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Hungarian Court grants SPC for MSD's ezetimibe-rosuvastatin product

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Just a few months before the CJEU's judgment in C-121/17 *Teva UK Ltd and Others v Gilead Sciences Inc*. came out a the Metropolitan Court of Budapest handed down a decision regarding Merck Sharp and Dohme Corp's (MSD) application for an SPC re the combination of ezetimibe and rosuvastatin.

The Hungarian court which regularly deals with SPC cases and referred questions for the CJEU in C-496/16 *Incyte* last year, this time took a position contrary to that of the Hungarian Intellectual Property Office (HIPO) regarding the interpretation of Article 3 a) of Regulation 469/2009 (the SPC Regulation), granted the SPC for MSD and further qualified the national practice regarding the interpretation of being "protected by a basic patent".

By way of background MSD already owned an SPC for ezetimibe alone and furthermore applied for an SPC for the combination of ezetimibe and rosuvastatin. The basic Hungarian patent contained a claim (claim 4) for a combination of ezetimibe – defined structurally in the claim – and another active ingredient defined as „a cholesterol biosynthesis inhibitor" in a pharmaceutically acceptable carrier. According to the application the combination of ezetimibe and rosuvastatin was protected by Claim 4 of the basic patent.

The HIPO rejected the application at first instance arguing the product did not meet the requirement of Art. 3a) of the SPC Regulation. The reason for the rejection followed from the HIPO's analysis of the CJEU's C-493/12 *Eli Lilly* judgment which – in the interpretation of the HIPO – required that at least the description of the patent should concretely refer to the active ingredient that is defined only functionally in the claim, in this case, rosuvastatin. The HIPO's view was that this requirement follows from *Eli Lilly* which underlines the importance of the description and provides multiple indications of the importance of the specification of the functionally defined active ingredient by using the terms „necessarily" and „specifically" in the test that was set up by the judgment.

As a second pillar the HIPO referred to the Metropolitan Court's earlier judgment in the Truvada SPC case, in which the court interpreted the *Eli Lilly* judgment in a way that it requires that based on the description the skilled person should necessarily choose the concerned (functionally defined) active ingredient as combination partner, i.e. the description shall leave no room for choice to the skilled person. Here the HIPO argued that even though HMG-CoA reductase

inhibitors are mentioned as a preferable group of biosynthesis inhibitors in the description, and while several types of statins are specifically mentioned in the patent (lovastatin, pravastatin, fluvastatin, simvastatin, atorvastatin) – rosuvastatin is not mentioned anywhere – hence the skilled person would by no means have chosen it for combining with ezetimibe based on the description.

Upon MSD's appeal, the Metropolitan Court reviewed the case and came to an opposite conclusion, agreeing with MSD's appeal arguments.

The court started out from declaring that rosuvastatin meets the functional definition of Claim 4 but that it is not mentioned anywhere in the description either by name or its structure. Then, just like the HIPO, the court looked at the CJEU's *Eli Lilly* judgment decision and stated that from that it is clear that in order to be eligible for an SPC for the combination there is no requirement for rosuvastatin to be mentioned structurally in the claim provided that the claim – interpreted in light of the description as provided in Art 69 EPC and the corresponding Hungarian rule – relates implicitly but necessarily and specifically to it.

The requirement of „implicitly" is fulfilled in the case of rosuvastatin by the functional definition given in Claim 4. The other two requirements – necessarily and specifically – shall be examined based on the description. Here the court agreed with MSD's appeal in that the HIPO's interpretation of the *Eli Lilly* judgment was wrong: it does not follow from this judgment that the concerned active ingredient should be mentioned by name or by structure in the description. Therefore the application cannot be rejected merely on the ground of rosuvastatin not being mentioned in the description. However, it should be examined whether the compound is disclosed in the description in a way that the skilled person would undoubtedly choose it for carrying out the invention.

The court examined the description in detail and highlighted that it unambiguously describes a pharmaceutical composition that contains the combination of ezetimibe and a cholesterol biosynthesis inhibitor. Furthermore, the description discloses suitable biosynthesis inhibitors, among them HMG-CoA reductase inhibitors and provides an exemplificative list of several statins including lovastatin, simvastatin, etc. The description further discloses the typical dose of the cholesterol biosynthesis inhibitor to be used and also reveals their lipid decreasing effect, while examples demonstrate the beneficial effects of the combination.

From this the court concludes that the description does not limit the combination to specific compounds, instead it names HMG-CoA reductase inhibitors (lovastatin, pravastatin, fluvastatin, simvastatin, atorvastatin) as suitable partners. Even though rosuvastatin is not listed, it goes beyond doubt that the skilled person knows that HMG-CoA reductase inhibitors are otherwise known as statins. The skilled person is also aware of the two main groups of statins and that rosuvastatin belongs to the same group of synthetic statins as fluvastatin and atorvastatin which are mentioned in the decription by name. The skilled person also knows that rosuvastatin is the strongest in terms of effect in its group. Also he knows that atorvastatin and rosuvastatin have a long term effect.

Based on this, it was the court's conviction that the skilled person would definitely choose rosuvastatin out of the potential combination partners being the strongest one with a long term effect. Also the court agreed with MSD that it was not expectable at the filing date for rosuvastatin to be mentioned by name as its disclosure preceded the priority date (September 1993) only by a few months and probably no INN existed at the time for it.

The court pointed out that the HIPO incorrectly interpreted the Hungarian court's earlier Truvada decision, as – in contrast to the facts there – in the present case the skilled person received sufficient guidance from the description in order to necessarily and specifically choose rosuvastatin as combination partner for ezetimibe.

As mentioned above, this decision came out before the CJEU's judgment in C121/17 *TEVA UK Ltd and others*. However, looking at the cornerstones of that judgment, especially the reference to the technical specifications of the invention to which the SPC product must correspond to, the inclusion of the general knowledge of the skilled person as well as the exclusion of technical information occurring after the filing date, it appears that the Hungarian decision is in line with the CJEU's newly formulated criteria as well. In fact the Hungarian court – by applying its own post-Lilly-test of „the skilled person would have necessarily and specifically chosen it" for the second time – seems to have consistently involved both the knowledge of the skilled person and implicitly the filing date as demarcation line.

As small as the world of SPC is, it is interesting that an often occurring point of reference in the ezetimibe-rosuvastain decision is the Hungarian court's (negative) Truvada ruling which precisely is the subject of the CJEU's judgment 121/17, following which the UK High Court also recently decided on invalidating the Truvada SPC.

Disclaimer: Danubia/Sár and Partners acted for MSD

This entry was posted on Thursday, October 11th, 2018 at 9:57 am and is filed under European Union, Hungary, Patents, SPC
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