

SPAIN.- ASTRAZENECA AB & OTHERS vs LABORATORIOS ALTER & OTHERS.

On 21st December 2015, The Supreme Court handed down a decision in the case of AstraZeneca AB & others v Laboratorios Alter and & others (EDJ 2015/244058).

AstraZeneca had filed an action against several generic companies for infringement of an SPC for the product quetaipina: The SPC's basic patent was EP 228.

EP 228 was validated in Spain when product claims were not yet allowed; the validated patent has a separate set of claims without any product claims.

Relying on Art. 27 and 70 of the TRIPS Agreement and in order to add product claims, AstraZeneca resorted to the modification of the translation of EP 228.

The patent owners considered that Art. 27 and 70 of the TRIPS Agreement allowed them to add product claims to validated European patents which included product claims but which had a specific set of claims for Spain, including process claims only.

In this case, the request for the modification of the translation was denied in the first instance by the Spanish Patent and Trademark Office (SPTO). The First Instance Court's judgment, handed down by a Madrid commercial court on 24 January 2011, held that the product claims could not be validly invoked in Spain, as the Spanish Patent and Trademark Office had refused to publish the patent's product claims.

AstraZeneca's appeal was also dismissed. The Appeal Court ratified that the product claims were unenforceable cause the SPTO had failed to publish these new claims in its official gazette.

The Court of Appeal understood that AstraZeneca's complaint was based on the product claims only and not on the process claims, so it dismissed the appeal without providing an extensive analysis of the infringement of the process claims.

AstraZeneca filed an extraordinary procedural and cassation appeal before the Supreme Court.

AstraZeneca's main appeal argument was that the Appeal Court's decision was contrary to all of the Supreme Court's case law concerning the application of articles 27 and 70 of the TRIPS Agreement.

The Administrative Chamber of our Supreme Court had issued several judgments on that matter, saying that the revision of a translation not only allows for the correction of errors or inaccuracies, but also enables the addition of product claims.

The Civil Chamber of our Supreme Court had also admitted the incorporation of new claims by modification of the translation as a determinant of the patent protection's scope.

AstraZeneca appealed before the Supreme Court, invoking the application of the case law adopted by our Supreme Court in similar precedent cases .

The question at stake was if the Spanish Supreme Court's case law invoked by Astra Zeneca was still applicable or, on the contrary, had become obsolete in view of the doctrine arising from the CJUE's decision in case C-414/11, Daiichi Sankyo Co. Ltd. This case received significant attention in Spain, as the Greek court asked the CJEU to clarify its jurisprudence on the direct effect and interpretation of the TRIPS Agreement.

In other words, the CJEU had to decide if, after the expiry of the reservation and the adoption of TRIPS, a patent with only process claims also protects the pharmaceutical product as such, or whether it still protects only the pharmaceutical product's manufacturing process.

The key question was what scope and limitation did the patent have after the expiry of the reservation of Art. 167(2) EPC in 1992 and the entry into force of the TRIPs Agreement.

The ECJ denied an extension of the patent's scope in the event of the TRIPS Agreement's entry into force with the following arguments:

"Nor does a reading of Articles 27 and 70 of the TRIPs Agreement in conjunction lead to a different conclusion. It is true that, as follows from the examination of Question 2, Article 27 of the TRIPS Agreement obliges members of the WTO to make it possible to obtain patents for inventions of pharmaceutical products. That obligation cannot, however, be understood as meaning that members of the WTO which, in a period

anterior to the date of that agreement's entry into force, excluded protection of inventions of pharmaceutical products claimed in patents granted for inventions of processes of manufacture of those products must, from that date, regard those patents as covering those inventions of pharmaceutical products."

The Spanish Supreme considers that it should revise its previous case-law on Articles 27 and 70 of the TRIPS Agreement and follow the CJEU's interpretation, stating: "*the fact that the European product's patent was validated in Spain by means of the publication of the process claims on the grounds of the reservation made by Spain (under Article 167(2) (a) of the EPC), the coming into force of TRIPS Agreement does not justify that, since then, by means of its articles 27.1 and 70.2, the patent protects the pharmaceutical product in Spain*".

This seems to suggest the end of an era, in which the possibility for patent holders to invoke the protection of a European patent's product claims through articles 27 and 70 of the TRIPS Agreement no longer exists.