

Patents

In 34 jurisdictions worldwide

Contributing editors

Michael N Zachary, Clifford A Ulrich and John W Bateman



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GETTING THE
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Patents 2015

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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?

From 2003 to 2012, patent infringement and nullity issues fell within the competence of the specialised industrial and intellectual property chambers, that had been established within 12 Italian courts and courts of appeal, namely in Bari, Bologna, Catania, Florence, Genoa, Milan, Naples, Palermo, Rome, Trieste, Turin and Venice. Despite the formal qualification as 'specialised', the degree of experience in patent issues varied considerably from one chamber to another. A certain degree of experience had been built up in Milan, Rome, Turin and Venice, whereas experience was lower or nil in other chambers.

At the end of 2012, the court system was partly restructured and some further matters of commercial interest were added to the jurisdiction of the said chambers, whose name was accordingly changed into specialised business chambers. Eight additional chambers were established within the courts and courts of appeal in Ancona, Brescia, Cagliari, Campobasso, Catanzaro, L'Aquila, Perugia and Trento. Whether this restructuring will improve the efficiency of court proceedings is doubtful, all the more so that the experience of said courts in patent matters is minimal or non-existent.

According to a recent law, competence is restricted to only some of the courts mentioned above, whenever one of the parties is a foreign company. This law also established a new specialised business chamber in Bolzano.

It must further be remembered that Italy is a signatory of the Agreement on a Unified Patent Court, that was signed by several European countries on 19 February 2013. This agreement, which is still awaiting ratification, will concentrate before the unified court all disputes relating to infringement and nullity of European patents (article 1). During a transitional period of seven years there will be a concurrent competence, so that it will be possible to opt for a national court instead of the unified court (article 83). The unified court will probably have one or two local divisions in Italy, although this is still under discussion.

Criminal proceedings are also possible, but they are not frequent in patent matters.

2 Trial format and timing

What is the format of a patent infringement trial?

Court proceedings in patent issues are quite different from what is understood as a 'trial' in common law countries. Submissions are mainly made in writing and oral discussions are normally limited.

Infringement and validity issues can be handled within the same court proceeding. When the plaintiff is the patentee, the defendant normally counters that there is no infringement and that the patent is invalid. In other cases, it is the alleged infringer who proceeds as a plaintiff, and requests a finding both of non-infringement and of patent nullity; in such a case, the defendant is the patentee who counterclaims for infringement.

An ordinary court proceeding is started by a summons that must contain a thorough statement of the case and be accompanied by supporting documents. The defendant must make an appearance by the date of the first hearing at the latest (see question 10 and, simultaneously, submit a thorough written reply, which must also be accompanied by supporting documents.

During the subsequent months it is possible to submit additional documents and requests for the taking of evidence, such as, for example, witness examination (see question 3).

The judge then decides whether any evidence is to be taken. In nearly all patent cases the judge appoints a technical expert to give an opinion, both on patent validity and infringement. In most cases the court-appointed expert is a European patent attorney who discusses the matter with the parties' patent attorneys (normally through exchanges of briefs), and eventually submits a report with his or her opinion.

Once the expert's report is available, the judge decides whether the case can proceed towards judgment or if any further taking of evidence is necessary. In the former case the parties can exchange final briefs and replies, and then the case is referred to the court panel for decision.

There is no oral discussion, unless one party expressly requests it.

The court is not bound by the expert's opinion. Nevertheless, it normally rules in accordance therewith. In the case of disagreement, the court judgment has to provide a more thorough explanation.

Normally, appeal proceedings are simpler because no taking of evidence is necessary.

With respect to the duration of the proceedings, see question 10.

3 Proof requirements

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

Basically, each party has the burden of proving its own allegations, although the other party, under certain conditions, can be requested to provide certain documents and information in its possession (see question 9).

In principle, infringement can be proved by any means, but a major role is played by documents, such as, for example, brochures, photographs and correspondence. An important means of proof is also an inspection at the factory or premises of the alleged infringer, which can be ordered by the judge if he or she is satisfied that there is a serious ground to suspect infringement.

