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Italy
Patent Litigation

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This country-specific Q&A provides an overview of patent litigation laws and regulations applicable in Italy.

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Italy: Patent Litigation

1. What is the forum for the conduct of patent litigation?

Patent litigation in Italy falls under the exclusive jurisdiction of the Specialised IP Courts, established within 22 First Instance and Appellate Courts. For disputes involving at least one foreign company, jurisdiction is further concentrated in only 11 courts (including Milan, Turin, Rome, Venice, and Naples).

Although Italian judges do not typically have a technical-scientific background, it is customary for the court to appoint a technical expert (CTU – *Consulente Tecnico d'Ufficio*) to provide a written opinion on validity and/or infringement, making the CTU the core of the technical-factual assessment. With the advent of the Unified Patent Court (UPC), Milan plays an even more central role, hosting both a Local Division and a section of the Central Division.

2. What is the typical timeline and form of first instance patent litigation proceedings?

Italy does not apply a bifurcated system. Infringement actions and invalidity counterclaims are heard and decided simultaneously by the same judge within the same proceedings. Issues of claim construction do not have a dedicated hearing but are addressed in the parties' written briefs and analyzed in the CTU's expert report.

A typical proceeding on the merits lasts from two to three years. The most substantial phase is the technical expertise (CTU), essentially a "technical mini-trial", which lasts 6 to 9 months and involves the exchange of written briefs and meetings between the party-appointed experts and the Court's expert. Often, Italian Courts issue a partial (interlocutory) judgment assessing liability and granting injunctive relief and subsequently remand the case to a separate accounting CTU to quantify damages in a later decision.

3. Can interim and final decisions in patent cases be appealed?

First instance decisions are provisionally enforceable (including permanent injunctions and monetary awards). The losing party may request the Court of Appeal to stay the execution only by demonstrating "very serious grounds" (e.g., imminent insolvency or irreversible market damage). The appeal against a first instance decision involves a new consideration of both the facts and the points of law, with stringent limitations on the possibility of filing new evidence. Appeal proceedings typically last from 18 to 24 months. A third-level appeal, before the Supreme Court (*Corte di Cassazione*) is admitted exclusively for violations of law (e.g., misinterpretation of the Italian Intellectual Property Code) or procedural defects, and never for a reassessment of the technical merits.

Preliminary measures can be appealed before a panel of three judges (not including the one who rendered the appealed decision) from the same Specialised Court within 15 days from the communication of the order.

4. Which acts constitute direct patent infringement?

Under Article 66 of the Italian Intellectual Property Code (CPI – *Codice della Proprietà Industriale*), direct patent infringement occurs when an unauthorized third party performs any of the acts exclusively reserved to the patent owner.

The statutory scope of direct infringement varies depending on the nature of the patent:

- **Product Patents:** manufacturing, offering for sale, placing on the market, using, importing, or stocking for any of these purposes the patented product.
- **Process Patents:** applying or using the patented process, as well as offering for sale, placing on the market, using, importing, or stocking the product directly obtained through the patented process.

From a substantive standpoint, direct infringement is established when the core inventive idea – as construed from the claims in light of the description and drawings – is reproduced in its essential elements. Literal reproduction of every single feature is not strictly required if a feature is non-essential; however, no literal direct infringement exists if even one essential feature of a claim is omitted.

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Under Italian law, liability for direct infringement is objective: injunctive and corrective relief (such as market recall or destruction) can be granted against any party commercializing or using the infringing goods regardless of fault or knowledge of the patent, whereas subjective intent or negligence is required only for the recovery of monetary damages.

5. Do the concepts of indirect patent infringement or contributory infringement exist? If so, what are the elements of such forms of infringement?

Yes, the concept of indirect (or contributory) patent infringement is fully recognized in Italy and is expressly codified under Article 66, paragraphs 2-*bis* and 2-*ter* of the Italian Intellectual Property Code (CPI), aligning Italian law with Article 26 of the Unified Patent Court Agreement (UPCA).

Under this framework, indirect infringement occurs when a third party, without authorization, supplies or offers to supply a person (other than those entitled to exploit the invention) with the means relating to an essential element of the patented invention for putting it into effect.

To establish liability for indirect patent infringement, the following key elements must be satisfied: the supplied means must relate to an essential element of the invention and be suitable for putting the invention into effect; the supplier knows, or it is obvious under the circumstances, that such means are suitable and intended to carry out the inventive teaching of the patent; the supply of staple commercial products does not constitute indirect infringement, unless the supplier actively induces the recipient to commit direct infringement.

6. How is the scope of protection of patent claims construed?

Under Italian law, the scope of protection conferred by a patent is determined by the claims, which are construed in light of the description and drawings pursuant to Article 52 of the Italian Intellectual Property Code (CPI) and Article 69 of the European Patent Convention (EPC), alongside its Protocol on Interpretation. The standard of construction seeks to strike a balance between fair protection for the patentee and a reasonable degree of legal certainty for third parties.

Doctrine of Equivalents:

The doctrine of equivalents is expressly codified under Article 52, paragraph 3-*bis* CPI. Italian Courts accept that patent infringement can occur not only through literal reproduction, but also when an essential feature is replaced by equivalent means that perform substantially the same function, in the same way, to achieve the same result (the Triple Test). Alternatively, Courts assess whether the variant would have been obvious to a person skilled in the art at the priority date.

