

Patents 2021

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Patents 2021

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Lexology Getting The Deal Through is delighted to publish the eighteenth edition of *Patents*, which is available in print and online at www.lexology.com/gtdt.

Lexology 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 Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Israel, Singapore, Turkey and the United Kingdom.

Lexology 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.lexology.com/gtdt.

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.

Lexology 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 editors, Louis E Fogel and Shaun M Van Horn of Jenner & Block LLP, for their continued assistance with this volume.



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PATENT ENFORCEMENT PROCEEDINGS

Lawsuits and courts

1 | 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 specialist civil courts. However, the procedure implemented in July 2012 provided the Superintendency of Industry and Commerce (SIC) with jurisdiction over infringement cases through an independent Judicial Division. The SIC is also where the Colombian Patent Office (CPO) resides. Civil actions may be pursued before the SIC (the preferred choice) or Civil Circuit Courts present in the larger cities. 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 SIC has become the principal venue to litigate infringements under the civil jurisdiction since it has proven to be very effective and reliable. However, according to its 2020 Annual Report, there was a 35 per cent annual decrease in complaints filed before the SIC (a total of 211 cases, including unfair competition, trademark and patent infringement cases compared to 322 complaints filed in 2019). This decrease may be related to the covid outbreak, given that the SIC was on hiatus from March to July 2020. The report pointed out that 203 IP proceedings were decided.

Trial format and timing

2 | What is the format of a patent infringement trial?

Civil patent infringement trials can start with the filing of a request for preliminary injunctive relief, along with or before the filing of a complaint (injunctive relief can, however, be sought at any time during the process). It is possible to request and obtain preliminary injunctive relief without serving or hearing the counterpart. However, the SIC will typically serve notice on the defendant in most patent cases involving a preliminary injunction. Considering that invalidity cannot be contested during the infringement process, cases are typically settled once a preliminary injunction is issued.

Outside the complaint and reply, the procedure is mostly oral and follows these stages:

- preliminary injunction request (optional) and decision;
- filing of the complaint;
- admission and service of the complaint to the defendant;

- reply by the defendant;
- conciliation hearing, evidence gathering process and oral closing arguments;
- prejudicial interpretation of applicable Andean law before the Andean Court of Justice (ACJ) (the prejudicial interpretation is optional in a first instance stage; however, it will become mandatory during an appeal); and
- a final ruling.

A standard infringement case before the SIC may take anywhere between one and two years to reach a final ruling.

The following types of evidence are admissible:

- expert opinions and testimony provided by a party (which can be cross-examined);
- 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 and controvert its conclusions. Party experts may be local or foreign, academic or professional. They can also be employees, but the judge will naturally affect credibility due to bias.

In addition, Colombian procedural law provides ample discovery through pre-litigation discovery motions for site inspections, document production and depositions.

The parties may appeal an adverse decision from the SIC before the Bogota Superior Tribunal or from a Civil Circuit Court before a Superior Tribunal from the corresponding city where the complaint was filed. An appeal can take one to two years.

Criminal trials are restricted to natural persons, are essentially accusatory and are almost completely oral in nature. However, criminal patent infringement cases are very rare; instead, they are typically used to pursue piracy or counterfeit cases.

Proof requirements

3 | 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 may be reversed for method claims if the plaintiff can show: (1) the product obtained by means of the patented process is a new product, or (2) (a) a substantial likelihood that the process is being infringed and (b) reasonable steps were taken to determine if the infringement process was taking place. If the reversal is triggered, the defendant must demonstrate that its accused method is different from the patented one.

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 party seeking to invalidate the patent, which must show the patent office erred when granting the patent, based on a clear and convincing standard.

Standing to sue

- 4 | 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: (1) any of the co-owners of the patent (individually and severally), unless otherwise agreed, or (2) under article 564 of the Commerce Code, the licensee, unless otherwise agreed and subject to prior notification to the patent owner.

Although extremely rare and not specifically contemplated under Colombian practice, whenever a patent infringement action has not yet been filed by the patent holder, a potential infringer may request a non-infringement declaration. Beyond a perceived threat (eg, a cease and desist letter, a warning letter to customers), there is no specific conduct that must be alleged or shown to have standing for such declaratory action. There may be some forum-shopping advantages for a potential defendant if there is a benefit to remove the case from the SIC to a civil court.