When a patented process results in a new product, any identical product is supposed to have been made by the protected process, unless otherwise proved (Industrial Property Code (IPC), article 67.1.a).

With respect to patent invalidity and unenforceability, prior art documents are the typical means of proof.

Witness deposition is also possible with respect to any type of issue. However, it is normally regarded as a means for supplementing documentary evidence, rather than independent decisive evidence. For example, if prior disclosure is likely from a certain brochure but not fully evidenced thereby, witness deposition can help to remove uncertainty. On the other hand, no court can be expected to regard a patent as invalid if prior disclosure has been simply stated by a witness without any supporting document being available.

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?

Apart from the patentee, according to prevailing opinion, an exclusive licensee may also sue for patent infringement, whereas a non-exclusive licensee is not entitled thereto.

An accused infringer may sue both for declaration of non-infringement and for patent nullity. He or she simply has to prove that he or she has been threatened on the basis of the patent at issue, for example, by means of a warning letter.

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?

Although there is no express provision, contributory infringement is substantially undisputed, at least when a party manufactures or sells something that:

- is essential to the manufacture of a patented product or to work a patented process; and
- either does not have any other function, or is supplied for the specific purpose of infringing a patent (which can be understood, for example, from the instructions for use).

All parties involved in contributory infringement can be jointly liable.

An express provision, which substantially confirms the principles outlined above, is going to be introduced by the Agreement on a Unified Patent Court, referred to in question 1. According to this Agreement, which is still awaiting ratification, the patentee's exclusivity includes:

the right to prevent any third party [...] from supplying or offering to supply, within the territory of the Contracting Member State in which that patent has effect, any person other than the party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect (art. 26.1).

This, however, does not apply to 'staple commercial products', unless the third party induces the person supplied to perform any act of direct infringement (article 26.2).

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?

Multiple parties can be joined as defendants in the same lawsuit if there is some connection between their respective conducts (Civil Procedure Code (CPC), article 33). This means that joinder of multiple defendants is possible, for example, when:

- defendants have taken part in the infringement of the same patent, as is typically the case of a manufacturer and his or her distributor;
- defendants are involved in contributory infringement (see question 5); and
- defendants have infringed different patents, which, however, are connected with each other (for example, different components of the same apparatus).

7 Infringement by foreign activities

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

According to IPC, article 66.1, a patent confers 'the exclusive right to work the invention and to benefit therefrom within the Italian territory'. This means that an activity performed abroad does not, in principle, constitute any infringement of an Italian patent. Nevertheless, contributory infringement can be imagined under some circumstances, for example, if an essential component of a patented product is made abroad and then supplied to an Italian manufacturer (see question 5).

When a process is protected by an Italian patent but it is carried out abroad, importing the product obtained by the process into Italy constitutes infringement (IPC, article 66.2.b).

8 Infringement by equivalents

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

According to IPC, article 52.3-bis, 'for the purpose of determining the extent of protection conferred by a patent, due account shall be taken of any element that is equivalent to an element specified in the claims'. This provision was introduced in 2010, in line with the latest version of the protocol on the interpretation of article 69 of the European Patent Convention (EPC).

Courts, however, were taking equivalents into account well before then. Although well established rules did not exist, equivalence had been recognised when:

- the triple identity test was satisfied (ie, identity of the technical problem, identity of the result and substantial identity of the means); or
- the difference from the patent claim could be regarded as an obvious modification or such a difference was regarded as being of a minor nature.

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?

When one of the litigants needs some documents or information that are in the possession of the other litigant, he or she can invoke IPC, article 121.2, which stipulates as follows:

Once a party has provided serious signs of the soundness of its submissions, and has identified documents, elements or other information held by the other party and confirming such signs, it can obtain from the judge an order to produce them or an acquisition of the information through deposition of the other party. It can further obtain from the judge an order to identify the parties involved in the manufacture and distribution of the products or services constituting infringement.

More comprehensive disclosure, inclusive of bank documents, can be ordered in the case of piracy (IPC, article 121.2 bis).