A strict formal doctrine of prosecution history estoppel (or file wrapper estoppel) does not exist under Italian civil procedure. However, Italian Courts and Court-Appointed Experts (CTUs) routinely consult the prosecution history – including examination files and correspondence before the EPO or Italian PTO – as a persuasive interpretive tool. Under principles of good faith and consistent representation, statements or claim amendments made by the applicant during examination to overcome prior art objections will be used to restrict claim scope, preventing the patentee from reclaiming through the doctrine of equivalents what was explicitly surrendered during prosecution.

7. What are the key defences to patent infringement?

Under Italian law, an alleged infringer can raise a broad range of procedural and substantive defences. Procedurally, defences may be raised either as mere procedural pleas (effective only between the parties) or as formal counterclaims (seeking remedies with *erga omnes* effect).

The key substantive defences include:

- **Non-infringement:** the defendant may argue that the accused product or process does not fall within the scope of the claims, either literally or under the doctrine of equivalents.
- **Patent Invalidity:** the defendant may challenge the validity of the enforced patent on statutory grounds (lack of novelty, lack of inventive step, insufficiency of disclosure, added matter, etc.). In proceedings on the merits, invalidity is typically raised as a counterclaim to achieve full (or partial) revocation of the patent *erga omnes* (Art. 76 CPI). In preliminary injunction proceedings, invalidity is raised as a defence to rebut the *fumus boni iuris* of the asserted patent.
- **Experimental use exemption (Art. 68(1)(a) CPI):** Acts done privately and for non-commercial purposes, or strictly for

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experimental purposes relating to the subject matter of the patented invention, are exempt from infringement.
- **Bolar exemption (Art. 68(1)(b) CPI):** Broadly applied under Italian law, this exemption permits the performance of studies, trials, and clinical tests necessary to obtain marketing authorization (MA) for generic or biosimilar human and veterinary pharmaceuticals, as well as the consequential practical acts strictly required for that purpose.
- **Prior use right (Art. 68(3) CPI):** Any person who, in good faith, used the invention in their business in secret within Italy during the 12 months preceding the filing or priority date has the right to continue using the invention, strictly within the limits of prior exploitation. This right can only be transferred together with the relevant business unit.
- **Exhaustion of rights (Art. 5 CPI):** Patent rights are exhausted once the patented products have been put on the market within the European Economic Area (EEA) by the patent owner or with their express consent.
- **FRAND defence (SEP Litigation):** In disputes involving Standard Essential Patents (SEPs), defendants routinely invoke the FRAND defence based on EU antitrust principles (*Huawei v. ZTE*, Art. 102 TFEU), arguing that the patentee's application for injunctive relief constitutes an abuse of dominant position if the patentee failed to make a fair, reasonable, and non-discriminatory licensing offer prior to litigation.

8. What are the key grounds of patent invalidity?

Under Italian law, the grounds for patent invalidity are expressly set out under Article 76 of the Italian Intellectual Property Code (CPI). This statutory list is considered exhaustive.

A patent may be declared null and void, in whole or in part, on any of the following grounds:

- **Lack of patentability requirements (Art. 76(1)(a) CPI):**
    - **Lack of Novelty (Art. 46 CPI):** The invention was disclosed or made available to the public anywhere in the world prior to the filing or priority date.
    - **Lack of Inventive Step / Obviousness (Art. 48 CPI):** Having regard to the state of the art, the invention would have been obvious to a person skilled in the art.
    - **Lack of Industrial application (Art. 49 CPI):** The subject matter cannot be made or used in any kind of industry, including agriculture.
    - **Non-patentable subject matter (Art. 45 CPI):** Inventions falling within statutory exclusions (e.g., discoveries, scientific theories, mathematical methods, software *as such*, business schemes, or methods for treatment/diagnosis practiced on the human body).
    - **Public order or morality (Art. 50 CPI):** Inventions whose commercial exploitation is contrary to public policy or accepted principles of morality.
- **Insufficiency of disclosure (Art. 76(1)(b) CPI):** The patent description fails to disclose the invention in a manner sufficiently clear and complete for a person skilled in the art to carry it out without undue burden.
- **Added Matter / Extension of scope (Art. 76(1)(c) CPI):** The subject matter of the granted patent extends beyond the content of the patent application as originally filed, or the scope of protection was unlawfully broadened following a post-grant limitation.
- **Lack of entitlement / Unlawful ownership (Art. 76(1)(d) CPI):** The patent applicant was not entitled to obtain the patent (e.g., in cases of misappropriation of the invention), and the rightful owner did not exercise their right to claim assignment under Article 118 CPI.

A Court may declare a patent partially invalid (Art. 76(2) CPI), in which case the nullity results in a limitation of the remaining claims. Furthermore, a final judgment of nullity has retroactive effect (*ex tunc*), meaning the patent is deemed never to have produced legal effects, subject to statutory protections preserving executed contracts and settled decisions (Art. 77 CPI). An invalid patent may also be converted into a valid utility model if the requisite criteria are met (Art. 76(3) CPI).

9. How is prior art considered in the context of an invalidity action?

In Italian patent litigation, the assessment of prior art strictly aligns with the substantive standards of the Italian Intellectual Property Code (CPI) and the European

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Patent Convention (EPC).