Inducement, and contributory and multiple party infringement

- 5 | 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 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 patentholder 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 above, it is possible that a broad interpretation of article 238 may also allow the patent holder to pursue different actors that may be contributing in a concerted fashion to materialise the infringement.

Joinder of multiple defendants

- 6 | 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 have some responsibility in the infringing conducts (eg, offer for sale, sale, use, manufacture or importation) and the conducts are related to the violation of the same patent or patents.

To the best of our knowledge, there are two recent cases (2015 and 2019) where the plaintiffs filed patent infringement lawsuits against various companies comprising a joint venture that collectively used a patent-protected invention. The lawsuit and preliminary injunction request named all the companies as defendants. The lawsuits were successfully admitted by the SIC and a Civil Circuit Judge of Bogota.

Infringement by foreign activities

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

Under the general territoriality rule applicable under Decision 486, the scope of patent protection is limited to acts taking place in Colombia, including importation. However, a Colombian court may also prevent the importation of a product resulting directly from a process patented in Colombia, even where such a process took place outside of Colombia.

Infringement by equivalents

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

Andean Decision 486 (IP law in Colombia) 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 claims. The patent specification, drawings and examples may be used to interpret the scope of the claims as granted. Additionally, prosecution history and closely related prior art could be used persuasively by the defendant to limit any such broad interpretation.

Discovery of evidence

- 9 | 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 and against third parties. Failure to comply in certain cases will allow the court to draw adverse inferences.

Pre-litigation evidence-gathering procedures may be requested by anyone who is a potential plaintiff or defendant in a future judicial proceeding. For patent infringement actions, the SIC also has jurisdiction over pre-litigation evidence motions and has become the principal venue for doing so since it has proven to be very effective and it is the specialist court for IP matters.

Litigation timetable

- 10 | 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 SIC in 2014, a standard patent infringement case litigated before the SIC 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 two weeks and one month if it is requested before the SIC. A PI request may take from one to three months to reach a decision before civil circuit judges.

There are no updated statistics that are publicly available.

Litigation costs

11 | 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-three-year period, covering pre-litigation and the 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 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. The National Bar prohibits contingency fees exceeding 50 per cent.

Court appeals

12 | 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 from the SIC before the Bogota Superior Tribunal, while an adverse decision from a civil circuit judge may be appealed before a Superior Tribunal from the city where the complaint was filed. Infringement cases, by petition of a party, may eventually be selected to be heard by the Supreme Court. Invalidity suits are single-instance procedures before the Council of State and no appeals are available. This will change in 2022 due to a recent amendment to the Colombian Administrative Procedural Code.

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 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 presented;
- when it tends to prove facts that 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 unforeseen circumstances or force majeure.

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

Competition considerations

13 | 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. However, on 11 December 2020, the Andean Court of Justice issued a Prejudicial Interpretation (02-IP-2019) in an Ecuadorian case that develops sham litigation using patent infringement preliminary injunctions as a basis for an antitrust violation.

Alternative dispute resolution

14 | 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 or arbitration. However, invalidity issues are, for the time being, not considered by the Colombian arbitration bar as subject of local ADR mechanisms because they are considered exclusive subject matter for the Council of State (Supreme Court for administrative matters). There is ample discussion surrounding this topic and a more flexible approach is being studied by the arbitration bar. However, until this happens, arbitration is not seen as a viable option to resolve a patent dispute where invalidity issues are under discussion.

SCOPE AND OWNERSHIP OF PATENTS

Types of protectable inventions

15 | 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 Andean Court of Justice (ACJ) and article 21 of Decision 486, use and second-use claims are not patentable subject matter, not even if drafted in the Swiss-type format.

Patent ownership

16 | 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). A copy of the employment contract will suffice. Multiple inventors share the right to patent the invention in the same proportion unless otherwise agreed. For joint ventures, the patent can be assigned 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 a holder of a patent right (article 22 of Decision 486). Any of the

companies in a joint venture or co-owners 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 when the assignment document from the inventor to the applicant is filed with the patent application before the Patent Office. Ownership is transferred upon execution of the assignment documents.

