



GETTING THE  
DEAL THROUGH 

# Patents 2019

*Contributing editor*

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**McCaulley Dowell LLP**

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# Preface

## Patents 2019

Sixteenth edition

**Getting the Deal Through** is delighted to publish the sixteenth edition of *Patents*, which is available in print, as an e-book, and online at [www.gettingthedealthrough.com](http://www.gettingthedealthrough.com).

**Getting the Deal Through** provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured.

**Getting the Deal Through** titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at [www.gettingthedealthrough.com](http://www.gettingthedealthrough.com).

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

**Getting the Deal Through** gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Richard T McCaulley Jr of McCaulley Dowell LLP, for his continued assistance with this volume.

GETTING THE   
DEAL THROUGH 

London  
February 2019

# Colombia

Carlos R Olarte, Alexander Agudelo and Liliana Galindo

OlarteMoure

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## Patent enforcement proceedings

### 1 Lawsuits and courts

**What legal or administrative proceedings are available for enforcing patent rights against an infringer? Are there specialised courts in which a patent infringement lawsuit can or must be brought?**

A patent holder may pursue civil or criminal actions either to stop or to prevent infringing acts. Before the Civil Procedure Law was reformed in 2012, there were no specialised courts. However, the procedure implemented in July 2012 provided the Colombian Patent Office (CPO) with jurisdiction over infringement cases through an independent Judicial Division. Accordingly, civil actions may now be pursued before civil circuit judges or before the CPO. Criminal actions may be pursued before a specialised unit for intellectual property affairs (according to articles 306 and 307 of the Criminal Code); however, criminal infringement actions are extremely rare. If the infringer is a public servant or a government entity, the patent holder must file a lawsuit before the contentious administrative jurisdiction.

The CPO has become the principal venue to litigate infringements under civil jurisdiction since it has proven to be a very effective and reliable way to enforce patents.

### 2 Trial format and timing

**What is the format of a patent infringement trial?**

Civil patent infringement trials start with the filing of a complaint, normally seeking preliminary injunctive relief (injunctive relief can, however, be sought at any time during the process). It is possible to request such preliminary injunctive relief without serving or hearing the counterpart. The defendant may eventually file a reconsideration action against the granted injunctive relief, though this would not suspend its enforcement or effects while the reconsideration is resolved. Considering that invalidity cannot be contested during the infringement process, cases are typically settled once a preliminary injunction is issued.

At present, Colombia is experiencing a transition from the old written procedure to an expedited oral procedure, which is already implemented in the CPO's Judicial Division. However, for procedures carried out by civil circuit judges, this transition is happening gradually but very slowly. Oral procedures shorten infringement trials and follow these stages:

- preliminary injunction request (optional);
- preparation and filling of the complaint;
- admission and service of the complaint to the defendant (the alleged infringer);
- reply to the lawsuit by the defendant;
- conciliation hearing, evidence gathering process and oral closing arguments;
- mandatory prejudicial interpretation of applicable Andean law before the Andean Court of Justice (ACJ); and
- final ruling.

A standard infringement case under the oral procedure (particularly carried out at the CPO's Judicial Division) may take anything from one to two years to reach a final ruling.

The following types of evidence are admissible:

- witness testimony;
- expert opinions provided by party;
- court-appointed expert opinions;
- site inspections; and
- requests for production of documents.

Affidavits are admissible, but the witness will most probably be ordered to provide oral testimony in order to provide the defendant with the opportunity to cross-examine the witness and controvert its conclusions.

Criminal trials are restricted to natural persons, are essentially accusatory and are almost completely oral in nature. However, criminal investigations are normally used for cases of piracy of counterfeit products.

### 3 Proof requirements

**What are the burdens of proof for establishing infringement, invalidity and unenforceability of a patent?**

The burden of proof to demonstrate infringement for product claims lies on the plaintiff and the standard is clear and convincing. This burden is reversed for method claims, assuming a lowered evidentiary threshold is met by the plaintiff (essentially showing the credible probability that the allegedly infringing process is in fact infringing); here the defendant must demonstrate that its accused method is different from the patented one (article 240 of Andean Decision 486).

The burden of proof to demonstrate criminal infringement for any patent is beyond reasonable doubt.

Grounds for patent unenforceability must be proven by the defendant, based on a clear and convincing standard.

The burden of proof to demonstrate invalidity is carried by the plaintiff (the party seeking to invalidate the patent), who must show the patent office erred when granting the patent, based on a clear and convincing standard.

