ES – Lacosamide / Commercial Court no. 5 of Barcelona, 14 April 2020, Docket No. 672/2017 / Invalidity action (public availability of a prior art document) & action for threat of patent infringement

On 8 September 2017 the plaintiff, LABORATORIOS NORMON, S.A. (hereinafter, "NORMON") filed an invalidity action against the companies RESEARCH CORPORATION TECHNOLOGIES INC., UCB BIOPHARMA SPRL and HARRIS FRC CORPORATION -and UCB PHARMA, S.A. as intervening party- (hereinafter, collectively referred to as "RTC"), holder, licensee and sub-licensee, respectively, of European patent EP 0,888,289 (EP '289).

The patent expired on 17 March 2017 and served as basis for the grant of Spanish Supplementary Protection Certificate no. 200900006 (SPC '006) protecting the product lacosamide.

Lacosamide, sold under the brand name VIMPAT®, had become one of the most widely used products for the treatment of epilepsy in more than 50 countries.

NORMON filed the invalidity action on the grounds that patent EP '289 was invalid for lack of novelty and inventive step.

In reply, RTC filed a counterclaim for infringement of its SPC '006 asking the Court to issue a declaration on infringement in the event that NORMON started selling generic drugs of lacosamide between the filing date of the counterclaim and the expiration date of the SPC.

In this context, Commercial Court no. 5 of Barcelona issued its judgment on 14 April 2020, which addresses some interesting issues, both regarding patent invalidity and infringement, as those explained below.

Public availability of a prior art document

One of the invalidity arguments raised by NORMON was the lack of novelty of EP '289 in view of a doctoral thesis called "Choi" which, according to the plaintiff, would have been made available to the public before the priority date of the patent (15 March 1996).

There was no discussion between the parties on the fact that this thesis met all technical features of patent EP ‘289. The controversial point was to ascertain whether this thesis was made available to the public before 15 March 1996, thus constituting part of the prior art, according to article 54 EPC.

To this end (to determine the public availability of this document), Commercial Court no. 5 of Barcelona referred to the criteria developed by the EPO according to which it should be decided what was “more likely than not” to have happened, that is, to apply the "balance of probabilities" standard of proof for the question of the public availability of a document (see, for example, EPO T 0381/87, 10 November 1988, or T 0750/94, 1 April 1997).

It was undisputed between the parties that the thesis was defended on September 1995 behind closed doors in front of a five-member tribunal.

Thus, from that point forward, the Court had to assess whether between September 1995 and 15 March 1996 it was likely (on a balance of probabilities standard) that the thesis was given the possibility of public access.

From the evidence submitted to the proceedings by the parties, the Court concluded that the date on which the document was more likely to have been made available to the public would be the cataloguing date, i.e. once the thesis had been indexed in the catalogue of the university library, which had taken place on June 2, 1997.

The Court considered that before that date it was most likely that the thesis would not have been made available to the public, given that:

- The research was carried out confidentially. The work between the thesis tutor and the doctoral student was carried out secretly. Besides, that was not the first time they applied for patents derived from their research.

- The thesis was defended behind closed doors in September 1995 before a five-member tribunal in order to preserve confidentiality.

- All post-court defence modifications and suggestions made before 15 March 1996 and until the deposit of the final version in the Faculty were also made secretly between the thesis tutor and the author.

- There was a letter from the thesis tutor to the Dean of the Faculty dated February 1996 formally requesting not to place the thesis in the library pending the filing of the patent application.

- There was also a fax dated August 1996 to RCT's lawyer stating that the thesis has not been placed on the Library shelves.

- And finally there was also an email from ProQuest stating that although the thesis was received from the University on July 1, 1996, it was made available on July 28, 1996.

The above facts were considered by the Court to have created an express or tacit agreement on secrecy, restricting the circle of persons entitled to have access to the thesis (just certain people in the University, the members of the research group, the five-members thesis tribunal, etc.).

In conclusion, the Court established that from September 1995 to 15 March 1996 it was *more likely* that the thesis was not made available to the public.

Moreover, the Court pointed out that such agreement on secrecy would have been broken on April 1996, when the author/inventor himself made the results of his research of public access on a published scientific article, just one month after the patent priority date.

The Court therefore concluded that the patent was not invalid for lack of novelty.

Action for threat of patent infringement

At the time NORMON filed its invalidity claim against RTC, NORMON had already obtained marketing authorizations for lacosamide generic drugs but it had not yet launched them on the market.

Thus, in view of the fact that NORMON had already obtained marketing authorizations, RTC filed a counterclaim asking the Court:

- to declare that NORMON had carried out acts constituting a "threat of infringement" of its SPC, and that,

- in the event NORMON decided during the course of the proceedings to launch lacosamide generic drugs before the expiration date of the SPC, to declare that NORMON had carried out infringement acts.

However, the Court rejected RTC's action for "threat of infringement". As stated in its judgment:

- The Court could not "*judge either the fears of one party or the intentions of the other party. Just facts. Actual facts, not mere hypotheses or possibilities*".

- The obtention of a marketing authorization does not constitute a commercial decision on the commercialization of lacosamide generic drugs. NORMON had still not submitted before the Spanish Medicines and Health Agency (AEMPS) any declaration of marketing intention.

- The appropriate legal instrument to deal with a risk of infringement by the imminent launch of generic drugs would have been a request for *ex parte* precautionary measures, not a main action for threat of infringement.

- The fact of being a holder of marketing authorizations for generic drugs shall be considered as just preparatory acts which do not constitute patent infringement acts.

Furthermore, the Court concluded that there was no provision whatsoever for this particular “action for threat of infringement” in the Spanish legal system, nor any case-law precedent, that recognizes the existence of this type of action for the purposes of obtaining a declaration of infringement by the Court before that such acts of infringement effectively take place. RTC action was thus dismissed.