ES – Lundbeck v. Cinfa et al. / Escitalopram / Supreme Court

H.Lundbeck A/S, Lundbeck España, S.A. v. Laboratorios Cinfa, S.A., Mylan Pharmaceuticals, S.L., Actavis Spain, SA. et al., Supreme Court (Civil Chamber, 1st Section), Spain, 29 April 2015, Docket No. 556/2013.

By means of a Judgment issued on 29 April 2015, the Supreme Court definitively ruled in the Escitalopram patent litigation brought by Lundbeck in Spain against a pool of generics companies, thereby confirming the earlier findings from the lower courts, which had declared the non-existence of patent infringement. The Judgment contains important teachings concerning the assessment of patent infringement under the doctrine of equivalents and the applicable standard of obviousness for the alternative which replaces an element of the invention, which the Supreme Court sets in the predictability of the variant. It further analyses the inapplicability of the test of inventive step to appraise the obviousness of the allegedly equivalent alternative.

Beginning in 2010, Lundbeck prompted legal actions for patent infringement against a number of companies which had recently obtained marketing authorizations for Escitalopram generic drugs from the Spanish Health Authorities. Such actions were based on Lundbeck's SPC 200300019 that extended protection of the Spanish validation of the EP 347066 patent ('EP 066'), which had been granted with a special set of claims for Spain with only two method claims protecting a process for preparing the active ingredient (API) Escitalopram.

The defendant companies were divided into two groups:

- On the one hand, Mylan and Germed, which were supplied the Escitalopram API by the manufacturer Natco. With respect to these companies, Lundbeck maintained that Natco's process for obtaining Escitalopram, as stated in the appropriate Drug Master Files (DMFs), infringed by equivalence the EP 066 patent and hence the related SPC.

- On the other hand, the other defendant companies (including, among others, Cinfa, Sandoz, Bexal, Ratiopharm and Actavis), which were supplied the Escitalopram API by the manufacturer Dr. Reddy's. Despite acknowledging that Dr. Reddy's manufacturing process, as described in the DMFs, was not patent-infringing, Lundbeck maintained that Dr. Reddy's stated process was not the only one used to manufacture the Escitalopram API in the defendants' generic drugs, but that an additional and patent-infringing process was likewise being used.

Lundbeck's infringement claims, both against the first and the second group of generics companies, were dismissed in the first instance by Commercial Court no. 4 of Barcelona in a Judgment dated 1 August 2011. This dismissal was later upheld on appeal by the Court of Appeals (15th Division) of Barcelona in its Judgment of 19 December 2012. Lundbeck then appealed this Court of Appeals' Judgment before the Spanish Supreme Court.

On the one hand, Lundbeck filed an extraordinary appeal for breach of procedural rules against the Court of Appeals' assessment and findings with respect to the companies which were supplied the Escitalopram API by Dr. Reddy's. Stated briefly, Lundbeck maintained,

through four different grounds for appeal, that the Court had not properly assessed the evidence, also in breach of the rules regarding presumptions and guarantees of due process, and had wrongfully applied the rules concerning burden of proof. Since Escitalopram was a new product on the priority date of the EP 066 patent, on application of the reversal of the burden of proof regarding the infringement of process patents referring to new products, instituted by Art. 61(2) of the Spanish Patents Act, the defendant companies had the burden to prove that the Escitalopram API in their tablets was produced exclusively by using Dr. Reddy's non-infringing process. In this sense, Lundbeck maintained that the defendants had not sufficiently proved that only Dr. Reddy's process was used, so the Court of Appeals had erred in not presuming that Escitalopram was also produced according to an infringing process.

Lundbeck's extraordinary appeal for procedural breach was rejected. In brief, according to the Supreme Court, the appeal as formulated was intended for the Supreme Court to completely reassess the facts and evidence, which, in accordance with constant case law, the Supreme Court can do in very exceptional circumstances, which ultimately were not present in that case. The Supreme Court understood that what Lundbeck regarded as manifest errors in the assessment issued by the Court of Appeals were just discrepancies and a reflection of Lundbeck's disagreement with that assessment. This could not serve as a basis for an extraordinary appeal before the Supreme Court. Particularly, with regard to the breach of rules on the burden of proof, the Supreme Court considered that these rules only apply when a certain relevant question remains unproven, while the Court of Appeals had indeed deemed proven that the Escitalopram in the defendants' tablets was produced using only Dr. Reddit's process; no breach of those rules occurred simply because one of the parties considers the evidence which led the Court to deem a fact proven to be insufficient.

On the other hand, Lundbeck also filed a cassation appeal (for breach of material law) against the Court of Appeals' finding that neither Mylan nor Germed (which were supplied the Escitalopram API by Natco) violated Lundbeck's SPC under the doctrine of equivalents, alleging an infringement of Art. 69 EPC and its Interpretation Protocol.

