

International Comparative Legal Guides

Patents 2021

A practical cross-border insight into patent law

11th Edition

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1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

The actions concerning industrial property, whose rights are granted or in the process of being granted, are brought before the Italian judicial authority, whatever the citizenship, domicile or residence of the parties may be.

In Italy, specialised divisions of the civil ordinary courts (*Tribunale delle imprese* “**Enterprises Courts**”) were established by Decree 168/2003 and have the jurisdiction to enforce patent infringements (and IP rights in general). In particular there are 22 specialised chambers, located in Ancona, Bari, Bologna, Bolzano, Brescia, Catania, Catanzaro, Campobasso, Cagliari, Florence, Genoa, L'Aquila, Milan, Naples, Palermo, Perugia, Potenza, Rome, Turin, Trento, Trieste and Venice.

However, only 11 of them have jurisdiction on cases involving a foreign defendant and these are Bari, Bolzano, Cagliari, Catania, Genoa, Milan, Naples, Rome, Trento, Turin and Venice. Appeals must be proposed before specialised sections of the courts of appeal of the same cities.

Patent claims are brought before the Enterprise Court of the place where the defendant has his residence or domicile, and if these are unknown, in the place where the defendant has his place of abode. When the defendant does not have a residence, domicile or place of abode in the territory of the Country, the actions are brought before the judicial authority of the place in which the plaintiff has his residence or domicile. If neither the plaintiff nor the defendant have their residence, domicile or place of abode in the territory of the Country, jurisdiction shall lie with the judicial authority of Rome. Actions based on circumstances that are presumed to harm the plaintiff's rights may also be brought before the judicial authority having specialised sections in the district where the acts were committed (Art. 120 of the Italian Intellectual Property Code “**IIPC**”).

Patent infringements could constitute a criminal offence as well (Art. 473 Criminal Code, R.D. n. 1398/1930 “**Italian Criminal Code**”), thus patents could also be enforced before Criminal Courts submitting a complaint before the public prosecutor (*Procura delal Repubblica*).

Anyone who counterfeits or uses counterfeited patents can be punished by a fine of up to 35,000 euros and/or one to four years' imprisonment (Art. 473 Italian Criminal Code).

Finally, there is also a procedure set forth in EU Reg. n. 608/2013 that enables right holders to apply for customs action

before customs authorities against goods (being imported in the EU territory) suspected of infringing patents' rights.

1.2 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

A mediation process before the judicial proceeding is not compulsory. Mediation or arbitration proceedings are available as alternative dispute resolution to the court proceedings, but they are not common in patent matters in Italy. Arbitration clauses are normally included in agreements related to patent rights in Italy.

1.3 Who is permitted to represent parties to a patent dispute in court?

All barristers enrolled in the Italian Bar Association (*Ordine degli Avvocati*) are entitled to represent parties to a patent dispute.

1.4 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

As ordinary proceedings on the merits, the first step is the litigation opening that takes place with the writ of summons notified by the plaintiff to the defendant. Then, the defendant can appear in the proceeding by filing a defence statement (which can include a counterclaim, exceptions and third-party notice) within 20 days from the first scheduled hearing, which can take place at least 90 days after the service of the writ (this term is extended to 150 days for foreign defendants).

Within 10 days from the service of the writ of summons, the plaintiff must appear in the judgment by registering the proceeding with the Court registry, otherwise the proceeding becomes ineffective (Art. 165 Civil Procedure Code “**CPC**”).

The writ of summons must contain a brief description of the facts, the list of the evidences in support of the claim and the remedies asked to the judge.

The first phase ends with the first hearing, during which the judge examines any preliminary issues (such as jurisdiction, the regular constitution of the parties, etc.) and sets the deadlines for filing the pleadings where parties could be allowed to submit new evidence and to request testimonial evidences if any. (Art. 183 CPC – see question 1.7.)

Preliminary measures could be requested to the judge before starting the proceeding on merit (so-called “*ante causam*” proceeding – see question 1.23).

The first instance judgment provides for the payment of a fee that varies according to the value of the claim from 86 euros up to 3,372 euros. The fees for the appeal can be up to 5,058 euros and the last instance judgment before the Supreme Court (“*Corte di Cassazione*”) can be up to 6,744 euros.

