Italian Court of Appeal awards EUR 1,5 mio damages in pharma patent case for 40 days infringement

Kluwer Patent Blog
June 30, 2020

Roberto A. Jacchia (De Berti Jacchia Franchini Forlani)

Please refer to this post as: Roberto A. Jacchia, 'Italian Court of Appeal awards EUR 1,5 mio damages in pharma patent case for 40 days infringement', Kluwer Patent Blog, June 30 2020, http://patentblog.kluweriplaw.com/2020/06/30/italian-court-of-appeal-awards-eur-15-mio-damages-in-pharma-patent-case-for-40-days-infringement/

Whilst the Italian Courts are not famous for awarding substantial damages in IP cases, a recent decision of the Rome Court of Appeal seems to have gone in the opposite direction, albeit taking a very long time to deliver the result. In this article, we report on a case started in 2012, which came to its conclusion in 2020 with a second instance judgment that awarded the holder of a significant pharmaceutical patent, EUR 1.5 mio damages approximately to compensate an infringement that lasted 40 days.

The script is not unheard of, and revolves around a generic company that chooses to enter prematurely the market of an established originator product approaching the sunset of patent protection.

In December 2012, Israeli generic player Teva decided to launch "at risk" in Italy its generic version of Montelukast, a leukotriene antagonist and a major respiratory medicine belonging to US based Merck Sharp & Dohme. More particularly, at the time of launch, the remaining life of MSD's patent EP '480717, as extended by Italian supplementary protection certificate CPC-UB99CC647, protecting medicine Singulair (Montelukast) was only 40 days. Teva's strategy arguably rested on the assumption that the approaching Christmas season would have hindered in practice the putting in place of an interlocutory injunction by MSD timely enough before the expiry of SPC '647 in February 2013. Which proved to be the case.

Against that background, in December 2012 Teva sued by a pre-emptive action MSD, its Italian subsidiary as holder of the Singulair marketing authorization and certain co-marketers of the latter before the Specialized Chamber of the Court of Rome, claiming the nullity of EP ' 717 for lack of novelty and inventive step as well as of SPC '647. The European patent had not been challenged elsewhere. The (only) purpose of the action, which could evidently not be adjudged in a 40 days' span of time, was to establish a pending litigation compelling defendant MSD to seek an injunction, if it chose to do so, before the same court seized of the merits, as opposed to by stand-alone proceedings. The nullity claim was supposed to cast doubt on the validity of MSD's patent, which would result in the court seized seeking an independent expert opinion from a patent attorney on validity in the interlocutory injunction phase, in that way "overtaking" for practical purposes the expiry of the SPC and defeating the very purpose of the injunction.

In March 2013 MSD entered appearance within the assigned procedural timeframe, defended its patent and SPC and counterclaimed infringement and damages. On the very day of filing of MSD's appearance, Teva served on MSD a waiver of its nullity action, since after the expiry of the SPC it had clearly lost interest in pursuing the case. Under Italian procedure, the waiver of an action requires the consent of the other party, which MSD denied, because its interest in obtaining a finding of infringement and an award of damages in respect of the 40 days' premature commercialization of Teva's generic montelukast remained unaffected. There followed protracted procedural arguments between the parties on the effectiveness of the waiver of the action by Teva, MSD's denial of consent to the waiver and Teva's allegation that the action had been procedurally extinguished. The procedural issues were finally determined in favour of MSD and are extraneous to the scope of this article.

The merit action went on before the Court of Rome, where party-expert opinions were filed both in support of and against the validity of EP' 077, and on the quantum of infringement damages. The Court adjudged the case in 2016. It dismissed all procedural arguments, made a finding of infringement by Teva with respect to the 40 days pre-expiry commercialization of its generic medicine and ordered the publication of the judgment in the press. However, it rejected MSD's other (key) counterclaim, surprisingly finding that no evidence of infringement damages had been provided.

MSD then challenged the first instance judgement before the Rome Court of Appeal, seeking an award of damages against Teva, consisting of: (a) loss of margins on the volumes of Singulair sales replaced by sales of the Teva generic, and loss of margins because of the lower price obtained from sales of its own Singulair medicine since Teva's premature entry had entailed a decrease of the reimbursed price of all respiratory medicines containing Montelukast, to which the originator had also needed to align itself: (b) loss by MSD of 40 days' depreciations corresponding to the length of Teva's market presence ahead of patent expiry; and (c) "springboard" damages caused to MSD by Teva's premature entry and its unjustly achieved first mover advantage. MSD challenged, in particular, the finding of the Court of first instance that no evidence of damages had been produced, and the intrinsic illogicity of a finding of infringement where at the same time any award of damages was denied, also on the strength of EU law (Directive 2004/48/EC) and constitutional grounds.

Teva defended in part the first instance judgment and filed a cross-appeal against the validity of EP '077 and the finding of infringement.

The Court of Appeal appointed two official experts, to advise it on the validity of EP '717 and the quantum of infringement damages respectively. The opening of an expert phase at the appellate level is uncommon, and was a first indicator of the prima facie errors of fact and law that had flawed the first instance decision. The court-appointed patent expert found for the full validity of EP ' 717 and SPC '647. The economic court-appointed expert concluded that MSD had suffered infringement damages in a range between EUR 1.5 mio and EUR 2.5 mio approximately, dependent on whether the Court would concur with either of two alternative methods of calculation of loss of profit. The court-appointed expert, though, recognized neither damages for loss of depreciation (because MSD's loss of profit would already be comprised of that item), nor "springboard" damages (because they had not been positively proved – which was inevitable because they, by definition, partake of the nature of a loss of chance).

