

Choose or lose: the importance of starting the right kind of proceedings without delay

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Noteworthy decision on the balance of interests within the framework of preliminary injunction proceedings: Antwerp Court refuses to issue a preliminary injunction because the patent holder could have started accelerated proceedings on the merits earlier.

By a decision of 15 March 2011, the President of the Antwerp Commercial Court dismissed the claims of the Spanish pharmaceutical company Almirall against Teva Pharma Belgium (**Teva**) relating to the generic ebastin. Almirall started preliminary injunction proceedings against Teva in order to obtain an injunction prohibiting Teva to commercialise the generic ebastin, which would allegedly infringe EP 614 362 (**EP 362**) of Almirall. The President of the Antwerp Commercial Court however refused to issue a preliminary injunction, taking into account that Almirall could have initiated accelerated proceedings on the merits earlier. It is interesting to note that the President referred to the Pharmaceutical Sector Inquiry Report of the Commission to justify his decision.

This case relates to EP 362 concerning "pharmaceutical compositions based on ebastine or analogues thereof" valid until 1 December 2012. Almirall's Belgian subsidiary commercialises the medicine Estivan (with micronised ebastine as active ingredient) in Belgium.

Teva also intends to commercialise the generic ebastine under the name "Ebastine Lindopharm" in Belgium and already obtained a marketing authorisation on 3 May 2010. The request for this marketing authorisation was based on the German marketing authorisation of the German company Lindopharm GmbH. Teva then filed the necessary requests for reimbursement for "Ebastine Lindopharm". A meeting of the reimbursement authorities was scheduled on 17 August 2010 and on 16 February 2011 a decision was taken to reimburse the generic "Ebastine Lindopharm".

In order to prevent Teva from commercialising the generic "Ebastine Lindopharm" in Belgium, Almirall started preliminary injunction proceedings as well as proceedings on the merits, invoking EP 362 in both cases. The preliminary injunction proceedings were initiated before the President of the Antwerp Commercial Court on 20 October 2010. A few weeks later, on 10 November 2010, Almirall started infringement proceedings on the merits against Teva before the Antwerp Commercial Court, and a hearing is scheduled on 21 October 2011.

In his decision relating to the preliminary injunction proceedings, the President of the Antwerp Commercial Court firstly reminded the parties about the several options available to patent holders. They can not only start preliminary injunction proceedings and 'normal' proceedings on the merits to stop the infringement but may also bring accelerated proceedings on the merits. These expedient proceedings allow the patent holder to obtain a court decision on the merits ordering the defendant to cease all infringing activities within a short period of time. In such proceedings, however, no damages can be claimed.

The President then considered the conditions to grant preliminary relief. Essentially, the President of the Commercial Court has to examine three questions in order to grant a preliminary injunction: (i) is the matter urgent, i.e. has the patent holder reasons to fear imminent damage in the absence of a preliminary injunction and would initiating mere proceedings on the merits not lead to a timely decision to prevent such imminent damage; (ii) does the patent holder have *prima facie* valid claims or rights; (iii) does the interests of the patent holder outweigh the other interests at stake (proportionality test)?

In his assessment of these conditions in this case, the President agreed that the case was urgent, taking into account the threatened alleged infringement. Whether or not this urgency is a consequence of the attitude of the plaintiff should be decided under the proportionality test, according to the President. In this respect, the President argued that Almirall was already several months aware of Teva's intentions to commercialise the generic ebastine (a marketing authorisation was obtained on 3 May 2010, a meeting of the reimbursement authorities was scheduled on 17 August), but nevertheless only initiated summary proceedings on 20 October 2010.

Taking into account this chronology, the President concluded that Almirall should have initiated accelerated proceedings on the merits earlier in order to obtain a decision on the merits relating to the alleged infringement instead of starting preliminary injunction proceedings, in order to obtain only a preliminary relief. According to the President, the requested preliminary injunction has a rather definite nature as it would stop Teva from commercialising the generic ebastine until there is a decision on the merits. Referring to the Pharmaceutical Sector Inquiry Report of the European Commission, the President argued that the preliminary injunction proceedings would therefore be used to extend the protection period of the patent rights of Almirall and to hinder companies to market generics. Although it is not up to the President to judge on such policy within the frame of preliminary injunction proceedings, this should be taken into account when assessing the proportionality test.

In the light of all these elements, the President held that the requested measures could not be granted.

To conclude, the President of the Antwerp Commercial Court has sent a warning to all patent holders (and more in particular within the pharmaceutical sector) not to wait too long before starting preliminary injunction proceedings. Moreover, they should carefully consider whether or not to start preliminary injunction proceedings or accelerated proceedings on the merits. As this case shows, the outcome may depend on it. Patent holders prefer initiating preliminary injunction proceedings as Belgian courts tend to deem a European patent as *prima facie* valid and will not look at any invalidity argument in preliminary injunction proceedings, not at the concrete circumstances (foreign invalidity proceedings, limitation of claims, type of patent, etc.). The judgement of the President of the Antwerp Commercial Court might require patent holders to change tactics.