



COURT OF JUSTICE OF THE ANDEAN COMMUNITY

CASE NO. 43-IP-2014

Preliminary interpretation, upon application by the consulting court, of Articles 30, 34, 45 and 46 of Decision 486 of September 14, 2000, issued by the Andean Community Commission and, *ex officio*, Articles 14, 16, 18 and 19 of the same law, in response to the consultation filed by the Eighth Chamber of Administrative Disputes, also specialized in Market Issues, Lima, Republic of Peru. Internal File No. 02838-2010-0-1801-JR-CA-07.

**Petitioner: MERCK FROSST CANADA LTD. And MERCK & CO. INC.
Patent: "PHARMACEUTICAL COMPOSITION FORMED BY ACID OR OTHER NICOTINIC AGONIST OF THE DP RECEPTOR".**

Opinion issued by Judge Leonor Perdomo Perdomo

THE COURT OF JUSTICE OF THE ANDEAN COMMUNITY, sitting in Quito, on the eighteen day of June in the year two thousand and fourteen in Judicial Session resolves by majority the Preliminary Interpretation filed by the Eighth Chamber of Administrative Disputes, also specialized in Market Issues, Lima, Republic of Peru, in accordance with the provisions of Article 32 of its Statute and Rule 21 of its Rules of Procedure. Judge José Luis Diez Canseco Judge Núñez dissents from the majority position and therefore does not endorse the present opinion.¹

FILINGS

The application for Preliminary Interpretation was filed by the Eighth Chamber of Administrative Disputes, also specialized in Market Issues, Lima, Republic of Peru, in filing No. 2838-2010-0/DRY-CSJLI 8th-PJ, dated May 12, 2014, and received by the Court on the same day, under internal case no. 02838-2010-0-1801-JR-CA-07.

The Court issued its opinion on June 11, 2014, declaring the application for a preliminary interpretation admissible.

I. BACKGROUND

On the basis of the documentation submitted, the Court considered it necessary to highlight the following as background to the internal case that engendered the application at hand:

¹ The reasons for his dissent are set forth in an explanatory document annexed to Record. No. 17-J-TJCA-2014.

II. THE PARTIES

Petitioner: FROSST MERCK CANADA LTD. and MERCK & CO. INC.

Respondent: NATIONAL INSTITUTE FOR THE DEFENSE OF COMPETITION AND PROTECTION OF INTELLECTUAL PROPERTY (INDECOPI)

III. RELEVANT INFORMATION

A. FACTS

the major facts, some collected from the factual submissions of the application and others from the application for preliminary interpretation and the administrative background to the acts at issue, are AS follows:

1. On May 6, 2004, MERCK & CO. INC. AND MERCK FROSST CANADA & CO./Merck Frosst Canada & CIE, applied for the patent entitled: "PROCEDURES AND PHARMACEUTICAL COMPOSITIONS FOR TREATING ATHEROSCLEROSIS, DYSLIPIDEMIA AND ASSOCIATED CONDITIONS ". This application was filed claiming priority for foreign application No. 60/470,665 filed on May 15, 2003 in the United States.
2. By interlocutory decision of June 22, 2005, the Office of Inventions and New Technologies of INDECOPI amended the title of the application thus: "PHARMACEUTICAL COMPOSITION COMPOSED OF NICOTINIC ACID OR OTHER NICOTINIC ACID RECEPTOR AGONIST AND A DP ANTAGONIST RECEPTOR" on the basis that the name of inventions should maintain a proper relationship with the object of the patent sought.
3. On 2 February 2006, **MERCK & CO. INC. and MERCK FROSST CANADA & CO./MERCK FROSST CANADA & CIE** submitted further statements of claims.
4. On February 28, 2006, **MERCK & CO. INC. and MERCK FROSST CANADA & CO. / MERCK FROSST CANADA & CIE** filed a statement asserting that the co-applicant **MERCK FROSST CANADA & CO. / MERCK FROSST CANADA & CIE** had transferred its rights to the patent application to **MERCK FROSST CANADA LTD.**
5. On April 4 2008, Technical Report AB 23-2008 was issued, stating the following: "(i) Claims 5-10, 12, 13, 15-20, 22, 23 and 25-30 do not meet the requirement of clarity, concision and support provided for in Article 30 of Decision 486; (ii) Claims 1-4, referring to a use, are not eligible for protection under Article 14 of Decision 486; (iii) Claims 11 and 14 do not meet the novelty requirement laid down in Article 16 of Decision 486; and (iv) Claims 21 and 24 lack the inventive step required under Article 18 of Decision 486".
6. On August 7, 2008, **MERCK FROSST CANADA LTD. and MERCK & CO. INC.**, responded to the aforementioned Technical Report. They attached a fresh statement of claims, two (2) items as Annexes 1 and 2, "on the Merck product TREDAPTIVE (also known as CORDAPTIVE)", and furnished a number of clarifications regarding the novelty and inventiveness of the patent applied for, accompanying the probative material.

7. On September 12, 2008, Technical Report AB 23-2008/A was issued. It opined that: "(i) Claims 1-15 do not meet the requirements of clarity and concision stipulated in Article 30 of Decision 486".
8. By Resolution No. 1262-2008/DIN-INDECOPI of 27 October 2008, the Department of Inventions and New Technologies of INDECOPI rejected the patent application.
9. **MERCK FROSST CANADA LTD. Y MERCK & CO. INC.** filed a Request for Reconsideration of the above-mentioned resolution, noting that it was annexing further statements of claims and documents proving that its applications for the patent sought had been granted in Panama, Singapore, Eurasia (including Belarus, Kazakhstan and Russia), China and Korea.
10. By interlocutory decision of November 24, 2008, the appeal was found admissible, but it was ordered that the new statement of claim should not be assessed.
11. By resolution No. 46-2009/DIN-INDECOPI of January 20, 2009, the Department of Inventions and New Technologies of INDECOPI declared the appeal to be without merit.
12. **MERCK FROSST CANADA LTD. Y MERCK & CO. INC.** filed an appeal against the above-mentioned resolution. The Intellectual Property Chamber of the Court of INDECOPI ordered the preparation of a Technical Report on the arguments advanced in the appeal.
13. On January 11, 2010, Technical Report PCG 89-2009 was issued, wherein it was stated that: "(i) Claims 1-15 do not meet the requirements of clarity, concision and support stipulated in Article 30 of Decision 486".
14. By resolution No. 0252-2010/TPI-INDECOPI of January 25, 2010, the Competition and Intellectual Property Court of INDECOPI determined the appeal, upholding the impugned administrative decision.
15. **MERCK FROSST CANADA LTD. AND MERCK & CO. INC.** filed an administrative dispute brief, alleging the nullity of the administrative decision, resolution No. 46-2009/DIN-INDECOPI, resolution No. 1262-2008/DIN-INDECOPI and all measures taken thus far, arguing a breach of its rights in relation to AB Technical Report 23-2008. In the alternative, the companies prayed: (i) that their appeal, in which a new statement had been incorporated, be granted in its entirety; and (ii) that they be allowed to exercise their *audi alteram partem* right in relation to Technical Report PCG 889-2009.
16. By Resolution No. 11 of April 24, 2013, the Ninth Transitory Court Specialized in Administrative Disputes of Lima, Republic of Peru declared the lawsuit to be without merit in its entirety.
17. **T MERCK FROSST CANADA LTD. Y MERCK & CO. INC.** filed an appeal against that judgment.
18. The Eighth Chamber of Administrative Disputes, also specialized in Market Issues, Lima, Republic of Peru, referred the matter to the Court of Justice of the Andean Community for a preliminary interpretation.