1.5 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

An order to disclose documents, materials and/or information can be issued by the judge, upon request of one of the parties, only during the trial.

During proceeding on merits, if the claimant has provided serious circumstantial evidence that its claims are well founded and has precisely identified documents, elements or information held by the other party that confirms their suspicions, it may request to the Court to order their production or request the information to the counterpart (pursuant to Art. 121.2 IIPC). The party may also request the Court to order the counterpart to provide elements for the identification of the persons involved in the production and distribution of the goods or services that constitute an infringement of the patent right.

The Court shall adopt measures suitable to guarantee the safeguarding of confidential information (so-called “protective orders”, Art. 121.3 IIPC).

The judge, at the request of one of the parties, can order the defendant or a third party to exhibit documents or information which he/she deems necessary for the decision of the pending case (pursuant to Art. 210 CPC). The court-appointed expert may require the parties to provide further documents and/or information useful for the issuing of the technical brief required by the Court if these documents/information are not in the file of the proceedings; the parties must be informed of the technical Expert’s request of documents/information (Art. 121.5 IIPC).

If the infringement was committed on a commercial scale through acts of piracy, the judge can also order the defendant to exhibit banking, financial and commercial documents (Art. 121.2*bis* IIPC).

However, the party who received the disclosure order can refuse to obey, but any unjustified refusal to comply with the orders could be assessed by the judge as an indirect evidence against the party that does not fulfil the disclosure order (Art. 121.4 IIPC).

1.6 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

No pre-trial steps are required.

1.7 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

Italian infringement proceedings are mainly conducted in writing. The plaintiff will submit its arguments in the writ of summon, while the defendant can present the counterclaim in its defence statement and both parties must submit the documents/evidences in support of their claim. The burden of proof is on the plaintiff.

During the first hearing, the judge, if requested by the parties, set the deadlines to submit further briefs (Art. 183 CPC): i) 30 days for amending their respective claims, exceptions and conclusions; ii) a further 30 days for replying to the first brief filed by the counterpart and producing evidence or requesting from the judge the admission of several examples of evidence; and iii) a further 20 days for replying and filing evidence in rebuttal. The first brief opens the gathering of evidence phase of the proceeding.

During the second hearing, the judge decides about the requests of evidence such as the request to hear witnesses. The list of questions to be asked to the witnesses are submitted in advance to the judge who decides which questions are relevant for the case. The third phase of the proceeding starts when all the evidence is before the judge. Given the high degree of specialisation in intellectual property matters required in this kind of proceedings, the court usually appoints technical patent experts in order for any technical questions to be answered. Furthermore, in the technical debate the parties usually appoint their respective technical experts, who draft technical briefs.

A party can change its arguments proposed in the first writ of summons or in the first defendant defence brief. The plaintiff cannot add new requests other than those proposed in the first writ of summons, but could specify/reduce the requests submitted in the first writ of summons.

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

The first instance judgment does not usually have a standard duration, but generally, it takes place within three years. If the first instance decision is appealed, the duration of this second ground of judgment varies from court-to-court and it can last from one to three years.

Judgment on the merits are normally made available in two to four months after the decision has been taken.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

A shorter or more flexible procedure is not available for IP rights matters in Italy.

However, it is possible to ask the judge for precautionary measures before the judgment on the merit is established (see questions 1.4 and 1.23).

1.10 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

The Court makes judgments available to the public by the deposit of the decision in the Court registry; the Court, in making the decision public, could adopt appropriate measures to ensure the protection of the confidentiality (personal data) and of business secrets.

The judge can order the publication of the judgment (or a summary of the judgment) on newspapers, websites, etc. as a corrective measure (Art. 126 IIPC).

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

Contrary to common law juridical systems, in Italy, courts are not obliged to follow precedents. However, precedents, especially from the Supreme Court of Cassation, could influence judges' decisions. Decisions of the European Court of Justice on the question referred for preliminary ruling, on the contrary, must be applied by the Italian Court.

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

In 2003, specialised intellectual property divisions were established; however, judges are not required to have a technical background and this is the reason why, in IP proceedings, judges usually appoint patent technical experts.

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

Parties must have an actual and legitimate interest in bringing the proceeding.

