

Pharmaceutical patents in Italy: hot topics

Timely issues preoccupying pharmaceutical patent owners in Italy include the duration of supplementary protection certificates, the extent of the Bolar exemption and the recovery of damages for infringement

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This article looks at three important and topical issues concerning pharmaceutical patents in Italy.

Duration of supplementary protection certificates: a happy ending?

The duration of supplementary protection certificates (SPCs) in Italy has changed slightly over the past 10 years. In the early 1990s, pharmaceutical patent holders in Italy enjoyed their exclusive rights for substantially longer than their counterparts in other EU member states. As this divergence was inconsistent with the policy of EU harmonisation, Italy had to take adequate measures to address it – something which inevitably attracted criticism from the pharmaceutical companies. A reduction in the duration of Italian SPCs is the price they have paid for the enforcement of European legislation.

SPCs were introduced in Italy in 1991, under Law 349/91. Article 1 of this law provides that an SPC should remain valid for a period equal to that which elapsed between the date of filing of a patent with the Italian Patent and Trademark Office and the date of grant of the marketing authorisation for the patented product (or the product containing

the patented active ingredient). So far, nothing new. For instance, if the patent were filed on 1st January 1989 and the first marketing authorisation for the relevant product were granted on 1st January 1995, the duration of the SPC would be six years exactly and the patent would expire on 1st January 2015 (26 years after the filing date).

The difference was in the practice, since the Italian authorities took many years to grant marketing authorisations (according to the official data, the average duration of SPCs granted after 1991 was seven years, but at least 30% of these exceeded nine years in duration). The authors of Law 349/91 were well aware of this phenomenon, as the maximum duration they allowed for SPCs was 18 years from the patent's date of expiry. Therefore, in extreme cases, a patent owner could enjoy exclusive rights for almost twice as long as the average period of validity of the patent.

This situation had to change after the entry into force in January 1993 of EC Regulation 1768/92, which provides for a five-year reduction in the duration of SPCs (Article 13). As a result, in the above example, under EC Regulation 1768/92 the duration of the SPC would be one year (six years less five years) and the patent would expire on 1st January 2010. The extra five years naturally made a big difference to patent holders, which viewed the longer duration of Italian SPCs as their inalienable right. This perception could well be supported by the wording of Article 20 of EC Regulation 1768/92, which provided that the five-year reduction did not apply to certificates granted or applied for prior to the Regulation's entry into force. In other words, notwithstanding the regulation, the patent holder in the above example could reasonably expect the duration of an SPC in Italy to extend for six years.

“ The courts now admit the possibility for patent holders to recover damages resulting from infringement simply where it is proved that the patent is valid and has been infringed ”

The surprise came 10 years after the enforcement of EC Regulation 1768/92. Law 112/02, which entered into force on 16th July 2002, reflected Italy's desire to catch up with European standards. Article 3.8 established that for all SPCs granted on the basis of the 1991 legislation, the period of validity would be reduced by six months for every year past 1st January 2004. Applying this provision to the above example, then, the final duration of the SPC would be three years (taking into account a six-month reduction for each of the six years originally allowed) and the patent would expire on 1st January 2012.

The Italian system now appears to comply, more or less, with the EC standards for the duration of SPCs (more in the case of SPCs granted after January 1993 and thus according with EC Regulation 1768/92; less in the case of SPCs granted before this date, which were longer lasting - although here too their duration has been reduced by 50% since 2004).

While there was undoubtedly a need to harmonise the Italian regime with EC law, it is arguable whether the further reduction undertaken in 2002 was the best solution. The duration of SPCs was reduced in good faith, in order to ensure greater harmonisation with EC Regulation 1768/92 (all Italian SPCs granted in 1991 and 1992 were left outside the scope of the Regulation, according to Article 20). However, the move was not welcomed by patent holders, which applied to several national authorities in order to preserve their rights (respected by the EC legislature, but not by the Italian legislature).

However, both administrative and judicial authorities (several decisions were issued on this point between 2005 and 2007) held that the Italian legislature was free retroactively to reduce the duration of SPCs. They reasoned that the interests of

patent holders should be balanced with the need for greater harmonisation within the European Community and with the interest of public utility (ie, greater accessibility of pharmaceutical products due to the lower prices after patent expiry).

The first argument is not very convincing, since the European legislature itself was not concerned about long-lasting Italian SPCs granted before 1993. As far as the public utility argument is concerned, it is evident that any exclusive right is contrary to the interest of public utility. The legislature may have got it wrong in 1991, but the solution adopted clearly violates the constitutional right of patent holders to rely on the letter of the law. In other words, this problem should have been resolved differently in 1991; but this did not happen. The only comfort is that the duration of SPCs applied for after 1993 cannot change.