### 4 Standing to sue

**Who may sue for patent infringement? Under what conditions can an accused infringer bring a lawsuit to obtain a judicial ruling or declaration on the accusation?**

Legal standing to sue for patent infringement cases is limited to the title-holder or any of the co-owners of the patent (individually and severally) unless otherwise agreed. Although extremely rare and not specifically contemplated under Colombian local practice, whenever a patent infringement action has not yet been filed by the patent holder, a potential infringer may request a civil judge or the CPO's Judicial Division to declare that its conduct does not infringe a particular patent. Beyond a general perceived threat, there is no specific conduct that must be alleged or shown in order to have standing for such declaratory action.

## 5 Inducement, and contributory and multiple party infringement

**To what extent can someone be liable for inducing or contributing to patent infringement? Can multiple parties be jointly liable for infringement if each practises only some of the elements of a patent claim, but together they practise all the elements?**

Colombian IP law (Andean Decision 486) does not specifically contemplate the figure of inducement or contributory infringement. There is likewise no case law on this point. However, article 238 of Andean Decision 486 provides that a patent holder may seek protection against acts that present the imminence of infringement. Under a broad interpretation of 'imminence', a patent holder could argue that acts of inducement present a high risk of infringement and hence could be stopped. Multiple-party infringement of a single claim is not specifically contemplated, nor is there case law on this point. However, as noted in above, it is possible that a broad interpretation of article 238 may allow the patent holder to pursue different actors that may be contributing in a concerted fashion to materialise the infringement.

## 6 Joinder of multiple defendants

**Can multiple parties be joined as defendants in the same lawsuit? If so, what are the requirements? Must all of the defendants be accused of infringing all of the same patents?**

The plaintiff may join various infringers in a single complaint, insofar as they share same corporate or commercial relationship in the infringing conduct and the conduct is related to the violation of the same patent or patents (in view of article 52 of Decision 486). In a case from 2015, a patent holder filed a patent infringement lawsuit against various companies comprising a joint venture that collectively used a patent-protected invention. The lawsuit named all the companies as defendants.

## 7 Infringement by foreign activities

**To what extent can activities that take place outside the jurisdiction support a charge of patent infringement?**

Under a general territoriality rule, the scope of patent protection is limited to the territory of the state where the right is granted. Regardless of this principle, a Colombian court may prevent the importation of infringing products, even if they were manufactured outside of Colombia. Similarly, a Colombian court may prevent the importation of a product directly resulting from a patented process in Colombia, even where such a process occurred outside of Colombia.

## 8 Infringement by equivalents

**To what extent can 'equivalents' of the claimed subject matter be shown to infringe?**

Andean Decision 486 does not specifically contemplate the doctrine of equivalents. There is, likewise, no case law on the point; at best a plaintiff may seek a broad interpretation of the terms in the claim. The patent specification, drawings and examples may be used to interpret the scope of the claim as granted.

## 9 Discovery of evidence

**What mechanisms are available for obtaining evidence from an opponent, from third parties or from outside the country for proving infringement, damages or invalidity?**

Colombian procedural law provides pre-litigation evidence preservation mechanisms, such as preliminary injunctions seeking to preserve a given document or the lien of a given product or goods that may serve as evidence of any sort of conduct or fact. It is also possible to request pre-litigation discovery motions for site inspections, document production or depositions, witness testimonies or expert opinions. There are also broader evidence gathering requests that can be made once a complaint is filed. Both pre-litigation and post-complaint evidence gathering may be requested outside Colombia. Failure to comply in certain cases will allow the court to draw adverse inferences.

## 10 Litigation timetable

**What is the typical timetable for a patent infringement lawsuit in the trial and appellate courts?**

According to official statistics published by the Chief of the Jurisdictional Department at the CPO in 2014, a standard patent infringement case litigated before the CPO may take from five months to one year to reach a first-instance decision. A second-instance decision may take approximately two more years. Preliminary injunctions are available and may be obtained any time between six to 15 days if it is requested before the CPO. This shows a considerable decrease in the time spent over a civil infringement process compared with the timing for the same action some years ago.

