Superintendence of Industry and Commerce is empowered by Article 2.2.2.24.7 of Decree 1074 of 2015 to make substantive decisions regarding compulsory license applications. Additionally, according to Article 3, Section 24 of Decree 4886 of 2011, the Superintendence has the authority to grant compulsory licenses. This administrative decision falls within the scope of Article 65 of Decision 486 of the Andean Community Commission, which assigns to the Competent National Office the task of determining the scope and terms of compulsory licenses for patents after declaring reasons of public interest. The Superintendence must assess whether the Ministry of Health and Social Protection's application for a compulsory license for governmental use meets the requirements outlined in the notice published on January 31, 2024, and the rules defined in the Circular Única of the Superintendence. In this process, the Superintendence exercises autonomy to define the scope, duration, compensation, and other conditions of the compulsory license based on the arguments presented by both the applicant and the patent holders.

II. Applicable Regulations

The application for the compulsory license under review was based on the provision established by Article 65 of Decision 486 of the Andean Community Commission, which grants licenses for reasons of public interest. As articulated in Prejudicial Interpretation 114-IP-2019 of the Andean Community Court of Justice, this flexibility aims to strike a balance between the general interest protected by the competent authority and the private interest held by the patent holder. Decree 1074 of 2015 mandates that the competent administrative authority must declare, through a duly motivated administrative act, the existence of reasons of public interest to subject a patent to a compulsory license. In this case, the Ministry of Health and Social Protection of the Republic of Colombia declared the existence of reasons of public interest over the patent with certificate No. 1887, granted under application No. 07115501A, through Resolution No. 1579 of October 2, 2023, an administrative act that is currently final and duly executed. Furthermore, it should be noted that within the present procedure, this Superintendence determined, in accordance with the authority granted to it by Article 65 of Decision 486 of 2000 and Article 2.2.2.24.7 of Decree

1074 of 2015, the economic compensation that the patent holders will receive as a result of the license.

III. Statement of the Owners of the Patented Invention

Based on the arguments submitted, the Superintendence groups them into four themes.

1. Government Use Modality

The legal representative of the rights holders argues that the Andean legal framework lacks provisions for government use and that such a concept is not developed within domestic legislation. They contend that the Ministry of Health and Social Protection's position during the administrative procedure leading to the declaration of public interest reasons, culminating in Resolution No. 1579 on October 2, 2023, was accepted without question by this Superintendence, despite the absence of a defined governmental use modality within the Andean industrial property framework.

Moreover, they assert that compulsory license types are clearly defined in Chapter VII of Andean Community Decision 486, and they do not include the modality of "non-commercial governmental use." They argue that although the Andean Court of Justice has interpreted a public interest reason as non-commercial public use, this interpretation does not constitute regulation within the Andean legal framework, nor can existing provisions be adapted to such a concept.

The Superintendence writes that to understand this issue, it's crucial to recognize the rationale behind flexibilities to patent rights. The Superintendence goes on to explain that intellectual property systems aim to benefit society by rewarding innovators by granting them exclusive rights. However, these rights cannot be absolute, and there are situations where they must be limited to mitigate adverse effects. Various intellectual property regulations worldwide, including those predating the TRIPS Agreement, provided for cases where authorizations for use and exploitation could be granted without the consent of rights holders.

During the negotiation of the TRIPS Agreement, member states agreed to include provisions ensuring a balance between the interests of intellectual property rights holders and society in special situations called "flexibilities." These flexibilities represent instances where rigorous protection can be relaxed to achieve a balance of rights and interests.

In the context of the ongoing procedure, this Supervisory Authority, acting as the National Competent Office, has adhered to the principle of the primacy of Community Law. This principle constitutes an essential characteristic and a basic requirement for the construction of a comprehensive and uniform interpretation of Andean decisions. Under this principle, the Andean Court of Justice has recognized that Member States have a supranational norm as a source to

regulate their activities, without such circumstance implying subordination of Community Law, as the Andean legal system prevails in its application over domestic norms.

Regarding the alleged creation of a compulsory license modality not provided for in Community Law, the Superintendence recalls the interpretation provided in the preliminary interpretation IP-144-2019, which broadened the scope of "public interest" to include other reasons qualifying as public interest, such as non-commercial public use and the need for specific products, including medications. Therefore, the ongoing discussion revolves around the designation of the license being processed, with patent holders claiming the existence of an atypicality and the purported creation of a non-existent cause in the Community regime. However, the Superintendence concludes that their argument lacks merit since Andean legislation, while providing three conceptually distinct reasons for public interest, also recognizes "other reasons qualifying as public interest," such as non-commercial public use and the need for population access to certain products, both of which are applicable in this case.

