

# Kluwer Patent Blog

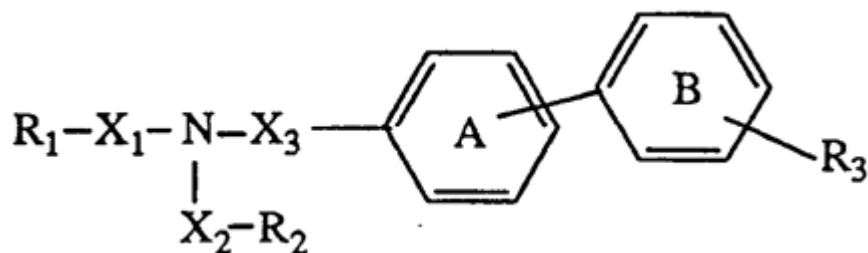
## A too distant expiry

Pierre Véron (Véron & Associés) · Wednesday, February 13th, 2013

Faithfully implementing Article 9 §4 of Directive No. 2004/48/EC, Article L. 615-3 of the French Intellectual Property Code (hereinafter referred to as “IPC”) authorizes French courts to grant an interim injunction order after an *inter partes* proceedings (before the Judge ruling in preliminary proceedings) but also after an *ex parte* proceedings. As required by the EC Directive, the *ex parte* proceedings is reserved for the appropriate cases, where it seems necessary, “when the circumstances require that such measure should not be taken in the presence of both parties, in particular when any delay would be likely to cause an irreparable damage to the claimant”.

But, in practice, what are these circumstances which may justify the *ex parte* proceedings? And especially, is the imminent expiry of the title by itself such a circumstance? This is the question considered and answered in a negative way by the *cour d’appel de Paris* in its 11 December 2012 decision.

Novartis AG was granted European patent EP 0 443 983 relating to “acyl compounds”, including Valsartan, and, after its expiry, a supplementary protection certificate (SPC) No. 97C0050 which was in turn the subject of a pediatric extension expiring on 13 November 2011.



Novartis Pharma held an exclusive licence for the patent and the SPC and also several marketing authorizations (MA) for proprietary drugs containing Valsartan marketed under the name Tareg or Cotareg.

Considering that the companies Sanofi-Aventis France, Sanofi Winthrop Industrie and Zentiva KS, by the products Valsartan hydrochlorothiazide, Zentivalab 80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg, were infringing their European patent and SPC, the Novartis companies requested and were granted an interim injunction in an *ex parte* proceedings before the Presiding Judge of the *tribunal de grande instance de Paris*, by order of 27 October 2011.

The Sanofi and Zentiva companies then served a summons on Novartis before the Judge ruling in

preliminary proceedings in an attempt to have the order revoked. However, by order of 31 October 2011, the Judge ruling in preliminary proceedings decided to uphold the order and its interim injunction.

Sanofi and Zentiva then lodged an appeal against the order of the Judge ruling in preliminary proceedings claiming that the conditions required by Article L. 615–3 IPC in order to obtain an interim injunction through an *ex parte* proceedings were not met.

The *cour d'appel de Paris*, in its 11 December 2011 decision, first reminded the nature and scope of its control in such a case. The request for revocation consists to deny that, on the day that interim injunction order was rendered, the legal conditions were really met. Consequently, the *cour d'appel*, as second level of jurisdiction, must proceed as the Judge ruling in preliminary proceedings, *i.e.* must assess whether, on the day that the Judge statuted, the conditions laid down by Article L. 615–3 IPC to obtain in an *ex parte* proceedings an interim injunction order were met or not. And, to this end, the *cour d'appel* may take into account circumstances of prior or contemporaneous moment (and especially the request and the order) but certainly not “facts revealed later and notably (...) records of the ordered measures”. The *cour d'appel* then states that there were in the present case few exhibits at its disposal which may be the evidence of the infringement (even if, contrary to the opinion of the court, one may think that the presence of palettes of Valsartan products in the French premises of Sanofi, mentioned by a *saisie-contrefaçon* report, may lead to the conclusion that somehow an infringement may have been committed in France, not necessarily by “marketing” but probably by “making”, “importing” or “stocking” for the purposes of offering or putting on the market, such as defined also by Article L. 613-3 IPC). However, the *cour d'appel* did not ground the revocation of the interim injunction on such an evidence failure but on the circumstances which had been invoked in order to justify the recourse to the *ex parte* proceedings.

Novartis, in order to justify the recourse to the *ex parte* proceedings, had underlined the very imminent expiry of the SPC. The request dated 27 October 2011 and the SPC was to expire on 13 November 2011, that is to say only 17 days later.