Prior art encompasses everything that has been made available to the public anywhere in the world prior to the filing or priority date, whether by written or oral description, use, or any other means. Furthermore, earlier Italian patent applications (or European patent applications designating Italy) that were filed *before* the priority date but published *on or after* that date constitute "secret prior art" (Art. 46(3) CPI) and are considered solely for the evaluation of novelty, not inventive step.

To destroy novelty, a single prior art disclosure must directly, explicitly, or implicitly – and unambiguously – disclose all the essential features of the claimed invention in combination (the strict "photographic" single-document test). Italian Courts strictly evaluate the effective public availability and prior date of asserted novelty-destroying documents.

For the evaluation of the inventive step Italian courts and Court-Appointed Experts (CTUs) strictly apply the EPO's Problem-Solution Approach:

1. Identification of the *closest prior art*;
2. Determination of the *distinguishing technical features* and the resulting *objective technical problem* to be solved;
3. Assessment of whether the claimed solution would have been obvious to a person skilled in the art (*could-would* test, strictly prohibiting hindsight bias).

10. Can a patentee seek to amend a patent that is in the midst of patent litigation?

Yes. Under Italian patent law, a patentee has two distinct ways to amend or limit the claims of a patent during pending litigation:

Judicial limitation in pending litigation (Art. 79(3) CPI): while a nullity action is pending before an Italian Court, the patent holder may submit a rewording or limitation of the claims directly to the Court at any stage or instance of the proceedings (including during appeal proceedings, up until the filing of final pleadings).

Administrative limitation (Art. 79(1) CPI):

Alternatively, the patentee may file a formal limitation application directly with the Italian Patent and Trademark Office (Italian PTO / UIBM) or, in the case of a European patent, with the European Patent Office (EPO). If an administrative limitation is pursued while national litigation is pending, the Court may suspend or adjust the schedule of the judicial proceedings awaiting the outcome of the official administrative decision.

Any proposed amendment submitted during litigation must comply with strict statutory limits under Article 79(3) CPI:

- It cannot extend beyond the content of the patent application as originally filed (prohibition of *added matter*);
- It cannot broaden the original scope of protection conferred by the granted patent.

The defendant in the nullity action has the full right to challenge and oppose any proposed amendment. Third parties/defendants may argue that the reworded claims introduce unallowable added matter, lack clarity, or remain invalid over the cited prior art.

If the Court – assisted by the technical evaluation of the Court-Appointed Expert (CTU) – finds the reworded claims valid and allowable, it issues a judgment of partial nullity, setting the new, limited claims (Art. 76(2) CPI). The partial limitation operates with retroactive effect (*ex tunc*).

As an alternative or subordinate defence, if the patent is declared invalid as an invention, the patentee may request the Court to convert the invalid patent into a utility model, provided the subject matter satisfies the validity requirements for utility models.

11. Is some form of patent term extension available?

Yes. While standard patent protection cannot be extended beyond its statutory 20-year term, Supplementary Protection Certificates (SPCs) are available in Italy for pharmaceutical (medicinal) products and plant protection products pursuant to EU Regulation No. 469/2009 and EU Regulation No. 1610/96, administered locally by the Italian Patent and Trademark Office (UIBM).

Duration and Pediatric Extension:

- Standard SPC duration: an SPC takes effect upon the natural expiration of the basic patent. Its duration equals the period elapsed between the date of filing of the basic patent application and the date of the first Marketing Authorization (MA / AIC) in the EU, reduced by 5 years, subject to a maximum overall duration of 5 years.
- Pediatric extension: under EU Regulation No.

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1901/2006, an additional 6-month extension is granted if the medicinal product has undergone completed studies in compliance with an approved Pediatric Investigation Plan (PIP), extending total potential protection up to 5.5 years.

An SPC will be granted only if, at the date of application (Article 3, Reg. 469/2009):

1. The product is protected by a basic patent in force (Art. 3(a));
2. A valid Marketing Authorization to place the product on the market as a medicinal product has been granted (Art. 3(b));
3. The product has not already been the subject of an SPC (Art. 3(c));
4. The authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product (Art. 3(d)).

SPC invalidity actions are frequently litigated before Italian Specialised IP Courts alongside basic patent litigation. Under Article 15 of Regulation 469/2009, SPCs are challenged on the following primary grounds:

- **Invalidity or lapse of the basic patent:** if the underlying basic patent is declared null and void, the SPC automatically lapses or is invalidated.
- **Non-compliance with Article 3(a):** disputes concerning whether the active ingredient is "protected" by the basic patent in force. Italian Courts strictly apply CJEU jurisprudence requiring that the active ingredient must be specifically identifiable or fall within a precise core inventive concept disclosed in the basic patent claims.
- **Non-compliance with Article 3(d):** arguments that an earlier MA was granted for the same active ingredient or combination, invalidating the SPC for lack of novelty of the authorization.

12. How are technical matters considered in patent litigation proceedings?

Because Italian judges do not typically possess a technical or scientific background, the assessment of technical issues regarding patent validity and infringement relies heavily on a Court-appointed technical expert system.