DEFENCES

Patent invalidity

17 | 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 (Colombia has a bifurcated system). Instead, the defendant in an infringement action seeking to invalidate the patent must bring a separate lawsuit (Annulment Action) against the Colombian Patent Office (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. However, this procedure will change in 2022 due to a recent amendment of our Administrative Procedural Code. Seeking to expedite this procedure, the Annulment Action will have a double instance and will have to be brought before the Administrative Superior Tribunal of Cundinamarca, and the appeal will be known by the Council of State.

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 four and six years depending on the complexity of the case, the amount of evidence that has to be gathered and, of course, the usual court backlog.

The Annulment Action will not automatically stay the infringement proceeding and it is practically impossible to obtain such a stay or suspend effects of the patent until the Annulment Action is decided. In practice, this situation generates an enormous presumption of validity for any patent and effectively removes invalidity as a viable defence.

Absolute novelty requirement

18 | 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, 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 CP).

The applicant has a 12-month novelty 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.

Obviousness or inventiveness test

19 | 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 the 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 (not in the Specification and generated after the priority date) may be submitted in response to inventive step objections during prosecution.

Patent unenforceability

20 | 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?

No, there are no grounds to consider a patent is unenforceable owing to misconduct by the inventors or the patent owner, or for some other reason. However, there are certain situations, mostly categorised as defences that may, in practice, render a patent unenforceable. Some of these are:

- Acts carried out privately and for non-commercial purposes, exclusively for experimentation, exclusively for purposes of teaching, exclusively for scientific or academic research (a complete list is contained in article 53 of Decision 486).
- International exhaustion of rights operates under article 54 of Decision 486. Accordingly, parallel imports are legal in Colombia.
- Colombia implemented a regulatory submission exception (Decree No. 729 of 2012), also known as a *Bolar* exemption. It allows third parties to use the claimed subject matter to generate the information necessary to support an application for the marketing approval of a pharmaceutical or agrochemical 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.
- Finally, compulsory licensing is available under Decision 486. Two of the grounds relate to patent owner conduct or omission, specifically non-working and abuse of dominant position. Although a compulsory licence is not proper grounds for unenforceability,

and notwithstanding the due compensation obligations, having a compulsory licence granted will in practice greatly limit a patent owner's capability of effectively enjoying its full rights afforded by a patent.

Prior user defence

21 | 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 (publicly or privately), 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 without encumbrance, 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

Monetary remedies for infringement

22 | 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.

Very few cases get to the damages stage (a preliminary injunction is often enough). Punitive damages are not available. Damages and causation must be proven through discovered evidence and expert testimony. There is little case law available on how royalties should be calculated (eg, what the royalty base should be, percentage of the royalty).

Attorney fees as set by the National Bar are available for the winning parties (ie, one cannot submit the true attorney invoices, and most often the National Bar fees are far below the true billable fees).

A patent holder may recover damages for acts of infringement occurring after the date of grant, plus pre- and post-judgment interest. The patent holder may also, 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).

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. The General Procedural Code provides a penalty for the plaintiff when it is proven that the calculated damages estimate was unreasonable. The penalty will be equivalent to 10 per cent of the difference between the estimated amount and the final proven amount ordered within the final ruling.

Injunctions against infringement

23 | 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.

According to the applicable law, a preliminary injunction (PI) may be requested and granted ex parte. However, in practice, the SIC serves the defendant in approximately 90 per cent of patent cases and provides the opportunity to file counterarguments to the request prior to issuing a decision. In contrast, civil circuit courts usually will not notify the defendant. The PI requires the plaintiff to show ownership of 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. A plaintiff does not need to show that it is working the patent to qualify for a PI or permanent injunctive relief.

The defendant may eventually file a reconsideration action against the grant of a PI. The PI may be suspended if the defendant posts a counterbond, but the suspension will only last until the reconsideration action is resolved. Also, depending on necessity, reasonableness and proportionality of an injunction, the judge may decide to suspend or modify it at any time. In most cases, a PI will become final if the plaintiff wins on the merits. Injunctive relief, if properly requested, may extend to the infringer's suppliers and customers.

In our experience, a decision on a PI request may take between one and three months, and three additional months for a final decision on appeal.