These provisions, which substantially correspond to article 43 of the Trips Agreement, do not provide for broad-scope discoveries like those existing in various common law countries. Indeed, they have the more limited purpose to relieve a rights owner from an unreasonably heavy burden of proof. Their rationale is not to remove such a burden, but simply to help a party who has fulfilled it as far as possible.

How these provisions are to be applied practically, is basically at the discretion of the judge. In particular, it is up to the judge to evaluate, in view of the specific circumstances, whether a rights owner has fulfilled its burden to provide 'serious signs of the soundness of its submissions', and accordingly whether there is a basis to order the other party to disclose some of the documents or information in its possession.

Possible non-compliance with the judge's order is subject to IPC, article 121.4, according to which 'the judge can derive elements of proof from the answers given by the parties and from their unjustified refusal to comply with the judge's orders'. This means, for example, that infringement can be assumed if the available evidence shows as such and the alleged infringer refuses to provide a document that should clarify a decisive detail. Likewise, prior disclosure can be assumed if the patentee refuses to provide a clarifying document, when the available evidence makes prior disclosure very likely.

IPC, article 121 does not differentiate between litigants located in Italy or in other countries. In other words, if a foreign litigant is addressed an order under IPC, article 121.2, he or she is bound by it exactly like an Italian litigant. If he or she fails to comply with the order, IPC, article 121.4 applies to him or her also.

Information about the origin and distribution networks of infringing goods or services can be requested by the judge from suppliers, distributors and manufacturers, even if they are not parties to the court proceedings (IPC, article 121-bis).

10 Litigation timetable

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

According to the CPC, the time limit for the defendant to appear must be at least 90 days if the summons has been served in Italy, and at least 150

days if the summons has been served abroad (summons for patent nullity are to be served upon the Italian attorney of record, so that the time limit is 90 days even if the patentee is a foreign company). Shorter time limits are exceptionally possible.

At the first hearing the judge has to set the following time limits upon request:

- 30 days for possible changes to the parties' submissions;
- 30 further days for possible evidence requests and submission of additional documents; and
- 20 further days for possible counter evidence.

At the subsequent hearing, the judge decides about the parties' requests for evidence and normally appoints a technical expert (see question 2). The time needed by the expert to study the matter, to review the briefs of the parties' patent attorneys and to prepare his or her report can vary considerably, and ranges from approximately six to 12 months in most cases.

Once the expert has submitted his or her report, a further hearing is held before the judge, who has to assess whether any further taking of evidence is necessary or if the matter can be referred to the court panel for judgment.

If the judge decides to take further evidence (eg, to hear witnesses), one or more further hearings are scheduled for this purpose. Otherwise, there is only one final hearing where the parties have to finally state their submissions. Within the subsequent 60 days, the parties have to exchange their final briefs, which are normally the most important papers because the whole matter must be thoroughly discussed therein. Final replies can be exchanged within the subsequent 20 days. The court then has to render its judgment. If one of the parties has requested oral discussion (see question 2), a hearing is held before then.

Although some time limits are relatively short as indicated above, the duration of a court proceeding can vary greatly from one case to another. On the one hand, the expertise may take more or less time, on the other hand the necessary hearings may be more or less numerous. Moreover, some judges schedule their hearings at intervals of two or three months, whereas intervals may be six or eight months or more with other judges. Also, the time needed for a judgment to be issued and become available, once the parties have exchanged their replies, may range from a few weeks to several months. Further delays may be caused by replacement of the judge or by other circumstances.

All in all, it is very rare to have a first-instance judgment in less than a couple of years, whereas three or four years are quite usual, and longer durations are possible according to circumstances.

Normally, appeal proceedings are shorter because no taking of evidence is necessary. Their duration, however, also depends very much upon circumstances.

11 Litigation costs

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

Costs may be very different from case to case depending on the complexity of a matter, on the time needed and regarding the appointed attorneys-at-law and patent attorneys, whose fees can be freely agreed.

In most cases, the order of magnitude is in the tens of thousands of euros in each instance.