B. POINTS OF LAW ARGUED IN THE PETITION

The petitioner based its referral on the following grounds:

19. Technical Reports 23-2008 and PCG 889-2009 AB were not notified and therefore violated the rights of the petitioner. Consequently, due process was violated.
20. Those principles had been protected by the Constitutional Court, the Civil Chamber of the Supreme Court and the Permanent Chamber of Constitutional and Social Law of the Supreme Court of Lima.
21. Andean legislation allows an applicant to amend its patent application, even before the competent national authority issues its decision exhausting administrative remedies. INDECOPI negated this facility by failing to consider the fresh statement which accompanied the request for reconsideration and thereby overlooked the supremacy of Community law.

C. CHALLENGE TO THE PETITION

INDECOPI advanced the following arguments in response:

22. In the administrative remedies of which it availed itself, the petitioner did not argue that the failure to notify Technical Report AB-23-2008/A infringed its rights. Accordingly, it was violative of the principle of congruence to argue thus before the Court.
23. The notification of Technical Report 89-2009 PCG was unnecessary, since Articles 45 and 46 of Decision 486 do not place an obligation upon INDECOPI to effect such notification.
24. The second paragraph of Article 45 provides that it is optional for the competent national office to notify a second or subsequent discrepancy if the applicant has addressed previous discrepancies.
25. Furthermore, Article 46 establishes the obligation to notify reports from experts or from scientific or technological bodies only once; it is optional for the competent national office to notify subsequent observations, whether or not they are supported by an expert opinion in the relevant field.
26. Otherwise, the approval process would never be completed and it would become a perpetual cycle.
27. In the case at hand, the applicant was notified of one Technical Report. Accordingly, the respondent took its decision at first and second instance in accordance with Technical Report AB-23-2008/A (second report) and PCG 89-2009 (third report), without having notified the applicant, since it was no longer mandatory.
28. The petitioner appeared to labor under the misapprehension that the filing of new claims is only allowed during the first-instance administrative procedure. The motion for reconsideration was instituted to allow the authority to consider new evidence to enable it to review its decision. Therefore, the new statement submitted with the application for reconsideration was a new claim that could in no way be reviewed on appeal.

29. For the sake of argument, if, the alleged nullity were to be confirmed, the result of the patent application would be the same: “[...] refused for lack of clarity”.

D. JUDGMENT AT FIRST INSTANCE

30. By Resolution No. 11 of April 24, 2013, the Ninth Transitory Court Specialized in Administrative Disputes of Lima, Republic of Peru, found the entirety of the petitioner’s complaint without merit, holding that:
31. Pursuant to Article 45 of Decision 486, it was obligatory to notify the first Technical Report. The decision whether or not subsequently to notify other Technical Reports was left to the discretion of the administration concerned, provided it fell within the purview of the second part of Article 45.
32. The new statement of claims submitted by the applicant as fresh proof of the request for reconsideration was in fact a new patent application.
33. The patent application was refused for lack of clarity and concision.

E. APPEAL

34. In their appeal, **MERCK FROSST CANADA LTD. and MERCK & CO. INC.** restated the arguments advanced in their original brief, adding that the first-instance judgment had misconstrued Articles 45 and 46 of Decision 486, in that:
35. These provisions (of lesser import) could not contravene the provisions enshrined in the Constitution (principle of due process and the *audi alteram partem* principle). INDECOPI could not be exempted from complying with the provisions of the Constitution and must notify all Technical Reports.
36. The above-mentioned provisions govern two different assumptions: Article 45 refers to the preliminary examination of patentability; while Article 46 refers to the possibility of seeking the views of third-party subject matter experts on the patentability of the invention. Hence, in the case at hand, **INDECOPI** evidently only complied with the conditions envisaged in Article 46 and omitted to conduct the preliminary examination of patentability.
37. **INDECOPI** is required to comment on Technical Reports and not just transcribe them.
38. A correct reading of Articles 45 and 46 of Decision 486 gives the following result: observations and expert opinion must be notified to the applicant to safeguard the *audi alteram partem* right.

IV. JURISDICTION

39. The Court of Justice of the Andean Community is competent to make a preliminary interpretation of the rules composing the legal system of the Andean Community, with a view to its uniform application in the territory of Member Countries.

V. LAWS TO BE INTERPRETED

40. The consulting court requested a preliminary interpretation of Articles 30, 34, 45 and 46 of Decision 486, circumscribing its request as follows:

"[...] 1. In interpreting a claim, how to analyze and construe Article 30 of the Decision in respect of the requirements of clarity and concision, as essential characteristics that allow reference to the description of the object for which a patent is sought. 2. How to interpret and analyze Article 34 of the Decision in respect of the appropriateness or otherwise of amending the patent application when a first series of claims having been rejected, remedies are sought by filing an administrative appeal against the administrative act refusing the patent. 3. How to interpret and analyze Articles 45 and 46 with respect to whether the competent national office is obligated to notify the reports of experts or scientific or technological bodies whenever they are requested."

41. The requested interpretation will be performed. The Court will also interpret *proprio motu* articles 14, 16, 18 and 19 of the same law.

42. Below is the text of the law to be interpreted:

DECISION 486

[...]

Article 14

Member Countries shall grant patents for inventions of both products and processes in all fields of technology provided that they are new, involve an inventive step and are susceptible of industrial application.

[...]

Article 16

An invention shall be considered new if it is not included in the prior art.

The prior art shall comprise everything made accessible to the public by written or oral description, utilization, marketing or other means before the filing date of the patent application or, where appropriate, of the priority.

Solely for the purpose of determining novelty, the contents of a patent application pending before the competent national office, with a filing date or priority date antecedent to the filing or priority date of the patent application under examination, shall likewise be considered part of the prior art, provided that such content was included in the earlier application when published or that the time period provided for in Article 40 has elapsed.

[...]

Article 18

An invention shall be considered as involving an inventive step if, to a person with average skills in the technical field concerned, it is neither obvious nor obviously derived from the prior art.

Article 19

An invention shall be regarded as susceptible of industrial application when its subject matter may be produced or used in any type of industry; industry being understood as any productive activity, including services.

[...]

Article 30

Claims shall specify the matter for which patent protection is sought. They must be clear and concise and be fully substantiated by the description.

Claims may be independent or dependent. A claim shall be independent when it defines the matter for which protection is sought without referring to any previous claim. A dependent claim defines the matter for which protection is sought by referring to a prior claim. A claim referring to two or more previous claims is considered a multiple dependent claim.

[...]

Article 34

At any time during processing, the applicant may request amendment of the application, provided such amendment is not taken to entail an extension of the scope of protection beyond the disclosure contained in the initial application.

Likewise, the applicant may request the correction of any material error.

[...]

Article 45

If the competent national office ascertains that the invention is not patentable or fails to comply with any one of the patentability requirements stipulated in this Decision, it shall notify the applicants accordingly. The applicants shall respond to such notification within sixty days after the date of notification. This time limit may be extended once only for thirty additional days.

The competent national office may notify the applicant two or more times pursuant to the preceding paragraph should it deem such notifications necessary for its assessment of the patentability of the invention.

If the applicant fails to respond to the notification within the stipulated time limit or if, despite their explanations, impediments to patentability persist, the competent national office shall refuse the patent.

Article 46

The competent national office may request reports from experts or from suitable scientific or technological bodies as to the patentability of the invention. It may also request reports from other intellectual property offices if considered necessary.”

[...]

VI. CONSIDERATIONS

43. The Court shall perform the preliminary interpretation requested, to which end the following aspects were analyzed:
- A. Primacy of the Andean Community legal system.
 - B. Patentability requirements
 - C. Claims and analysis of patentability. The clarity and concision requirement
 - D. Modification of the patent application. Its appropriateness
 - E. Notification of technical reports.

