

SPC revoked, PI lifted, but no damages awarded

Kluwer Patent Blog
June 18, 2015

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Please refer to this post as: Daniela Ampollini, 'SPC revoked, PI lifted, but no damages awarded', Kluwer Patent Blog, June 18, 2015, <http://patentblog.kluweriplaw.com/2015/06/18/spc-revoked-pi-lifted-but-no-damages-awarded/>

In the Sanofi v. Teva ruling of 10 July 2014, the Court of Milan clarified the test for abuse of process, and denied an award of damages allegedly caused by the issue of a preliminary injunction which was later lifted due to the revocation of the enforced SPC.

The case concerned the Italian part of the irbesartan saga, in which Sanofi was engaged in several countries in the enforcement of its CoAprovel SPCs, covering irbesartan + hydrochlorothiazide. In the aftermath of the [Medeva/Georgetown](#) decisions, Sanofi obtained preliminary injunctions against generic CoAprovel in several jurisdictions, on the assumption that the combination irbesartan + hydrochlorothiazide was "specified in the wording of the claims" of the basic patent, as the claims in question expressly mentioned a combination of irbesartan with a diuretic.

As far as Italy is concerned, a preliminary injunction was issued in December 2012. However, in December 2013, the CJEU in [Actavis/Sanofi](#) stated that the Sanofi's irbesartan + hydrochlorothiazide SPCs could not be upheld as the previous grant of SPCs on irbesartan as a single ingredient made those in breach of Article 3(c) of the SPC EU Regulation. The PI was therefore lifted. Merits proceedings followed, and Teva therein moved to obtain compensation for damages for having been wrongly enjoined and thereby forced to remain out of the market during almost one year.

Under Italian law, compensation for damages in cases of this type must be framed within the concept of abuse of process according to the provision of Article 96(2) of the Civil Procedural Code. The latter provides that "The judge, after having ascertained the inexistence of the right upon which a preliminary measure was executed (...) upon motion by the damaged party, shall order the compensation of the damages by the applicant (...) who acted without ordinary prudence". Historically, this provision has always been interpreted in a rather restrictive manner, so that awards of damages in case a preliminary injunction is later lifted due to the revocation of the enforced rights are all but frequent in the Italian case-law. In any event, this provision clearly indicates that in order for liability for damages to exist, the relief must have been sought imprudently, which at least rules out the concept of objective liability.

In the Sanofi case, Teva attempted to argue that the provision of Article 96 Civil Procedural Code, for the very fact of imposing an element of "negligence" as a prerequisite of liability, would be in breach of Article 9(7) of the [Enforcement Directive](#). According to the latter, "where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures"

However, the Court of Milan expressly stated that Article 96(2) of the Civil Procedural Code is not in breach of the Enforcement Directive, as the language of Article 9(7) must be interpreted as only imposing that the judge have the possibility - depending on the specific circumstances of the case - to issue an award of damages in case the preliminary measure is lifted. According to the Court, this conclusion would be supported by the language of the directive's provision, as well as by the fact that no form of objective liability would be allowed by the principles.

Based on the above, the Court concluded that Sanofi had not acted without ordinary prudence, as the SPC had been granted by the PTO, as several injunctions had already been obtained in various countries, and in any event as the future revocation of the SPC was far from certain when the injunction was issued, considering that a CJEU referral was needed to resolve conflicts in the interpretation of the law. Nor could it be said - the Court continued - that Sanofi should have refrained from seeking relief in view of the fact that the opposing parties were sound enough to guarantee the future reimbursement of the damages caused by the infringement, as otherwise the very enforcement of IP rights would be denied and as, in any event, damages caused by patent infringement are by definition "irreparable".