12 Court appeals

What avenues of appeal are available following an adverse decision in a patent infringement lawsuit?

Appeal on factual or legal grounds is always possible before the competent court of appeal (see question 1).

Further appeal on legal grounds is possible before the Supreme Court.

Both types of appeal are subject to a preliminary examination, which results in immediate rejection when an appeal is found to be inadmissible or evidently groundless (CPC, articles 348-bis, 375 and 380-bis).

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?

Starting a court proceeding for infringement, or threatening a competitor therewith, may constitute unfair competition if the patentee either is aware

of the groundlessness of his or her threats, or ought to be aware of it. This may apply, for example, when the patentee knows, or could have easily realised, that his or her patent is invalid or when infringement evidently does not exist.

In such cases the court, in addition to costs, can award to the defendant a damage compensation, which can be set on an equitable basis if necessary (CPC, article 96).

14 Alternative dispute resolution

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

Arbitration is possible under various rules, including the arbitration rules of the World Intellectual Property Organization. Arbitration, however, is not at all usual in patent disputes.

The same applies to mediation.

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?

In line with the EPC, any type of invention is patentable apart from some medical procedures and a few other exceptions. Software and business methods are not regarded as inventions.

The relevant provision is article 45 IPC, whose paragraphs 1 to 5 correspond to articles 52 and 53 EPC, which reads as follows:

1. *Inventions in all fields of technology can be the subjects of patents, provided that they are new, involve an inventive step and are susceptible of industrial application.*
2. *The following in particular shall not be regarded as inventions within the meaning of paragraph 1:*
 - (a) *discoveries, scientific theories and mathematical methods;*
 - (b) *schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;*
 - (c) *presentations of information.*
3. *Paragraph 2 shall exclude the patentability of the subject matter referred to therein only to the extent to which a patent application or patent relates to discoveries, theories, schemes, rules, methods, programs and presentations of information as such.*
4. *Patents shall not be granted in respect of:*
 - (a) *methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body;*
 - (b) *plant or animal varieties and essentially biological processes for the production of plants or animals, including new plant varieties with respect to which the invention only consists of the genetic modification of another plant variety, even if such modification is the result of a process of genetic engineering.*
5. *The provision of paragraph 4 does not apply to microbiological processes nor to products obtained thereby, nor to products, particularly substances or compositions, for the use of one of said methods.*
5-bis Biotechnological inventions referred to in article 81-quinquies cannot be the subject of any patent.

IPC, article 81-quinquies, referred to in 5-bis, relates to some inventions regarded as contrary to human dignity or public order, such as methods of human cloning and use of human embryo stem cells.

In what cases subject matter constitutes a computer program or a business method as such, or rather includes some technical contents that may justify a patent, is a matter of interpretation. The case law of the European Patent Office (EPO) can be referred to in this respect.

Computer programs as such are protected under the Copyright Law (article 1.2, articles 64-bis, 64-ter and 64-quater).

Plant varieties are subject to a special type of protection in accordance with the UPOV Convention (IPC, articles 100 to 116).

Semiconductor topographies are also subject to a special type of protection, in accordance with European Directive 54/1987 (IPC, articles 87 to 97).

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?

If there is a relationship between the invention and the employee's tasks, as is normally the case, the invention and the patent relating thereto belong to the company. If research and development belong to the employee's contractual tasks, he or she is not entitled to any specific compensation. Otherwise he or she is entitled to an equitable award, provided that the employee obtains a patent upon the invention or makes use of it under secrecy (IPC, article 64, paragraphs 1 and 2).

The entity of the said equitable award depends upon the importance of the invention, upon the employee's tasks and salary and upon the contribution the employer's organisation has given to the invention (article 64.2). If the invention has nothing to do with the employee's tasks (for example, a mechanical device invented by an accountant), but it falls within the company's field of activity, the invention belongs to the employee but the company has an option to purchase it (article 64, paragraph 3).

There is no provision for inventions made by independent contractors. If an invention is the result of a research or project contract, the common opinion is that the rights to it belong to the company.