The Novartis companies drew the conclusion that firstly it was not possible for an *inter partes* decision to be rendered against Sanofi-Aventis and Zentiva before a significant part of the remaining duration of the SPC has already passed and secondly the presence of infringing generic products would cause them an irreparable damage. Through these two arguments, the Novartis companies tend to present the SPC expiry as a deadline, before which it was necessary to react quickly since it would be impossible and useless after the title expiry.

These two arguments have been rejected by the *cour d'appel*.

The first argument, according to which it would be necessary to proceed *ex parte* because the imminent expiry of the SPC would not give enough time for an *inter partes* proceedings, is not completely unfounded since one may certainly not ask for an interim injunction when the protection is expired. When the expiry date is near, it is certainly useful to proceed the fastest possible in order to give as much time as possible for the interim injunction to deploy its effects. And the closer this expiry date gets, the less the interim injunction may have practical value.

However, the *cour d'appel* states that it exists “preliminary proceedings with an emergency motion to be heard on very short notice that make it possible to respect due process in a short timeframe”

and furthermore that in the scope of this special proceedings “courts may grant urgent hearing dates on weekends or on holidays and (...) school holidays have no bearing on this possibility, much less in November when there are no court holidays”. And, precisely, the *cour d’appel* find a useful example in the revocation request that Sanofi and Zentiva have submitted in such a preliminary proceedings with an emergency motion to be heard on very short notice: the Judge managed to hear the parties on Saturday 29 October 2011 and to render its order on 31 October 2011, the eve of a public holiday, that is to say still 14 days before the expiry of the SPC.

Does this mean that the argument of the imminent expiry of the title can never by itself justify the recourse to the *ex parte* proceedings for an interim injunction request? It does not seem so. The *cour d’appel* in its decision shows that pursuant to Article L. 615-3 IPC the condition for the *ex parte* proceedings is that “the circumstances require that such measures are not taken in the presence of both parties”. And the hypothesis that the “delay would be likely to cause an irreparable damage to the claimant” is introduced with the words “in particular” which mean that this is only an example. The *ex parte* proceedings may therefore find its justification only in a protection expiry too close to even be compensated by the recourse to the preliminary proceedings with an emergency motion to be heard on very short notice, that is to say, in practice, probably an expiry within the next few days.

The second argument, according to which the presence of infringing generic products would cause them an irreparable damage, is rejected for two reasons. Firstly, the *cour d’appel* does not agree with the irreparable nature of the damage. The damage is repairable, “can be resolved through the payment of damages” even after the expiry of the protection – within the three years’ time limit (the proceedings for infringement are barred after three years from the acts concerned; Art. L. 615-8 IPC) – provided that the damage was contemporaneous with the protection. Secondly, the *cour d’appel* denies the severity of the damage considering that “the investments made to discover the branded products were compensated by the protection granted by the patent and the SPC for several years”. By a more debatable considering, as it tends to deny the continuation of the effect of the title until its end and to give to the MA a meaning (excuse for infringement) that it does not have, the *cour d’appel* adds that “the existence of generic products is favoured by public powers concerned with public health and that the damage resulting from marketing of such products that necessarily leads to a loss of market share for Novartis is the result of this authorization and this marketing independently of whether the marketing is recognized to have been premature by 17 days”.

The court still adds that “*inter partes* proceedings were essential, the issue at stake were important and the injunction measures that were sought entailed heavy consequences for the opposing parties”. And it therefore concludes that, the reasons given to justify the derogation from the principle of due process being not serious, the Judge ruling in preliminary proceedings, who had to examine the reason given to justify the derogation from this principle, could do no other than to revoke the 27 October 2011 order and its decision must therefore be reversed on this ground.

[Original French decision.](#)

[English translation .](#)

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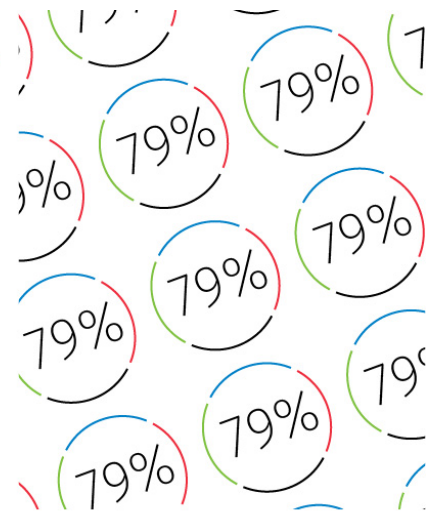
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