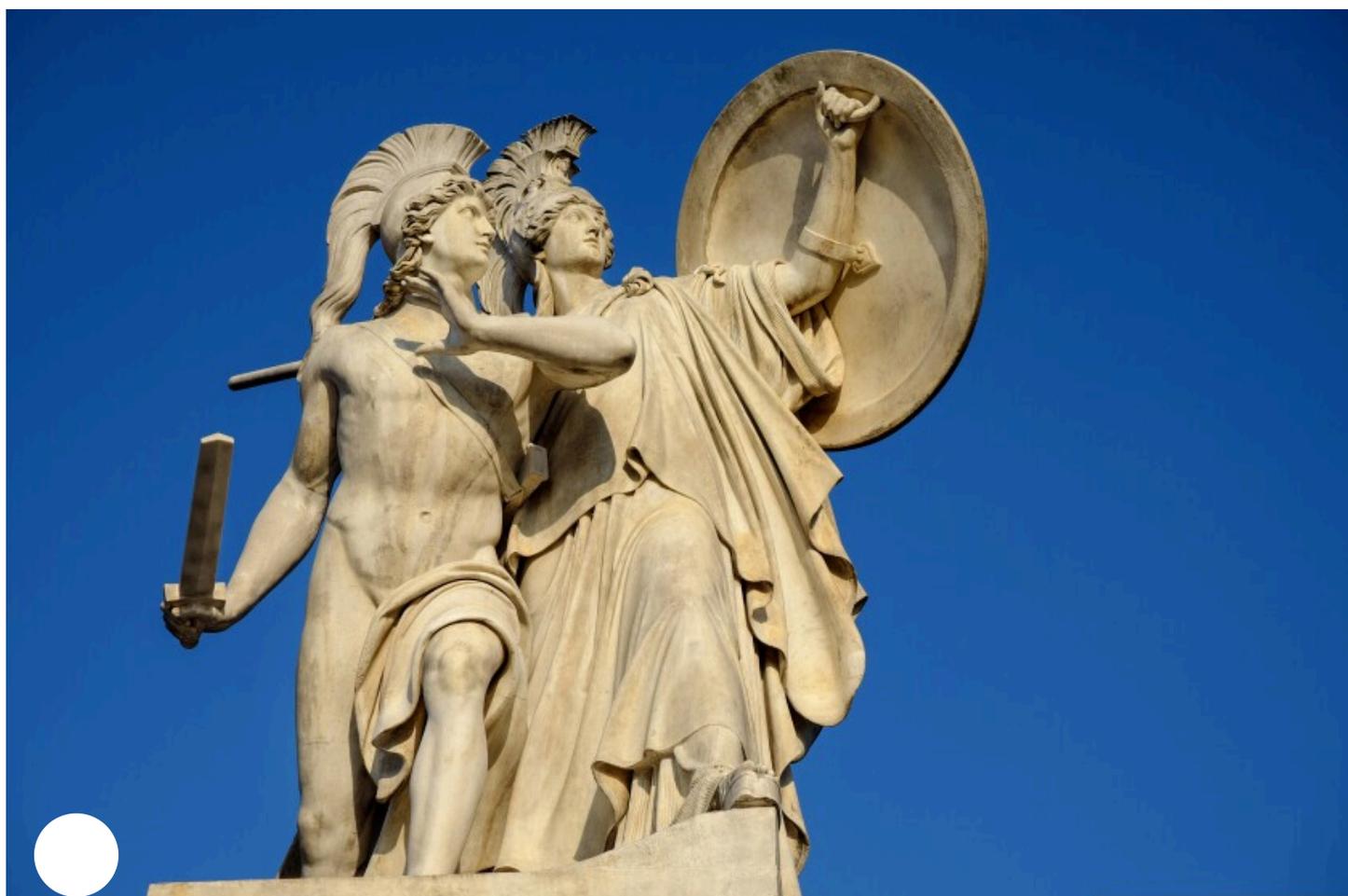


Preliminary injunction based on a combination product SPC is denied by Athens court

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Constantinos Kilimiris May 25 2023



Constantinos Kilimiris of Patrinos & Kilimiris calls for clarity on how to apply the SPC Regulation with regard to combination products after a Greek case appeared to overturn national case law on the matter

A recent decision by the Athens First Instance Single Member Court, hearing a request for a preliminary injunction (PI) based on a supplementary protection certificate (SPC) for a pharmaceutical product combining two active ingredients, seems to overturn national case law on the interpretation of Article 3 (c) of the SPC Regulation.

Case background and ruling

The PI application was filed by an originator company alleging infringement of its combination SPC by a generic company attempting to launch its product at risk.

The defence of the generic company was to challenge the validity of the combination SPC. The generic company alleged that:

- The SPC was granted in violation of Article 3 (c) of the SPC Regulation as another SPC had already been granted for the first active ingredient of the marketed combination; and
- The basic patent could not be interpreted as disclosing the active ingredients' combination as a separate, independent invention.

While the reasoning of the decision is not very clear, it seems that the Athens court based its decision on Court of Justice of the European Union (CJEU) case law, C-443/12 and C-577/13, looking into whether the combination of active ingredients could be regarded as an independent invention of the basic patent. It ruled that this is not the case and, accordingly, that an SPC had already been granted for the same invention. Thus, the combination SPC was granted in violation of Article 3 (c) of the SPC Regulation and was invalid.

Analysis of the decision

This decision is contrary to previous case law from the same court, which, in hearing a PI application based on a combination SPC, had found that the grant of a combination SPC had not violated Article 3 (c) of the SPC Regulation as it was sufficient that the combination be expressly mentioned in the claims, without examining whether the combination could be regarded as an independent invention.

While it is true that the national case law on this issue is divergent among EU member states, it also seems that the Greek case law on this matter is far from settled. Given that referrals are pending on the same issue before the CJEU, one should hope for some clarity on how to apply the SPC Regulation in practice as regards combination products.

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Constantinos Kilimiris

PARTNER Patrinos & Kilimiris
