

Patents 2021

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Patents

2021

Contributing editors**Louis E Fogel and Shaun M Van Horn****Jenner & Block LLP**

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.

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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?

Civil courts have jurisdiction to hear patent infringement claims and offer the most effective approach to enforce patents. Occasionally, patents are enforced in criminal courts by filing a complaint with the public prosecutor. Customs authorities may also enforce patents following their registration in accordance with EU Regulation No. 608/2013 by detaining goods suspected of infringement. Patent enforcement lawsuits must be brought before the specialised IP division operating in 21 out of 136 tribunals.

Trial format and timing

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

Patent enforcement proceedings essentially use a written procedure. The matter is presented by way of written submissions with limited opportunities to make oral submissions to the judge. The proceedings can be divided in four distinct phases.

The first phase starts with the service of the summons, followed by the filing of the answer, including any counterclaim and third-party notice, and the case management hearing, when the judge decides any preliminary plea, such as jurisdiction, venue and standing, and sets the dates for the completion of the gathering of evidence phase.

The second phase consists of the filing of documentary evidence and requests to hear witnesses or to take other evidence by way of disclosure of information from the other party. Once all evidence is in front of the judge, the proceedings will move to the third phase. The judge will appoint an expert of his or her choice – usually an European Patent attorney with a background in the patent technology – to assist the judge in understanding the underlying technology and in deciding the questions of the patent's infringement and validity.

As soon as the court-appointed expert submits his or her report, the case will move to the fourth and final phase, where each party makes its final written submissions and rebuttal. Only at the end of this phase, there is an oral hearing where each party may answer questions asked by the court and focus on the main issue of the dispute in a short oral presentation.

Given the written nature of the procedure, documentary evidence has a prominent role. However, written declarations cannot be used to prove facts, but only to present opinions (such as those of the experts). When a fact can only be proved by way of testimony, this must be given orally before the judge. There is very little room for cross-examination. The list of questions concerning the examination of the witness

are submitted in advance to the judge who decides which question is relevant and therefore admissible. The cross-examination is limited to obtaining details or clarifications on the answers already given.

Proof requirements

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

The burden of proof rests on the party making the claim. The patentee must prove the facts supporting the claim for infringement and the alleged infringer the facts supporting the claim for invalidity of the patent. The judge decides the case based on the evidence presented by the parties that must be assessed in accordance with Rules of Civil Procedure.

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?

The patent owner and exclusive and non-exclusive licensees have standing to sue for infringement, unless the licence agreement states otherwise. The party accused of infringement whether in writing or orally has standing to sue for a declaration of non-infringement. The accusation does not need to be detailed, it is sufficient that it identifies the patent allegedly infringed – even indirectly. There is still an open question – and contradictory judgments – as to whether the party that contacts a patent owner to inform the owner of his or her intention to offer on the market a product that in the party's opinion does not infringe, and requesting a confirmation that no action shall be taken has standing to sue in the event no answer is given.

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?

Any party inducing or contributing to the patent infringement committed by another is liable for patent infringement. However, there is a distinction between inducing infringement and contributing to infringement. While the party inducing to infringement is generally liable, the party contributing to infringement is liable if two conditions are met, namely that the component supplied is essential for working the patent invention and that the supplier is aware, or could have been aware by using average diligence, that the component infringes the patent.

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 patent owner can sue all parties involved in the infringement of the same patent or patents together on condition that they concur in the same infringement. For example, the producer, distributor and retailer of the same infringing product can be sued together even if they are unrelated businesses and their place of business is located in the jurisdiction of separate courts. On the contrary, the producer of an alleged infringing product and the distributor of a different alleged infringing product cannot be generally sued together even if they infringe the same patent and are related businesses.

Infringement by foreign activities

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

Activities that take place outside the jurisdiction can support a charge for patent infringement only if such activity is capable of creating a profit in the jurisdiction and that profit is an expected or predictable consequence of such activity. For example, a party producing and selling a product in a jurisdiction where there is no patent protection becomes liable for infringement of a patent in another jurisdiction if it promotes sales in that jurisdiction or if it supplies the product to a party that will predictably export the product in that jurisdiction.

Infringement by equivalents

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

Article 52 of the IP Code determines the scope of protection granted to patents and specifies that one must take into account any features of the alleged infringing product (or process) that are equivalent to a feature of the claims. In order to determine whether a certain feature of the product or process, albeit non-identical, is equivalent, the courts take two distinct approaches. They apply either the triple test copied from US law (assessing function, means and results) or the obviousness test. The obviousness test consists of comparing the feature of the product or process accused of infringement with that of the patent claim and if the substitution appears obvious to the skilled person, then there is infringement by equivalents.