Moreover, the legal representative of the patent holders contends that although the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) are part of Colombian domestic law, they cannot be directly applied without regulatory or normative development, as this would disregard the autonomy principle of the Andean legal system. The Superintendence notes that it's crucial to reaffirm that the essence of the ongoing procedure is a compulsory license for public interest reasons, which, as previously mentioned, falls within the scope of Article 65 of Andean Decision 486. Thus, the designation of a non-commercial governmental use arises from the need to grant access to products, specifically ensuring access to medications for treating various conditions, including HIV/AIDS.

Additionally, the legal representative argues procedural errors in the publication of notices, claiming that certain requirements were omitted. However, these requirements were not included because they do not apply to a compulsory license for public interest reasons. The purpose of the Ministry of Health and Social Protection's declaration is to enhance the efficiency of the healthcare system, ensuring Colombian citizens' full access to the fundamental right to health, particularly for those affected by HIV/AIDS, constituting a public interest pursued by the Colombian State. Therefore, the argument presented by the patent holders' representative lacks substance, as the procedure adheres to Andean Community Law and fulfills the objectives set forth.

The legal representative of the patent holder's emphasizes the need to adhere strictly to Colombian law and questions the validity of certain procedures, such as the "government non-commercial use" modality. They argue that any deviation from established Colombian legal procedures could violate constitutional principles and undermine the rights of citizens. In response, the Superintendence clarifies that the process is guided by Andean Community law, particularly Decision 486, which allows for compulsory licenses for reasons of public interest. They highlight the importance of considering public interest when issuing such licenses, especially in cases involving vital medications like those for treating HIV/AIDS.

The attorney further raises concerns about the fairness of the compensation process and the legality of certain requirements outlined in the Circular Única of the Superintendence. They contend that these requirements are not applicable to licenses granted for public interest reasons. The Superintendence reiterates that the process follows the guidelines set forth in Decision 486 and the Circular Única ensuring that the issuance of compulsory licenses is in line with Andean Community law. They emphasize the importance of prioritizing public interest and ensuring access to essential medications for vulnerable populations.

2. The Notice

The attorney representing the patent holders begins by pointing out inconsistencies in the administrative procedure, arguing that the process outlined in the Circular Única of the Superintendence was not followed. They highlight that the compensation proposal was not requested from the applicants, and the arguments proposed by their clients were not analyzed in determining the compensation. They assert that the unilateral determination of the compensation amount by the Superintendence violates due process.

In response, the Superintendence reiterates that the requirements outlined in the Circular Única do not align with the essential criterion of a compulsory license for reasons of public interest. They emphasize that the purpose of the requirements in the Circular Única is different and does not consider the broader public interest, such as ensuring access to medication for HIV/AIDS patients.

Regarding the determination of compensation, it's clarified that there is substantial flexibility in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) concerning this issue. However, the establishment of "adequate" remuneration has been subject to debate and judicial interpretation. Various methodologies for determining royalties have been proposed by organizations like the World Health Organization (WHO) and the United Nations Development Programme (UNDP).

The Superintendence asserts its authority, stating that it has the competence under Article 65 of Andean Decision 486 and Decree 1074 of 2015 to set the amount and conditions of economic compensation for compulsory licenses issued for public interest reasons.

3. Methodology for Calculating Compulsory License Compensation

This section of the decision discusses a dispute over the methodology used to calculate compensation for a compulsory license, specifically focusing on patent 07115501A. The representative of the patent holders raises several objections, asserting that the methodology, outlined in the document "Methodology for Calculating Compensation for Compulsory Licensing for Patent 07115501A" by the Economic Studies Group of the Advisory Office for Planning of the Superintendence, contains inaccuracies and fails to consider crucial factors. They argue that the

methodology's reliance solely on the value in Colombian pesos is flawed, as it overlooks other relevant variables.

Furthermore, the representative of the patent holders contend that the proposed methodology results in a fixed compensation value in pesos, determined based on product sales value, which they argue should be variable due to market dynamics. They also challenge the notion of fair compensation, claiming that it disregards the legitimate interests of the patent holders. They criticize the use of methodologies based on a Japanese model, which sets royalty rates between 2% and 4%, arguing that it does not adequately consider the unique characteristics of the dolutegravir-containing medications or the Colombian market.