- **Court-Appointed Expert (*Consulente Tecnico d'Ufficio* – CTU):** the court appoints an independent technical expert. The CTU acts as an officer/auxiliary of the court and owes an absolute legal duty of impartiality and independence exclusively to the judge, taking a formal oath before assuming the mandate.
- **Party-Appointed Experts (*Consulenti Tecnici di Parte* – CTPs):** each party has the right to appoint one or more private technical experts. CTPs represent and defend the technical positions of their respective parties throughout the investigation, participating in all technical meetings and submitting written briefs to the CTU.

The technical assessment is conducted through a structured, multi-stage written procedure:

1. **Formulation of technical questions:** At an initial hearing, the judge formulates specific technical questions regarding validity and/or infringement after consulting with the parties.
2. **Technical investigation:** The CTU conducts meetings with the CTPs, exchanges technical documentation, and, where necessary, performs site inspections or laboratory tests.
3. **Draft report:** The CTU prepares a preliminary written report setting out their findings and sends it to the CTPs.
4. **CTP comments:** The CTPs file written observations and critiques within a Court-mandated deadline.
5. **Final CTU report:** The CTU files the final written report with the Court, explicitly answering all objections and comments raised by the CTPs.

Common law cross-examination of technical experts does not exist in Italian civil procedure. The technical debate is almost entirely written. However, the judge may, at their discretion or upon request of a party, order the CTU and CTPs to appear at a dedicated hearing to answer oral questions and provide clarifications.

Under the principle of *iudex peritus peritorum*, the judge remains the ultimate authority on technical matters. While Courts follow the CTU's conclusions in the vast majority of cases, the judge is not legally bound by them and may depart from the CTU's findings or adopt a CTP's dissenting opinion, provided the judgment contains detailed, reasoned justification.

Under Article 128 CPI and Article 696-*bis* of the Code of Civil Procedure, a party may petition the Court to appoint a CTU *prior* to commencing proceedings on the merits. This pre-trial technical assessment evaluates validity and infringement primarily to facilitate an amicable settlement between the parties. If settlement fails, the

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expert report can be directly admitted into subsequent litigation on the merits.

13. Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?

Broad pre-trial discovery or general disclosure does not exist under Italian civil procedure. However, pursuant to Directive 2004/48/EC (Enforcement Directive) as implemented into the Italian Code of Intellectual Property (CPI), Italian law provides powerful, targeted judicial mechanisms for evidence gathering, preservation, and search orders.

1. **Description Order (*Descrizione* – Art. 129 CPI):**

- The description order is the primary pre-trial evidence-gathering tool in Italian patent litigation. It allows a patentee providing *prima facie* evidence of infringement to request a judicial search and preservation order. A Court bailiff, typically accompanied by Court-appointed IT forensic experts and party technical experts, enters the alleged infringer's premises to inspect, photograph, sample, and copy infringing goods, production equipment, manufacturing drawings, and commercial/accounting records.
- Modern description orders routinely authorize IT forensic specialists to create bit-stream copies of servers, hard drives, and cloud storage containing technical or financial data.
- In cases of special urgency or where prior notice would risk the destruction or concealment of evidence, description orders are granted *ex parte* (*inaudita altera parte*). A mandatory confirmation hearing is held within 15 days, where the Court may confirm, modify, or revoke the order.

2. **Seizure Order (*Sequestro*, Art. 129 CPI):**

- Beyond mere inspection, the Court may order the physical seizure of infringing products, components, and the specific machinery univocally used for their manufacture to prevent their placement or continued presence on the market.
- Where the patentee demonstrates circumstances likely to endanger the recovery of monetary damages, the Court may order the preventive seizure of the infringer's assets, including the freezing of bank accounts and access to commercial documents.

3. **Order for Exhibition / Production of evidence (*Ordine di Esibizione*, Art. 121 CPI):** During pending proceedings on the merits, if a party has provided plausible circumstantial evidence of infringement, the judge may order the opposing party or a third party to produce specific documents, accounting ledgers, or banking records necessary to establish infringement or quantify damages.
4. **Right of Information (*Diritto di Informazione*, Art. 121-*bis* CPI):** The Court may order the defendant or third parties involved in the production or distribution network to provide detailed information regarding the origin, quantities, pricing, and distribution channels of infringing goods or services. Refusal to answer or providing false information triggers criminal sanctions.

14. Are there procedures available which would assist a patentee to determine infringement of a process patent?

Yes. Establishing infringement of a process patent (*brevetto di procedimento*) presents unique evidentiary challenges because the manufacturing method is typically carried out within the defendant's private facilities. Italian law provides specific procedural mechanisms and statutory presumptions to assist patentees in determining and proving process patent infringement.

1. Reversal of the Burden of Proof (Article 67 CPI):

Under Article 67 of the Italian Intellectual Property Code (CPI), the burden of proof shifts from the patentee to the defendant in either of the following circumstances:

- If the identical product obtained by the patented process is “new” (i.e., not disclosed prior to the patent filing date), any identical product manufactured by a third party is presumed, in the absence of proof to the contrary, to have been obtained via the patented process.
- If there is a substantial likelihood that the identical product was made using the patented process and the patentee, despite having taken reasonable efforts, has been unable to

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determine the process actually used by the defendant.

Where the burden of proof is reversed, the defendant must prove that its product was manufactured using a different, non-infringing process.