A. PRIMACY OF THE ANDEAN COMMUNITY LEGAL SYSTEM

44. Relying on Articles 45 and 46 of Decision 486 of the Andean Community Commission, **MERCK FROSST CANADA LTD. and MERCK & CO.** argue in their appeal that these provisions, which are of less import, cannot contravene constitutional principles.
45. Accordingly, it is necessary to examine the primacy of Andean Community law. To this end, an excerpt of the Preliminary Interpretation of September 25, 2013, issued in Case No. 87-IP-2013, is reproduced below.
46. “The Tribunal has established the “Primacy of Andean Community Law” as the fundamental principle of Andean Community Legal System, asserting it in other principles: the “Direct Effectiveness of the Andean Legal System “, the “Immediate Applicability of the Andean Legal System” and the “Autonomy of the Andean Legal System”.
47. Following an analysis of the position or hierarchy of the Andean legal system, it has become evident that the system enjoys primacy over the legal systems of Andean Community Member Countries and international law concerning matters transferred into the purview of Andean Community law. Hence, it has been established that in the event of contradictions between Andean Community Law and the domestic law of Member Countries, the former prevails, as it does when the same situation arises between Andean Community Law and international law.

48. This position has been upheld sufficiently in the case law of this distinguished Court, *inter alia* in the following cases: Case No. 118-AI-2003; Judgment of April 14, 2005, published in the Official Gazette of the Cartagena Agreement No. 1206 of June 13, 2005, Case No. 117-AI-2003; Judgment of April 14, 2005, published in the Official Gazette of the Cartagena Agreement No. 1156 of May 10, 2005, Case no. 43-AI-2000; Judgment of March 10, 2004, published in the Official Gazette of the Cartagena Agreement No. 1079 of June 7, 2004, Case No. 34-AI-2001; Judgment of August 21, 2002, published in the Official Gazette of the Cartagena Agreement No. 839 of September 25, 2002, Case No. 7-AI-98; Judgment of July 21, 1999, published in the Official Gazette of the Cartagena Agreement No. 490 of October 4, 1999, Case No. 2-IP-90; Preliminary Interpretation of September 20, 1990, published in the Official Gazette of the Cartagena Agreement No. 69 of October 11, 1990, Case No. 2-IP-88. Preliminary Interpretation of May 25, 1988, published in the Official Gazette of the Cartagena Agreement No. 33, of June 26, 1998, Case No. 02-AN-86. Judgment of April 16, 1986, published in the Official Gazette of the Cartagena Agreement No. 21 of July 15, 1987.
49. A key point in the analysis of the primacy of Andean Community Law, as noted above, is the principle of autonomy, which develops and establishes the Community's legal system as a true legal system in that in addition to coherence and unity, enshrines the legal system as a set of principles and structural rules emanating from the system itself and not derived from an external legal framework.
50. In respect of the principle of autonomy of the Andean legal system, the Court has opined as follows:

In this context, it should be emphasized that Community law does not stem from systems of Member Countries, be they of domestic or international origin, but from the Treaty establishing the Community. Thus, by virtue of its autonomy, the legislation of the Community, both primary and secondary, is established as neither depending on or subordinate to the domestic law of international origin of Member Countries. Consequently, international treaties concluded proprio motu by Member Countries, such as the TRIPS Agreement, do not bind the Community or have a direct effect in it, without prejudice to the binding force that such instruments possess in relations between said member countries and third-party countries or international organizations.” (Case No. 01-AI-2001, Judgment of June 27, 2002, published in the Official Gazette of the Cartagena Agreement No. 818 of July 23, 2002)

51. However, it is very important to consider that under the essential complement principle, national law may govern matters that are not regulated by Andean Community legislation, in order to ensure their proper implementation. On this principle, the Court has stated as follows:

[...] It is not possible to issue national legislation on the same subject, except as necessary for the proper application of such. (Case No. 10, IP-94, Preliminary Interpretation of March 17, 1995, published in the Official Gazette of the Cartagena Agreement No. 177 of April 20, 1995).

This means that Member Countries cannot issue legislation on matters governed by Community law, except as necessary for their proper execution and therefore cannot, under the guise of regulating Community laws, establish new rights or obligations or modify those already existing in Community law.

Thus, the Member Country could only have regulated this issue if such regulation was expressly provided for in Community law, or where Community law was silent on the matter. (Preliminary Interpretation issued on February 25, 2010, in Case No. 115-IP-2009, published in the Official Gazette of the Cartagena Agreement No. 1828 of April 30, 2010).

52. This principle is enshrined in Article 276 of Decision 486 of the Andean Community Commission, as follows:

Intellectual Property matters not covered by this Decision shall be regulated by the domestic legislation of Member Countries.

53. This does not mean that Andean Community law has no category of limitation or that Community institutions have no limit to their action, and specifically that the Court is completely untrammelled, since its activities are confined to ensuring respect for human rights within the universal and inter-American protection system. This represents a confluence with national human rights charters which, while not prevailing over Community law, which has primacy,² do meet the same standards of protection as mentioned in Inter-American and universal schemes.³

B. PATENTABILITY REQUIREMENTS

54. Technical Report AB 23-2008 argued the lack of novelty and inventiveness of some of the claims of the patent application. **MERCK FROSST CANADA LTD. y MERCK & CO. INC.** responded to the report, attaching a new statement of claims and providing a series of clarifications as to the novelty and inventiveness of the patent sought.
55. In accordance with the foregoing, the Court considers it appropriate to refer to patentability requirements. To this end, it rehearses its prior statement in its Preliminary Interpretation issued on July 20, 2012, in Case No. 46-IP-2012.
56. The requirements to obtain a patent are stipulated in Article 14 of Decision 486 and further developed in Articles 15 to 19 thereof.
57. As stipulated in Article 14 of Decision 486, there are three requirements for an invention to be considered patentable: it must be innovative, involve an inventive step and be susceptible of industrial application.

² On the primacy of Andean Community law, see, for example, Perdomo Perdomo Leonor, *El Ordenamiento Jurídico Comunitario Andino y el Bloque de Constitucionalidad*. Revista Tinta Jurídica III, Universidad Internacional SEK, May 2014, Quito, Ecuador.

³ On the work of the Court of Justice of the Andean Community and the defense of human rights, see, for example, Vargas Mendoza, Marcelo, *El Tribunal de Justicia de la Comunidad Andina y la Defensa de los Derechos Humanos*. Revista Tinta Jurídica III, Universidad Internacional SEK, May 2014, Quito, Ecuador.

Novelty

58. Article 16 of Decision 486 states: “An invention shall be considered new if it is not included in the prior art”. Under Andean Community law, novelty required for inventions must be absolute or universal, that is, in relation to the prior art worldwide.

59. As to what is meant by “invention”, the Court of Justice of the Andean Community has held that:

[...] The concept of invention, for the purposes of granting a patent, comprises all those new products or procedures which, as a result of human creativity, involve a technological breakthrough – and therefore do not obviously arise from the “prior art” – and are also susceptible of being produced or used in any industry. (Case No. 21-IP-2000. Preliminary Interpretation of 21 October 2000, published in the Official Gazette of the Cartagena Agreement No. 631, of January 10, 2001)

60. However, for an invention to be innovative, it must not be included in the prior art. This means that before the filing date of the patent application or priority, both the innovation and expertise that flows from it should not been accessible to the public by any means, it being understood that the dissemination must contain sufficient information about the invention so that a person skilled in the art can use it to design the invention.

