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SPC for medicinal products: interpretation of a "product" definition by the Polish Patent Office and the District Administrative Court in Warsaw in the "QLAIRA" case

The District Administrative Court in Warsaw ("DAC") has recently issued a reasoning to its ruling of 5 August 2011 (case no. VI SA/Wa 87/11) concerning an SPC for a medicinal product. The DAC dismissed the appeal of Bayer against the decision of the Polish Patent Office ("PPO") in which the PPO refused to grant an SPC for the product included in QLAIRA contraceptive medicinal product.

QLAIRA is covered by a patent in Poland, no. PL 186339 filed on 21 October 1996 by Bayer Pharma AG. The subject matter of the patent is multiphase contraceptive preparation which comprises (a) a first phase of 2-4 daily dose units, each containing exclusively natural oestrogens as an active agent, (b) a second phase of 22-16 daily dose units, each containing a combination of a least one natural oestrogen and at least one natural or synthetic gestagen as an active agent, (c) a third phase of 2-4 daily dose units, each containing exclusively natural oestrogens as active agents and (d) a further phase of 2-4 daily dose units, each comprising a pharmaceutically inactive placebo. The first marketing authorization which Bayer relied on was the Belgian authorization of 3 November 2008.

CLIMODIEN is a medicinal product applied in hormone-replacement therapy, which comprises of a combination of estradiol and dienogest, and was authorized for marketing in the Netherlands on 13 December 2000. In the PPO's view both QLAIRA and CLIMODIEN include the same product, i.e. a combination of estradiol valerate and dienogest, although they are not the same medicinal products. The PPO referred in its decision to the ruling of the Court of Justice of the European Union in the cases: C-431/04 ("*MIT*" case), C-31/03 ("*Pharmacia Italia*" case) and C-202/05 ("*Yissum*" case), as well as to Clause 11 of the Explanatory Memorandum to the Regulation 1768/92.

In the PPO's view the CJEU's case law supports strict interpretation, i.e. a new dosage regime, new esters or salts, different pharmaceutical form, a further therapeutical indication, do not render a "product" new. Usually a new use of a known product results from different proportions of active ingredients in a combination. Therefore, the PPO took the position that products that include a combination of the same active ingredients, though in different proportions, cannot be considered different products. A different interpretation of a "product" would result in patent protection for a product being excessively extended. Although the same product may be the subject matter of various patents and admitted to marketing based on various marketing authorizations, it may be

the subject matter of just one SPC.

Bayer argued that products included in QLAIRA and CLIMODIEN are not the same – they have different physiological functions and the active ingredients of the product differ in proportions. If the PPO view was correct, one would have to exclude the (a), (c) and (d) elements from QLAIRA, which would frustrate the innovation subject to the basic patent. QLAIRA is not merely a generic version of CLIMODIEN, which issues particularly from the fact that each of them was the subject of a different marketing authorization, and separate clinical trials before such authorizations were completed. Additionally Bayer argued that in other countries, such as Germany and the UK, QLAIRA was granted an SPC.

On appeal against the PPO's decision to the DAC, Bayer raised both meritorious and procedural arguments. Bayer challenged the evaluation report issued by the Dutch authorities with respect to the Dutch marketing authorization of CLIMODIEN, since it is not an original marketing authorization document. Interestingly, this document was submitted by a third party which filed its observations with the PPO after an SPC was published in an official journal. Bayer claimed that the PPO had not notified Bayer that such document was submitted, and could not take a position in this regard. The PPO argued that before publication of the SPC application, the PPO informed Bayer of marketing authorization for CLIMODIEN as an obstacle to granting an SPC, and Bayer responded to this.

DAC upheld the decision of the PPO on refusal to grant an SPC to Bayer, and substantially supported the PPO's reasoning, in particular with respect to interpretation of a "product". The DAC pointed out that the patent claims which are decisive when determining the scope of a patent, merely specify certain combinations including natural oestrogen and gestagen as active ingredients. It was the patent description and not the patent claims that specified that, as a natural oestrogen ingredient, one can use estradiol valerate, and as a gestagen ingredient one can use dienogest, and the patented combination includes estradiol valerate and dienogest. Additionally, the prior art indicated in the patent description included estradiol valerate and dienogest, as well as a combination of a natural estradiol ingredient with a gestagen ingredient. Thus, what was important in this case, was a new dosage regime of active ingredients with the use of a placebo.

Furthermore, in the DAC's view the argument of Bayer that in this case the product is not only a combination of active ingredients, but a combination of estradiol valerate with combination of estradiol valerate and dienogest, is inconsistent with prior argumentation from the patent description[1], i.e. that gestagen has its own contraceptive function, and natural oestrogen as an oestrogen ingredient does not find any application. As a result, the PPO was right in stating that other pills which contain only estradiol valerate, merely extend the effect of a combination of active contraceptive ingredients. A contraceptive combination imitates the physiological process of the menstrual cycle, which spreads over time the effect of estradiol and diagonest.

[1]" *The sole administration of natural estrogens has currently not found a practical application. Thus H.D. Taubert and H. Kuhl (Kontrazeption mit Hormonen, H.D. Taubert and K. Kuhl, Eds. Georg Theme Verlag, Stuttgart, New York, 1995) fail to suggest the use of natural estradiols as estrogen ingredients in oral contraceptives. While the gestogen ingredients alone provide a reliable contraceptive protection, the proliferation of the endometrium by the natural estrogen is insufficient.*" (page 4 of the patent description of PL 186339 B1)

The argument that the product was subject to an SPC in other countries, such as Germany or the UK remains without merit to this case. The PPO has its own competence to analyze an SPC application based on the applicable provisions of law. However, the requirements on granting an SPC are not clear in some cases, which leaves some room to each competent national authority for interpretation.

The DAC dismissed the procedural argument as without impact on the outcome of the case. In the DAC's view the public authority - the Medicine Evaluation Committee stated in the evaluation report not only that a Dutch marketing authorization was granted on 13 December 2000, but also confirmed on 17 January 2001 that CLIMODIEN may be permanently manufactured. As a result, the DAC considered the Dutch marketing authorization of 2000, instead of the Belgian marketing authorization of 2008, as the first marketing authorization.

The DAC also referred to Art. 3.2 of Regulation 1610/96 which, based on recital 17 to this regulation, may be applied when interpreting Regulation 469/2009 concerning an SPC for medicinal products. The DAC dismissed the argument that the PPO breached Art. 4 of Regulation 469/2009, as an SPC strictly relies on a basic patent and a marketing authorization corresponding to a particular medicinal product. One may not confuse requirements concerning patent grant proceedings and proceedings concerning a grant of a marketing authorization.

It is quite likely that Bayer will appeal against the DAC's ruling to the Polish Supreme Administrative Court, which has already had experience with SPC cases, in particular in the case concerning YENTREVE – duloxetine tablets for intestinal administration (Eli Lilly) (case no. II GSK 52/10).

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