Where the statutory presumption does not automatically apply, the primary procedural tool is the description order. A Court bailiff, accompanied by Court-appointed technical experts, is authorized to enter the defendant's manufacturing plant *in situ*. The expert is empowered to inspect operating machinery, observe live manufacturing steps, examine batch records, standard operating procedures (SOPs), and technical files, as well as take physical samples of intermediate and final products for laboratory testing.

During litigation on the merits, upon a justified request by the patentee supported by plausible circumstantial evidence, the judge can order the defendant to produce a detailed technical description of its manufacturing process, along with supporting technical and accounting records.

In ordering the defendant to prove its manufacturing method or disclose process documentation, the Court must safeguard the defendant's legitimate interest in protecting its trade secrets and proprietary manufacturing know-how. Italian Courts frequently restrict access to confidential process descriptions (*Art. 121-ter CPI*), ensuring that sensitive technical documentation is disclosed exclusively to the judge, the Court-Appointed Expert (CTU), external legal counsel, and bound independent experts under strict non-disclosure obligations.

15. Are there established mechanisms to protect confidential information required to be disclosed/exchanged in the course of patent litigation (e.g. confidentiality clubs)?

Yes. Following the implementation of Directive (EU) 2016/943 on trade secrets into Italian law, Article 121-*ter* of the Italian Code of Industrial Property (CPI) was enacted to provide explicit, robust statutory mechanisms to safeguard trade secrets, proprietary know-how, and confidential information required to be disclosed during litigation.

Italian Courts are highly receptive to implementing protective measures to ensure that sensitive technical, commercial, or financial information exchanged during proceedings is strictly protected.

1. Confidentiality Clubs: upon a reasoned application by a party, the Court may restrict access to confidential documents, expert briefs, or physical evidence strictly to a designated "Confidentiality Club".

Under Article 121-*ter* CPI, access is restricted to the judge, Court staff, the Court-Appointed Expert (CTU), external legal counsel, and independent party-appointed experts (CTPs). To respect constitutional rights of defence and fair trial principles, the Court must also grant access to at least one natural person representing each party (e.g., a designated in-house counsel or corporate officer), subject to strict non-disclosure obligations.

Confidentiality Clubs routinely cover highly sensitive assets such as source codes, chemical formulas, manufacturing know-how, unreleased R&D data, cost structures, customer lists, and financial records.

2. Additional procedural safeguards (Art. 121-*ter* CPI):

In addition to confidentiality clubs, the court may order further protective measures:

- Parties may file redacted, non-confidential versions or summaries of technical/commercial documents where confidential passages are blacked out.
- The Court may order that specific hearings, or portions thereof devoted to examining trade secrets or proprietary know-how, be held in closed session.
- Specific confidential exhibits and technical report annexes may be sealed and excluded from public or general court registries.

3. Sanctions and enforcement:

Any breach of confidentiality obligations or unauthorized use of protected information outside the scope of litigation triggers statutory procedural penalties, civil liability for damages, potential disciplinary proceedings for attorneys/experts, and criminal sanctions under Article 623 of the Italian Criminal Code (unauthorized disclosure of industrial secrets).

16. Is there a system of post-grant opposition proceedings? If so, how does this system interact with the patent litigation system?

If an EPO opposition and a national invalidity action are

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pending simultaneously, the Italian Court may stay the national proceedings (Art. 295 Code of Civil Procedure). Historically, stays were common; however, given the current speed and efficiency of the Companies' Courts, courts are now reluctant to grant a stay unless a final EPO decision (especially from the Technical Boards of Appeal) is deemed imminent.

17. To what extent are decisions from other fora/jurisdictions relevant or influential, and if so, are there any particularly influential fora/jurisdictions?

Decisions from foreign Courts on equivalent patents are not binding but can have a persuasive effect. The case law of the EPO's Boards of Appeal is held in particularly high regard, offering significant guidance on validity issues, especially in matters not expressly considered by domestic legislation.

18. How does a court determine whether it has jurisdiction to hear a patent action? And in what circumstances will a court anti-suit to preserve its jurisdiction.

Jurisdiction over patent disputes in Italy is determined under EU Regulation 1215/2012 (Brussels I bis) and Article 120 of the Italian Code of Industrial Property (CPI):

- **General Jurisdiction (Art. 4):** Italian Courts have jurisdiction if the defendant is domiciled in Italy.
- **Special Jurisdiction for infringement (Art. 7(2)):** Jurisdiction lies in Italy if the infringing act occurred or caused damage within Italian territory.
- **Multiple Defendants (Art. 8(1)):** Jurisdiction extends to foreign EU co-defendants if the claims are closely connected (e.g., corporate group entities in a supply chain).
- **Exclusive Jurisdiction over validity (Art. 24(4)):** Italian Courts have exclusive jurisdiction to adjudicate the validity or nullity of national Italian patents or Italian validations of European patents.

Italian Courts do not issue anti-suit injunctions (ASIs) against foreign proceedings, as ASIs are incompatible with EU law and the principle of mutual trust between sovereign Courts. However, in high-stakes disputes (such as SEP/FRAND litigation), if a foreign Court issues an ASI restraining a party from enforcing Italian patent rights, Italian Courts can grant anti-anti-suit injunctions (AASIs) or urgent protective measures to safeguard their jurisdiction and protect the litigant's constitutional right of access to justice (Art. 24 Italian Constitution).