## 11 Litigation costs

**What is the typical range of costs of a patent infringement lawsuit before trial, during trial and for an appeal? Are contingency fees permitted?**

The costs of prosecuting an infringement lawsuit vary depending on the complexity of the case and are normally invoiced on an hourly basis. Excluding the invalidity portion, in terms of an average case, it is reasonable to budget anywhere between US\$50,000 and US\$150,000 for a one- to four-year period, which is the normal length of time at first instance. Reaching a settlement could significantly reduce costs. For the second instance, it would be prudent to budget US\$50,000 to US\$100,000 over a one- to two-year period. The cost of an invalidity suit will vary greatly, depending on the amount of evidence that requires processing and also, as noted previously, on the complexity of the case. A prudent budget would range between US\$75,000 and US\$250,000 over a four-year period.

Contingency fees are permitted and also vary depending on the complexity of each case, and are generally in the range of 10 to 30 per cent of the amount of damages recovered, according to the reasonable estimation calculated by the plaintiff. Attorneys' fees in these terms, as set by the National Bar, are only available for winning parties and should never exceed 50 per cent of said amount.

## 12 Court appeals

**What avenues of appeal are available following an adverse decision in a patent infringement lawsuit? Is new evidence allowed at the appellate stage?**

The parties may appeal an adverse infringement decision issued by a trial court before a superior court. Infringement cases, by petition of a party, may eventually be selected to be heard by the Supreme Court. Invalidity suits are single-instance procedures and no appeals are available.

A second-instance decision may take approximately one to two more years to obtain a final decision.

New evidence at second instance is allowed in the Colombian Procedural Law in the following cases:

- when all parties agree on the request of new evidence;
- when such evidence was requested and accepted by the judge at first instance but, through no fault of the requesting party, the evidence was not performed at that time;
- when it tends to prove facts occurred after requesting said evidence at the proper opportunity during the first instance; and
- when it relates to documentary evidence that was not able to be provided at first instance because of unforeseeable circumstances or force majeure.

In addition, the judge has the discretion to request any additional evidence considered useful in order to issue a final ruling.

## 13 Competition considerations

**To what extent can enforcement of a patent expose the patent owner to liability for a competition violation, unfair competition, or a business-related tort?**

IP rights are a legitimate exception to free-market rights. Patent rights, however, are not absolute rights and are limited to the scope of the claims as granted. In that sense, for example, making an unduly broad interpretation of the granted claims could be interpreted by the

defendant as an abuse of IP rights, providing an alleged infringer with legal standing to seek relief relying on unfair competition arguments. From an antitrust perspective, if the patent holder has a dominant position in a relevant market, an abusive exercise of its patent rights could be taken as an abuse of dominant position. To the best of our knowledge, neither the courts nor the antitrust authorities have issued a decision on this issue.

#### 14 Alternative dispute resolution

##### To what extent are alternative dispute resolution techniques available to resolve patent disputes?

Disputes regarding patent infringement or patent unenforceability may be resolved by conciliation, mediation or arbitration. However, invalidity issues are, for the time being, not considered the subject of local ADR mechanisms because they are considered exclusive subject matter for the Council of State (Supreme Court for administrative matters).

#### Scope and ownership of patents

#### 15 Types of protectable inventions

##### Can a patent be obtained to cover any type of invention, including software, business methods and medical procedures?

As a general rule and pursuant to the TRIPS Agreement, Colombian authorities have to provide patent protection for inventions in all fields of technology (article 14 of Decision 486). However, there are certain limited exceptions to that rule either in the form of subject matter that is not considered an invention (article 15 of Decision 486) or that is excluded from patentability (article 20 of Decision 486). Business methods are not considered inventions and medical procedures (for treatment or diagnosis) are expressly excluded from patentability. Software as such is not considered an invention; it is protected by copyright (Andean Decision 351 of 1993). However, computer-implemented inventions are patentable insofar as they provide a technical contribution. According to the position of the ACJ and article 21 of Decision 486, use and second-use claims are not patentable subject matter, not even if drafted in the Swiss format.

#### 16 Patent ownership

##### Who owns the patent on an invention made by a company employee, an independent contractor, multiple inventors or a joint venture? How is patent ownership officially recorded and transferred?

The right to a patent belongs to the inventor (individual) and may be transferred to third parties by written assignment or succession in title (to an individual or a corporation). There is a presumption of assignment for inventions developed within the framework of an employment relationship or performed by an independent contractor (article 539 of the Colombian Commercial Code and article 29 of Law 1450 of 2011). It is not necessary to submit an assignment in Colombia as a copy of the employment contract will suffice. Multiple inventors share the right to patent the invention in the same proportion unless otherwise agreed. This is also the case for patent ownership for joint ventures. The patent is granted jointly to each company constituting the joint venture in the proportion previously agreed. As a joint venture is not considered a legal person, it may not be holder of a patent right (article 22 of Decision 486). Any of the companies in a joint venture may initiate a patent infringement lawsuit against third parties, regardless of the percentage of the patent held (article 238 of Decision 486). Patent ownership is officially recorded and transferred when the assignment document from the inventor to the applicant is filed with the patent application.