61. This Court, relying on criteria set by legal doctrine to define the concept of novelty, has held that:

“Guillermo Cabanellas identifies the characteristics of the concept of novelty as follows:

- (a) Objectiveness. The novelty of the technology is not determined in relation to certain specific people or the alleged inventor, but in relation to the objective prior art at a given time.*
- (b) Irreversibility of the Loss of Novelty. [...] Once a technology loses its novelty because it has been absorbed into the prior art, that loss of novelty becomes irreversible.*
- (c) Universal Character of Novelty [...] the novelty of the invention is determined in relation to existing knowledge in the country or abroad.*

[...] A patent cannot be claimed in relation to technology already known abroad, even if it is novel in the country.

- (d) Public Character of novelty. [...] The patented invention shall become known upon its publication, which is part and parcel of the patenting process, and shall enter the public domain upon expiry of the patent.”⁴*
(Case No. 07-IP-2004. Preliminary Interpretation of March 17, 2004,

⁴ CABANELLAS, Guillermo. “DERECHO DE LAS PATENTES DE INVENCION” [Patent Rights]. Vol. 1. Heliasta, Buenos Aires 2001, pp. 702-704.

published in the Official Gazette of the Cartagena Agreement No. 1057 of April 21, 2004).

62. Further substantiating the concept of novelty, the Court has clarified the concept of absolute novelty as a prerequisite for granting a patent. Although the analysis is conducted having regard to Decision 344, the concept is applicable in the context of Decision 486:

The concept of absolute novelty in respect of an invention implies that for an invention to be new and not encompassed by prior art, it should not have been known either within the territory in which the patent is sought or in any other country. This is what is known as absolute novelty; it is not enough that an invention is new and is not in the prior art of a given territory, but it must be so in the rest of the world, except for the priority year referred to in Article 12 of Decision 344. Absolute novelty, as a criterion for determining the patentability of an invention, has been a leading concept in international circles. Thus in the United Kingdom, as from 1977 (United Kingdom Patents Act). The Federal Republic of Germany began to require absolute novelty when it enacted the Law of 16 December 1980. European Community Member States have imposed the requirement of absolute novelty as one of the consequences of European patents, according to the Munich Treaty of October 5, 1963. (Bercovitz, Alberto, PROTECCIÓN DE LA TECNOLOGÍA' [Protection of Technology], Journal of Industrial Law No. 35, Depalma, 1990, p. 321). "(Case no. 1-AI-1996. Judgment of 30 October 1996, published in the Official Gazette of the Cartagena Agreement No. 234 of April 21, 1997).

63. The Court took as reference points criteria of the Boards of Appeal of the European Patent Office (EPO), whereby "for an invention to lack novelty, its subject-matter must be clearly and directly derivable from the prior art and all its features must be known from the prior art". With regard to the interpretation of the prior art, the EPO Boards of Appeal have developed a number of principles: (i) general rules of interpretation; (ii) combination within a prior art document; (iii) taking implicit features into account; (iv) taking intrinsic features into account; (v) taking equivalents into account; (vi) taking drawings into account; (vii) taking examples into account; (viii) taking prior use into account; (ix) broad claims; (x) deficiencies and mistakes in a disclosure; (xi) accidental disclosure; (xii) possibility of implementation'. Regarding combination within a prior art document, the Boards of Appeal has stated that ' in a case where a document comprised in the state of the art referred to "a usual manner" of preparing a product, it was permissible to use documents of reference such as handbooks, encyclopaedias or dictionaries in order to determine what the skilled person would have understood by such a reference on the effective date of the prior document." (European Patent Office, Case Law of the Boards of Appeal, interactive CD "Special Edition - Legal Espace", DG 3 (Recours), 4th edition, 2001). (Case No. 13-IP-2004, published in the GOAC No. 1061 of April 29, 2004, patent, TRIHYDRATE (2R.3S) -3-TERT-BUTOXYCARBONYLAMINO-2-HYDROXY-3-PHENYLPROPIONATE 4-ACETOXY -2-BEZOILOXI-5B, 20-EPOXY-1, 7B, 10B-TRIHIDROXY-9-OXO-TAX-11-EN-13-ILO).⁵

⁵ This was considered in the Preliminary Interpretation of December 2, 2009, issued in Case No. 85-IP-2009.

64. Having defined the concept of novelty, it is appropriate to note that the Court has defined a number of rules with the aim of determining the novelty of the invention:

- (a) *Identify the technical regulation applicable to the patent application, for which the technical examiner must rely on the claims, which ultimately determine this aspect.*
- (b) *Specify the date on whose basis the comparison is to be made between the invention and the prior art, which may be the date of the application or the priority.*
- (c) *Determine the content of the state of the heart (prior art) on the priority date.*
- (d) *Finally, the invention should be compared with the technical rule. (Case No. 12-IP-1998. Preliminary interpretation of May 20, 1998, published in the Official Gazette of the Cartagena Agreement No. 428 of April 16, 1999).*

65. The Manual for the Examination of for Patent Applications in Industrial Property Offices of Andean Community Countries established certain criteria, which are worth reproducing.

An invention claimed is considered new if it is not part of the prior art. The examiner must show that the invention is not new. As such, when an inventor files a patent application and no data exists to show that it is not new, the claimed invention shall be considered new.

An analysis of novelty cannot combine different documents of the prior art. However, if a document expressly refers to another document to provide further detail about each feature, it can be taken that the contents of the second document relating to this feature are incorporated in the former.

A prior art document may contain information implicitly, that is, everything the person skilled in the art can derive directly and unambiguously from the document. For example, if a document speaks of a bicycle, it implicitly refers to the wheels of the bicycle although they are not mentioned.

For the purposes of illustration, below are some concepts borrowed from European legislation (Art 52(1) and 54 of the European Patent Convention (EPC)):

Novel: everything that is not part of the prior art.

Lack of novelty: the novelty of the claimed matter is affected if it is derived from a part of the prior art directly, whether explicitly or implicitly by a person skilled in the art.

The examiner may find lack of novelty in disclosures made in documents, conferences, fairs, drawings, etc., or based on his own knowledge provided he is duly accredited. A challenge to novelty must be made from the same

disclosure, taking into account that different reference sources cannot be combined.

If an element is equivalent to another, the objection may not be for lack of novelty but for lack of inventive step. Thus, a copper wire and a silver wire are equivalents in that they have the same function, but they are not the same.

If the same element is assigned different names, but their technical features are the same, novelty is affected. This is the case for “blanket” or “towel”, which do not have distinct technical characteristics.

A specific description affects the novelty of a general description, but not vice versa.

For ranges, novelty is destroyed if the prior art comprises examples in that range. For example, if the application claims a process between 120 and 150 degrees and the prior art describes the same process at 130 degrees, there is no novelty.⁶

[...]“.

66. The consulting court shall determine whether claims 11 and 14 meet the requirement of novelty, if possible in accordance with the stipulations of Sub-Section D of this judgment, and analyze this requirement having regard to the new list of claims presented, in light of the opinions expressed herein.

67. Preliminary Interpretation No. 46-IP-2012, issued on July 20, 2012, states the following.

“[...]

Inventive step:

68. In accordance with Article 18 of Decision 486, an invention shall involve an inventive step if, for a person in the trade with average skills in the technical field concerned, the invention is neither obvious nor obviously derived from the prior art. This requirement allows an examiner to determine whether, with the expertise that existed at the time of the invention, it was obviously possible to achieve the invention, or if the result would have been obvious to a person with ordinary skill in the art in question, that is, for a person with normal skills in the corresponding technical field.