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?

The options available to force the opponent or a third party to produce evidence during litigation are limited. As a general rule, during the litigation, each party is responsible for producing evidence that support its case and the possibility to force opponents or third parties to produce evidence is limited to those cases where the evidence under the control or possession of the other party is necessary for the decision and cannot be obtained otherwise. The request must clearly identify each document or thing to be produced and any request for the production of categories of documents or things is inadmissible. In addition, the patent owner may also seek to gather evidence before filing the infringement lawsuit by applying to the court for an order for description. The order enables the applicant to obtain access – usually without notice – to the premises of the alleged infringer and make copies of documents or things (which must be described, hence the use of the term description). The

enforcement of this order enables the applicant to obtain access to categories of documents and things, and it is often used in disputes relating to patents covering processes, as it may be otherwise difficult to obtain the necessary evidence to prove infringement.

Litigation timetable

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

The overall duration of a lawsuit for patent infringement, which always includes a counterclaim for invalidity of the asserted patents, is about four years. The fastest courts will decide the case in about three years, the slowest in five.

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 Italian procedure is mainly a written one without distinction between the pre-trial and trial phases of the lawsuit. The global cost depends on the number of patents involved and the area of technology. Assuming only one patent is involved, costs vary from €100,000 for a relatively simple mechanical case to €800,000 for a complex pharmaceutical or telecommunications case. Contingency fees arrangements are permitted, but uncommon for two reasons: Italian law does not contemplate the grant of damages other than compensatory damages; and because the prevailing party is entitled to recover its legal fees. Although the legal fees awarded are in the area of 30 per cent to 50 per cent of the actual cost, this has further discouraged the popularity of contingency fees arrangements.

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 aggrieved party may file an appeal within 30 days with the appellate court having territorial jurisdiction over the tribunal that issued the judgment. The appeal stage is a full review of the first instance proceedings (both facts and law) with, however, limited possibility to produce new evidence. In particular, during the appeal, the parties can produce only the evidence that it was not possible to produce during the first instance proceedings for reasons beyond the control of the party producing it.

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?

Patent enforcement can expose the patent owner – or the licensee – to liability for breach of competition law, if the enforcement is based on a patent that is known to the owner to be invalid. In a landmark decision issued by the Supreme Administrative Court (Council of State 12 February 2014, No. 693), the Court held that even the acquisition – not just the exercise – of a patent in the absence of the requisites of entitlement may amount to an abuse. If the patent owner enjoys a dominant position, the patent abuse may result in an abuse of a dominant position under article 102 of the Treaty on the Functioning of the European Union.

Alternative dispute resolution

- 14 | To what extent are alternative dispute resolution techniques available to resolve patent disputes?

Alternative dispute resolution methods, such as mediation and arbitration, are available but rarely relied upon in patent disputes

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?

Business methods and medical procedures are not patentable. Software per se is not patentable, but Italy follows the European Patent Office approach, according to which software may be patentable if it has a technical character. In order to have a technical character, a computer program must produce a further technical effect when run on a computer. A further technical effect is a technical effect going beyond the normal physical interactions between the program (software) and the computer (hardware) on which it is run. On the contrary, computer-implemented inventions are patentable, provided the other legal requisites are met.

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?

Inventors are entitled to apply for a patent covering their inventions; however, that rule suffers from a number of exceptions. If an employee makes the invention during the performance of his duty, the invention belongs to the employer, even if the carrying out of an inventive activity is not among his duties. If the employee makes an invention during his free time, but the invention relates to the business of the employer, the employer has a right of first refusal to acquire the invention. If an independent contractor under commission makes an invention, the invention belongs to the principal. In the latter two cases, there is no need to record a change of ownership because the invention belongs to the employer or the principal by operation of law.

Change of ownership in a patent is recorded by applying to the Italian Patent and Trademark Office and providing a copy of the executed assignment agreement.

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?

A patent can be challenged on any grounds provided in the law and on no other. A patent can be challenged for lack of novelty, lack of inventive step, insufficiency, lack of industrial application, non-patentable subject matter and contrariness to accepted principles of morality.

There is a specialist IP chamber in 21 tribunals that have exclusive competence to hear a claim for invalidity. There is no separate court for invalidity claims and, in general, the same court decides infringement and validity together.

