CLIENT ALERT

Important Change in Belgian Patent Litigation: The Belgian Supreme Court Adopts a Less Strict Approach to the Prima *Facie Validity* of a European Patent

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Introduction

Preliminary injunction (PI) and seizure proceedings are powerful weapons in the hands of patentees in Belgium. Often, the success of a product launch and the outcome of a patent dispute will in practice be determined by a PI or seizure that prevents or ceases market entry by the alleged infringer.

In the context of such proceedings, Belgian courts assess the parties' rights and claims on a *prima facie* (first sight) basis. As a result, they have tended to refuse to take patent invalidity arguments into account on the basis that European patents are *prima facie* valid given the substantive examination by the European Patent Office (EPO). In the last few years, this traditional approach received some support in various judgments of the Belgian Supreme Court. However, in a series of judgments since July this year, the Supreme Court has substantially watered down, and in some circumstances perhaps lifted, the presumption of validity. This has important implications for the launch strategies available to generic pharmaceuticals companies in Belgium.

The Traditional Approach

In its Novartis/Mylan (*fluvastatin*) judgment of 5 January 2012, the Belgian Supreme Court held that a European patent remains *prima facie* valid even after revocation by the EPO Opposition Division given the suspensive effect of an appeal against revocation to the EPO Technical Board of Appeal. The Supreme Court thus upheld the presumption of patent validity in the context of PI proceedings.

This reasoning was taken one step further in the Lundbeck/Eurogenerics (*escitalopram*) judgment of 24 June 2013. In that case, the issue was the effect of an appealed first instance judgment of a Belgian court (as opposed to an administrative EPO division) invalidating the patent. In those circumstances, the Supreme Court held that a PI could be granted pending the appeal, notwithstanding the first instance finding of invalidity. This finding was—again—based upon the suspensive effect of the appeal. The apparent effect of this decision was that a patentee can continue to rely on the *prima facie* validity of its patent to obtain PI relief until all appeals are exhausted and a final decision on validity has been reached. This means that clearing the path by initiating a timely and successful invalidity action was no longer a guaranteed route to effective product launch.

The legal situation became even more difficult when, on 15 March 2013, the Brussels Court of Appeal held in Bayer/Sandoz (*drosperinone*) that a PI granted prior to the invalidity decision in first instance proceedings on the merits automatically remained in effect notwithstanding the invalidation of the patent, as long as the first instance decision was under appeal.

The New Case Law

However, in two judgments of 26 June 2014 – AstraZeneca/Sandoz (*quetiapine*) and Bayer/Sandoz (*drospirenone*) – the Supreme Court rejected the Brussels Court of Appeal's approach, holding that a PI does automatically come to an end if the patent is invalidated at first instance. An invalidity judgment on the merits terminates any PI (see here).

Even more importantly, in the same judgments, the Supreme Court imposed important limits on its previous case law regarding *prima facie* validity. It affirmed the outcome in its *escitalopram* judgment, i.e that a PI can still be awarded following a finding of invalidity at first instance. However, it made clear that, following an invalidity finding at first instance, a judge in PI proceedings is no longer bound by the *prima facie* validity of the patent where an appeal has been brought. Instead, a PI can only be granted if the patentee demonstrates with sufficient certainty that (i) the appeal against the first instance decision will be successful and (ii) the PI is necessary in all the circumstances of the case, including the likely length of the proceedings and the scale of potential damages. In other words, a PI judge in said circumstances cannot start from the assumption that the patent is *prima facie* valid.

More recently still, following the oral hearing of 12 September 2014 in Syral/Roquette (*maltitol*), the pendulum appears to have swung even further. The Supreme Court nullified an Antwerp Court of Appeal decision granting a seizure on the basis of the *prima facie* validity of a European patent. The Supreme Court's full reasoning is not yet available. However, it is likely to have followed the reasoning of the Advocate-General in his Opinion of 6 June 2014. According to the Advocate-General, the traditional view of the Belgian courts that a European patent remains *prima facie* valid despite nullification at first instance—or in other jurisdictions—ignores the reality of a European right. A European patent is a bundle of national patents, but they all stem from the same basic European right. A proper evaluation of the validity of a patent requires more than a simple finding that the invalidity decision at first instance is subject to appeal. The presumption of validity in relation to a patent that has been provisionally declared null and void is no more than a presumption. The force of the presumption is subject to the argument and evidence advanced by the parties. As a result, the judge in PI or seizure proceedings cannot disregard a judgment in another EU jurisdiction—in that case the UK—invalidating the patent in that jurisdiction. To the contrary, under the Brussels I Regulation, the legal force of such a judgment must be respected and even creates a presumption of invalidity in relation to the Belgian part of the European patent.

If this is indeed the reasoning followed by the Supreme Court, it represents an important development. Once a favorable decision has been obtained in one of the major patent jurisdictions, a launch in Belgium can be prepared (provided that there are no contradictory decisions in other foreign jurisdictions).

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