Banning importation of infringing products

24 | 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 a PI, where the judge can order customs and border control authorities to bar any customs operations. It is worth noting that there are no border measures for patents in Colombia; these measures apply only for trademark and copyright infringement.

Attorneys' fees

25 | 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.

The National Bar has regulated that the attorney's fee in the first instance ruling must be between 3 to 7.5 per cent of the amount claimed as damages and, for the appeal, between one and six times the Colombian monthly minimum salaries.

Wilful infringement

26 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 against a deliberate or wilful infringement. Opinions of counsel may be useful in rare criminal cases to rebut criminal intent.

Time limits for lawsuits

27 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 Andean Court of Justice, 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. The five-year limit should be calculated from the time the last act of infringement occurred, which varies depending on the type of infringement.

Patent marking

28 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

Voluntary licensing

29 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 restrictions 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.

Compulsory licences

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

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

- *lack of working*: 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 license under reasonable commercial terms. In the framework 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 or a viable excuse justifying non-working;
- *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 the applicable Ministry 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;
- *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.

To date, although various investigations have been opened seeking a declaration of public interest against pharmaceutical patents, no compulsory licences have been granted in Colombia.

PATENT OFFICE PROCEEDINGS

Patenting timetable and costs

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

In practice, the Colombian Patent Office (CPO) averages between 24 and 28 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.

Expedited patent prosecution

32 | 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 to expedite prosecution and avoid additional examinations. For PCT cases filed in Colombia, publication typically occurs about one month after it is filed (provided no formal examinations are issued).

Various Patent Prosecution Highway (PPH) options exist to speed up examination based on counterpart applications filed in participating intellectual property offices. The CPO has signed several bilateral PPH agreements with different Patent Offices in the world (the US Patent Trademark Office, the Japanese Patent Office, the Korean Intellectual Property Office, the European Patent Office and the Spanish Patent and Trademark Office), and is part of multilateral PPH agreements in Latin America, such as PROSUR-PROSUL (including Argentina, Brazil, Costa Rica, Chile, Ecuador, Paraguay, Peru and Uruguay – Panama, the Dominican Republic and Nicaragua have recently joined this Agreement but the particular PPH Guidelines have not been issued yet), the Pacific Alliance (including Chile, Peru and Mexico) and the Global PPH (including other 26 patent offices).

Patent application contents

33 | 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 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 specification must contain the best mode to produce the invention.

As a general rule, specifications that comply with European Patent Office standards will normally not have a disclosure issue before the CPO.

Prior art disclosure obligations

34 | 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 patent offices.

Pursuit of additional claims

35 | 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?

No, if the earlier application is not claimed as priority, a later filed application cannot claim aspects or features of an invention previously disclosed in an earlier filed application.

At best, the only way to pursue additional claims are through divisionals (article 36 of Decision 486), which legally have the same filing date as the parent application. Such divisionals should be directed to material split out from the parent application and must be filed before a final decision is issued. In September 2020 (through Resolution No. 59669), the CPO modified the requirements for filing divisional applications, and now the only request is that the claimed subject-matter is different from the one recited in the parent case. Finally, splitting out divisionals from divisionals is not allowed.

Amendments to the Specification or claims in the parent case 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 in the specification (article 34 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 (articles 70 and 72 of Decision 486).

Patent office appeals

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

Yes. Before seeking judicial review, the applicant may file a reconsideration action in pursuing to revoke, clarify or modify the rejection of one or more claims (the reconsideration action is optional and is not required to exhaust administrative remedies). This action must be filed before the CPO against the adverse decision within 10 business days. If the CPO confirms its decision, the Applicant may additionally 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.

Oppositions or protests to patents

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

Yes. 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 (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 reconsideration actions against a resolution granting a patent. Filing a reconsideration action automatically suspends the effect of the granted patent until it is resolved. In theory, the patent owner should be notified of an opponent's reconsideration action and will be allowed to file arguments in response. Nevertheless, in practice, the CPO states that there is no legal obligation to inform the patent owner and provide a term to submit arguments unless the opponent includes new evidence (eg, new prior art documents) within the reconsideration action.

Priority of invention

38 | 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 22 of Decision 486 establishes that whoever has an earlier priority date wins in a priority dispute.