The Court of Appeal delivered its judgment no. 2421/2020 in late May 2020, (a) granting in part MSD's appeal and awarding it infringement damages in an amount of EUR 1.5 mio approximately, plus interest and currency devaluation from the filing on the first instance action, plus legal costs, (b) and dismissing Teva's cross-appeal.

Bearing in mind the immense prudence with which the Italian case-law tends to address infringement damages, and the reluctance of appellate judges to re-open factual investigations before themselves, the judgment of the Rome Court of Appeal was a considerable success for MSD for several reasons.

First, whilst an amount of EUR 1.5 mio as damages is in absolute terms not earth-shaking, one should realize that this covered a span of time of 40 days only, which means EUR 37,500 for each day of infringing conduct. The Court of Appeal clearly understood that Teva's strategy had been devised in order to make its early market entry fade away in the mists of procedure and to let the handful of days remaining before the end of patent protection run out prior to the taking of enforcement measures by MSD. Says the Court of Appeal: " … Teva's cross-appeal … which is unfounded … rests on the alleged modest gravity of the infringement. The outcome of the damage claim proves the opposite, and it is indeed something of not modest gravity to commercialize an equivalent generic medicine before the expiry of the patent protection secured through the investment of large sums of money in studies and trials in order to come to the realization of the originator medicine …". So, an infringement is an infringement and no *de minimis* rule may be invoked.

Further, MSD had filed as evidence in support of the inventive step of EP ' 717 the sworn depositions rendered by expert witnesses in a parallel US case, which the Court of first instance plainly disregarded. The Court of Appeal finds that sworn expert depositions in foreign proceedings constitute evidence in a technical sense fully capable of being reliede on in the Italian nullity action also.

In its cross-appeal, Teva had argued that the finding of infringement in first instance had not been supported by any expert evidence. The Court of Appeal rejects this argument, holding that the very nature of "generic equivalent" to MSD's originator medicine of that commercialized by Teva, and its commercial name "Montelukast Teva", per se made that line of thinking implausible.

Coming to damages, the judgment is less straightforward.

On the one hand, the Court of Appeal rejects Teva's argument to the effect that the IMS (now IQVIA) sales and market share data relied on by MSD to quantify its damages in first instance would not amount to proper evidence. This holding is significant and will hopefully help putting an end to an argument frequently brought forward by infringers, in the sense that only party-sourced analytical – as opposed to statistical and third-party – data could be utilized in making an actual damage award.

However, whilst the IQVIA data are accepted by the Court of Appeal as evidence of the damage caused by the reduction of the originator medicine's reimbursed price, it remains unexplained why it felt unable to accept the same IQVIA data as evidence of the damage caused by the loss of volumes of MSD's Singulair replaced by Teva's generic. In this respect, MSD had moreover argued in first instance that the loss of margins on lost volumes should at least have been compensated by the virtual royalty method, and had presented along with the submissions of its own economic expert reference rates extracted by industry data banks and independent studies. However, the Court of Appeal does not accept that evidence either, and ends up awarding to MSD an otherwise unexplained lump sum compensation "in fairness" of EUR 100k for loss of volumes.

In partial contradiction with its own premises, the Court of Appeal dismisses MSD's damages claim for partial loss of depreciations, saying that it was implausible that any R&D investments should remain unamortized during the last 40 days of life of supplementary protection, which by definition went beyond the original term of the basic patent. The Court apparently fails to see that depreciation takes places by a linear arithmetic function, spreading the cost evenly across the entire useful life of the asset.

Finally, the Court of Appeal finds that "springboard" damages caused by the premature entry of Teva in the Montelukast market and the first mover advantage it gained in that way, could be at the source of a loss of chance suffered by other, non- first mover generic entrants , but not the originator, for whom that damage (if any) remained one from loss of profit, not of chance. Here too, the reasoning is not very clear. The conclusion of the Court of Appeal is not surprising, since no awards of "springboard" damages in patent cases are so far reported in the domestic case-law.

To sum up, the Roman judgment presents light and shadow.

It doubtless marks progress made towards the recognition of true (i.e. non-nominal) compensation to the patentee whose patent is deliberately infringed. This ought to serve as a deterrent to counter the aggressive, entry "at risk" habits common to the major generic players who are not unwilling to take shortcuts in order to gain first entrant status in the market for commercially successful nearly off-patent active principles. And indeed, a EUR 1.5 mio award for 40 days' infringement should be no trivial price to pay for any infringer.

On the other hand, the Court of Appeal's economic approach remains weak and blurred. Springboard damages aside, one is at a loss in understanding why, taking the lead from the same facts, the same infringing conduct and the same evidence, loss of margins caused by the decrease in the medicine's reimbursed price triggered by generic entry should be capable of compensation, whereas loss of margins caused by loss of volumes should not. The reason why loss of depreciations should not count also remains economically unjustified.

Despite ultimate success in the case, the Roman judgment does show a persistent weakness in the failure of the Italian court system to provide for preliminary injunctions at short notice as a patent or SPC reaches it expiry. True, the case now makes it worthwhile to pursue generics who 'jump the gun' for damages (although this will take several years), but how much better it would be if the courts were willing to prevent the damage

occurring in the first place.

Last but not least, legislators and courts should hopefully not lose sight of the fact that an effective and well-functioning judicial enforcement system protecting intellectual property is a potent factor to encourage R&D in the originator pharmaceutical industry, which, as recent history dramatically shows, remains of cardinal importance to the well-being of patients and, ultimately, of society.

De Berti Jacchia Franchini Forlani represented MSD in these proceedings.