69. In that regard, the Court of Justice of the Andean Community has found as follows:

With the inventive step requirement, the aim is to provide the technical examiner with information that allows him to state whether or not the invention under study could not have been achieved from the expertise that existed at that time within the prior art [...]. Here, it should be noted that one

⁶ Manual for the Examination of Patent Applications in Industrial Property Offices of Andean Community Countries. General Secretariat of the Andean Community, World Intellectual Property Organization and European Patent Office. 2004, available at <http://www.comunidadandina.org/public/patentes.pdf>.

aspect is the examination of novelty by an average person skilled in the art and another is the examination with respect to inventive step; although either is used as a benchmark with regard to the “prior art”, in the case of novelty, the invention is compared with the “anticipations” comprised therein, each [sic] separately, while inventive step requires that the average technician performing the examination start from his general knowledge of the prior art and perform a comparison relying on his overall assessment, determining whether with the existing expertise, such an invention could or could not have been achieved. (Case No. 12-IP-98. Preliminary Interpretation of May 20, 1998, published in the Official Gazette of the Cartagena Agreement No. 428 of April 16, 1999).

70. However, for the purposes of Article 18 of Decision 486, it is appropriate to define what is meant by “obvious” and “evident” and, consequently, determine what should be understood as inventive step.
71. What is obvious is “found or placed in front of the eyes; very clear or not difficult. What is evident is “clear and manifest certainty which cannot be doubted.”⁷ As is apparent, what is obvious is not necessarily evident; however, what is evident is also obvious.
72. Thus, it can be concluded that an invention has an inventive step when in the eyes of an average expert in the field, its creation requires more than simply applying expertise in the field, that is, the invention is not a clear and direct consequence of the prior art; it represents a qualitative step or leap in the development of the technical rule.
73. The Manual for the Processing of Patents Applications in Industrial Property Offices of Andean Community Countries establishes certain criteria for determining the inventive step, which it is important to cite:

Inventive step is considered to be a creative process whose results are not deduced from the prior art as apparent to a person with ordinary skill in the art at the date of filing of the application or the priority.

The examiner must determine whether the claimed invention is not obvious to a person skilled in the art. The existence or lack of any technical advantage is not an absolute criterion for recognizing an inventive step. The examiner should not determine which “quantity” of inventiveness there. The inventive step either exists or it does not, there are no intermediate stages.

The examiner should not rely on personal assessments; any objection citing the lack of inventive step of an invention must be based on the prior art.

To determine whether the invention defined by the claims indeed obviously derives from the prior art, it must be determined whether it lacks inventive step when considering the differences between it and the state of the closest prior art. The examiner has the burden of proving that the invention

⁷ **DICCIONARIO DE LA LENGUA ESPAÑOLA [Dictionary of Spanish]**. Twenty-Second Edition. Madrid, Spain, 2001. “DEFINITIONS OF *EVIDENTE*, *EVIDENCIA* AND *OBVIO*”, pp. 686 and 1089.

lacks inventive step and the examination should not merely be confined to the differences between the application and the prior art.

When the lack of novelty of the invention is established, it is not necessary to evaluate the inventive step, since there are no differences between the invention and the prior art.

Normally, the state of the closest prior art is in the same field as the invention, or seeking to solve the same problem or a similar one. For example, in chemistry, the state of the closest prior art may be the one that describes a product structurally similar to the product of the invention or a similar activity or use of the invention.

10.2 Method for evaluating inventive step

10.2.1 Problem-solution analysis

To determine whether the object of the claim is obvious or obviously derived from the prior art, the problem-solution method should be used whenever possible.

To this end, the following steps must be taken:

- Identification of the state of the closest prior art;*
- Identification of the technical features of the invention that are different from the prior art; and*
- Definition of the technical problem to be solved based on the state of the closest prior art.*

The question is: what problem is solved by the technical differences between the invention and the closest prior art?

These differences, in terms of technical features of the invention and the closest prior art, represent the solution to the technical problem at hand.

The problem must be defined without including elements of the solution, because then the solution would be obvious.

The technical problem may not always be stated in the application and must sometimes be restated based on search results. The closest prior art may differ from that known to the applicant and from which he started.

Conduct an assessment, based on the closest prior art and the technical problem, of whether the claimed invention is obvious to a person skilled in the art.

The question then is whether, considering the prior art as a whole, there is an indication that leads a person skilled in the art to modify or adapt the

closest prior art to solve the technical problem so as to achieve a result that was included in the wording of the claim(s).

Technical information must always be considered in context; it should not be extracted or interpreted outside its context. That is, the technical feature being analyzed should be sought in the same technical field or in a field that a person skilled in the art would consider in any event.

It should be noted that the prior art search is done a posteriori, taking the same invention as a starting point. Therefore the examiner should make the intellectual effort to place himself in the situation in which the technician with ordinary skill in the art was at a time when the invention was not known, that is, before the invention.

The claimed invention must be considered as a whole. If it consists of a combination of elements, it is invalid to argue that each discrete element is obvious, since the invention may be in the (technical) relationship between them. The exception to this rule is the case of juxtaposition, in which the elements are combined with no technical relationship between different features.

A new composition of AB, where A and B are independently known, will be inventive if there is an unexpected effect. If the effect is reduced to the sum of the effects of A and B, there is no inventive step.

In sum, the examiner should ask the following questions:

- Was a technician with ordinary skill in the art able to pose the problem;*
- To solve it in the way claimed; and to*
- Anticipate the outcome?*

*If the answer is yes in all three cases, there is no inventive step.
[...]⁸*

74. The consulting court shall determine whether claims 21 and 24 meet the inventive step requirement and, if possible, in accordance with what was stated in Sub-Section D hereof, analyze this requirement in connection with the new list of claims submitted, following the findings herein.

75. Now, in addition to the issue of inventive step, it is appropriate to reiterate the provisions of the Preliminary Interpretation of April 2, 2004 issued by Judge Leonor Perdomo Perdomo in Case No. 238-IP-2013:

⁸ Manual for the Examination of Patent Applications in Industrial Property Offices of Andean Community Countries. General Secretariat of the Andean Community, World Intellectual Property Organization and European Patent Office. 2004, available at <http://www.comunidadandina.org/public/patentes.pdf>.

76. “The Court considers it important to highlight the role of ordinary skill in the art, or a person trained in a technical area with ordinary or current skill in the relevant field. This presupposes the following for proper analysis of inventive step:

- Analysis of inventive step should not start from the activity of a genius or a person with knowledge and education beyond the ‘normal average’ in the technical field concerned. This is an important reason: the purpose of the exercise is to determine that there is no ‘obviousness’, and this can only be achieved if the starting point is standard knowledge for a person working in the relevant technical field.
- Analysis of inventive step in relation to a person with ordinary skill in the art requires the construct of an examiner situating himself in the context of the prior art that existed at the time of the patent application or the priority date. This is very important, since a suitable mechanism must be generated for this to be achieved, that is, it is imperative for system efficiency to establish an appropriate setting, in accordance with the state of art at the time of application, for a technician ‘today’ to easily go back to that time. Therefore, the patentability analysis must clearly show the above-mentioned ‘at the time’ analysis of inventive step.

77. In the case at bar, the patentability analysis conducted by the trademark registration office must show these two elements, that is, in order to analyze the inventiveness of the patent applied the concept of a person with ordinary skill in the art, and made an ‘at the time’ inventive step analysis.”

Susceptibility of industrial application

Similarly, for an invention to be protected through a patent, it must be susceptible of industrial application, that is, it can be produced or used in any production or service activity, as evidenced by Article 19 of the Community rule which is interpreted.

This requirement is justified in that the grant of a patent encourages development and industrial growth, providing economic benefits to those who exploit it; for this reason, only inventions that can be put into practice are susceptible of being patented [...].” (Preliminary Interpretation 46-IP-2012, issued on July 20, 2012, published in the Official Gazette of the Cartagena Agreement No. 2108 of October 22, 2012).

