

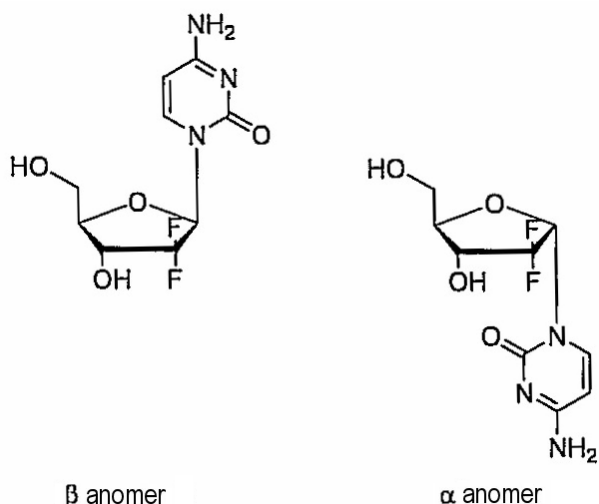
**SAS SANDOZ V. ELI LILLY AND COMPANY, Court of Appeal of Paris, France, 13 January 2012, Case No. 10/17727.**

On 13 January 2012, the Court of appeal of Paris confirmed the judgment which found that the French part of Eli Lilly's patent No. EP 0 577 303 regarding a process for stereoselective glycosylation shows inventive activity, is sufficiently disclosed and consequently valid. The failing generics company is ordered to pay half a million Euros in attorney's fees.

**1. The patented process**

The patented process concerns the preparation of the nucleoside gemcitabine. The active ingredient gemcitabine is a medicament used for the treatment of cancer.

A nucleoside may have two isomers. These two isomers are called  $\alpha$  anomer and  $\beta$  anomer:



Gemcitabine takes the form of a  $\beta$  anomer.

All the processes enabling gemcitabine to be obtained lead to a mixture of anomers. The  $\alpha$  anomer is of no therapeutic interest and must be separated from the  $\beta$  anomer

The subject matter of the patent consists of a process which, for the first time, enables the manufacturer to obtain directly a mixture with more gemcitabine ( $\beta$  anomer) than  $\alpha$  anomer. According to the patent, this is done following a stereoselective process called an SN2 reaction.

**2. On inventive step**

The Court, referring specifically to the case law of the Boards of Appeal of the EPO dealing with the "Could-Would" approach, fully upholds the judgement issued by the First Instance Court of Paris on 2<sup>nd</sup> July 2010 and confirms that the point is not whether the skilled person could have reached the invention by modifying the prior art, but rather whether, in expectation of the advantages actually achieved, he would have done so because of promptings in the prior art.

In the present case, two processes could theoretically be implemented to produce acceptable quantities of the desired enantiomer called gemcitabine (the  $\beta$  anomer).

However, the prior art only taught the production of gemcitabine through a SN1 reaction leading to the production of both the  $\beta$  anomer than  $\alpha$  anomer in an anomeric ratio of 1:1, at the very best.

The SN2 reaction was known only from scientific research, was rare in the field of nucleoside synthesis and had not been implemented to produce gemcitabine or anything similar to it.

In light of this technical background, the Court of appeal notably finds that *"beginning with the prior art implementing a pure SN1 reaction, the man skilled in the art would have had no incentive to apply the specific reaction conditions of an SN2 reaction, which is considered by specialists as an uncommon reaction, and if this idea had ever come to his mind, he would not have known what conditions to change to get an anomeric ratio [of gemcitabine over the  $\alpha$  anomer] greater than 1:1."*

Eli Lilly's patent No. EP 0 577 303 is consequently inventive.

### **3. On sufficient disclosure**

For the first time on appeal, Sandoz had relied on insufficiency of disclosure to seek the nullification of the French part of Eli Lilly's patent No. EP 0 577 303.

However, the Court, having noted that it was up to the claimant claiming that the invention is not sufficiently described to provide evidence that the man skilled in the art *"would be unable to perform the invention with its own scientific and technologic knowledge, it being stressed that this evidence must be established beyond a reasonable doubt and that the a doubt should benefit the patent holder."*

In the case at stake, having indicated that the many examples in the description of the patent as well as general prior knowledge allowed for implementing the claimed invention, the Court finds sufficient disclosure.

### **4. Attorney's fees**

Sandoz had already failed to make its case on first instance and had consequently been ordered to bear all of the counsels' costs of ELI LILLY. On appeal, the Court not only confirms the judgment but adds to it, by ordering SANDOZ to pay the additional fees incurred by ELI LILLY to defend its patent again on appeal.

As a consequence, SANDOZ is ordered to pay on appeal a record-high total of 504,000 Euros in Attorney's fees.