

# Italy

## When to take action against infringement in Italy

IP matters in Italy are regulated by the Code of Industrial Property, which came into force in 2005, superseding all previous IP laws (ie, the Patent Law, the Trademark Law, the Design Law and the Utility Model Law). The code was last revised in Summer 2010 to introduce some aspects that were inadvertently left out of the 2005 version.

One interesting aspect, which could be significant to companies wishing to protect their IP rights in Italy, is the code's focus on when an infringement actually begins. It is becoming more common for rights holders to discover an infringement not on the market, but rather as a result of an IP watch service which tracks a conflicting trademark or a patent application. Can it be argued that the act of filing a trademark or patent represents a first indication of a competitor's commercial interest with respect to that patent or trademark?

Such matters can be of crucial importance for companies that want to act against alleged infringers as early as possible in order to keep the market clear of potential competitors. Nonetheless, this matter is treated differently, depending on the type of IP right at issue.

### Patents

The code grants patent owners the exclusive right to implement the patented invention and to make a profit from it. In particular, Article 66 of the code defines 'infringement' in the following manner:

- If the subject matter of the patent is a product, 'infringement' is the production (even if destined for export), use, marketing or sale of the patented product, or the import of the product for these purposes; and
- If the subject matter of the patent is a process, 'infringement' is the application of such process, as well as the use, marketing or sale of the product obtained by means of the process, or the import of the product for such purposes.

In addition, the following may constitute

infringement, according to case law and commentators:

- manufacturing infringing products abroad while being aware that they are destined for the Italian market;
- deliberately supplying non-patented but essential components used to produce an infringing product (so-called 'indirect infringement');
- preparing means that are specifically and uniquely used to produce a patented invention; and
- producing elements of an infringing product which are then assembled abroad in a territory in which the product does not enjoy patent protection, when the activity in Italy would be considered as covering a major part of the patent claim.

Nothing on this list includes the act of filing a patent application similar to a prior patent. It seems, thus, that this kind of administrative request is not considered to be an act of infringement.

### Pharmaceutical patents

Within the world of patents, particular attention must be paid to pharmaceutical patents.

Among the changes introduced by the code in 2005, the article relating to experimental activities that may be carried out on an invention patented by third parties (included in Article 1(3) of the old law on inventions and now in Article 68(1) of the code) was amended in order to introduce precise indications that have since turned out to be important.

In particular, while Article 1(3) of the old law on inventions simply provided that a third party's patent could not preclude experimental activities on the claimed invention, Article 68(1) of the code now states that the exclusive right provided by the patent is not extendable, whatever the subject matter of the invention, to activities carried out on a trial basis, "even if they are meant to obtain – also in foreign countries – an authorisation to a pharmaceutical product and the consequential practical requirements to market, including the preparation and use of pharmacologically active raw

materials which are strictly necessary for this purpose”.

Therefore, the new article seems to include test activities for the purpose of obtaining a marketing authorisation (MA) among the test activities that are allowed in the course of a patent’s term.

Several recent decisions of the Court of Milan have now applied this article and have confirmed that the MA request in itself, in addition to those test activities aimed at the preparation of similar requests (ie, bio-equivalence studies), should not be considered to be infringing activities.

Before examining the decisions of the Court of Milan, it is worth noting that the same matter was also previously discussed by the Court of Rome, which argued in a decision of 2006 that filing an MA request for a pharmaceutical product does not fall within the scope of the exception provided for by Article 68(1) of the code, but rather “constitutes an activity which is preliminary to the introduction of the same onto the market and as such is meant to obtain such an economic utility which is mentioned in the case law of the Supreme Court”. This decision, issued in summary proceedings, was followed by a technical discussion within the lawsuit on the merits, which discussed only the technical validity of the patent and of the infringement. This lawsuit resulted in a new decision from the court holding that the enforced patent was partially null, and that its valid part was not infringed, while the MA request was not discussed any further.

However, in several recent cases the Court of Milan has adopted a position that is diametrically opposed to that taken by the Court of Rome.