C. CLAIMS AND ANALYSIS OF PATENTABILITY: THE CLARITY AND CONCISION REQUIREMENT

78. The consulting judge put the following question: In interpreting a claim, how should Article 30 of the Decision be analyzed and interpreted in respect of the requirements of clarity and concision as essential features that enable reference to the description of the object for which a patent is sought?

79. To answer this, the Court rehearses Judge Leonor Perdomo Perdomo’s interpretation of April 2, 2014, issued in Case No. 243-IP-2013.

80. “The first point of note is that the claims are fundamental to the analysis of registrability. To fulfill their role, they must be clear and concise and must be supported by the description (Article 30 of Decision 486), which ultimately serves as a parameter for interpreting them. It is also important to note that the description may be composed of drawings (Articles 26(d) and 28(d)), and supplemented by the filing of biological material, in accordance with Article 29 of Decision 486. This certainly places a burden on the examiner to study the patent application comprehensively and systematically.
81. Claims must be understood as the technical characteristics of the invention for which legal protection is sought by grant of a patent.
82. For the purposes of clarification, below is an excerpt from the Preliminary Interpretation of September 4, 2013, in Case No. 165-IP-2013:

[...]

The description of the invention allows the examiner to conduct the examination of patentability properly and arrive at a more precise definition of novelty, inventive step and industrial applicability of the invention.

Community legislation also stipulates as one of the basic requirements for obtaining a patent that it must contain “one or more claims”.

The doctrine holds in that regard that “[...] in principle, the claims must specify the invention alone, without needing to rely on other technical elements, such as the description, drawings or examples [...]. However, [...] in case of doubt, the description and drawings serve to interpret the claims; that is, the claim does not necessarily define strictly the limit of the protection, but it can go further if, on the basis of the description, it can be interpreted that the patent protects similar solutions to the one specifically claimed.”⁹

Thus, the doctrine has specified the existence of product claims when they involve a physical item (product, device, machine, substance, composition) or process claims, which involve an activity (process, method, use). The difference is that, as Carmen Salvador states, “The claims that involve a physical entity confer an “absolute” protection, that is, with them, the product is protected irrespective of the production process and the use to which it is put, whether or not it is known at the time of the patent application [...]”. However, “[...] claims that concern an activity confer “relative” protection in that they protect the claimed activity, but not the various devices or objects used when such are used outside the specified activity. Nonetheless, in process patents, protection extends to the product obtained directly by the patented process, which also does not enjoy ‘absolute protection’, but is only protected when it has been produced by the patented process or its equivalent”.¹⁰

⁹ **ÁLVAREZ**, Alicia. “Derecho de Patentes”. Ciudad Argentina, Buenos Aires. 1999, p. 99.

¹⁰ **SALVADOR**, Jovaní, Carmen. *El ámbito de protección de la patente*. Editorial Tirant lo Blanch. Valencia, 2002. pp. 133-134.

It can then be determined that the description and drawings appearing in the application allow the examiner to better interpret the claims, since the description of the invention is the specification of the research that results the invention for which a patent is sought. The inventor has the tendency to overextend the industrial protection of his product or process, which is why descriptions are relevant to claims because they are precisely what circumscribes the protection.

Compliance with the requirements will enable identification of the principal features of the “object”, and other constituent elements of the invention for which a patent is sought, with the claims playing a key part in determining the scope of the application. Once the subject of the patent application is fully known, it can be determined whether or not it is patentable.

One of the most important issues in patent law is the determination, essence and scope of an invention whose features must be set down in a written document that provides an idea of the object or process in question.

Thus, the claims are, legally speaking, the most important element in a patent application; the technical patent examiner find in the claims the information necessary to determine what is to be patented, the scope of the invention and its definition for the purposes of beginning the comparative analysis of the prior art. This is to claim what is considered new and involving an inventive step.

Under Article 26 of Decision 486, “Patents applications shall be filed with the competent national office and shall contain the following: [...] (b) [t]he description”. Article 28 ejusdem generis adds: “The description of the invention shall be sufficiently clear and complete to be understood and for the invention to be executed by a person skilled in the art.”

This means that the clarity of the claims refers to a requirement, an essential feature that allows reference to the description in order to interpret a claim.

As previously stated, “defining an invention in functional terms is generally permissible, but for the purposes of clarity, the description should not only contain examples of several cases covered by such functional terms, but also an explanation of the general term comprising the generalization of the term”.¹¹

Through this fundamental requirement, it is intended that the claims be defined so that they are easy to understand and their content is distinguishable.”

83. Since the claims define the invention to be protected, they must be analyzed taking into account their systematic presentation, that is, taking them as a set that has the same purpose. Therefore, the examiner must examine the clarity of claims considered

¹¹ *Guía de Procedimientos y estrategias para la solicitud de patentes en biotecnología*. Genoma, España Patentes. Garrigues Agencia de Propiedad Industrial e Intelectual S.L., 2004, p. 48.

individually and collectively, to determine the unity and coherence of the patentable object, and also so that he can conduct a proper analysis of the novelty and inventive step requirements. In addition, it should be noted that the clarity requirement is met if they are properly interpreted, that is, supported by the description and their complements, as expressed herein. If, once this is done, there is no clear observation of the technical features of the invention for which protection is sought, these claims would not meet the clarity requirement.

84. It is pertinent to rehearse an excerpt of the Manual for the Examination of Patent Applications in Industrial Property Offices of Andean Community Countries:

The claims are the most important part of the application in that they define the invention to be protected and define the scope of this protection (Art. 51). It is essential that they are clear and concise (Art. 30), so that:

1. *They can be compared and contrasted with the prior art in order to verify compliance with patentability requirements; and*
2. *The rights of the patent-holder can be unambiguously circumscribed.*

The clarity and concision requirement applies to the claims considered individually, as well as to the claims as a whole.

85. It is worth noting that the concision requirement goes hand in hand with clarity. The claims are concise if they are accurate and written in a language specifically oriented towards defining the invention. Concision is aimed at establishing simplicity in understanding the object for which a patent is sought, taking into account an individual analysis of each claim, together with a systematic analysis of the claims as a whole. The Patent Manual aptly puts this as follows:

The concision requirement of Art. 30 D 486 applies both to each individual claim and to all claims. The purpose of this requirement is to avoid excessive complexity when the examiner is analyzing the claims and prevent others from clearly apprehending the scope of the claims as a result of their excessive number and complexity.

D. MODIFICATION OF THE PATENT: RATIONALE

86. The applicant argued that the Andean legislation allows the applicant to change its patent application before the competent national authority reaches a decision which exhausts administrative remedies. Meanwhile, INDECOPÍ maintained that the possibility of presenting new claims is only allowed at the first level of processing.
87. The consulting court put the following question to the Court of Justice of the Andean Community:
88. How to interpret and analyze Article 34 of the Decision in respect of the appropriateness or otherwise of amending the patent application when a first series of claims having been rejected, remedies are sought by filing an administrative appeal against the administrative act refusing the patent.