As far as joint ventures are concerned, there is also no specific provision. With respect to inventors, an employee who has made an invention has, therefore, the same rights mentioned above. This applies both in the case that the joint venture is a new company established for the specific purpose of conducting research and development and in the case that the joint venture is merely an agreement between two parties without the establishment of a common company. With respect to the joint-venture partners, it is normally the joint-venture agreement that rules how the rights upon a common invention are to be shared between them.

Special provisions apply when the inventor is a researcher employed at a university or research institute. The general rule is that the patent belongs to the inventor, whereas possible royalties are to be shared between the inventor and his or her employer. The inventor is entitled to at least 50 per cent of such royalties anyway (article 65).

If an invention is made by multiple inventors, in the absence of any employment or contractual relationship, all of them are jointly entitled to the patent because patent rights belong to the inventors and to their successors in title (article 63.2).

A transfer of ownership is recorded by filing a petition accompanied by a supporting document (articles 138, 195 and 196).

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?

The grounds on which the validity of a patent can be challenged are the same ones provided by the EPC, specifically:

- the subject matter is not a patentable invention (IPC, article 76.1.a) (what constitutes a patentable invention is indicated in article 45 IPC, referred to in question 15);
- the subject matter lacks either novelty or inventiveness or industrial application, or it is contrary to public order or morality (article 76.1.a);
- the subject matter extends beyond the content of the application as filed, or the protection conferred by the patent has been extended (article 76.1.c); and
- the patent owner was not entitled to obtain it, and the entitled party has not claimed its transfer (article 76.1.d).

If a nullity ground affects a patent only to a limited extent, a court can declare partial invalidity and leave the patent in force for the unaffected part (article 76.2). Also, a court may convert a patent into a utility model and vice versa, if this is regarded as the proper title of protection (article 76.3).

The competent courts are those where specialised business chambers exist (see question 1).

18 Absolute novelty requirement

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

Yes, absolute novelty is a requirement in accordance with the EPC.

The relevant provision is article 46 IPC, which corresponds to article 54 EPC and whose initial paragraphs read as follows:

1. *An invention shall be considered to be new if it does not form part of the state of the art.*
2. *The state of the art comprises everything made available to the public by means of a written or oral description, by use or in any other way, in the Italian territory or abroad, before the date of filing of the patent application.*

The following exceptions are provided by article 47 IPC, which corresponds to article 55 EPC and whose first paragraphs read as follows:

1. *For the application of article 46, a disclosure of the invention shall not be taken into consideration if it occurred within the six months preceding the filing of the patent application and it results directly or indirectly from an evident abuse to the detriment of the applicant or his legal predecessor.*
2. *Disclosure in an official or officially recognised exhibition, recognised pursuant to the convention on international exhibitions, signed in Paris on 22 November 1928 and subsequently revised, is also not taken into account.*

When priority is claimed, the state of the art must be referred to the priority date (article 47.3).

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?

The technical experts who are normally appointed in patent disputes are usually Italian and European patent attorneys. As such, they tend to follow the problem-and-solution approach developed by the European Patent Office (EPO), as the courts do, who normally base their judgments on their experts' opinions, although such opinions do not have any binding effect (see question 2).

As a result, the problem-and-solution approach constitutes the basis for most court decisions relating to inventiveness, although express reference thereto is rather infrequent in judgments.

In short, the problem-and-solution approach involves the following stages:

- (i) determining the closest prior art;
- (ii) establishing the objective technical problem to be solved; and
- (iii) considering 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 (EPO Guidelines, G, VII-5).

With specific reference to stage (iii), the various indicators of non-obviousness referred to by the EPO are normally also taken into account by Italian courts. This applies, for example, to surprising results, unexpected technical effects, long-felt need and commercial success (EPO Guidelines, G, VII-10).

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?

According to article 68 IPC, the exclusive rights conferred by a patent do not extend to:

- activities performed in the private sphere and for non-commercial purposes, and activities having an experimental purpose;
- studies and experiments for the purpose of obtaining a marketing authorisation for a medicament in Italy or abroad, including 'the preparation and the use of the raw materials strictly necessary for this purpose'; and

- extemporaneous preparation of medicaments upon medical prescription in a pharmacy, provided there is no use of industrially manufactured active principles.