(i) Infringement

Pursuant to Art. 131 IIPC, only the owner of the enforced patent may commence infringement proceedings, but according to the main case law decisions, the exclusive licensees could also be entitled to bring infringement actions unless otherwise provided in the licensing agreement. The standing to sue of a non-exclusive licensee is controversial in case law and in legal doctrine; however, the Decision n. 15350/2014 of the Italian Supreme Court, stated that the distributor of the patented good/service is also entitled to act for the patent infringement. In this decision, the Supreme Court has also developed the principle that all the subjects who are suffering damages from the patent infringement have the interest to bring the proceeding.

(ii) Revocation

Whoever has a commercial interest and operates in the field where the patent is effective, has a legitimate interest to bring the revocation proceeding.

(iii) Declaratory

Pursuant to Art. 122.1 IIPC, when there is a real and actual uncertainty, the action aimed at obtaining a declaration of forfeiture or nullity of a patent title, may be exercised: i) by whomever has an interest in doing so (i.e. any competitor, even potential or future, who claims that the existence of the challenged patent represents an obstacle to its activities); or ii) brought directly by the Public Prosecutor.

1.14 If declarations are available, can they (i) address non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

In general, there are no restrictions to declaratory judgments. Declarations of non-infringement are available as technical standard and hypothetical activity declarations, but, in the latter case, it is necessary that at least a preparatory activity has been carried out. In particular, pursuant to Art. 120.1 IIPC, the patent applicant may enable an infringement/declaratory trial even if the patent has not yet been granted.

1.15 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?

In Italy, case law has, for a long time, been developing the concept of indirect or contributory infringement. In 2016, the contributory infringement has been introduced in Art. 66.2*bis* IIPC, thus a party can be liable for secondary or indirect infringement.

In particular, Art. 66.2*bis* IIPC provides that the patent owner has the exclusive right to prohibit third parties from supplying or offering to supply subjects other than those entitled to the use of the patented invention, with means relating to an essential element of that invention and necessary for its implementation in the territory of a Country in which it is protected if the third party has knowledge of the suitability and intended use of such means to implement the invention or is able to have it with reasonable care.

According to Art. 66.2*quater* IIPC, there may be a case of contributory infringement also when there is no downstream direct infringement, i.e. when the means relating to an essential element of that invention and necessary for putting it into effect are supplied to third parties in order to perform acts that, under the specific circumstances, would not represent an infringement of patent rights.

The IPC provides an exception to this rule when the means are constituted by-products that are currently on the market, unless the third party induces the person to whom they are supplied to perform prohibited acts.

1.16 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes, a party may be liable unless it has obtained the patent owner's previous consent (see question 6.1).

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

Yes, the full reproduction of all the elements claimed in the patent constitutes literal infringement. A patent infringement also occurs if the patented invention is reproduced by equivalence (Art. 52.3*bis* IIPC).

If the suspected infringing product or process does not include all the elements claimed in the patent, it may constitute an infringement by equivalence if it solves the same technical problem solved by the patent and if the modified means are mere substitutes of those claimed in the patent. Infringement by equivalence is usually ascertained by using the triple test approach: i) the same function; ii) the same effect; and iii) the same way.

The Italian Supreme Court, in a recent decision (n. 2977/2020) stated that the judge, in order to ascertain a patent infringement by equivalents, must check whether the contested implementation allows to reach the same final result by adopting means without originality.

1.18 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

A defence of invalidity could be raised in the defence statement both as a counterclaim or as an exception (see question 1.4).

Issues of invalidity and infringement are not bifurcated and can be claimed in the same proceeding; if separate proceedings have been brought, they should be joined in order to avoid conflicts between the two decisions. If the proceedings could not be joined (it can happen for several reasons, i.e. whether joining the proceedings would lead to an excessive delay in judgment), the infringement proceeding will remain suspended until the judgment on the invalidity is available.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the “*Formstein* defence”)?

The “*Formstein* defence” can be proposed before the Italian Courts in an argument.

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

The invalidity of a patent can also be claimed if: i) the invention is not suitable to have an industrial application (Art. 49 IIPC); ii) the invention’s implementation is contrary to public policy or accepted principles of morality (Art. 50 IIPC); iii) the invention has not been described in a sufficiently clear and complete manner (Art. 52 IIPC); iv) the object of the patent extends beyond the contents of the initial application or the protection of the patent has been extended (Art. 76 IIPC); and v) the owner of the patent did not have the right to obtain it (Art. 76 IIPC).

