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Precipitation is no micronization, according to the Antwerp Court of Appeal

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The Antwerp Court of Appeal dismissed the claims of the Spanish pharmaceutical company Almirall against Teva Pharma Belgium (Teva) relating to the generic ebastin. It confirmed the decision of the President of the Antwerp Commercial Court, although the Court of Appeal based its decision on other grounds.

As discussed in a previous post, Almirall started summary proceedings against Teva invoking its European patent EP 614 362 (EP 362). EP 362 relates to "pharmaceutical compositions based on ebastine or analogues thereof" and expires on 1 December 2012. Almirall's Belgian subsidiary commercialises the medicine Estivan (with micronised ebastine as the active ingredient) in Belgium.

Teva intends to commercialise generic ebastine under the name "Ebastine Lindopharm" in Belgium and obtained a marketing authorisation on 3 May 2010. In order to prevent Teva from commercialising the generic "Ebastine Lindopharm" in Belgium, Almirall started proceedings on the merits as well as summary proceedings, invoking EP 362 in both cases. A hearing is scheduled on 21 October 2011 to hear the proceedings on the merits.

With regard to the summary proceedings, the President of the Antwerp Commercial Court refused to issue a preliminary injunction as the urgency requirement was not fulfilled: Almirall could have initiated accelerated proceedings on the merits earlier as it had already been aware of Teva's intentions to commercialise the generic ebastine "Ebastine Lindopharm" for several months. Almirall lodged an appeal against the President's decision and, by decision of 13 July 2011, the Court of Appeal confirmed the refusal to issue a preliminary injunction.

The Court of Appeal first concluded that patent holders may initiate summary proceedings in urgent matters even though accelerated proceedings on the merits are available to the patent holder. It considered that this case, relating to an alleged imminent patent infringement, was urgent per se, referring to article 9.1 of the Enforcement Directive.

The Court then reminded that, in order to obtain a preliminary injunction, the patent holder must not only establish the existence of a prima facie valid patent, but must also provide prima facie evidence of the infringement.

In its assessment of the alleged infringement, the Court stated that claim 1 of EP 362 requires that

the ebastine is “micronized”. According to the Court, referring to the description of the patent, this means that the size of the particles is reduced by fragmenting them, which requires a mechanical operation by a specific device.

The Court of Appeal then stated that the generic ebastine “Ebastine Lindopharm” does not on its face contain such micronized ebastine. “Ebastine Lindopharm” indeed uses the precipitation technique, in which particles are formed in a specific size during the spraying of the solution on the carrier. No reduction of the size of the particles is needed. The Court considered this to be different from the patented micronized ebastine, excluding a prima facie patent infringement.

It should be applauded that the Antwerp Court of Appeal looked at the technical arguments, and did not render a decision on the basis of a formal prima facie assessment, which is very often the case in Belgian patent litigation.

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