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?

Article 68.3 IPC reads as follows:

Anyone who has made use of the invention within his business firm, during the twelve months preceding the filing or priority date of the patent application, may continue to use it within the limits of his prior use. Said right can only be transferred together with the business firm where the invention is used. The burden to prove prior use and its extension belongs to the prior user.

This provision only refers to prior activities that had been in no way performed in public, and accordingly cannot affect the validity of the patent. This can apply, for example, to the use of a certain machine or process within a factory. Had there been any public use, for example, a sale on the market making the patented product available to the public, the patent would be invalid due to lack of novelty (see question 18).

This applies to all types of inventions because article 68.3 does not make any distinction.

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?

According to article 125 IPC, which is in line with European Directive 2004/48, a patentee can base his or her claims to compensation essentially on one of the following criteria:

- profits lost as a consequence of the infringement (article 125.1);
- profits achieved by the infringer (article 125.3); or
- royalties that the infringer should have paid had he or she obtained a licence from the patentee (article 125.2).

How the profits under (i) and (ii) are to be calculated is not fully clear from court decisions. In particular, there has been some discussion as to whether or not certain general costs should be deducted from sales revenues.

As to the royalties under (iii), it has sometimes been decided that their amounts should be higher than market value, as a compensation for the fact that there has been a sort of 'extorted licence'. However, there is no general agreement on this subject.

Since precise calculations are normally impossible, usually any of the criteria mentioned above ultimately amounts to a lump sum that is regarded as equitable by the court (article 125.2).

Damages start to accrue from the moment they are caused, which in most cases means when the infringing products begin to be offered or sold. The patent must not necessarily have already been granted: a pending application can also be a basis for damage claims, provided it has already become open to the public, which normally happens 18 months after the filing or priority date.

Punitive damages do not exist in Italian law. Nevertheless, damage compensation can be very substantial if courts believe that this is justified by circumstances.

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?

At the end of an ordinary proceeding, if the court finds there is an infringement, it will issue a final injunction prohibiting its continuation.

Since ordinary proceedings are normally lengthy (see question 10) it is possible to request temporary injunctions by way of precautionary

proceedings. Since this can have heavy consequences upon a defendant, courts are normally cautious and grant a temporary injunction only if they feel sure that the patent is valid and that infringement has really occurred. A technical expert can be appointed to review both patent validity and infringement. In such a case, a decision about a request for temporary injunction may take some months, despite the intrinsically urgent nature of a precautionary proceeding.

In cases of both final and temporary injunctions, the court normally sets a penalty for possible violations.

An injunction can be accompanied by an order to withdraw the infringing products from the market, which can mean that the infringer has to buy back the products from his or her customers or distributors. Such an order can be expressly extended to third parties being in possession of the said products (articles 124.1 and 131.1) with the exception of final consumers using the products in their private spheres (see question 20).

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?

Upon request, the customs authorities can suspend the release of goods suspected of infringement, pursuant to European Regulation 608/2013. Seizure and destruction are also possible by proceedings that depend on the circumstances.

Request for customs action must be addressed to the management of the Italian customs, specifically the Ufficio Antifrode Centrale. The authority to order seizure and destruction depends on circumstances. In the case of piracy, destruction is possible upon authorisation by the president of the specialised business chamber of the competent court (IPC, article 146 (see question 1)).

25 Attorneys' fees

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

In principle, a winning party is always entitled to recovery of costs and attorney fees, unless he or she has been successful only in part or if the dispute is partly due to his or her responsibility. In such cases the court can discretionally diminish the award of costs and fees or refuse it altogether.

At any rate, the awards granted by the courts are based on criteria that have little to do with the costs actually incurred, so that only a part of the costs can really be recovered, even in the case of a full victory (50 to 60 per cent in fortunate cases).

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?