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

See question 1.18.

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

The other grounds of defence, which could be raised are the following:

- (i) **Exhaustion of rights**
Art. 5 IIPC provides that the patent owner’s exclusive right is exhausted once the products protected by the patent have been put on the market by the owner or with his consent in the territory of the country or in another EU/EEA Member State. The exhaustion does not apply if the patentee can oppose reasonable grounds, in particular where the marketed product has been modified or altered.
- (ii) **Licence**
The alleged infringer can prove that he acted on the basis of a valid licence (i.e. licence on the basis of an effective agreement).
- (iii) **Prior Use**
During the 12 months prior to the date of filing of the patent application or the date of priority, whoever has made use of the invention in his own business may continue to use it within the limits of previous use (Art. 68.3 IIPC).
- (iv) **Actions carried out in the private sphere**
The exclusive rights attributed to the patent owner do not extend to actions carried out in the private sphere and for non-commercial purposes, or as experimentation (Art. 68.1 lett. (a) IIPC).

(v) **Residual Hypothesis**

Pursuant to Art. 68.1 IIPC, the exclusive rights attributed to the patent owner do not extend to: i) studies and trials aimed at obtaining a marketing authorisation for a drug, including in foreign countries, and the resulting practical requirements including the preparation and utilisation of the pharmacologically active raw materials strictly necessary for the same; and ii) the infrequent preparation of unit doses of drugs in pharmacies on prescription, and the drugs thus prepared, provided that active principles produced industrially are not utilised.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) Is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

Preliminary injunctions are available through urgency proceedings whether on an *ex parte* basis (however, in patent cases, Italian courts are quite reluctant to grant them) or an *inter partes* basis and they are not conditional on the posting of a bond (but it could be requested, it depends on the cases).

Where convening the counterpart could jeopardise the implementation of the preliminary measure, the judge provides on the precautionary request with a reasoned decree. In this case, the judge sets a hearing within 15 days and the claimant must notify the decree to the counterpart within eight days. After the hearing, the judge can confirm, amend or revoke the measures provided with the Decree (Art. 669*sexies* CPC).

On the contrary, when the preliminary injunction has been requested on an *inter partes* basis, the judge immediately provides on the request with a reasoned order.

Preliminary reliefs require: i) the urgency to obtain the requested measures (so-called “*periculum in mora*”) consisting of the fact that the claimant would likely suffer irreparable damage if he had to wait until the end of the issuing of the final judgment to obtain an injunction (i.e., the market share erosion that the patentee will suffer if the infringer continues to carry on with the infringing conduct); and ii) that, on the basis of a preliminary assessment of the case, the claim appears to be grounded (so-called “*fumus boni iuris*”).

Precautionary injunctions could also be requested during the merit proceeding.

We have no provision allowing the judge to deny injunctive relief based on public interest factors or as a part of an equitable assessment.

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive damages available?

The judgment on damages necessarily requires a prior assessment of the infringement. However, the assessment of damages is characteristically very complex and can take a long time, and it is usually in the interest of the patentee to obtain a judgment quickly, that inhibits the prosecution of the infringement. For this reason, courts often divide the trial into two phases: in the first one, the judge decides on the patent right validity/infringement; and, in the second one, on damages.

Pursuant to Art. 125 IIPC, compensation due to the damaged party shall be set taking into account all of the pertinent aspects, such as the negative economic consequences, including lost income of the owner of the infringed right, the benefits achieved by the infringer and, in certain specific circumstances, non-economic elements, such as the moral damage caused to the owner of the right by the infringement. Damages may also be assessed (on the basis of a discretionary evaluation of the judge) on an equitable basis and, in this case, at least a reasonable royalty is due.

The loss of profits shall be determined as an amount not less than the royalties that the author of the infringement would have had to pay, had he obtained a licence from the owner of the infringed right.

In any event, the owner of the infringed right may request the recovery of the profits obtained by the infringer, either as an alternative to compensation for the loss of profits or to the extent that they exceed that compensation.