Absolute novelty requirement

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

Patentability requires absolute novelty, namely that the invention is not part of the state of the art. The state of the art is made of any disclosure either in writing, in oral statements or by way of public use of the invention made anywhere in the world. The state of the art also includes unpublished national patent applications and unpublished European applications designating Italy. To be part of the state of the art, it is sufficient that the publication that destroys novelty is accessible to the public. It is irrelevant that no one at the date of the filing of the patent application had actually known it. However, any disclosure made in the six months preceding the filing of a patent application is not taken into account if it is the consequence of a tort committed against the inventor or his successor in title.

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?

An invention is inventive if it does not appear obvious to the skilled person in the light of the state of the art. The state of the art of the obviousness test does not include unpublished Italian patent applications or unpublished European patent applications designating Italy. To determine inventiveness, Italian courts have adopted the European Patent Office problem-solution approach. The test consists of three stages, namely determining the closest prior art, establishing the objective technical problem to be solved, and assessing whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person. Although the closest piece of prior art has already been identified, the court should not exclude alternative prior disclosures that, if used as a starting point, may lead to invalidity, even if other prior disclosure qualify as closest prior art.

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?

There are no specific grounds. However, it is a general principle of Italian law that no right can be enforced for the exclusive purpose of damaging another party and this applies to patent rights too.

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 private use of an invention prior to the filing of a patent gives to the private user the right to continue to use the invention also after its grant within the limits of the prior use. Therefore, the private use defence is admissible and can be raised in relation to any type of patent, but has the effect of freezing the quantity and quality of the permitted use to what the prior user was doing on the date of the filing of the application.

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?

Following a finding of infringement, a patent owner is entitled to compensatory damages. Punitive damages are not permitted. Compensatory damages are calculated by establishing the profit lost by the patentee because of the infringement. Alternatively, the patentee is also entitled to the profit made by the infringer and if that profit is higher, he or she can choose to seek damages based on the infringer's profit instead of its loss of profit. As an alternative, the patentee can seek a reasonable royalty on the sales made by the infringer. The reasonable royalty is usually calculated as the royalty that the infringer would have paid if he had obtained a licence plus an extra from 50 per cent to 100 per cent to compensate the fact that the consent was not sought before the infringement.

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?

Both temporary and final injunctions are available, and final injunctions are granted as of routine following a finding of infringement. Temporary injunctions can be obtained if the patent owner can prove that he is likely to prevail in the main action and that waiting for the final injunction would cause irreparable harm. In general, courts are quite generous in assessing irreparable harm. If the patent owner can prove that he has reacted swiftly to the infringement by applying for a temporary injunction and that he has a product incorporating the patent or made according to the patented process already on the market, or that he is about to launch such a product, the court will normally conclude that there is a risk of irreparable harm. An injunction, either temporary or final, cannot be enforced against the infringer's suppliers or customers, unless they were party to the lawsuit. In addition, the patent owner can seek the seizure of all infringing products still on the market, including those products that are in the possession of third parties for the purpose of trade together with an order for recall of the infringing products from the market.

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?

There is no specific procedure or court to block the importation of products found to infringe. However, injunctions usually include an order not to import the infringing products and its violation amounts to contempt of the court.

Attorneys' fees

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

Recovery of costs and attorneys' fees in favour of the prevailing party is the rule and they are awarded based on the value of the dispute, in accordance with the schedule published by the Ministry of Justice. Consequently, while attorneys' fees awarded for valuable patent cases

can be in the area of several hundred thousand euros, the fees and costs awarded for the average patent litigation are in the region of €50,000 to €100,000. Courts have some degree of discretion in awarding only part of the costs if the prevailing party has won only on some of the counts or if it has raised frivolous claims or requests that have unnecessarily increased the cost of litigation.

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?

There are no additional remedies in civil courts against wilful infringement. However, wilful infringement is a crime and the opinion of an external counsel – or of an internal qualified counsel – is a defence against an indictment for patent infringement in a criminal proceedings.

Time limits for lawsuits

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

There is no specific time limit for starting an action for patent infringement. However, the statute of limitation of five years applies in respect of a claim for damages. Infringement is sometimes considered an on-going or permanent unlawful act, which, therefore, should not be affected by a statute of limitations as long as the claim for damages is made within five years from the last infringement. In that case, the patent owner can seek an award for damages from the beginning of the ongoing infringement, even if it started more than five years before the filing of the lawsuit.

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?

There are no marking requirements. However, an administrative fine of up to €516 is imposed on those affixing a false marking.