The main difference between Lundbeck's patented process and Natco's process centered on the starting products: enantiopure cyano-diol in Lundbeck's invention and enantiopure bromo-diol in Natco's process. The controversial issue was, then, whether or not the alternative of using enantiopure bromo-diol was equivalent to the use of enantiopure cyano-diol as a starting product, in order to determine whether or not the variant fell within the scope of the SPC. Both the Commercial Court and the Court of Appeals had ruled that this alternative was not obvious to the skilled person, so Natco's process was not an infringing equivalent of Lundbeck's invention.

In essence, Lundbeck alleged in the cassation appeal that the Court of Appeals of Barcelona had wrongly equated the obviousness of a variant, in the context of the assessment of infringement by equivalence, to the absence of inventive step. This because, when applying the "Improver" three-question protocol on equivalence, imported from UK case law, and particularly when replying to the second question, the Court stated in the Judgment that *"If the variant was not obvious, i.e. it is inventive, there is no equivalence"*. According to Lundbeck, this led the Court to wrongly apply a very strict standard pursuant to which only variants which appeared to be absolutely certain to the skilled person, without any doubt, would be infringing equivalents, but not those which just presented a reasonable expectation of success. Lundbeck had defended the view that such "reasonable expectation of success" of the alternative (such as the use of enantiopure bromo-diol instead of enantiopure cyano-

diol as a starting product), as opposed to total certainty, was enough to render it obvious for purposes of establishing infringement by equivalence.

Additionally, Lundbeck argued that, even assuming that the inventive step test applied to determine the obviousness of a variant in assessing infringement by equivalence, then the applicable standard should be whether the skilled person "would have regarded" that variant with a reasonable expectation of success, and not whether he would be absolutely certain that the variant would work.

The Supreme Court, however, also dismissed Lundbeck's grounds for the cassation appeal.

First, the Supreme Court denied that the Court of Appeals had equated the test of infringement by equivalence to the test of inventive step, and stated that the alternative process is only obvious when it is one hundred percent certain. The Supreme Court noted that the Court of Appeals had rejected the appellant's argument that a "reasonable expectation of success" of the variant would suffice, not because it found a total degree of certainty necessary, but because something beyond and more persuasive than a "reasonable expectation" was required to prove equivalence. The Supreme Court highlighted that the Court of Appeals had actually declared that an alternative which replaces an element from the invention is obvious when it is easy to see or understand, in other words, when it is considered predictable by the skilled person.

The Supreme Court further rejected the appellant's argument that, if the test of inventive step applied, the variant would be obvious if the skilled person "would have regarded" it with a reasonable expectation of success. The Court pointed out that in the context of the test of inventive step under the "could-would" approach", the "would" element ("would have prompted") actually expresses a more stringent requirement, which raises the threshold of predictability of success against a mere possibility ("could have arrived"). And it is within this higher level of predictability that reasonable chances of success must be considered.

To the above the Supreme Court added that, in any case, the assessment of inventive step and the assessment of obviousness under the doctrine of equivalents are addressed for different purposes and hence make use of different parameters, so they are not interchangeable. Thus, while inventive step is examined by taking the technical solution as a whole, such that it is the whole invention which is compared to the prior art, assessing infringement by equivalence requires making an element-by-element comparison, so obviousness refers only to the particular element of the variant which is allegedly equivalent to the replaced element of the patented invention. In addition, an inventive embodiment might infringe an earlier patent (which would then make it a dependent invention), and conversely, a non-inventive embodiment might not infringe the earlier patent if the alternative that replaces one of the elements of the invention was not obvious on the priority date of the patent. Also, the relevant moment for assessing obviousness for infringement purposes (the priority date of the allegedly-infringed patent) is different from and earlier than the relevant moment for considering inventive step (the priority date of the applied-for patent).

Due to all of the above, the Supreme Court upheld the findings of the Court of Appeals and considered the standard of predictability to be more appropriate for assessing obviousness in the context of infringement by equivalence, rather than the less stringent mere possibility of success, as argued by the appellant. The Supreme Court agreed with the Court of Appeals' assessment and conclusion that, in view of the evidence examined, it was not predictable

that the skilled person, on the priority date of Lundbeck's basic patent, would have used enantiopure bromo-diol to obtain Escitalopram. Consequently, the required threshold for the variant to be considered obvious was not reached.

The Supreme Court further added that, by setting the standard of obviousness in the predictability of the equivalent alternative, the Court of Appeals had achieved a proper balance between the patentee's exclusive rights and the reasonable degree of certainty that must be conferred to third parties which intend to operate in the same market as the patented invention.