The affected party may seek the annulment of patent (article 77 of Decision 486), or the transfer of the pending application or the patent (article 237 of Decision 486).

Modification and re-examination of patents

39 | 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 at any time 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 a patent by the CPO is theoretically possible, whenever it is contrary to the law, contrary to the public interest or causes unjustified harm. However, for the CPO to revoke a granted right, the patent owner must also authorise such a revocation. This makes the direct revocation impractical when seeking invalidation, making the annulment action the proper route.

Patent duration

40 | 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 Patent Cooperation Treaty: National Phase applications: article 11.3 PCT).

There is term restoration available for patent holders for unreasonable delays (excluding 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. To the best of our knowledge, this restoration has not been requested or applied in Colombia, most probably given the short prosecution average times.

UPDATE AND TRENDS

Key developments of the past year

41 | What are the most significant developing or emerging trends in the country's patent law?

Changes in divisional practice and issuance of additional examinations after the first office action

Pursuant to Resolution No. 59669 of 2020, the Colombian Patent Office (CPO) modified some aspects of the CPO Directives regulating patent prosecution in Colombia. Some of the most relevant changes are the following:

- A literal division of claims and filing an adapted specification to the subject-matter of the divisional are no longer requirements to file a divisional. Thus, the only requirements for filing a divisional are (1) that it is not a divisional of a previous divisional; and (2) that the claims of the parent and divisional(s) recite structurally

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different subject-matter (ie, any overlapping subject-matter should be avoided). Furthermore, there is no limit in the number of divisionals filed from the parent case, and they can be filed at any time during prosecution.

- The applicant must pay the corresponding fee for amending the claims, figures, specification, or sequence listing, whether they are filed in response to an office action response or voluntarily.
- The Examiner may require the payment of an additional examination fee if he or she considers that the amendments submitted with the response to an office action require a new search and exam. Nevertheless, the applicant could request up to two additional exams by paying the respective fee (this fee will not be reimbursed if a Resolution granting the patent is issued).

Amendments to the Administrative Procedure Code (CPACA)

On 25 January 2021, government-sanctioned bill No. 2080, amending the CPACA. Among numerous changes, we highlight: (1) the use of new technologies and telecommunications are encouraged in all proceedings; (2) judges are given the possibility of issuing a summary judgment before or during the initial hearing; (3) the Superior Tribunal of Cundinamarca will hear annulment action cases, and only appeals will be decided by the Council of State; pre-judicial interpretations issued by the Andean Tribunal Court of Justice will only be mandatory during the appeal stage (this changes the current situation where the Council of State solved all annulments concerning IP matters in a single instance procedure, where no appeals were available).

The rules regarding the competence of the Superior Tribunal for Annulment Actions will only become effective for complaints filed on and after 20 January 2022.

Coronavirus

42 | What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

Regarding the covid-19 emergency, the Health Authority and the Ministry of Health identified and prioritised more than 1,500 procedures associated with medications that can be used to manage covid-19 symptoms and complications. They can all be consulted online by visiting INVIMA.

In addition, specifically in relation to patents, the government issued Decree 476 of 2020, by means of which article 1.7 established that the Ministry of Health (MoH) was authorised to issue a declaration of public interest (DPI) for medicines, vaccines, medical devices and other health technologies related to covid-19 treatment. A DPI is the required first step for the imposition of a CL. Article 1.7 had been interpreted by many to facilitate the grant of CLs in Colombia.

However, on 28 May 2020, the Colombian Constitutional Court ruled that articles 1 and 2 of Decree 476 of 2020 are unconstitutional as they do not comply with the 'necessity test' required for statutory provisions issued in a state of emergency. For the Court, it was clear that the MoH already has the power to follow existing administrative procedure to pursue a DPI and eventually a CL.

Finally, regarding litigation, due to covid-19, courts and judicial proceedings were in abeyance from March to July 2020. To guarantee justice during the pandemic, Colombia took actions to resume operations. The main guidelines to resume operations were issued through Decree 806 of 4 June 2020, which mainly encouraged the use of new technologies and telecommunications in all proceedings, including virtual hearings. The parties have to provide an email for service and notifications and have to always copy the counterpart of all the briefs filed within the file.

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