

Italy



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1 Patent Enforcement

1.1 How and before what tribunals can a patent be enforced against an infringer?

A patent can be enforced against an infringer with a full scale litigation (ordinary litigation or in a fast way with an interim proceeding). This can be done before the specialised Court in IP matters. In Italy there are 12 courts spread all over the territory. The competent court is the court in the district in which infringers have their head office or where the infringement took place. Recently an approach held by some courts is that if the infringement is carried out via the Web, any of the 12 specialised courts have jurisdiction.

1.2 What are the pre-trial procedural stages and how long does it generally take for proceedings to reach trial from commencement?

The pre-trial procedural stages are: exchange of the introductory briefs (i.e. writ of summons for the plaintiff and defence for the defendant) and an exchange after the first hearing of three sets of briefs (containing also trial requests); then the trial, i.e. technical expertise and/or deposition of witnesses may start. Normally it takes around 1 year from the service of the writ of summons to arrive at the trial.

1.3 Can a defence of patent invalidity be raised and if so how?

A defence against the patentee is very often the (counter) demand of invalidity of the patent enforced by the plaintiff. This demand has to be raised as a counterclaim 20 days before the first hearing and should be structured indicating the reason why the patent enforced should be considered invalid. In this case the full judgment in case a pronouncement of invalidity of the patent may be rendered will be effective *erga omnes* (i.e. the integral or partial nullity of the patent decision will be published at the patent office and valid *erga omnes*). If the claim of invalidity is raised not as a main demand but as an exception it can be raised also at a later stage, i.e. directly at the first hearing. But in this case it will not be effective *erga omnes* but only *inter partes*. On the other hand it is possible to start a nullity action and declaratory proceeding of non infringement where the alleging infringing company starts a litigation suing the patentee and basing its demands on patent invalidity and non infringement.

1.4 How is the case on each side set out pre-trial? Is any technical evidence produced and if so how?

See *sub* question 1.2. In addition, as an overall scenario, it should be considered that trial activity in Italy is different from trials carried out in other jurisdictions. A trial in patent litigation mainly consists of technical expertise (first on the validity and infringement of the patent and after on the possible accountant expertise to calculate damages) and deposition of witnesses. Technical expertise is the process whereby the Judge appoints a Court Expert as a *super partes* person and the parties appoint their own experts. The experts are quite frequently patent attorneys. During the trial, there is an exchange of technical briefs between the experts of the parties and at the end the Court Expert then files his or her final technical opinion – normally before doing that she/he will file a draft report to allow the other experts to submit further comments and then he/she will file the final version.

1.5 How are arguments and evidence presented at the trial?

The arguments presented at the trial have the aim of substantiating the infringement on one side and the nullity of the patent on the other. Arguments for the infringement in addition to technical arguments (to evaluate, element by element, whether the contested product is reproducing the patent enforced) are presented to show whether there has been some commercial activity relating to such product which should be corroborated with documents and/or witness. The nullity arguments are based on documents but sometimes they are also based on witnesses who should corroborate, for instance, pre-disclosure.

1.6 How long does the trial generally last and how long is it before a judgment is made available?

The trial based on the technical expertise should last 6/8 months; they sometimes last for longer. Sometimes Judges may receive the deposition of witnesses in just one hearing and sometimes they will be heard in more than one hearing. Quite frequently the hearings are not held one after the other but a few months apart. Once the trial is finished the judgment may be rendered within one month. However, a patentee may immediately start an interim proceeding and file an application for injunction.

1.7 Are there specialist judges or hearing officers and if so do they have a technical background?

Patent litigations are held before specialised sections in IP matters.

Nevertheless Judges often have no technical background; this is why in almost all patent litigation cases a Court Expert is appointed. However, the more time that lapses from the institution of the specialised court, the more courts are starting to specialise and are happy to enter into technical details of the case at hand.

1.8 What interest must a party have to bring (i) infringement (ii) revocation and (iii) declaratory proceedings?

Sub (i) an infringement action can be started by the patentee or by the licensee.

Sub (ii) a revocation action can be carried out by any company which proves to have an interest (normally a current or potential competitor). Although some courts may request that the plaintiff should have been warned of infringement by the patentee.

Sub (iii) declaratory proceeding of non infringement can be started by the company which has received a complaint from the patentee of its licensee (such as a warning letter or similar).

1.9 Can a party be compelled to provide disclosure of relevant documents or materials to its adversary and if so how?

It could be possible that the Judge, according to art. 121 *bis* of the IP Code, may order the alleging infringing company to disclose relevant documents or material relating to the alleged infringing activity such as declaration relating to the network of sales of the contested products, invoices and so on.