#### Defences

#### 17 Patent invalidity

##### How and on what grounds can the validity of a patent be challenged? Is there a special court or administrative tribunal in which to do this?

Invalidity does not provide grounds for a defence within an infringement case. Instead, the defendant in an infringement action seeking to

invalidate the patent must bring a separate lawsuit (annulment action) against the CPO before the Council of State and request the joinder of the patent holder as an interested third party. The Council of State is the highest court in charge of reviewing the legality of administrative acts. The annulment action is a single instance procedure with no appeal available. The purpose of an invalidity complaint is to demonstrate that the Resolution that granted the patent was issued in violation of the Colombian Constitution, Decision 486 or any procedural or substantive Colombian law.

According to the Colombian Administrative Procedural Code (Law 1,437 of 2011, in force from 2 July 2012), a typical annulment action for a patent case involves:

- filing of the complaint;
- admission and service on the defendant (CPO) and the interested third party (the patent holder);
- formal reply by the CPO and the patent holder;
- preliminary hearing, comprising the agreement on the facts to be litigated and the opening of the evidence gathering stage;
- evidence gathering process;
- evidence hearing (up to 15 consecutive days);
- closing arguments hearing;
- mandatory prejudicial interpretation of applicable Andean law before the ACJ; and
- final ruling.

With the exception of the complaint and reply, the foregoing procedure is almost completely oral and intended to last less than two years. However, a reasonable expectation is that in reality the overall procedure will take anywhere between three and five years depending on the complexity of the case, the amount of evidence that has to be gathered and, of course, the usual court backlog.

#### 18 Absolute novelty requirement

##### Is there an 'absolute novelty' requirement for patentability, and if so, are there any exceptions?

There is an absolute novelty requirement. An invention is novel when it is not disclosed in the prior art. The prior art includes any public worldwide disclosure, including any written or oral description (classes, conferences or seminars in which the main elements of the invention are disclosed), use, offer for sale or sale before the claimed priority date. Solely for the purpose of determining novelty, the content of an earlier patent application pending before the CPO shall also be considered part of the prior art, provided that the said content is included in the earlier application when published or after 18 months from the filing or priority date have passed. The applicant is provided with a 12-month grace period counted from the priority date for any disclosure of the contents of the patent, providing that the disclosure was attributable to:

- the inventor or the inventor's assignee;
- a competent national office that publishes the contents of a patent application filed by the inventor or the inventor's assignee in contravention of the applicable law; or
- a third party who obtained the information directly or indirectly from the inventor or the inventor's assignee.

#### 19 Obviousness or inventiveness test

##### What is the legal standard for determining whether a patent is 'obvious' or 'inventive' in view of the prior art?

A patentable invention must involve inventive step, that is, it cannot be deemed obvious or evidently derived from the prior art by a person ordinarily skilled in the art. Inventive step in Colombia is usually assessed by means of a problem-solution approach. Additionally, evidence of unexpected or surprising results, as well as secondary indicia of non-obviousness (such as the solution of an unresolved need in the art, the existence of contrary teachings in the art, etc), may be persuasive to rebut a prima facie case of obviousness. As such, experimental results may be submitted in response to inventive step objections during prosecution.

## 20 Patent unenforceability

### Are there any grounds on which an otherwise valid patent can be deemed unenforceable owing to misconduct by the inventors or the patent owner, or for some other reason?

A patent can be deemed unenforceable regarding acts carried out privately and for non-commercial purposes, for experimentation, for purposes of teaching, for scientific or academic research or when the patent protects biological material (article 53 of Decision 486). Further, a patent can be deemed unenforceable in cases of international exhaustion of rights (article 54 of Decision 486). Finally, Colombia implemented a regulatory submission exception (Decree No. 729 of 2012) allowing third parties to use the subject matter protected in a given patent to generate the information necessary to support an application for the marketing approval of a pharmaceutical product under the condition that it will not be made, used, sold, offered for sale or imported into the territory, other than for the purposes of meeting marketing approval requirements, before the patent expires.

## 21 Prior user defence

### Is it a defence if an accused infringer has been privately using the accused method or device prior to the filing date or publication date of the patent? If so, does the defence cover all types of inventions? Is the defence limited to commercial uses?