The IPC refers to deliberate infringement in the case of piracy, which is defined as 'evident infringement [...] being performed deliberately and in a systematic way' (article 144). Particularly stringent measures are provided in such cases, including seizure of the infringer's properties, such as real estate and bank accounts (article 144-bis), and destruction of the infringing goods by simplified proceedings (article 146).

Apart from piracy cases, for the purposes of a request for injunction there is no difference between deliberate or unintentional infringement. In other words, if objectively there is infringement, this must be prohibited anyway, regardless of whether its nature is deliberate or unintentional.

On the other hand, if the court believes that infringement has been entirely unintentional, it may set damages at a lower level based on equitable considerations (see question 22).

The deliberate nature of infringement can play a role in criminal proceedings, which, however, are not frequent in patent matters (see question 1).

27 Time limits for lawsuits

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

As long as a patent is in force and infringement is continuing, there is no time limit for starting an ordinary proceeding against an infringement.

However, if a patentee seeks a temporary injunction but fails to proceed promptly, the court may find that the case is not an urgent one and accordingly reject the request. How long a patentee may wait and still claim urgency is evaluated at the court's discretion. Most courts are not very stringent in this respect, and some months are normally tolerated.

With respect to damage compensation, the alleged infringer may invoke the statute of limitations for sales or other activities occurred five or more years before the beginning of the court proceedings (Civil Code, article 2497).

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?

Marking is not compulsory and there is no consequence of failure to mark.

On the other hand, falsely suggesting that a product is protected by a patent is subject to a fine up to €516.46 (IPC, article 127.2). Moreover, such a false suggestion may be regarded as an act of unfair competition.

Licensing

29 Voluntary licensing

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

The only restrictions are those dictated by antitrust principles. At a national level, such principles are based on European provisions, including Regulation 316/2014 about certain categories of technology transfers. Typically, forbidden contractual terms are, for example, the restriction of a party's ability to determine its prices (article 4.1.a), the limitation of output (article 4.1.b) and the allocation of markets or customers (article 4.1.c).

30 Compulsory licences

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

A compulsory licence can be granted in the following cases (with some details omitted):

- if the patentee has not worked the patented invention in Italy for three or more years after grant, or has worked it to an insufficient extent in comparison to the country's needs, importation from a country of the European Union or of the World Trade Organization is regarded as valid in Italy (IPC, article 70.1, 70.2);
- if an earlier patent debars the working of a later patent, provided that the later patent constitutes 'an important technical progress of considerable economic significance', there may be compulsory cross-licences (IPC, article 71); and
- if a patented biotechnological invention is needed for the exploitation of a plant variety, or conversely if it is desired to use a patented biotechnological invention upon a protected plant variety, this is also subject to the condition that either the biotechnological invention or the plant variety constitutes 'an important technical progress of considerable economic significance' and cross-licences may be granted in this case also (article 81-octies).

A party seeking a compulsory licence must prove that it has unsuccessfully asked the patentee for a voluntary licence under equitable conditions (IPC, article 72.1). A compulsory licence cannot be granted to an infringer, unless he or she can evidence he or she has acted in good faith (IPC, article 72.3).

A request for a compulsory licence must be filed with the IPTO and include the amount of the offered royalties (IPC, article 199.1). Such a request is notified to the patentee, who has the right to oppose (IPC article 199.2). In the case of opposition, the IPTO summons the parties to a meeting in an attempt to reach agreement (IPC, article 199.4). In the absence of an agreement the IPTO then makes a decision, which may be either a rejection of the request or the grant of the licence (IPC, article 199.6).

The compulsory licence may be revoked if the licensee fails to pay the due royalties or fails to fulfil other licence requirements (IPC, article 73.1). Revocation is also possible if the conditions that had brought about the grant of the licence have ceased to exist (IPC, article 73.2).

IPTO decisions about compulsory licences may be appealed before the administrative court for the Lazio region.

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 procedure before the IPTO takes about two years, running from the filing date of the application.