1.10 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of but not all of the infringing product or process?

A party can be liable for contributory infringement if it carried out an activity which is univocally directed to reproduce the principles, protected by the patent or in case such company is aware that its activity is directed to reproduce the principles protected by the patent.

1.11 Does the scope of protection of a patent claim extend to non-literal equivalents?

Yes. Most infringement cases are infringement by equivalence. The leading case of equivalence held by the Supreme Court stated that there is infringing activity if the difference between the contested product (or process) and the patent is banal and/or obvious.

1.12 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

Additional grounds are for lack of industrial character and for insufficient disclosure and if the patent object extends beyond the content of the initial application (art. 76.1.c of the IP Code). Other grounds of nullity are based on the method for surgery of therapeutic treatment of the human or animal body and the method for diagnosis (art. 45 of the IP Code).

1.13 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

Generally not, but some courts recently stated that the infringement

litigation could be stayed pending a litigation of invalidity before another court. Infringement proceedings are not stayed pending an opposition before EPO.

1.14 What other grounds of defence can be raised in addition to non-infringement or invalidity?

See above *sub* question 1.12. In addition, the defence of prior use could be raised but this defence entitles the alleging infringing company to carry on the use within the limit made before the patent has been filed. Of course prior use does not imply the disclosure of the use. Otherwise it determines the lack of novelty and/or inventive step, as the case may be.

1.15 Are (i) preliminary and (ii) final injunctions available and if so on what basis in each case?

Sub (i) a preliminary injunction can be granted if *prima facie* it is proved that the patent is valid and infringed (*fumus boni iuris*) and the issue of urgency is covered (no more than a few months have passed since the patentee became aware of the infringing activity) and irreparable damages are proved (*periculum in mora*).

Sub (ii) if the patent has been infringed and if requested by the patentee, the injunction is granted with the full judgment.

1.16 On what basis are damages or an account of profits estimated?

According to art. 125 of the IP Code, a patentee is entitled to obtain at least reasonable royalties. In addition he can claim the restitution of the profit earned due to the infringing activity as an alternative to reasonable royalties.

1.17 What other form of relief can be obtained for patent infringement?

The patentee may obtain the withdrawal from the market of the contested product, penalty for any violation of the injunction, the destruction of the contested product, assignment to himself of the contested products, and/or the publication in a newspaper or magazine of the conclusion/disposal of the judgment.

1.18 Are declarations available and if so can they address (i) non-infringement and/or (ii) claim coverage over a technical standard or hypothetical activity?

Affidavits are normally corroborating elements but should be preferably accompanied by a deposition before the court if the court deems them to be appropriate. Recently modifications of the Civil Procedural Court admit the parties if both agree to give substantial validity as evidence to the affidavits. Nevertheless affidavits should not contain technical references since the witnesses should not be admitted to render a deposition on technical issues. A witness in fact (as well as an affidavit) should render a declaration only on circumstances of facts.

1.19 After what period is a claim for patent infringement time-barred?

The claim period is 10 years from becoming aware of the infringement. But since normally the infringement is a continuous activity, there is no statute of limitation to contest the infringement.

Statutes of limitation may apply to claim damages (5 years). Some authors sustain that the patentee may claim a sort of remuneration also as unjustified enrichment (art. 2041 civil code). In this case the statute of limitation is 10 years.

1.20 Is there a right of appeal from a first instance judgment and if so is it a right to contest all aspects of the judgment?

Yes - 30 days from the service of the judgment upon the other parties or, in case of no service, 6 months (according to the recent art. 327 Civil Procedural Court).

1.21 What are the typical costs of proceedings to first instance judgment on (i) infringement and (ii) validity; how much of such costs are recoverable from the losing party?

A patent litigation includes normally both the infringement and validity aspects. Costs may totally change case by case. Generally pharmaceutical cases are more complicated; this is why normally a patent litigation may vary from EUR 50 to EUR 100,000, and sometimes, in particular cases, even more. The losing party is sometimes condemned to refund part of these costs. Even 50% of the same, if not more.

2 Patent Amendment

2.1 Can a patent be amended *ex parte* after granting and if so how?

A patent can be limited according to art. 79 of the IP Code, by filing an application before the Italian patent office. Such application to be effective *erga omnes* should be granted. Sometimes the patent office, if put under pressure, can render a decision on that in a few months.