Boundaries of Bolar exemption according to Italian case law

Another interesting issue recently discussed in Italy concerns the extent to which the Bolar exemption applies. A patent owner can prohibit anyone from using the patented product or process except in relation to certain activities provided for under national law.

In the case of pharmaceutical patents, two legislative provisions make explicit the exemptions to the aforementioned rule.

The first provision establishes that in the case of a company that intends to commercialise a pharmaceutical product containing an active ingredient covered by a third party's patent, the former can start the process for registration of the product in the final year before expiry of the latter's patent (Article 61.5 of the Industrial Property Code). This exemption, established by the Italian legislature in 2002, makes it possible for producers of generics to begin

registration of their products one year before the expiry of the target patent SPC, so as to be ready to put their own products on the market immediately thereafter.

The second provision relates to research activities carried out privately and for non-commercial purposes, but where a company is nonetheless seeking to obtain a marketing authorisation for a pharmaceutical product (Article 68.1(a) of the Industrial Property Code). This provision clearly refers to trials and to all subsequent activities, such as preparation and use of pharmaceutical raw materials that are strictly necessary for such trials.

Both exemptions allow generics producers to prepare their products for commercialisation even though the relevant patents are still in force. Both refer to various activities that are more specific (eg, “trials”) or less specific (eg, “start of a new product registration procedure”). Therefore, the extent of the Italian Bolar exemption is not fully clear.

Indeed, the Italian courts have been asked to establish whether the filing of a marketing authorisation request for a pharmaceutical product can be regarded as an activity suitable for exemption under the above provisions. At first glance, it seems that the filing of a marketing authorisation is part of the activity required to start a new product registration procedure (exemption under Article 61.5 of the Industrial Property Code). Consequently, one could reasonably expect that the filing of a request for marketing authorisation constitutes an exempted activity. Nevertheless, according to recent case law, this provision regarding

SPCs introduces no valid exception to the exclusive rights deriving from a patent. Such an exception, by contrast, is set forth in Article 68.1(a) of the Industrial Property Code, which apparently limits the activities suitable for exemption exclusively to trials that are conducted for the purpose of obtaining a future marketing authorisation.

On these grounds, the Court of Rome has established that the filing of a marketing authorisation request for a pharmaceutical product, even in the year before the expiry of a third-party patent, constitutes infringement (23rd October 2006). In Italian case law, this activity is thus regarded as preliminary to the marketing of a product covered by a third-party patent and as such should be prohibited (Italian Supreme Court, No 5112/2003).

Damages recovery for infringement: a new era

Damages recovery in Italian industrial property cases has always been disappointing. Until the late 1990s, the Italian courts rejected most claims for damages recovery filed by patent owners. There were two main reasons for this.

The first concerned the difficulties that Italian courts experienced in applying civil damages recovery principles to IP cases. More specifically, according to the Italian rules of civil law, three requirements must be met in order to recover damages:

- The defendant must have committed an illegal act.
- The plaintiff must have suffered a prejudice.
- There must be a logical connection



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between the illegal act committed by the defendant and the prejudice suffered by the plaintiff (in other words, no prejudice would have been suffered had no illegal act been committed).

In patent and trademark litigation, the second and third requirements above were often difficult to demonstrate. Patent holders had a hard time proving lost profits where their sales still increased despite the infringement; and where sales decreased, this was not necessarily due to infringement alone. However, in the past few years the approach of the Italian courts to this issue has begun to shift. Finally, the courts now admit the possibility for patent holders to recover damages resulting from infringement simply where it is proved that the patent is valid and has been infringed. For instance, the Court of Milan (one of the most prominent Italian IP courts) has held that “every infringement causes a prejudice to the patent owner” (Court of Milan, 29th June 2006). Indeed, if it is impossible for patent holders to prove a typical prejudice (lost profits), the existence of actual damages should be presumed in order to punish the infringer. Otherwise, damages recovery could never be applied as a penalty in patent infringement cases.

The second reason for the lack of adequate damages recovery measures in

patent litigation in the past was that serious discovery on specific accounting issues (turnover, costs and profits) was rarely conducted. Obviously, where at least one of the above requirements for damages recovery was not met, the court would not examine all information necessary to calculate possible damages. As a result, the three principles for damages calculation in patent infringement cases were seldom examined (damages could correspond to the infringer’s net profits resulting from sales of the product made in violation of the patent; from the profits which the patent holder would have made had it sold the product sold by the infringer; or from the reasonable royalties which the patent holder would have received for licensing the patent to the infringer).

This is no longer the case. The Italian courts do recognise that patent owners are entitled to seek and recover damages caused by patent infringement, and they also fully examine (with the help of court experts in accounting matters) the accounting data necessary to calculate these damages. For instance, the Court of Milan recently rendered a decision in a pharmaceutical patent infringement case where the damages acknowledged for infringing activity over three years amounted to approximately €4.6 million (8th March 2007). *iam*