Official fees for filing are set at about €90 but an additional fee of €45 is payable for each claim after the 10th claim. The claims should be provided in both Italian and English. If the English translation of the claims is missing, an additional fee of €200 is applicable since the Italian administration must provide the said translation to the EPO. In fact, the IPTO and the EPO have entered into an agreement according to which each Italian application (excepted those claiming the priority of a prior application) undergoes a prior art search performed by the EPO on behalf of the IPTO. However, the official search made by the EPO on request by the IPTO is not charged to the applicant.

No official fee for the grant is payable. Maintenance fees are required for each year subsequent to the fourth year from the filing date. Such annual fees range from €60 (fifth year) to €650 (from the 15th year onwards).

32 Expedited patent prosecution

Are there any procedures to expedite patent prosecution?

There are no specific procedures to expedite patent prosecution. However, since in Italy infringement court proceedings can be started on the basis of a pending patent application, the proof that a litigation is in place is a ground for requesting the IPTO to proceed with an accelerated examination and grant of the patent.

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?

There are no specific guidelines in connection with the documentation to be included in a patent application. The requested documents are indicated in the law and in the rules, which provide that the application must include the description, the claims and the drawings when necessary.

Since Italian Patent Law is harmonised with the European Patent Convention, it includes the same provisions about patentability (see above) and similar requirements for obtaining a date of filing. Specific provisions concern the patentability of biotech inventions (IPC, articles 81-bis to 81-septies). Some requirements of Italian law that are not provided for in the EPC include the necessity of a declaration of the origin of the biological material and of a declaration of consent by the person from whom this material has been taken in the case that the biological material is of human origin.

34 Prior art disclosure obligations

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

There are no law provisions about an obligation to disclose prior art to the IPTO. There is merely a general requirement provided for by the ministerial decree, which, in 2008, introduced a prior art search in the grant procedure of the Italian patent applications. According to the said requirement, the applicant should indicate in the description of the invention the state of the art as far as known to the applicant at the time the patent application is filed.

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?

While European and Italian patent laws do not encompass the possibility of filing an application equivalent to the United States continuation, divisional applications, either voluntarily filed or filed in reply to an invitation from the IPTO, are allowed under the IPC and can be filed during

pendency of the parent application. In principle, additional claims can be pursued in a divisional application, apart, of course, from a general prohibition of double-patenting. The claims of the divisional application must have a clear basis in the parent application. Although the addition of subject matter in a (divisional) application is prohibited, Italian Patent Law and the associated case law and doctrine have not, so far, expressed a clear position about how strictly this prohibition must be interpreted.

36 Patent office appeals

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

A rejection of an application can be appealed before a special board (the Appeals Commission), within 60 days from receipt of the relevant communication (IPC, article 135). Further appeal, with respect to matters of law, is possible before the Supreme Court.

37 Oppositions or protests to patents

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

Patent oppositions are not possible. Informal objections can be filed with the IPTO, however, the IPTO is not bound to take them into account.

Formal objections are only possible by proceedings in court. What is typically requested from the court is a finding that the subject matter of the application is not patentable, and that the possibly resulting patent is invalid.

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?

No, disputes between different applicants can only be decided by a court.

If the two applicants have developed the invention and applied for it independently from each other, the one who has filed first or has the earlier priority date prevails (priority can be claimed either from a foreign or from an Italian application).

If any misappropriation is suspected, this must of course be scrutinised by the court, bearing in mind that patent rights belong to the true inventor or to his or her successor in title (IPC, article 63.2).

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?

Re-examination or revocation by the IPTO is not possible. On the other hand, the IPTO can limit a patent upon request by the patentee (IPC, article 79.1, 79.2).

During a nullity proceeding the patentee can submit a new set of limited claims to the court (IPC, article 79.3).

40 Patent duration

How is the duration of patent protection determined?

A patent is granted for the maximum term of 20 years running from the filing date of the application. A supplementary patent protection certificate, in certain conditions, can be obtained for patents relating to a medicinal or plant product for a period that cannot exceed five years. In connection with a medicinal product involving specific data for paediatric use, an additional period of up to six months can be added to the supplementary patent protection. No other types of patent term adjustments are provided.



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