Specifically, they highlight concerns regarding the base compensation rate of 4%, arguing that it does not necessarily align with the patent holders' interests and may underestimate the true value of the patent. They propose that adjustments should be made to account for factors such as the therapeutic capacity of dolutegravir, its market innovation, and Colombia's socioeconomic context, which they argue warrant a higher compensation rate.

Additionally, they challenge the methodology's basis for determining the compensation rate, questioning the justification for selecting specific values and suggesting that it lacks a clear mathematical rationale. They argue that factors such as the cost of product development, research and development investments, and public health emergencies should be considered in setting the compensation rate.

In response, the Superintendence of Industry and Commerce defends the chosen methodology, asserting that it adheres to the guidelines of the Japan Patent Office (JPO) and considers principles of sustainability, universal access to health, legitimacy, and flexibility. The Superintendence argues that the base compensation rate of 4% was determined based on the expected profitability of the medication, with adjustments made to reflect market realities and the importance of dolutegravir in treating HIV.

Moreover, the Superintendence provides statistical evidence to support their decision, citing data on the sales performance of dolutegravir-containing medications and their significant contribution to specialized medication sales. They also emphasize the importance of considering Colombia's unique socioeconomic conditions and healthcare landscape in determining the compensation rate.

Regarding the objections raised by the patent holders' representative, the Superintendence rebuts the claims, arguing that the proposed methodology is robust and well-supported by market data and international standards. They assert that the chosen compensation rate is reasonable and reflects the value of the patent in the Colombian context.

The Superintendence maintains that the methodology used to determine the compensation for the compulsory license is appropriate and justified, dismissing the objections raised by the

patent holders' representative as unfounded. They assert that the chosen methodology aligns with international best practices and accurately reflects the market realities of Colombia.

3. [sic] Ministry of Health Capacity

Representatives of the patent holders indicate that the Ministry of Health does not have the real capacity to comply with the established conditions, which translated into having the capacity to import and or manufacture generic antiretroviral drugs.

The superintendency notes that this is based on an assessment that ignores the compensation proposal and ignores the request which clearly states the method for control and monitoring of mg manufactured or imported.

In a second point, the representatives argue that there was not evidence that proves that an attempt has been made previously and without success to obtain a contractual or voluntary license with his authorized parties under conditions and reasonable terms.

However, this is not relevant in this case. The requirement to exhaust the voluntary license was not mandatory. However, the Ministry did so, which warned the competent authority that declared the existence of reasons of public interest did exhaust the possibility of obtaining a voluntary license or contractual license with the owner of the invention patent.

In a third point, the representatives indicated that the MoH does not inform how it expects to acquire the medicine to import it or through whom it intends to manufacture it.

The superintendency finds that in accordance with art. 71 of Law 1753 of 2015, the MoH does have the legal authorization in terms of its competence to carry out the acquisition and import of the products that are protected by the patent on which the granting of the CL is expected.

IV. Documentary Evidence Provided by the Owners of the Patented Invention

The Superintendency acknowledges that the documentary evidence provided by the patent holders' representative is admissible, as there's no specific legal provision dictating the means for proving such matters. It's deemed relevant as it aims to present a more favorable scenario regarding compensation, directly related to the subject matter of the proceeding.

While the evidence doesn't fully clarify the alleged impact claimed by the patent holders' representative, it was considered in the evaluation, not leading to the Ministry's request. The purpose of the evidence is to demonstrate what the patent holders consider as infringement on their legitimate interests and disregard for other licensing exercises related to dolutegravir. Therefore, the evidence should be analyzed logically and critically.

However, the Ministry argues that the evidence provided doesn't directly relate to the compulsory license process in Colombia, as it concerns sublicensing agreements not involving Colombia as a beneficiary for adult medication. They claim that the terms of these agreements are solely determined by the patent holder, thus not reflecting a negotiated agreement.

The Superintendency clarifies that the compulsory license process is driven by public interest, and while the evidence provided may inform compensation determination, the ultimate decision is based on relevant factors. The terms of sublicensing agreements, where Colombia is not included, aren't directly applicable to the compulsory license context.

The Superintendency concludes that the evidence provided doesn't decisively affect the conditions required by the Ministry for the compulsory license. While the evidence suggests alternative compensation models, it doesn't discredit the proposed annual payment, which is deemed valid and not prejudicial to the patent holders' interests.