The rights conferred by a patent may not be asserted against a third party that, in good faith and before the priority date or the filing date of the application on which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparation for such use or exploitation. This defence covers all types of inventions and said third party has the right to start or continue using or exploiting the invention, but that right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place (article 55 of Decision 486).

## Remedies

## 22 Monetary remedies for infringement

### What monetary remedies are available against a patent infringer? When do damages start to accrue? Do damage awards tend to be nominal, provide fair compensation or be punitive in nature? How are royalties calculated?

Article 243 of Decision 486 provides the plaintiff with a variety of alternatives to calculate the compensation to be paid for damages, including:

- lost profits and actual damages;
- unjust enrichment; or
- reasonable royalty.

However, very few cases get to the damages stage (a preliminary injunction is often enough). Punitive damages are not available. Attorneys' fees as set by the National Bar are available for the winning parties. Obviously, a patent holder may recover damages for acts of infringement occurring after the date of grant. The patent holder also may, additionally and once the patent is granted, recover damages for pre-issuance acts of infringement occurring after the date of publication (article 239 of Decision 486).

Effective since mid-2012, the General Procedure Code determined a provision whereby a plaintiff seeking to be granted monetary remedies must include a reasonable estimate of the amount of the damages with the complaint.

Note that there is no particular formula stated in Colombian law in order to calculate a reasonable royalty, nor is there precedent available.

## 23 Injunctions against infringement

### To what extent is it possible to obtain a temporary injunction or a final injunction against future infringement? Is an injunction effective against the infringer's suppliers or customers?

The patent holder may request a court to grant injunctive relief to stop or prevent an infringement from occurring. This relief may consist, among others, of the following:

- an order to stop all infringing activities;
- the seizure of all infringing products;
- the suspension of the importation or exportation of the infringing products;
- the establishment of a bond; and
- the temporary closure of the business belonging to the defendant, if necessary to avoid the continuation or repetition of the alleged infringement (article 246 of Decision 486).

The injunction may be requested and granted *ex parte* and requires the plaintiff to show ownership to the patent, the existence of the patent and summary evidence of the infringement (normally an expert attesting to the fact the allegedly infringing product or process reads on the claims). A bond must be offered and posted to cover potential damages caused by the injunction should the plaintiff eventually lose the case on the merits.

The defendant may eventually file a reconsideration action against the grant for injunctive relief; however, this would not suspend enforcement or effects until a final decision. Depending on necessity, reasonableness and proportionality of the injunction, the judge may decide to suspend it at any time. In most cases, a preliminary injunction will become final if the plaintiff wins on the merits. Injunctive relief, if properly requested, may extend to the infringer's suppliers and customers.

## 24 Banning importation of infringing products

### To what extent is it possible to block the importation of infringing products into the country? Is there a specific tribunal or proceeding available to accomplish this?

Importation is an act of infringement. Accordingly, it is possible to block the importation of infringing products by requesting injunctive relief before the CPO or a civil court (see questions 8 and 23). Additionally, article 614 of Decree No. 390/2016 (issued by Ministry of Finance and Public Credit) established that the holder of an intellectual property right may request the suspension of the importation or exportation of the infringing products to the National Office of Taxes and Customs (DIAN from its initials in Spanish), while the infringement lawsuit is decided.

## 25 Attorneys' fees

### Under what conditions can a successful litigant recover costs and attorneys' fees?

The successful litigant may recover attorneys' fees by simply requesting the judge to order the losing party to pay. However, in practice, the amount recognised by the judge does not correspond to the true invoiced fees, but rather to predetermined fees set by the National Bar.

## 26 Wilful infringement

### Are additional remedies available against a deliberate or wilful infringer? If so, what is the test or standard to determine whether the infringement is deliberate? Are opinions of counsel used as a defence to a charge of wilful infringement?

No, there are no additional remedies available and opinions of counsel are not used as a defence to any kind of infringement charges in civil litigation (they may be useful in criminal cases to rebut criminal intent).

## 27 Time limits for lawsuits

### What is the time limit for seeking a remedy for patent infringement?

The time limit for seeking a remedy for patent infringement is two years counted from the date the patent holder had knowledge of the infringement or, in any case, five years counted from the date the last act of infringement occurred.

According to Prejudicial Interpretation No. 205-IP-2018 issued by the ACJ, the two-year limit should be counted from the date the plaintiff had knowledge of the infringing act, regardless of whether the infringement is instantaneous, continuous, permanent or complex. However, the five-year limit should be calculated from the time the last act of infringement occurred, which varies depending on the type of infringement.