19. What are the options for alternative dispute resolution (ADR) in patent cases? Are they commonly used? Are there any mandatory ADR provisions in patent cases?

Arbitration is expressly provided for under the Code of Industrial Property. While arbitration is undoubtedly available to resolve issues of patent infringement and damages, its admissibility regarding patent invalidity issues with *erga omnes* effect remains heavily debated, as prevailing opinion suggests that only a state Court can issue a cancellation decision effective against all third parties. Mediation is mandatory only in specific, limited cases (e.g., determining equitable remuneration for employee inventions).

20. What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?

- Sending a formal warning or cease-and-desist letter before commencing litigation is not compulsory under Italian law. However, sending a warning letter is common practice to put the alleged infringer on formal notice, which is relevant for establishing bad faith or calculating the statute of limitations for damages. Caution is required, as making unfounded or reckless public threats of patent infringement can trigger liability for acts of unfair competition.
- General patent infringement and invalidity actions are exempt from mandatory pre-litigation mediation.
- Main proceedings on the merits are formally initiated by drafting and serving a writ of summons on the defendant. Under Italian civil procedure, the claimant sets the first hearing date, respecting statutory minimum notice periods between the service date and the hearing: at least **90 days** if service is effected in Italy, or **150 days** if service is to be effected abroad.
- While not a prerequisite for actions on the merits, a patentee seeking preliminary relief (e.g., preliminary injunctions, description

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orders, or seizures) must act promptly. Although according to some decisions the urgency requisite (*periculum in mora*) exists as long as the infringement is in place, a delay of more than six months from the date the patentee became aware of the infringement is frequently considered by Courts to negate the requirement of urgency, leading to the rejection of interim applications.

Limitation Periods (*Prescrizione*):

- Claims for monetary damages resulting from patent infringement are subject to a 5-year statute of limitations (*prescrizione*) under Italian tort law, running from the date on which the tortious act occurred or when the patentee became aware (or should reasonably have become aware) of the infringement and the resulting harm.
- Patent infringement is treated as a continuous tort. Consequently, the expiration of the 5-year period does not bar the patentee from bringing an action for an injunction or other corrective remedies; it merely limits the recovery of monetary damages to those that accrued within the 5 years prior to the date of service of the writ of summons or formal written demand.
- Actions seeking a declaration of patent invalidity or declaratory non-infringement are imprescriptible and may be brought at any time during the life of the patent.

21. Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?

1. Standing of the Patent Owner and assignees:

- **Patent Owner (Proprietor):** The owner of the economic rights in the patent (whether the original inventor, company, or assignee) has full standing to bring an infringement action (Art. 120 and Art. 122 CPI).
- **Assignees:** An assignee of a patent has standing to bring an infringement action for acts committed after the assignment. An assignee may also sue for past infringements committed prior to the assignment if the right to claim past damages was explicitly transferred in the assignment agreement.

2. Standing of Patent Licensees under Italian Law:

- **Exclusive Licensees:**
  - *Independent Standing:* An exclusive licensee has full, independent legal standing to initiate patent infringement proceedings and seek all available remedies (preliminary relief, permanent injunctions, market recall, and monetary damages) in its own name.
  - *Licensor Involvement:* Unless contractually agreed otherwise in the license agreement, an exclusive licensee is not required to join the patent owner as a mandatory co-claimant. However, the patent owner may voluntarily intervene or be joined to protect its title.
  - *Effect of Registration:* Registration of the license agreement with the Italian Patent and Trademark Office (Italian PTO / UIBM) is not a prerequisite for the licensee to establish standing in Court; the existence of the license can be proven by any admissible evidence. However, registration is recommended to make the license enforceable against third-party good-faith assignees.
- **Non-Exclusive Licensees:**
  - *Restrictive Standing:* Prevailing Italian case law holds that a non-exclusive licensee does not possess independent standing to sue for patent infringement solely on its own.
  - *Requirements for Standing:* A non-exclusive licensee may bring or participate in an infringement action only if: (i) the action is brought jointly with the patent owner (joinder), or (ii) the patent owner has expressly authorized the non-exclusive licensee in the license contract or via a specific power of attorney to initiate legal proceedings.

22. Who has standing to bring an invalidity action

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against a patent? Is any particular connection to the patentee or patent required?

Under Article 122 of the Italian Code of Industrial Property (CPI), an action to declare a patent null and void can be initiated by anyone who demonstrates a legitimate, real and actual interest (pursuant to Article 100 of the Code of Civil Procedure).

Unlike patent infringement actions no pre-existing legal, commercial, or contractual connection to the patentee or the patent is required to challenge validity.

Any competitor operating (or planning to operate) in the relevant technical or commercial sector has standing to bring a standalone invalidity action to "clear the path" for its commercial activities.

The sole exception to the general rule of open standing concerns invalidity grounds based on lack of subjective entitlement (e.g., misappropriation of the invention). Under Article 76(1)(d) and Article 118 CPI, an invalidity action on this specific ground can be brought exclusively by the rightful owner (the true inventor or their lawful assignee).

