

Barcelona Court of Appeal confirms invalidity of Roche's valganciclovir patent

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First-instance decision

Appeal decision

On May 22 2017 the Barcelona Court of Appeal confirmed the previous Barcelona Commercial Court Number 5 judgment which had revoked EU Patent 0694547 (EP'547) in Spain.

Facts

F Hoffmann-La Roche AG is the holder of EP'547, which claims:

- valganciclovir;
- its salts;
- a process for its preparation; and
- its use in a pharmaceutical composition for the treatment of antiviral and related diseases.

Valganciclovir is a prodrug of ganciclovir. In particular, valganciclovir is the mono L-valine ester of ganciclovir, which improves the oral bioavailability of ganciclovir.

In November 2013 Teva Pharma, SLU and ratiopharm España, SA filed a revocation action challenging the validity of EP'547 due to lack of novelty and an inventive step in view of three prior art documents:

- the patent application for EU Patent 0375329 (EP'329);
- its priority document, GB 8829571 (GB'571); and
- its druckexemplar.

During first-instance proceedings, Roche unconditionally limited the patent by amending its claims, which were constrained to the use as a therapeutically active agent of valganciclovir's hydrochloride salt in the form of mixtures of its (R)- or (S)- diastereomers.

In turn, Teva and ratiopharm maintained their lack of an inventive step challenge with regard to the new claims (except with regard to a dependent claim relating to a crystalline form of the claimed product).

First-instance decision

On September 14 2015 the Barcelona Commercial Court Number 5 found in the plaintiffs' favour and revoked the relevant patent claims due to lack of an inventive step.

Roche appealed this decision, arguing that the court had incorrectly applied the problem-solution approach. In particular, Roche argued that the druckexemplar of EP'329 was not relevant prior art and that, in any event, the objective problem to be solved by the alleged invention should have been defined as improving the oral bioavailability and toxicity of the bis L-Valine ester of ganciclovir, and not improving the oral bioavailability of the parent compound ganciclovir.

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Teva and ratiopharm opposed the appeal, refuting Roche's allegations. In particular, the plaintiffs emphasised that by limiting the patent, Roche had implicitly acknowledged that valganciclovir was not patentable at the priority date of the patent, whereas the features added to the claims (ie, use as therapeutically active agent, hydrochloride salt and mixtures of diastereomers) could not confer inventiveness on the alleged invention.

Appeal decision

The Barcelona Court of Appeal confirmed the first-instance decision in its entirety.

Regarding the druckexemplar of EP'329, the Barcelona Court of Appeal confirmed that it was relevant prior art – in particular, the closet prior art – as it was accessible to the public as of May 9 1994 (ie, before the priority date of the patent at stake). The court dismissed Roche's arguments regarding the alleged difficulties to access the document due to the fact that European Patent Office files could not be accessed online in 1994.

Regarding the technical problem solved by the alleged invention, the Barcelona Court of Appeal reiterated that the statements of the patent specification itself are relevant in this regard (except in certain circumstances which do not apply in this case). Further, in line with Teva and ratiopharm's arguments and the first-instance decision, it concluded that the problem was to improve the oral bioavailability of ganciclovir.

Finally, regarding obviousness, the Barcelona Court of Appeal considered that valganciclovir was an obvious solution at the priority date, as the druckexemplar of EP'329 had already disclosed that both valganciclovir and the bis L-Valine ester of ganciclovir increase the oral bioavailability of ganciclovir, and that it did not prefer either of them.

Further, pursuant to the allegations of Teva and ratiopharm, the Barcelona Court of Appeal stated that none of the three features added to the claims conferred an inventive step on the alleged invention.

As Roche has not further appealed this decision to the Supreme Court, the revocation of the relevant patent claims is final.

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