89. To answer this question, the opinion of the Court as set forth in Judge Leonor Perdomo Perdomo's Preliminary Interpretation of April 2, 2014 in Case No. 243-IP-2013 is quoted:
90. In accordance with the foregoing, the Court shall address the issue of the appropriateness of filing a modification of the patent application.
91. The first salient point that came to the Court's notice was that Community legislation does not regulate the mode of appeal against an administrative act granting or refusing a patent. In this sense, the type of remedies, requirements, ability to present evidence, *inter alia*, should be regulated in accordance with the essential complement principle by the relevant national legislation.
92. The essential complement principle allows internal legislation to govern matters not provided for in Community legislation. This principle is enshrined in Article 276 of Decision 486 of the Andean Community Commission, as reflected in Section (A) above.
93. Now, to answer the question of the consulting judge it is appropriate to reiterate what was stated in the Preliminary Interpretation of October 16, 2013 by the same judge in Case No. 127-IP-2013:
94. "The first paragraph of Article 34 of Decision 486 of the Andean Community Commission states that an applicant may seek to amend its patent application. Immediately afterwards it circumscribes such modification: it cannot include an extension of the protection corresponding to the disclosure contained in the initial application. From the above the following is evident:
- The applicant may amend its patent application at the request of the competent authority or *motu proprio* at any time during the process.
 - Such modification is not as of right, but conditional upon not being an extension of the scope of the protection. Consequently, the applicant may amend his application by redrafting the claims, clarifying certain passages in the description of the invention, or reformulating aspects of the claim which may lead to total or partial refusal by the Administration, but may in no circumstance expand the previously determined object of the protection.
 - From a comprehensive analysis of the rules governing the patent application, it is clear that the amendments should have regard to the requirements of the modified object. For example, if the claims are modified, they must comply with the unity of invention principle and remain clear and concise (Articles 25 and 30 of Decision 486).
95. The Manual for the Examination of Patent Applications for Industrial Property Offices of Andean Community countries provides some patent application scenarios:
- In the case of a chemical compound, modifications shall be inadmissible where changes are made to the significance of the substituents or the radicals. For example, the initial claims R1 correspond to a C1-C6 alkyl and in the modifications R1 is defined as an alkyl. Although the initial claims also concern an alkyl, the modifications are extending the protection and therefore cannot be accepted.*

In accepting modifications, it is important to analyze carefully when the change made concerns terminology, as this can lead to an extension of the object of the protection when moving from specific to very general terms. If the move from specific to general terms is properly substantiated, it will be admissible.

Example:

The initial object is a transmission device and modification corresponds to a signal processor. The latter is a very general term; it not only encompasses transmission devices, but also devices for reception, processing, selection etc.

96. The analysis of the rule generates a further question: can modification be effected by filing an administrative appeal against the administrative decision refusing a patent?
97. Since the rule makes no such provision, because it is a strictly procedural matter for domestic law, regulations vary with the rules of procedure of Member Countries.
98. This is the criterion reiterated in the Preliminary Interpretations in Cases 21-IP-2000 and 28-IP-2002. It is therefore appropriate to reproduce some of its findings:

Moreover, the amendment to the patent application can be made at any stage of the proceedings and will depend on whether domestic law in the Member Countries allows for such amendment, including the filing of an administrative appeal against the refusal of the patent. Consequently, it is for the consulting court to determine, in accordance with the applicable internal rules of procedure, if the challenge through administrative channels may be based, in addition to the grounds of illegality, on grounds of expediency or, in general, new arguments or facts that could not be analyzed when issuing the initial decision. (Preliminary Interpretation of October 27, 2000, issued in Case no. 21-IP-2000).

99. The Court clarifies one final aspect: to determine whether a change in the statement of claim establishes an extension of the protection, it is crucial that an interpretation of the claims is made in order to determine their clarity, in accordance with Section C above.

E. NOTIFICATION OF TECHNICAL REPORTS

100. The applicant argued that technical reports PCG AB 23-2008 and 889-2009 were not notified and, therefore its *audi alteram partem* rights were violated. **INDECOPI** maintained that a reading of Articles 45 and 46 of Decision 486 shows that it had no obligation of notification.
101. The consulting judge put the following question: How to analyze and interpret Articles 45 and 46 to determine whether the competent national office is obliged to notify expert reports or reports of scientific and technological bodies whenever so requested?
102. To answer the question, we shall return to Preliminary Interpretation of October 31, 2013, issued in Case No. 169-IP-2013:

103. “In relation to the notification of technical reports, the Court has found as follows:

[...]

In accordance with Article 46 of Decision 486, the competent national office may invite the submission of reports from experts or from suitable scientific or technological bodies to secure their opinions on the patentability of the invention. Also, when appropriate, it may invite reports from other industrial property offices.

The option of taking into account the expertise, that is, the expert advice, consisting of expert reports or scientific or technological bodies considered suitable, should be exercised by persons who can address the technical aspects of the patent application, as it is a lengthy and specialized study; many times, if these views are not considered, it is not possible to accurately determine if the application meets the patentability requirements and, consequently, whether or not it is appropriate to grant the patent.

Article 46 does not expressly indicate that the applicant must be notified of the contents of the expert report. However, from a comprehensive reading of the decision and the paragraph that refers to substantive examination, it follows that if reports are requested under Article 46 of Decision 486, notice should be given to the applicant. This is essential in order to give effect to the audi alteram partem principle in the administrative procedure for granting the patent.

Accordingly, whenever the Patent Office requests such reports, it must always notify the applicant, preserving the audi alteram partem principle of in administrative procedures, since it concerns reports from bodies and entities outside the Patent Office.

In addition, it should be considered that the applicant may, in accordance with the appropriate procedure for each case, seek remedies under the law to challenge the decision of the competent national office in administrative and dispute courts Cases No. 33- IP-2013 on patent “BISPHOSPHONIC ACID COMPOSITIONS AND THEIR SALTS” and No. 104-IP-2013 on patent: “PHARMACEUTICAL COMPOSITIONS FOR TREATING ASTHMA”.

104. The Court considers it necessary, in accordance with the case at hand, to clarify further the issue of notification of technical reports. The notification provided for in Article 45 is very different from the notification of technical reports under Article 46. With the Article 45 notification, the applicant is expected to respond to the patentability analysis carried out by the Patent Office itself. Here it is optional to notify the applicant two or more times “if this is necessary for the examination of patentability” (second paragraph of Article 45). With the Article 46 notification, the applicant is expected express its opinion following a technical report of a person or body external to the Patent Office. In this event, given the relevance and influence that these reports would have on a substantive examination, the Court favors the right of the applicant, noting that whenever these technical reports are produced, they should be notified to the applicant.

105. In any event, the Court notes the following: whether the Patent Office requests a new technical report to resolve controversial issues in relation to the first report, it is compulsory to notify the applicant if the report contains topics, points, or items that are new or different from those contained in the first report, regardless of whether or not the new report supports the previous finding. This means that if the second or subsequent reports come to the same conclusion as the previous report(s), there is no notification obligation since there is no risk of breaching the *audi alteram partem* right, given that the material that supports the finding of the relevant office is identical. Conversely, if the second report does not support the previous finding, or if the finding is supported but also supports the argument in other parts or elements, it is the duty of the institution to notify the above reports.

106. If a technical report is requested at the second administrative level, the same rule applies in relation to the last or only report submitted in the first administrative level, that is, if it does not include new or different elements, no notification obligation is triggered; but if it contains new or different elements and reiterates the conclusion, it is obligatory to notify the applicant in order to safeguard the *audi alteram partem* right. The same would apply in relation to the first report at the second administrative level if reports are subsequently sought.

107. The Court notes that an external expert is one who has no employment contract with the entity. If a service contract is signed, or if any other activity that does not create a relationship of dependency is undertaken, the person concerned is a technical expert.