23. Are interim injunctions available in patent litigation proceedings?

Yes. Preliminary injunctions are among the most common and effective remedies in Italian patent litigation, governed by Articles 124 and 131 of the Italian Code of Industrial Property (CPI) and Article 669-*bis et seq.* of the Code of Civil Procedure (CPC). An interim injunction can be requested either prior to or during pending litigation on the merits.

To obtain a preliminary injunction, the applicant must satisfy two cumulative legal requirements:

- ***Fumus Boni Iuris* (Prima facie case):** The applicant must demonstrate a likelihood of success on the merits, establishing *prima facie* evidence of patent validity and infringement. If the defendant raises credible invalidity defences supported by prior art, the Court may conduct a expedited preliminary technical evaluation (often appointing a CTU under a shortened schedule) before ruling.
- ***Periculum in Mora* (Urgency and irreparable harm):** The applicant must prove that awaiting the final judgment on the merits would cause serious and irreparable economic or reputational harm (e.g., permanent loss of market share, price erosion, or brand dilution).

Urgency must be asserted promptly. A delay exceeding 6 months from the date the patentee acquired full knowledge of the infringement generally leads courts to dismiss the application for lack of *periculum in mora*.

Ordinarily, interim injunction applications are heard *inter partes*. The judge schedules a discussion hearing shortly after filing (typically within 2 to 4 weeks), where evidence is gathered informally and private technical experts (CTPs) are heard.

In situations of extreme urgency or where prior notice would prejudice the enforcement of the measure (e.g., imminent trade fairs, risk of inventory concealment, or sudden market entry), the Court can grant an interim injunction *ex parte*. In such cases, the judge must schedule a confirmation hearing within **15 days** to allow the respondent to appear and defend, following which the order is confirmed, modified, or revoked.

Injunctions prohibit the manufacturing, offering for sale, marketing, importing, or stocking of the infringing goods, and can be extended to intermediaries whose services are used to commit the infringement.

Injunction orders are almost universally coupled with a Court-ordered monetary penalty payable to the patentee for any subsequent violation or delay in compliance (e.g., a fixed sum per infringing item sold or per day of delay).

24. What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought and which are typically ordered?

Under the Italian Code of Industrial Property (CPI), a wide range of final remedies – both non-monetary (real/injunctive) and monetary – is available to a patentee upon a final Court finding of infringement. These remedies are governed primarily by Articles 124, 125, 126, and 127 CPI.

- **Permanent Injunction (*Inibitoria Definitiva*, Art. 124 CPI):** Prohibits the defendant from manufacturing, offering for sale, placing on the market, using, importing, or stocking
- **Recall and removal from market (*Ritiro dal Commercio*, Art. 124 CPI):** The Court may order the definitive removal or recall of infringing goods from distribution channels, binding the infringer and all intermediaries who are parties to the litigation.

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- **Delivery up or destruction (*Assegnazione in Proprietà o Distruzione*, Art. 124 CPI):** Infringing goods, as well as the specific machinery univocally used to manufacture them, may be ordered to be destroyed at the infringer's expense or delivered up to the patentee.
- **Publication of the Judgment (*Pubblicazione della Sentenza*, Art. 126 CPI / Art. 120 CPC):** The Court may order the publication of the judgment (in full or as a summary) in national newspapers, specialized trade magazines, or online websites at the losing party's expense.

While patentees almost invariably seek the full statutory catalogue of remedies in their pleadings – combining injunctive relief, real sanctions, publication, and maximum monetary compensation – Italian Courts tailor their final orders based on evidence and proportionality. Upon establishing infringement, courts almost routinely issue permanent injunctions backed by daily monetary penalties, alongside market recall and destruction of infringing inventory (unless product modification is feasible or destruction is disproportionate). Compensatory damages or disgorgement of profits are consistently awarded, frequently via an interlocutory judgment on liability followed by a dedicated accounting CTU to quantify damages, whereas judgment publication is regularly granted as a complementary remedy to inform the market and repair reputational harm.

25. On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages?

Monetary remedies under Italian law are strictly compensatory, as punitive or exemplary damages are not available under Italian civil liability principles. Monetary recovery is calculated based on:

- **Lost profits:** Compensation for the actual economic loss suffered by the patentee, including lost sales, price erosion, and lost market share.
- **Reasonable Royalty / Lump Sum:** As a statutory floor, lost profits cannot be less than the royalties the infringer would have paid under a regular market license. Recent case law frequently applies a statutory uplift (usually increasing market rates by 25% to 50%) to reflect the fact that an infringer did not bear R&D, marketing, or contractual licensee overheads.
- **Disgorgement / Reversion of Infringer's Profits:** Introduced under the EU Enforcement Directive, the patentee may claim the actual net profits earned by the infringer as an alternative to lost profits, or to the extent they exceed lost profits.
- **Non-monetary / Moral damages:** Compensation for non-economic harm, such as injury to commercial reputation, brand tarnishment, or market confusion.

26. How readily are final injunctions granted in patent litigation proceedings?

In Italian patent litigation, permanent injunctions) are granted almost as a matter of course once patent validity and infringement are established. Unlike interim injunctions, obtaining a final injunction does not require proof of urgency or irreparable harm. Italian Courts apply a strong presumption of continuing or future infringement unless the defendant demonstrates that all infringing acts have definitively ceased and provides a binding formal undertaking not to resume them, or the patent has reached its natural expiration.