2.2 Can a patent be amended in *inter partes* revocation proceedings?

According to the decree of 13th August 2010 n. 131 of the modification of the IP Code, the patent can be amended *inter partes* in revocation proceedings sub art. 79 of the IP Code in any state and instance of the proceeding (even in the appeal proceeding).

2.3 Are there any constraints upon the amendments that may be made?

The reformulation of the claim should be carried out in order that the claims will remain within the limits of the content of the original application of the patent and will not extend the scope of protection beyond the protection given to the patent as originally granted.

2.4 Do reasons for amendment need to be provided and if so is there a duty of good faith?

No, they do not.

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

No, but it must adhere to European and national antitrust law.

3.2 Can a patent be the subject of a compulsory licence and if so how are the terms settled and how common is this type of licence?

Yes. According to art. 70 of the IP Code, 3 years after the patent is granted or 4 after the application of the patent has been filed, if the principles of the patent have not been reproduced by the patentee or its licensee locally, a compulsory licence can be granted to any company which has an interest in reproducing such principles. This type of licence is very rarely applied.

4 Patent Term Extension

4.1 Can the term of a patent be extended and if so (i) on what grounds and (ii) for how long?

Yes, in particular for pharmaceutical patents there is an extension with a supplementary certificate protection in Italy according to art. 61 of the IP Code. The extension can be up to 5 years. Recently, a further extension of 6 months can be granted for paediatric use of those pharmaceutical patents. Without medical treatment and so on, see above under question 1.12 for comments on art. 45 of the IP Code.

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable and if not what types are excluded?

According to article 45 of the IP Code, the following cannot be patented:

- the method for surgical or therapeutic treatment of the human or animal body and the method for diagnosis applied to the human or animal body; and
- varieties of plants and races of animals and essentially biological procedures aimed at obtaining the same.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents?

Formally no. But to some extent if the patentee is aware of such documents and does not disclose them before the patent office and those documents are found by competitors and necessary to corroborate the following nullity and/or revocation of such patent, then there could be a problem associated with the abuse of the patent or another problem also relevant for antitrust law, in particular, if the patentee meanwhile has enforced such patent. To this regard decision T-321/01 of 25th June 2010 should be considered.

5.3 May the grant of a patent by the Patent Office be opposed by a third party and if so when can this be done?

A patent granted can be opposed with an action for revocation/nullity before the specialised court in IP matters (ordinary court).

5.4 Is there a right of appeal from a decision of the Patent Office and if so to whom?

Decisions of the Italian Patent Office can be appealed before "Commissione dei Ricorsi" and the decisions of "Commissione dei Ricorsi" can be appealed before the Supreme Court (*Corte di Cassazione*) but just for violation of law.

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

Disputes over entitlement can be resolved before an ordinary court with a full scale litigation. Art. 64.6 of the IP Code is also relevant; according to which, if the past employee, within 1 year from the termination of an employment contract, files a patent application then the company can claim ownership of such patent.

5.6 What is the term of a patent?

The term of a patent is 20 years; but for a utility model/industrial model it is 10 years.

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products and if so how quickly are such measures resolved?

It could be possible to seize an infringing product at customs with a special customs procedure. After the application before the Central Authority, it could be possible in a few days to obtain the seizure when the contested products are passing the border. In this case, further action after the seizure is needed within 10 days either before the Criminal Court or the Civil Court. Measures are resolved via either full scale litigation or preliminary proceedings. Full scale litigation could be more appropriate for many reasons.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

Yes in theory, for the abuse of a patent, but it is quite rare.

7.2 What limitations are put on patent licensing due to antitrust law?

A licence agreement should not contain any elements which can distort the market.

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

Relevant developments with the modification of the IP Code in August 2010 are:

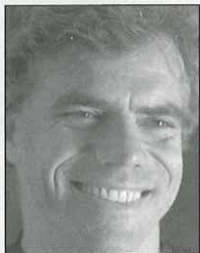
- (i) declaratory proceedings of non-infringement being carried out even on an interim base (art. 120.6 *bis*);
- (ii) technical expertise being carried out before litigation (art. 128 of the IP Code);
- (iii) the general admission of the technical expertise in the interim proceedings; and
- (iv) the possibility to seize contested goods found during a discovery (art. 129 of the IP Code).

8.2 Are there any significant developments expected in the next year?

No, there are not any significant developments.

8.3 Are there any general practice or enforcement trends that have become apparent in Italy over the last year or so?

A technical report in an urgency proceeding is quite frequently applied all over the territory now.



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