LICENSING

Voluntary licensing

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

There are no specific restrictions on the contractual terms of a patent licence agreement other than those relating to the application of anti-trust provisions and, primarily in Commission Regulation No. 772/2004 of 27 April 2004 (the Technology Transfer Regulation). While a review of the Technology Transfer Regulation would exceed the scope of this chapter, clauses fixing the price of licensed products, partitioning geographical markets or, if the agreement is entered into between two competing undertakings, limiting the output of the licensed products, are unlawful. In addition, if the combined market share of the parties to the technology transfer transaction exceeds the thresholds of article 3 of the Technology Transfer Regulation, the patent licence cannot benefit from the exemption provided in article 2 of the Technology Transfer Regulation.

Compulsory licences

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

Although it is possible to obtain a compulsory licence, the system is rarely used. An application for a compulsory licence can be made after three years from the grant of the patent or four years from the filing of the application, if the patent owner has not put in practice the patented invention or if he or she is doing so in a manner that is seriously insufficient for the demand of the national market. The application can be made only after the patent owner has refused to grant a licence. In addition, the application for a compulsory licence cannot be made by an infringer. The Patent and Trademark Office determines the terms of the compulsory licence – usually upon indication by the prospective licensee. However, the patent owner can object to the terms of the compulsory licence within 30 days and, in such a case, the terms are determined by a board of three arbitrators, one each appointed by the parties and the third arbitrator appointed by the President of the Board of Appeals of the Patent and Trademark Office.

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?

The average duration of the procedure from filing to grant of an Italian patent is about 18 months. The average cost of drafting, filing and applying for a grant of an Italian patent is around €10,000.

Expedited patent prosecution

32 | Are there any procedures to expedite patent prosecution?

Yes. In the event of litigation concerning the enforcement of a patent for which the application is still pending, the patent owner can request a fast-track procedure for the grant. The application is then granted in about two months.

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?

The general rule is that the application must contain enough information to enable the skilled person to work the invention. Further, it must describe the invention to distinguish it from the prior art and must describe in full details at least one specific embodiment – not necessarily the best embodiment.

Prior art disclosure obligations

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

No, there is no obligation to disclose the existing prior art.

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?

There is no specific procedure for filing an application to pursue additional claims to an invention disclosed in an earlier application. The only way to do so is by filing the subsequent application claiming priority from the previous application.

Patent office appeals

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

The party aggrieved by an adverse decision of the Patent and Trademark Office can file an appeal with the Board of Appeals. Board of Appeals decisions are subject to legal review by the Italian Court of Cassation, which is the court of last instance.

Oppositions or protests to patents

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

No, there are no procedures for opposing or objecting to the grant of a patent.

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?

The decision is made by the courts of law and not by the Patent and Trademark Office. The fundamental rule is that the patent that is the first to be filed has priority, unless the first filer acted in bad faith, for example, by unlawfully obtaining the information relating to the invention.

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?

The Patent and Trademark Office cannot re-examine or revoke a patent. However, before the grant of the patent, a patentee can modify the application by supplementing it, adding further embodiments or limiting the description and claims. After the grant, the patentee can only restrict the scope of the claims of a patent. During a lawsuit, the patent owner can submit to the court a restricted list of claims if he or she thinks that the original claims would be held invalid in the light of the prior art. The court may also limit the scope of the patent by issuing a judgement declaring the patent partially invalid.

Patent duration

40 | How is the duration of patent protection determined?

The patent is protected for 20 years from the date of filing.

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?

There have been no significant developments over the past 12 months.

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?

While there have been no changes relating to substantive law on patents, the rules of procedure have been amended to provide for remote court hearings by video call. Hearings with the physical presence of the lawyers and parties are very rare and take place only when holding a remote court hearing might compromise one party's right of defence or the effective management of the hearing, for example, when examination of a 3D object is required.

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Copyright	Healthcare M&A	Private Banking & Wealth Management	Technology M&A
Corporate Governance	High-Yield Debt	Private Client	Telecoms & Media
Corporate Immigration	Initial Public Offerings	Private Equity	Trade & Customs
Corporate Reorganisations	Insurance & Reinsurance	Private M&A	Trademarks
Cybersecurity	Insurance Litigation	Product Liability	Transfer Pricing
Data Protection & Privacy	Intellectual Property & Antitrust	Product Recall	Vertical Agreements
Debt Capital Markets		Project Finance	
Defence & Security			
Procurement			
Dispute Resolution			

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