**28 Patent marking**

**Must a patent holder mark its patented products? If so, how must the marking be made? What are the consequences of failure to mark? What are the consequences of false patent marking?**

Neither Andean Decision 486 nor local regulations provide any regulation in relation to patent marking.

**Licensing****29 Voluntary licensing**

**Are there any restrictions on the contractual terms by which a patent owner may license a patent?**

Technology transfer agreements involving voluntary patent licences must not include provisions limiting the right of experimentation, research and development of the licensee. These types of restriction fall within the unenforceable clause types contemplated in the Common Regime for the Treatment of Foreign Capital. Attempting to enforce such a clause could also run afoul of local antitrust legislation (Decree No. 2,153 of 1992), forbidding, in general, any sort of illegal restriction of access to a given market.

**30 Compulsory licences**

**Are any mechanisms available to obtain a compulsory licence to a patent? How are the terms of such a licence determined?**

The CPO may declare compulsory licences (CLs) for the following reasons (article 61 et seq of Decision 486):

- lack of working: patent owners are obligated to exploit the patent either directly or through authorised third parties. The standard for granting a CL under these grounds is unjustified lack of working after three years following grant, or four years counted from the filing date, whichever is the longest. Potential licensees must first contact the patent owner and attempt to obtain a voluntary licence under reasonable commercial terms. In the frame of a CL procedure, the patent owner will have a 60-day term counted from the notice of the CL procedure to file a statement evidencing the working of the patent. Failure to file documentation related to the exploitation of the patent will probably result in a CL granting;
- public interest, emergency and national security reasons: whenever public interest, emergency or national security reasons are declared by the Colombian government, the CPO may open a CL public bid over those patents subject to the prior declaration. Interested third parties meeting the terms of reference established by the CPO may subsequently submit offerings to obtain CLs. On 13 November 2008, the Colombian Ministry of Trade (MoT) issued Decree No. 4,302, modified by Decree No. 4,966/2009 (later the two decrees were compiled in Decree No. 1,074/2015), establishing a procedure for the declaration of public interest, providing each ministry of the government with the authority to declare, after an investigation, the existence of a public interest related to the subject matter under its jurisdiction. The declaration of a public interest (DPI) might also take place upon the request of interested parties. On 25 April 2017, the MoT issued Decree No. 670/2017, which modified Decree No. 1,074/2015. The new decree:
  - created the Interinstitutional Technical Committee (ITC), comprising a delegate of the competent authority, a delegate of the MoT and a delegate of the Director of the National Planning Department, which has the faculty to evaluate the arguments and evidence provided during the procedure and issue a recommendation to the competent authority to issue a final decision regarding a DPI request; and
  - eliminated the possibility of ordering alternative measures to overcome a DPI situation (in essence, if the competent authority issues a DPI, the CL is a foregone conclusion);
- abuse of dominant position: the Colombian antitrust authority, either ex officio or at the request of a party, may grant CLs to correct practices previously declared as contrary to the exercise of free competition, especially where they constitute an abuse by the patent owner of a dominant position in the market; and
- patent dependence (compulsory cross-licensing): the CPO shall grant a CL, upon request by the owner of a patent whose

exploitation necessarily requires the use of another patent, and where the right holder has been unable to secure a contractual licence to the other patent on reasonable commercial terms. The dependent patent must claim an invention that constitutes an important technical advance and of considerable economic importance over the senior patent.

Note that, in addition to the reasons listed above, article 68 of Decision 486 provides certain relevant conditions that must be followed by the CPO when compulsory licences are declared.

**Patent office proceedings****31 Patenting timetable and costs**

**How long does it typically take, and how much does it typically cost, to obtain a patent?**

The patent prosecution usually takes, depending on the art section, approximately one to three years. Colombia shall make its best efforts to process patent application expeditiously with a view to avoiding unreasonable delays (article 16.9.6(b) of the US-Colombia Free Trade Agreement).

In practice, the Colombian Patent Office averages between 20 and 22 months to issue a non-final decision after filing.

The costs of filing, prosecuting and obtaining a patent will range, depending on the complexity of the case and the amount of office actions, between US\$2,500 and US\$8,000 over the course of the prosecution, including official and professional fees.