Punitive damages are not provided under the Italian law; however, the Italian Supreme Court, in a recent decision (n. 16601/2017) about the enforceability in Italy of a US judgment about punitive damages, stated that the sanctioning function of damages is no longer incompatible with the general principles of the Italian legal system. However, Italy is still waiting for a proper legislative action.

1.25 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

Pursuant to Art. 137 IIPC, at the end of the trial, if the losing party does not comply with the court's order, the winning party may establish an enforcement proceeding in order to force the other party to comply. There are two forms of enforcement: i) specific enforcement, when the winning party has the right to obtain an irreplaceable performance from the losing party (i.e. this procedure could be used for the order to cease the unlawful conduct); and ii) generic enforcement for fungible performance (i.e. money). In addition, the court may also fix a fine due by the infringer for each single day of delay in complying with the enforced order.

1.26 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

In infringement proceedings, the patentee is entitled to obtain: i) the definitive recall of the infringing goods from the market; ii) the destruction of the infringing products; and iii) the transfer of the property of both the infringing products, as well as of the specific means univocally destined to manufacture the infringing goods, or, in case of contributory infringement, to implement the patented method or process.

In addition, all the corrective and preliminary measures provided by the EU IP Rights Enforcement Directive are available in Italy.

Proceeding concerning patents validity or registration can only be raised before courts of the Member State where the deposit or registration has been applied for (Art. 24, EU Reg. n. 1215/2012).

Cross-border relief may be granted if requested, provided that no objection regarding the validity of the patent is raised. Thus, it is possible to establish an infringement proceeding before an Italian Court not only for the Italian fraction of the patent right, but also for the foreign fraction in order to obtain a cross-border relief.

In relation to the “torpedo effect” for non-infringement declaratory, the assessed counterfeiter may establish the judgment before the court of the place where the assessed unlawful activity is put in place pursuant to Art. 7, par. 2 EU Reg. n. 1215/2012. Where the jurisdiction of the court first seised is established, any court other than the court first seised shall decline jurisdiction in favour of that court (Art. 29 EU Reg. n. 1215/2012). In case the infringer has the option to submit a request of a negative assessment of the infringement in more than one national Courts, it could strategically choose the national Court where the average time of the proceedings is longer than the other courts having jurisdiction for this proceeding.

1.27 How common is settlement of infringement proceedings prior to trial?

The settlement of infringement proceedings before the trial is quite common in Italy.

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

There is not a time-barred period for acting on a patent infringement, because this kind of infringement is considered an on-going or permanent illicit conduct. However, there is a five-year time limit from the end of the infringement for claiming damages.

1.29 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?

A first instance judgment can always be appealed before the territorially competent Court of Appeal, within six months from the decision's publication or within 30 days if the judgment has been formally served by one of the parties to the other party.

The losing party in the first-instance judgment could seek a full review of the decision, both facts and law, but the parties cannot ask the Court of Appeal for new requests or exceptions other than those already proposed in the first instance judgment.

There is also a very limited possibility of producing new evidence, thus the parties cannot produce new evidence and new documents unless they prove that they have not been able to produce this evidence earlier for reasons not attributable to them.

1.30 What are the typical costs of proceedings to a first instance judgment on (i) infringement, and (ii) validity? How much of such costs are recoverable from the losing party?

A first instance judgment may have costs from 20,000 to 100,000 euros, including fees and costs to appoint technical experts (however, costs may be significantly higher where the case involves multiple patents). The fees of the experts appointed by the Court are normally paid half each by the parties during the proceedings; however, at the end of the proceeding, the winning party recovers these costs from the losing party.

The winning party is entitled to recover its legal costs from the losing party; however, courts have broad discretion to set the amount and they assess attorney's fees based on tariffs set forth by the Ministry of Justice, which are lower than the real attorney's fees.

In conclusion, the winning party usually does not recover the entire amount of the costs from the losing party.

1.31 For jurisdictions within the European Union: What steps are being taken in your jurisdiction towards ratifying the Agreement on a Unified Patent Court, implementing the Unitary Patent Regulation (EU Regulation No. 1257/2012) and preparing for the unitary patent package? Will your country host a local division of the UPC, or participate in a regional division? **For jurisdictions outside of the European Union:** Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

Italy is a party to all major international agreements, including: the WIPO Patent Cooperation Treaty and other WIPO-administered treaties (e.g., the Paris Convention for the Protection of Industrial Property of 7 July 1884, the Trademark Law Treaty of 1994 and the Berne Convention for the Protection of Literary and Artistic Works of 5 December 1887); IP-related multilateral treaties (e.g., the WTO Agreement on TRIPs of 1 January 1995); and IP regional treaties (e.g., the European Patent Convention of 1 December 1978).

