Benjamin May, partner
may@aramis-law.com
+ 33 (0)1 53 30 77 03

September 2018

France - Exceptional interim measures ordered against Teva

The Paris *Tribunal de Grande Instance* [Regional Court] recently issued a landmark decision in the pharmaceutical industry[1]. With 13 million euros of provisional damages – a record amount for an interim measure – the order issued by Mrs Courboulay, Vice-President of the 3rd Chamber, is particularly severe on the generic manufacturer Teva.

The decision also orders a preliminary injunction against Teva, a rare measure in the pharmaceutical industry. More importantly, the court order this injunction as a result of a counter-claim of Novartis in the course of a nullity action against Novartis' patent. **Not only did the court not take into account the nullity application filed by Teva, but it criticises it for not having waited until the end of the proceedings before commercialising its product. If this decision is upheld, it will be a significant case law reversal in the 'clearing the way' doctrine.**

The decision covers important issues such as the assessment of the sufficiency of description and the application of a compensatory fee. It specifically raises a strategic issue for manufacturers of generics and/or biosimilars.

Context

The dispute is between Novartis group and Teva Sante. Novartis commercialises Exforge®, a drug that treats hypertension, which is protected by the EP 2 322 174 '*Combined use of valsartan and calcium channel inhibitors for therapeutic purposes*' (**EP 174**)[2].

Using the so-called 'abridged'[3] procedure, Teva had obtained marketing authorizations for each of the generic specialties of each of the doses of Exforge®[4]. On 13 October 2016, Teva commenced nullity proceedings against EP 174 in the Paris Court. While the substantive issues in the nullity proceedings had not yet been examined, Novartis filed counterclaim proceedings for infringement after having discovered that Teva was marketing generic specialties of Exforge®[5] in France and subsequently applied for an interim injunction.

The interim judge, after a detailed examination of the conditions for the granting of provisional measures, ordered an interim prohibition on selling the generic medicines in question and record provisional damages and interest (more than €13 million).

[1] Paris court, 7 June 2018, Gen. Reg. no. 16-15196.
[2] The Opposition Division of the European Patents Office dismissed the oppositions filed by eight companies against patent EP 174 during the issuing procedure.
[3] The abridged procedure enables an applicant for MA to refer to the results of preclinical and clinical trials carried out by the holder of the reference specialty.
[4] Teva also obtained registration of specialties on the list of generic groups, on the social security list, the list of pharmaceutical specialties that are reimbursable for beneficiaries of social security, the list of pharmaceutical specialties that are accredited for use by local authorities and various public services and the issuing of a price and reimbursement rate.
[5] Patent EP 174 expires on 9 July 2019.

Abridged procedure excludes Bolar exemption

In holding that there was "probably infringing", the judge found that the generic of Exforge® necessarily reproduced the claims in patent EP 174. The judge continued by setting aside the *Bolar* exemption on the grounds that the MA for generic specialties had been filed using the so-called 'abridged' procedure and, as a result, had been obtained with reference to the clinical trials conducted for the originator.

How to assess 'supplementary' therapeutic effect

The judge examined each of the nullity arguments raised by Teva and set them aside, concluding that EP 174 was *prima facie* valid. The in-depth analysis of the grounds for the nullity carried out by the interim judge is uncommon. Generally, such judge is restricted to determining the serious or otherwise nature of the dispute rather than carrying out an in-depth study, which is the role of the judge ruling on the merits.

The claims relating to the insufficiency of the description merits specific attention. Teva argued that the results of the tests carried out by Novartis on rats were not sufficiently specified and that the doses of the active substances administered to rats were quite different from the doses to be administered to humans.

The judge first clarified that EP 174 does not protect a second therapeutic use of a known substance but the combination of two previously known molecules[6] in treating hypertension. The inventive activity here relates to the "supplementary therapeutic effect" obtained due to the combination of those two molecules.

Referring to the decision of the French Supreme court of 6 December 2017[7], the judge continued by stating that the patent "*does not need to clinically prove [the] therapeutic effect, but must directly and unambiguously reflect the claimed therapeutic application in such a manner that a skilled professional understands, on the basis of currently accepted models, that the results reflect such therapeutic application*". Following the Supreme court, the judge confirms the necessity of stating in the patent the benefit or technical effect that results from the combination of those two molecules and proving the at least potential[8] effectiveness of the combination.

In the instant case, in order to set aside the grounds of nullity, the judge held that "*while the results are not specified in the patent, the tests are explicit as a pre-clinical study with spontaneously hypertensive rats and the trial protocol and administration methods are described*" and adds that a skilled professional clearly knows how to relate the data obtained for a rat to that necessary for a human.