V. Final Arguments or Statements

The Superintendency acknowledges the final arguments presented by both the Ministry of Health and Social Protection and the patent holders' representative. The Ministry argues that the compulsory license for government use is legally defined in Colombia's framework, referencing the Law 170 of 1994 and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), highlighting the importance of balancing patent rights with public health interests. They assert that the government use provision is also recognized in Andean legislation, specifically through a precedent set by the Andean Tribunal of Justice.

Regarding the process timeline, the Ministry explains the delay in proceeding with the application until the administrative act declaring the public interest became final. They also mention the suspension of terms due to the previous Superintendence's recusal and the subsequent appointment of an ad-hoc Superintendence.

Concerning compensation, the Ministry defends its proposal for annual payment based on budgetary constraints and the total volume of medication supplied in Colombia, emphasizing it's not for direct patient supply.

In response, the patent holders' representative reiterates their initial arguments, questioning the legality of the process and criticizing the compensation terms proposed by the Ministry. They argue that the government's proposal doesn't align with fair compensation principles and dispute the relevance and validity of the evidence provided by the Ministry.

The Superintendency will now consider these final arguments to reach a conclusion regarding the compulsory license application.

VI. Conclusions of the Superintendency of Industry and Commerce

Context and Legal Framework: The section begins by referencing Decision 486 of the Andean Community Commission and its interpretation regarding compulsory licenses for governmental use due to public interest reasons. It also mentions the regulations outlined in Chapter 24 of Decree 1074 of 2015, which establish the procedure for subjecting a patent to a compulsory license for public interest reasons.

Justification for Compulsory License: The Ministry of Health and Social Protection declared public interest reasons for subjecting a patent to a compulsory license for governmental use, specifically for the medication Dolutegravir. This decision was based on factors such as the increase in reported HIV cases and the lack of standardized treatment.

Legal Presumptions and Constitutional Basis: The resolution declaring public interest enjoys legal presumption, supported by constitutional and legal provisions guaranteeing access to healthcare, particularly for HIV patients.

Procedural Compliance: The process for obtaining a compulsory license adhered to the legal framework established by Decree 1074 of 2015 and the Circular Única of the Superintendence of Industry and Commerce. The publication of notices and requirements for license applications were conducted according to regulations.

Determining Compensation: The Superintendence of Industry and Commerce is empowered to determine the compensation for the license, and this authority is not contingent upon agreement with the patent holder. The methodology for calculating compensation was deemed appropriate.

Rejection of Counterarguments: Arguments against the validity of the process, such as alleged deviations from legal procedures or unreasonable compensation terms, were dismissed. The Ministry's competency for license acquisition and the rationale behind the payment schedule were justified within the legal and budgetary frameworks.

RESOLVES

The resolution grants the Ministry of Health and Social Protection a compulsory license for the patent involving dolutegravir for public interest reasons, exclusively for governmental use. The license allows importation and manufacturing of the drug for government use, subject to specific conditions.

The conditions of the license:

- **Object of the license:** This compulsory license for reasons of public interest grants the licensee the authority to import and manufacture the product protected by invention patent with certificate No. 1887, granted to application No. 07115501A, which comprises

the active ingredient dolutegravir, conditioning it to the requirement that all medication introduced or manufactured in the Colombian market under this license be destined for governmental use by the Ministry of Health and Social Protection, who will take the necessary measures for the distribution of the product subject to this license within the framework of its competencies.

- **Term of the license:** The license will be valid as long as invention patent with certificate No. 1887, granted to application No. 07115501A, is valid; the conditions on which the declaration of the existence of public interest reasons contained in Resolution No. 1579 of October 2, 2023, issued by the Ministry of Health and Social Protection, remain in force and the conditions published in the notice published on January 31, 2024, on the website of the Superintendence of Industry and Commerce are met. In any case, the license will expire on April 28, 2026.
- **Amount:** The licensee shall recognize in favor of SHIONOGI & CO., LTD. and VIIV HEALTHCARE COMPANY, owners of invention patent with certificate No. 1887, granted to application No. 07115501A, the value of \$0.11 Colombian pesos current currency, for each milligram of dolutegravir introduced or produced in the country on the occasion of this license, plus the direct and indirect taxes applicable.
- **Conditions for payment of economic compensation:** Payment of the compensation amount indicated in the previous item shall be made by electronic transfer in favor of SHIONOGI & CO., LTD. and VIIV HEALTHCARE COMPANY on an annual basis, within the first three months of the year, to the account designated for this purpose by the owners. The owners shall submit the corresponding compensation payment request, accompanied by the corresponding electronic invoice and any other accounting supports that may be required.

The resolution also outlines the process for notification and appeal, and it becomes effective upon enforceability.