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Supreme Court further clarifies the scope of reversal of the burden of proof in process patents

Miquel Montañá (Clifford Chance) · Thursday, August 11th, 2011

After years of not having handed down judgments in patent cases, in recent months the Supreme Court has handed down several interesting judgments which will hopefully give more guidance to lower level Courts. The last judgment in this recent saga, handed down on 18 July 2011, has confirmed the judgment of 19 December 2006 from the Madrid Court of Appeal (Section 12), which, in turn, had upheld the judgment of 19 October 2004 from Court of First Instance Number 71 of Madrid. This judgment had concluded that Laboratorios Alter, S.A. had infringed Pfizer's patents ES 520,389 and EP 244,944. The first patent protected a process to obtain amlodipine and, optionally, a pharmaceutically acceptable salt thereof, while the second patent protected a process to obtain one specific salt: besylate amlodipine. To sum up, the process protected in the second patent comprised a reaction between amlodipine base and bencenosulphonic acid or its ammonium salt in an inert solvent and recouping besylate amlodipine.

In their statement of defence, the defendants had questioned the inventive activity of the second patent alleging that making a reaction between a "base" and an "acid" to form a "salt" had been known for many decades. The Supreme Court rejected this argument after highlighting that in this type of patents the novelty and / or inventive activity of process claims may come from applying for the first time a known reaction (for example, a base-acid reaction to form a salt) to obtain a new product with unexpected properties. In particular, the Supreme Court noted that the Madrid Court of Appeal had found that the process was a new and inventive selective process because it had applied for the first time this reaction to bencenosulphonic acid or its ammonium salt for the purpose of obtaining a specific salt (i.e. besylate amlodipine) with a good combination of formulation properties (stability, solubility, processability, no higroscopicity…). The Supreme Court confirmed the judgment of the Madrid Court of Appeal on these grounds, which had found that this combination of formulation properties would not have been obvious to the person skilled in the art.

As regards infringement, article 61.2 of the 1986 Patent Act reads as follows: "If the object of a patent is a process for the manufacture of new products or substances, it shall be presumed, unless otherwise proved, that every product or substance of the same characteristics has been obtained through the patented process". One of the arguments traditionally used by companies accused of infringing process claims, is that this article would simply require them to disclose the process used to obtain their product. Once this process has been disclosed, the burden of proving that this disclosed process invades the scope of protection of the process claim would correspond to the patentee. This narrow interpretation, which was already rejected by the Barcelona Court of Appeal (Section 15) in their judgment of 9 May 2008 (Pfizer v. Stada), has now also been rejected by the

Supreme Court after noting that said article "[…] exempts the beneficiary party of the burden of proving the fact deduced by the Legislator".

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