**32 Expedited patent prosecution**

**Are there any procedures to expedite patent prosecution?**

Neither Decision 486 nor local regulations provide accelerated procedure options. However, a diligent prosecution practice may reduce the timeline of the application significantly, for example, by requesting examination shortly after publication takes place, by modifying the application excluding use claims, method of treatment claims, or any other non-patentable subject matter. It is also convenient to interview examiners in charge of the case and discuss alternatives in order to expedite prosecution and avoid additional examinations.

Patent Prosecution Highway (PPH) is considered a way to speed up examination for corresponding application filed in participating intellectual property offices that have agreed that when an applicant receives final ruling from a first patent office where at least one claim is allowed, the applicant may request fast-track examination of such as claim(s) in a corresponding patent application that is pending in a second patent office. Colombia has agreed PPH with some patent offices around the world, including the US, Japan and Spain. More recently, in 2016 the Regional Cooperation System for Industrial Property (PROSUR) organisation started PPH agreements with eight South American patent offices: Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru and Uruguay. Furthermore, in the frame of the Pacific Alliance initiative, as of September 2016, Colombian, Chilean, Peruvian and Mexican IP offices also agreed to launch pilot PPH programmes over the following three years. Finally, in July 2017, the offices of Costa Rica, Nicaragua, Panama and the Dominican Republic were recognised as members of PROSUR.

Therefore, 12 Latin American countries are currently members of PROSUR. In addition, since July 2017 Colombia has been part of the global PPH programme, which includes 22 different countries.

**33 Patent application contents**

**What must be disclosed or described about the invention in a patent application? Are there any particular guidelines that should be followed or pitfalls to avoid in deciding what to include in the application?**

Decision 486 requires the specification to include sufficient disclosure of the invention in order to allow a skilled artisan to reproduce the invention and make clear the inventor was in possession of the invention at the time the application was filed. Additionally, the description must contain the preferred embodiment of the invention.

Examination guidelines certainly exist and are commonly applied by the examiners and relied upon by applicants, such as the Andean

## Update and trends

### DPI procedure for Hep-C related patents

On 20 December 2017, the Ministry of Health (MoH) issued Resolution No. 5246, formally opening a DPI procedure for unidentified patents covering Hepatitis C products. The DPI was requested by a patient's NGO (IFARMA) in 2015. The MoH served Resolution No. 5246/2017 to 'potential' pharma patent titleholders with marketing approvals currently in force covering Hepatitis C medicines. In addition, in February 2018 the Regulatory Authority submitted a writ with information on marketing approvals covering Hepatitis C products.

The CPO is obliged to provide the MoH with notification information regarding Hep-C patents. However, the CPO has advised the MoH it cannot provide this information since its database does not have a link between commercialised active ingredients and patents.

The companies notified by the MoH were not obligated to provide comments. To date, the only companies that replied to the MoH invitation were BMS, Janssen, Novartis, Abbvie and Roche. In addition, some pharma associations filed comments against the DPI procedure, to wit: AFRIDRO, PhRMA, FIFARMA and BIO.

The main arguments provided in writs filed by the cited companies and pharma association are related to the violation of due process of this DPI procedure, as there is no single patent identified. In addition, there are arguments related to the exceptional nature of the DPI procedure and how it has been erroneously used by the MoH.

On 5 April 2018, the Minister of Health designated the Vice-minister of Health and the Legal Director to represent him in the Intersectorial Committee. In addition, the National Planning Department Director designated the National Planning Department

Subdirector. To the best of our knowledge, the Ministry of Trade has not designated a delegate, and therefore, the procedure has practically been suspended since last April. The referred Technical Committee will issue a recommendation report for the MoH, which will adopt a final decision on the DPI procedure.

By December 2018, the MoH had not decided on the DPI request. Further developments are expected during the first part of 2019.

### Patent linkage

On 14 June 2018, the MoH published the first standardised database of medicines completed with the marketing approval files sent by holders and authorised distributors. Furthermore, on 3 August 2018, the MoH issued Resolution No. 3311 and defined and implemented the Medicaments Data Standard for the Development of a National Pharmaceutical Information System.

The foregoing standard provides, perhaps unwittingly, toward a more useful and functional linkage system. In practice, this generates two situations: innovators are able to list all patents associated with their products; and generics are able to consult this listing.

Although there will be no Orange Book-style certification process, innovators are more easily able to build scenarios where infringements are easier to show and preliminary injunctions easier to obtain.

### Updated official fees

On 10 September 2018, the CPO, through Resolution No. 69831, updated the fee for industrial property procedures in Colombia, increasing the fees by 4.1 per cent as of 1 January 2019.