While Article 124 CPI and EU Enforcement Directive 2004/48/EC embody the principle of proportionality, Italian judges rarely deny permanent injunctive relief based solely on general commercial hardship or economic inconvenience to the infringer. Italian law lacks a broad "public interest" exception allowing Courts to deny an injunction to a valid patentee. In exceptional cases—particularly involving public health, critical medical supplies, or complex supply chain realignments—Courts may exercise judicial discretion to grant a brief, transitional grace period (*carve-out* or delayed enforcement) allowing the defendant to orderly withdraw products or reconfigure operations without compromising patient care or public safety. Strategic or systemic public interest concerns are handled via statutory compulsory licensing (*licenza obbligatoria*, Art. 70 CPI) rather than through judicial refusal of a final injunction.

To guarantee full effectiveness, permanent injunctions under Article 124(2) CPI are almost universally coupled with Court-ordered monetary penalties (*penale / astreinte*) payable directly to the patentee for any subsequent breach or delay in compliance, calculated as a fixed sum per infringing item sold or per day of delay. The scope of injunctive relief comprehensively covers all acts of manufacturing, offering for sale, marketing, using, importing, or stocking infringing products, or practicing patented processes across the entirety of Italian territory.

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Where a final injunction cannot be issued—most notably because the patent expired prior to judgment—or in specific statutory scenarios, Courts award monetary compensation under Article 125 CPI. In calculating reasonable royalties in lieu of injunctive relief or for past infringement, Italian Courts frequently apply a statutory uplift (typically 25% to 50% above standard market licensing rates) to ensure the infringer does not effectively obtain a retroactive compulsory license on ordinary commercial terms. Furthermore, under Article 124(3) CPI, if the patent expires during or shortly after litigation, the Court may order the post-expiry seizure of infringing inventory manufactured prior tor to expiration or order its delivery up to the patentee against payment of an expert-determined price, thereby neutralizing any unfair market lead-time advantage gained by the infringer.

27. Are there provisions for obtaining declaratory relief, and if so, what are the legal and procedural requirements for obtaining such relief?

Italian law provides robust mechanisms for declaratory relief in patent disputes, primarily through actions for a declaratory judgment of non-, as well as declarations of validity, infringement, or patent exhaustion. Under Article 100 of the Code of Civil Procedure (CPC), the fundamental procedural prerequisite is demonstrating a real, actual, and legitimate legal interest, as Courts will dismiss purely academic or hypothetical actions.

To establish the legitimate legal interest in a non-infringement action, the claimant must demonstrate active commercial launch – or advanced, concrete preparations to enter the market – coupled with objective commercial uncertainty created by the patentee. While a formal cease-and-desist letter is the standard trigger, an explicit threat is not strictly mandatory if the patentee's market enforcement strategy creates a tangible risk that hampers the claimant's business.

28. What are the costs typically incurred by each party to patent litigation proceedings at first instance? What are the typical costs of an appeal at each appellate level?

Litigation costs depend heavily on the case's complexity. Generally, costs in Italy are lower compared to other major European jurisdictions.

First Instance: Legal costs typically range from EUR 50,000 to EUR 150,000.

Preliminary Proceedings: Ranging from EUR 15,000 to EUR 50,000.

Appeal: Ranging from EUR 30,000 to EUR 70,000.

These figures exclude out-of-pocket expenses, translations, and fees for private technical experts (CTPs).

29. Can the successful party to a patent litigation action recover its costs?

The general rule is that the losing party must reimburse the legal costs of the winning party ("loser pays" principle). However, the Court has broad discretionary power and liquidates the amount based on statutory ministerial fee scales. Consequently, the awarded amounts are usually much lower than the actual legal costs incurred, typically allowing the winning party to recover between 60% and 70% of their actual spend. Recently, however, Courts have started to award costs more generously. There is no procedural mechanism strictly requiring a foreign claimant to post security for costs.

30. What are the biggest patent litigation growth areas in your jurisdiction in terms of industry sector?

The Pharmaceutical/Biotech sectors (particularly concerning biologics and biosimilars) and the Telecommunications sector (Standard Essential Patents – SEPs) represent the most significant growth areas for high-stakes patent litigation in Italy. Italian Courts are developing a robust body of case law regarding FRAND royalties.

31. What do you predict will be the most contentious patent litigation issues in your jurisdiction over the next twelve months?

The inauguration of the UPC Central Division in Milan (competent for human necessities, including chemistry, metallurgy, and prospectively life sciences) has profoundly reshaped the landscape. Over the next twelve months, the most contentious issues will likely involve the interplay between national proceedings and UPC actions. National case law will increasingly interact with the first appellate decisions of the UPC, fostering further harmonization and elevating Italy's profile as a premier forum for cross-border patent disputes.

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32. What are the biggest challenges and opportunities confronting the international patent system?

The biggest challenges confronting the international patent system revolve around the uniform interpretation of SEPs/FRAND obligations and the patentability and enforcement of AI-generated inventions. Conversely, the successful implementation of the Unitary Patent system represents an unprecedented opportunity for streamlined enforcement and cost-effective protection across Europe, an initiative in which Italy is a full and active participant.

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