In 2016, Italy also ratified EU Reg. n. 1257/2012; Milan and Turin are in contention to host a local Division of the UPC.

2 Patent Amendment

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

Patent amendments are possible only if the amendment limits and does not exceed the scope of protection originally granted (Art. 79.1 IIPC). The patent owner can ask the limitation of the patent before the Italian Patent and Trademark Office (“IPTO”). In a recent decision (n. 11910/2017), the Court of Milan stated that whilst the amendment can consist of additions and specifications drawing on the content, they must not extend the scope of the right and the original application, since in such cases the patent is void.

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

Pursuant to Art. 79.3 IIPC, in a proceeding concerning nullity, the patentee is entitled to submit to the Court, at any stage of judgment, modified claims that remain within the limits of the content of the patent application as initially filed and that does not extend the protection conferred by the patent granted.

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

See question 2.1.

3 Licensing

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

There are no specific restrictions on the contractual terms of patent licence agreement other than the antitrust limits provided by Commission Reg. n. 316/2014 (Technology Transfer Regulation).

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, the IIPC provides compulsory licences, as follows:

- i) **Compulsory licence due to lack of implementation**
Pursuant to Art. 70 IIPC, once three years have passed from the date of issue of a patent, or four years from the date of filing of an application (whichever comes last), if the patent owner has not implemented the patented invention or has implemented it to an extent that is gravely disproportionate to the Country’s needs, a mandatory licence may be granted for the non-exclusive use of the invention to any interested party who so requests. The compulsory licence may also be granted if the implementation of the invention has been suspended or gravely reduced for more than three years. A compulsory licence is not granted if the lack of implementation is due to causes outside of the control of the patent owner.
- ii) **Dependent patent**
Pursuant to Art. 71 IIPC, a compulsory licence may be granted if the invention protected by the patent cannot be used without harm to the rights, relating to a patent granted based on a previous application. In this case, the licence may be granted to the extent necessary to exploit the invention of the later patent, if it represents an important technical progress of considerable economic importance.

In any case, a compulsory licence may be granted only against payment of fair compensation by the licensee to the patent owner (Art. 72 IIPC).

Compulsory licences are not so common in Italy.

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?

The only possible patent term extension is available for medicinal products and for plant protection products (Supplementary Protection Certificate) for a maximum of five years in order to recover the time required for registration.

5 Patent Prosecution and Opposition

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

Pursuant to Art. 45 IIPC, patents may be granted for inventions, in all technical sectors, that are new, imply an inventive activity, and are suitable for industrial application.

In Italy, the following subject matters are not patentable:

- i) discoveries, scientific theories and mathematical methods;
- ii) plans, principles and methods for intellectual activities, for games, or for business activities and computer programs;
- iii) presentations of information;
- iv) methods for surgical or therapeutic treatment of the human or animal bodies and diagnostic methods applied to human or animal bodies;
- v) plant varieties or animal species and essentially biological processes for the production of animals or plants, including new plant varieties with respect to which the invention consists exclusively of the genetic modification of other plant varieties, even if that modification is the result of a genetic engineering process;

- vi) the human body, from the moment of conception and in the various stages of its development, nor the mere discovery of one of the elements of the body itself, including the sequence or partial sequence of a gene; and
- vii) inventions whose commercial exploitation is contrary to human dignity, public order and morality, the safeguarding of health, the environment and the life of persons and animals, the preservation of plants and biodiversity and the prevention of serious environmental harm.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

No, there is no such duty.

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?

No, third parties can challenge a patent only before the Court.

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

In Italy, an appeal may be filed with the Patent and Trademark Office Board of Appeal (so-called “*Commissione dei Ricorsi*”) by the person who filed the patent application, against the decisions that partially reject the application, refuse registration or prevent the recognition of a right.

The decision of the Board of Appeal can be appealed before the Supreme Court of Cassation.

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

If a patent application has been denied, the applicant can appeal this decision before the Board of Appeal (see question 5.4).