108. To bring greater clarity to technical reports, the Court considers it appropriate to quote what was said about the suitability of the experts or agency that issues the above-mentioned reports:

With a view to ensuring a smooth and efficient examination of patentability, Article 46 of Decision 486 empowers the Patent Office to request a report from experts or scientific or technological bodies regarding the patentability of the object of the application. The rule is very clear in noting that these individuals or agencies outside the Patent Office should be suitable; in these cases that suitability would only apply to experts and agencies properly engaged in the technical, scientific or technological field of the object of the patent application. An expert who has no knowledge and expertise in the particular field can in no way be classified as suitable. Therefore, a patentability analysis based on a report from an unsuitable expert or organization invalidates the act that grants or refuses a patent. "(Preliminary Interpretation of October 16, 2013, issued in Case No. 127-IP-2013)."

109. Accordingly, whenever it requests such reports, the Patent Office should transmit them to the applicant, provided the relevant conditions are met, thereby safeguarding the *audi alteram partem* principle in administrative proceedings, since the issue at stake is expert reports, agencies and entities outside the Patent Office.

THE COURT OF JUSTICE OF THE ANDEAN COMMUNITY

FINDS AS FOLLOWS

FIRST: In case of contradictions between Andean Community Law and the National Law of Member Countries, the former prevails, reflecting the relationship between Andean Community Law and rules of international law; accordingly, any law contrary to Andean Community law is automatically inapplicable.

Nonetheless, it is important to note that under the essential complement principle, national legislation may regulate matters that are not provided for in Andean Community legislation, in order to ensure its proper application.

SECOND: Novelty, inventive step and industrial application are absolutely necessary, unavoidable and mandatory requirements for the granting of a patent, whether for products or processes, in all fields of technology.

The inventive step requirement provides the examiner with the ability to determine whether, given the expertise that existed at the time of the invention, the invention could have been achieved by obvious means, or whether the result would have been obvious to a person with ordinary skill in the art concerned, that is, a person with normal skills in the corresponding technical field.

The consulting court must determine whether claims 11, 14, 21 and 24 meet the novelty requirement and, if possible, in accordance with Section D hereof, analyze this requirement in relation to the new claims submitted in accordance with the views expressed herein.

THIRD: The first issue of note is that the claims are fundamental to the analysis of registrability. To fulfill their role, they must be clear and concise and must be supported by the description (Article 30 of Decision 486), which ultimately serves as a parameter in their interpretation. It is also important to note that the description may be composed of drawings (Articles 26(d) and 28(d)) and supplemented by the depositing of biological material, in accordance with Article 29 of Decision 486. This certainly imposes on the examiner the burden of examining patent application comprehensively and systematically.

The claims should be understood as the technical features of the invention for which legal protection is sought through a patent.

Since the claims define the invention to be protected, they must be analyzed with due regard for their systematic presentation, that is, taking them as a set that has the same purpose. Therefore, the examiner must examine the clarity of claims considered individually and collectively, to determine the unity and coherence of the patentable object, and so as to conduct a proper analysis of the novelty and inventive step requirements. In addition, it should be noted that the clarity requirement is met if a proper interpretation of the claims, that is, an interpretation supported by the description and its complements, as set forth herein. If, once this is done, the technical features of the invention for which protection is sought

are not clearly observed, then the claims do not meet the clarity requirement.

The concision requirement goes hand in hand with clarity. The claims are concise if they are accurate and written in a specific language aimed at defining the invention. Concision is aimed at establishing simplicity in understanding the object to be patented, taking into account an individual analysis of each claim, as a systematic and holistic analysis.

FOURTH:

The first paragraph of Article 34 of Decision 486 of the Andean Community Commission states that an applicant may seek to amend its patent application. Immediately afterwards it circumscribes such modification: it cannot include an extension of the protection corresponding to the disclosure contained in the initial application. From the above the following is evident:

- The applicant may amend its patent application at the request of the competent authority or *motu proprio* at any time during the process.
- Such modification is not as of right, but conditional upon not being an extension of the scope of the protection. Consequently, the applicant may amend his application by redrafting the claims, clarifying certain passages in the description of the invention, or reformulating aspects of the claim which may lead to total or partial refusal by the Administration, but may in no circumstance expand the previously determined object of the protection.
- From a comprehensive analysis of the rules governing the patent application, it is clear that the amendments should have regard to the requirements of the modified object. For example, if the claims are modified, they must comply with the unity of invention principle and remain clear and concise (Articles 25 and 30 of Decision 486).

The analysis of the rule at issue generates the following question: Can the modification be made by filing an administrative appeal against the administrative decision that refused the patent?

As there is no relevant legal provision, this being a strictly procedural matter in domestic law, regulations vary with the rules of procedure of Member Countries.

The Court clarifies one final aspect: to determine whether a change in the statement of claims establishes an extension of the scope of the protection, it is crucial that an interpretation of the claim is made in order to determine its clarity, as set forth in Section C above.

FIFTH:

Article 46 does not expressly indicate that the applicant must be notified of the report containing the expert opinion; however, from a comprehensive reading of the decision and the paragraph that refers to substantive examination, it follows that if reports are requested under Article 46 of Decision 486, notice should be given to the applicant. This is

essential in order to comply with the *audi alteram partem* principle in the administrative procedure for granting the patent.

Having regard to the matter at hand, The Court considers it necessary, in accordance with the case at hand, to clarify further the issue of notification of technical reports. The notification provided for in Article 45 is very different from the notification of technical reports under Article 46. With the Article 45 notification, the applicant is expected to respond to the patentability analysis carried out by the Patent Office itself. Here it is optional to notify the applicant two or more times "if this is necessary for the examination of patentability" (second paragraph of Article 45). With the Article 46 notification, the applicant is expected express its opinion following a technical report of a person or body external to the Patent Office. In this event, given the relevance and influence that these reports would have on a substantive examination, the Court favors the right of the applicant, noting that whenever these technical reports are produced, they should be notified to the applicant.

In any event, the Court notes the following: whether the Patent Office requests a new technical report to resolve controversial issues in relation to the first report, it is compulsory to notify the applicant if the report contains topics, points, or items that are new or different from those contained in the first report, regardless of whether or not the new report supports the previous finding. This means that if the second or subsequent reports come to the same conclusion as the previous report(s), there is no notification obligation since there is no risk of breaching the *audi alteram partem* right, given that the material that supports the finding of the relevant office is identical. Conversely, if the second report does not support the previous finding, or if the finding is supported but also supports the argument in other parts or elements, it is the duty of the institution to notify the above reports.

If a technical report is requested at the second administrative level, the same rule applies in relation to the last or only report submitted in the first administrative level, that is, if it does not include new or different elements, no notification obligation is triggered; but if it contains new or different elements and reiterates the conclusion, it is obligatory to notify the applicant in order to safeguard the *audi alteram partem* right. The same would apply in relation to the first report at the second administrative level if reports are subsequently sought.

The Court notes that an external expert is one who has no employment contract with the entity. If a service contract is signed, or if any other activity that does not create a relationship of dependency is undertaken, the person concerned is a technical expert..

Accordingly, whenever the Patent Office requests such reports, it must transmit them to the applicant if the above requirements are met, safeguarding the *audi alteram partem* right in administrative proceedings, given that the reports are from expert, agencies and entities outside the Patent Office.

In accordance with Article 35 of the Treaty Creating the Court of Justice of the Andean Community, the National Consulting Judge, when issuing the ruling in the domestic proceedings No. 02838-2010-0-1801-JR-CA-07, must follow this interpretation. He must also comply with the provisions contained in the third paragraph of Article 128 of the Statute in force.

The Consulting Judge shall be notified by certified copies and a copy shall be transmitted to the General Secretariat of the Andean Community for publication in the Official Gazette of the Cartagena Agreement.

Leonor Perdomo Perdomo
PRESIDENT

Cecilia Luisa Ayllon Quinteros
Magistrate

José Vicente Troya Jaramillo
Magistrate

Gustavo Brito Garcia
Secretary

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