Compensatory licence increased by 100%

This decision is also significant for damages ordered, ie, €13,154,913, even though Novartis applied for €10,291,839.63. As the proceedings were civil proceedings between private parties, the judge should, in principle, have issued an order up to the limit of the claims filed. It will be interesting to see if this part of the decision is upheld by the Court of Appeal.

Novartis Pharma AG, the holder of the patent, applies for the payment of a fixed fee of 40%, i.e. double that which it would have contractually consented to. Stating that "*taking into account the prejudice suffered and including moral prejudice*", the judge applied, for the first time in the pharmaceutical domain, that compensatory fee rate to the turnover resulting from sales of the generics in question as at the date of the issuing of the decision. It should be noted that such fee rate is particularly high compared with those normally applied in other areas[9].

As licensee of patent EP 174, Novartis Pharma S.A.S. can claim damages and interest only in relation to unfair competition. Surprisingly, the judge considers that "*damages and interest [in relation to unfair competition] can only relate to loss of profits*" (thus excluding other losses such as moral prejudice, profits of the infringer, reduction or loss of a competitive advantage, etc.). This

decision is thus in contrast to the recent judgment of the Supreme Court[10] in which the Court considered that the lower court judge could apply infringement law when assessing the losses associated with acts of unfair competition. To calculate the loss of earnings, the judge applied a profit margin of 50% to the turnover achieved by Teva.

A re-shuffle of the French doctrine on 'clearing the way'?

The judge ordered an interim prohibition on selling generic specialties of Exforge®, subject to a penalty of €100 per box sold. The nullity proceedings commenced by Teva were not, therefore, sufficient to question the *prima facie* validity of the patent and prevent the granting of interim measures.

Traditionally, generic and/or biosimilars manufacturers apply a 'clearing the way' strategy before launching their products by commencing nullity or opposition proceedings against any relevant patents. In France, such strategy remains, in principle, optional. It could be expected, therefore, that a manufacturer who takes the precaution of commencing nullity proceedings is not criticised for not having waited for the results of its proceedings.

In the decision in question, the judge states that "it was [Teva] that decided to take the financial risk of launching its generic specialties before the expiry date of the patent without waiting for the decision from the substantive judges on the validity of that patent". Just like in the decision of the Paris Court of Appeal, until now alone on the issue, the judge sanctions the manufacturer for not having waited for the result of the nullity proceedings and, consequently, appears to require a manufacturer to terminate nullity proceedings in order to avoid any breach of the rights of the holder of a patent[11].

Lastly, the judge orders the seizure of stocks held by Teva but refuses, however, to uphold the application for seizure of stocks held by wholesalers and pharmacies, considering them disproportionate, particularly in light of the granting of provisional damages and the interest and the granting to Novartis of a right to be informed.

Conclusion

While this decision, due to its rarity and severity, merits closer attention, it must, however, be put into perspective. It is the work of a single judge and remains, at this stage, an interim decision. The positions of the Court on the substantive issues and, if an appeal is filed, that of the Court of Appeal on the interim prohibition and the 'clearing the way' obligation are not yet known.

Benjamin May
Associé, Aramis

Marina Jonon
Avocate, Aramis

[6] Valsartan and amlodipine.
[7] Court of Cassation, Commercial Chamber, 6 Dec. 2017, no. 15-19726: "It is not necessary to clinically prove such therapeutic effect, but the patent application must directly and unambiguously reflect the claimed therapeutic application in such a manner that a skilled professional understands, on the basis of commonly accepted models, that the results reflect such therapeutic application"
[8] The technical effect must be at least 'plausible', to use the term applied by the European Patents Office: EPO, Technical Board of Appeal, 27 August 2014, T.1616/09.
[9] By way of example, the courts have applied 4% in the robotics industry (Paris court, 2 July 2015, Gen. Reg. no. 12-11488), 10% in the electronics industry (Paris COURT, 16 Sept. 2009, Gen. Reg. no. 00/07925) and 2.5% in the telecommunications industry (Paris court, 8 Nov. 2011, Gen. Reg. no. 04-02152).
[10] Court of Cassation, Commercial Chamber, 18 Oct. 2017, no. 15-29094, *Delta Sport et Lidl v. Decathlon*
[11] Cour d'appel de Paris, 21 mars 2012, RG n° 11/12942 : *« Qu'il suffisait, cependant, à MYLAN et QUALIMED de délivrer l'assignation en nullité dudit brevet dans des délais leur permettant d'obtenir un jugement au fond, avant de procéder, le cas échéant, à la commercialisation du médicament litigieux, pour éviter toute atteinte aux droits des titulaires de ce brevet ; »*