In particular, in a decision issued in 2009 the Court of Milan ruled that simply filing an MA request for a medicinal product “does not constitute evidence of infringing activity, even if it is a matter of preparation of such an activity”. In this case the judges held that an MA request is merely an administrative act, which should not be considered as an act taken to prepare for a commercial activity, especially if there is no evidence that the infringer is actually producing and commercialising the product covered by the MA. It is worth emphasising that in this decision the court referred to Article 68(1) of the code – precisely the part that focuses on experimental activity as a provision that, in the opinion of the judges, “seems to justify the activity in question” – as if to say that this article includes MA requests among the lawful experimental activities.

This is a decision of first instance and is therefore subject to revision on appeal.

Nevertheless, the same position was also adopted by the Court of Milan in two more recent decisions of 2009, issued during appeals as a result of requests for

preliminary injunctions. Both decisions confirmed what was argued by the judge during the corresponding preliminary injunction proceedings of first instance. Both decisions considered the same patent, enforced in two different but virtually simultaneous preliminary injunction proceedings, which were started against two different producers of generic drugs. In both cases the preliminary injunction was rejected, both at first instance and on appeal, because of a lack of imminent danger deriving from delaying the injunction (the so-called *periculum in mora* principle), notwithstanding that in both cases the MA for the generic drug had already been granted when the preliminary injunctions were requested.

The second of these two appeal decisions dwelt longer on the issue of MAs. The judge confirmed what had been expressed in the first decision, basing his ruling on Article 18(1) of the code. He found that “it does not seem to be allowed to distinguish between a test activity considered to be lawful and the submission of the MA request – requiring and presupposing test activity – which instead has to be considered as illegal”. In support of this position, the judge referred to EU guidelines in relation to medicinal products, which allow third parties to perform studies, experiments, tests and “consequential practical requirements” during the patent’s validity period. The judge thus interpreted “consequential practical requirements” as including preparations that are necessary to obtain an MA for a generic drug, while maintaining that a request for an MA for a generic drug in itself does not constitute patent infringement.

The judge noticed that the absence of the so-called *periculum in mora* principle was not justified since a simple request for an MA for a generic drug is not the “kind of fact that can constitute valid evidence of the imminent violation required by the Code”, in particular in the absence of other activities such as activity of actual introduction on the market or preliminary activity such as the purchase of raw materials, the packaging or warehousing of products or promotional or informational activity in the field of healthcare.

In light of these recent cases, the Court of Milan’s present tendency seems to be to consider that a simple request for an MA for a generic drug or relating to a product covered by a patent does not in itself constitute infringing activity or preliminary activity giving rise to the so-called *periculum in mora* principle such as to justify a preliminary injunction. It remains to be seen whether this tendency will be confirmed in the future.

### Trademarks

As far as trademarks are concerned, Article 20(1) of the code establishes that infringement occurs when third

parties use in the course of economic activity a sign which is identical or similar to a prior trademark, in order to distinguish goods or services of the same or a similar type (or in the exceptional case of a famous trademark, to distinguish different goods or services). Article 20(2) of the code specifies what is considered as ‘use’ and prohibits the following:

- affixing potentially infringing signs on goods or their packaging (regardless of whether the goods are then marketed in Italy);
- offering labelled goods or services, regardless of whether the offer is for sale;
- placing goods bearing the potentially infringing signs on the Italian market or detaining them for commercial purposes;
- importing or exporting for commercial purposes the labelled goods (even if they are not intended to be marketed in Italy); and
- using the potentially infringing sign in advertising and correspondence.

As to the question of whether the act of filing could be

deemed an infringement, the prevailing case law in Italy has indicated that merely filing a subsequent trademark application cannot be considered as an act of infringement of a prior trademark. This was confirmed by a decision of the Court of Rome of July 12 2001, according to which “the mere filing of a trademark registration application lacking the requirement of novelty does not constitute an act of infringement of the prior trademark of third parties”.

Thus, in order to qualify as an infringement, the use must be effective (ie, it must at least consist of an offering on the market), whereas the administrative act of filing a trademark application is not considered an act of infringement.

### Conclusion

In view of the above, the administrative act of filing an application for an IP right is usually insufficient to amount to infringement. Nonetheless, it can be used as an early warning sign by the rights holder to monitor actively a competitor’s activities and to be ready to act quickly in case of more explicit acts of infringement.



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