Patent Manual and CPO's Guidelines for Examination. Note that examination guidelines are not binding.

## 34 Prior art disclosure obligations

### Must an inventor disclose prior art to the patent office examiner?

Applicants have the obligation to include in the specification of patent applications the prior technology known to the applicant that would help the invention to be understood and examined and references to previous documents and publications that discuss the technology involved. (article 28(b) of Decision 486). The foregoing has not been interpreted by the CPO as a specific duty to disclose prior art that may be materially relevant to the patentability of the invention. Additionally, according to article 46 of Andean Decision 486, the CPO may request search results and examination reports of counterpart applications in other industrial property offices.

## 35 Pursuit of additional claims

### May a patent applicant file one or more later applications to pursue additional claims to an invention disclosed in its earlier filed application? If so, what are the applicable requirements or limitations?

In general, amendments to the specification or claims are possible at any time during prosecution before the issuance of a final resolution, as long as said amendments do not extend the original scope of the invention and find support on the specification (article 34 of Decision 486). Divisional applications directed to material split out from the parent application are possible, as long as they are filed before a final decision is issued. Divisional application practice must carefully carve out claimed subject matter that will remain in other applications (article 36 of Decision 486). Post-grant amendments to the specification are not possible; however, the applicant may limit the scope of one or more granted claims or divide them.

## 36 Patent office appeals

### Is it possible to appeal an adverse decision by the patent office in a court of law?

Before seeking judicial review, the applicant may file a reconsideration action or a revocation action in both cases pursuing to revoke, clear or modify the rejection of one or more claims. This action must be filed before the CPO against the adverse decision within five days

after the notification for cases older than 2012 and 10 days for cases filed after 2012. If the CPO confirms its decision, the applicant may seek judicial review by filing an annulment action against the Council of State within four months following the notification of the final resolution from the CPO.

## 37 Oppositions or protests to patents

### Does the patent office provide any mechanism for opposing the grant of a patent?

Andean Decision 486 provides a pre-grant opposition system. Interested third parties may file an opposition within 60 days following the publication of the application, which can be extended for an additional 60-day term upon request. The CPO will consider the relevance of the opposition in the framework of the examination and will take a final decision at the time of granting (that is, there is no separate opposition procedure to delay prosecution of the application). In addition, third parties may also file observations providing arguments and evidence to the CPO at any time (for example, even after the time to file an opposition has expired). However, unlike an opposition, the CPO is not compelled to take this information into consideration.

Additionally, opponents (which have filed oppositions in time), may file reconsiderations actions against a resolution granting a patent. In this case, the patent owner will be notified of this action and will be allowed to file arguments in response. Filing a reconsideration action automatically suspends the effect of the granted patent until it is resolved.

## 38 Priority of invention

### Does the patent office provide any mechanism for resolving priority disputes between different applicants for the same invention? What factors determine who has priority?

Article 9 of Decision 486 establishes the right of priority in filing for a patent or registration on the same subject matter. In case of priority disputes, the affected party may seek the transfer of the pending application or the patent before the CPO, providing evidence of the prior right of the patent.

**39 Modification and re-examination of patents**

**Does the patent office provide procedures for modifying, re-examining or revoking a patent? May a court amend the patent claims during a lawsuit?**

Post-grant limitations to the claims may be made before the CPO (article 70 of Decision 486). Additionally, division of granted claims is possible (article 72).

There is no re-examination procedure available.

A patent granting can be challenged via judicial review through an annulment action filed before the Council of State. It is not possible for a court to amend the patent claims during an infringement lawsuit.

Additionally, the direct revocation of administrative acts (eg, a resolution granting a patent) is possible, whenever it is contrary to the law, contrary to the public interest or causes unjustified harm. However, in order to revoke a granted right, the patent owner must also authorise such revocation. This makes the direct revocation impractical when seeking invalidation, making the annulment action the proper route.

**40 Patent duration**

**How is the duration of patent protection determined?**

Patents are granted for a 20-year period from the date on which the application was filed (for conventional applications: article 50 of Decision 486) or from the international filing date (for PCT National Phase applications: article 11.3 PCT). In this respect, note that Colombian legislation provides compensation to patent holders for 'unreasonable' delays (not available for pharmaceutical products), wherein prosecution has lasted more than five years from the filing date or three years counted from the date of examination request, according to the established compensation standards listed via Decree No. 1873 of 2014, which came into force on 29 September 2014.

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