In other cases, priority or ownership must be challenged before a Civil Court.

5.6 Is there a “grace period” in your jurisdiction, and if so, how long is it?

No, in Italy a grace period is not provided. The only grace period that applies is the one provided by the 1928 Paris Convention.

5.7 What is the term of a patent?

A patent has a duration of 20 years starting on the date of filing of the application and may not be renewed, nor may its duration be extended (Art. 60 IIPC). For pharmaceutical patents, see question 4.1.

5.8 Is double patenting allowed?

No, in our jurisdiction only alternative patenting is provided by Art. 84 IIPC. A person, who applies a patent for an industrial invention, is allowed to simultaneously file a patent request for a utility model, to be valid in the event that the former is not granted or is granted only in part.

In any case, the Patent Office will approve only one of the two requests.

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?

EU Reg. n. 608/2013 (Customs Enforcement Regulation) applies in Italy, thus, customs authorities can detain or suspend the release of goods suspected of infringing a patent right.

Where the customs authorities identify goods suspected of infringing patent’s right covered by a decision granting an application, they suspend the release of the goods. Before suspending the release of the goods, the customs authorities may ask the holder of the decision to provide them with any relevant information with respect to the goods (Art. 17 Reg. n. 608/2013).

7 Antitrust Law and Inequitable Conduct

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

IP rights are subject to competition law in the Italian jurisdiction both under Law n. 287/1990 (the “**National Competition Law**”) and the Treaty on the Functioning of the European Union (“**TFEU**”) when trade between Member States is affected.

In some cases of patent infringement, defence of abuse of dominant position, such as refusal to licence, unfair or discriminatory licensing, excessive pricing, or anti-competitive use of SEPs, could be raised.

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

EU Reg. n. 316/2014 applies to patent licensing agreements concerning the transfer of technology rights.

The Regulation prevents anti-competitive effects of such agreements by prohibiting certain kinds of clauses. Licence agreements that have as their object the restriction of the party’s ability to determine its prices, the limitation of the output of the licensed products or portioning geographical markets, are unlawful (Art. 3, EU Reg. n. 316/2014).

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

Technical trials and FRAND licensing conditions could be examined in the same proceeding, or in separate proceedings, depending on the claim submitted by the plaintiff and by the possible defence and/or counterclaim of the defendant. It is clear that a technical trial on patent validity and infringement is different in nature from a FRAND assessment.

For example, if an SEP patent (“**SEP**”) holder acts for SEP infringement, the defendant cannot counterclaim that its infringement concerns an SEP in absence of any licence agreements (and the courts could reject the request of a defendant counterclaim to ascertain that the patent is a SEP in that proceedings).

Thus, if the defendant needs a FRAND licence it could request the Court in a different proceeding i) to ascertain that the patent is an SEP, and ii) to impose to the SEP's holder a duty to licence an SEP on a non-discriminatory basis.

For an Italian case concerning the recognition of a patent as an SEP, see Trib. Genova, 8 May 2004, *Orange-Bookstandard and Court of Milan*, order 5, 2012, Apple Samsung, where the Court of Milan rejected the request for a preliminary injunction for alleged infringement of refusal to deal a FRAND concerning SEPs.

8 Current Developments

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

On 27 March 2019, Italy adopted the Decree n. 18/2019 in order to fully implement the EU legislation for the creation of European unitary patent protection. However, the ruling of the German Constitutional Court and Brexit have complicated the way to the European Unified Patent.

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

Milan is one of the main candidates to take over from London as the location of one of the three UPC centralised courts.

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

In relation to infringement by equivalents, the Supreme Court of Cassation (Decision n. 2977/2020) stated the principle that the judge, in determining the patent scope extension, must not consider only the literal content of the patent, but he must reconcile the protection of the patent's owner with the reasonable legal certainty of third parties. Therefore, the judge must consider each element substantially equivalent to an element referred to the patent extension. For the purpose of ascertaining the equivalence, the judge can verify if the contested invention allows achieving the same result by adopting not original variants (obvious variants for an average field expert). On the contrary, the judge cannot consider the subjective intentions of the patent applicant.



Luciano Vasques concentrates on antitrust, consumer protection, energy and other regulatory matters in Italy and the European Union, and on corporate law (bankruptcy proceedings).

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