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Switzerland's SPC granting practice drawn into a future mess?

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In the aftermath of the CJEU decisions Eli Lilly/Medeva and Actavis/Georgetown II, the Swiss Federal Institute of Intellectual Property proposes changes in its SPC granting practice.

One hot topic in connection with the granting of SPCs concerns the question on how to define whether a product is protected by a basic patent (Art. 3 (a) SPC Regulation (EC) No. 469/2009). This discussion became particularly relevant with respect to combination products with multiple active ingredients. The national courts in the EU member states basically have applied two different approaches: the so called “infringement test” and the “disclosure test”.

In Switzerland SPCs for combination products have been granted on the basis of the infringement test. This goes back to the “Fosinopril” decision of the Swiss Federal Supreme Court in 1998. In this decision the Federal Supreme Court confirmed that as long as the product, a process for manufacturing it or a use of it, was protected by the patent the certificate would be granted (Art. 140b para. 1a Swiss Federal Patent Act).

As is well known, the CJEU – in its more recent decisions “Eli Lilly” and “Medeva” – rejects the infringement test which has been practiced by the Swiss Federal Institute of Intellectual Property.

According to the CJEU, what has to be examined is whether all the active ingredients in a product are specified in the wording of the claims of the basic patent relied on in support of the application for a SPC (see for example Rik Lamber’s post of 12 December 2013).

Switzerland is not a member of the EU and Swiss courts and authorities are not bound by the CJEU case law. However, the **Swiss Federal Institute of Intellectual Property(FIIP)** notes that the CJEU jurisprudence, which is rejecting the infringement test, has been and will be implemented by the national patent offices of the EU member states. In its view, this trend will lead to a narrower granting practice which cannot be ignored because in the long term Swiss practice should – whenever possible – be compatible with European law. The Institute, therefore, recommends adopting the interpretation test utilized in the CJEU jurisprudence. Accordingly, the FIIP recommends determining whether the product is specified in the wording of the claims of the basic patent from the view of a person skilled in the art.

Another issue which has been addressed by the CJEU in recent case law concerns the question whether Art. 3 (c) SPC Regulation precludes the grant of more than one SPC per patent, even where the patent covers more than one product. In its decisions “Actavis” and “Georgetown II” the court held that the said provision is to be interpreted as – in principle – not precluding the granting

of more than one SPC per basic patent. However, in a case where the invention relates to an innovative substance on the one hand and – on the other hand – to the combination of this substance with other products which are not "protected as such" by the patent an additional SPC cannot be granted. According to the CJEU, the additional substance has to form part of the "core inventive advance" of the invention. In conclusion there can only be one SPC per core incentive advance per patent (again, see for example Rik Lamber's post of 12 December 2013).

The FIIP believes that the CJEU case law in this regard is coherent and aims at limiting an extended SPC protection resulting from the granting of multiple SPCs. The Institute therefore recommends adopting this jurisprudence as well.

The FIIP has contacted the Swiss IP organisations and stake holders and invited them to provide comments on its plans and additional background information **by the end of April 2015**. In particular, the FIIP wants to know in what respect the current Swiss approach differs from the practice in the EU and what the consequences are if the CJEU approach in its case law were adopted in Switzerland. In addition, the FIIP would like to learn how many SPCs would be affected by the possible change of practice.

The rushing ahead of the Swiss Federal Institute of Intellectual Property raises several questions: Unlike in the EU, the FIIP has not been obliged to change its practice by a higher authority. Therefore, even if the FIIP changes its granting practice this does not mean that the Swiss Federal Patent Court will deviate from the Fosinopril ruling of the Swiss Federal Supreme Court as well. It remains unclear whether the Swiss Federal Patent Court, which has nationwide exclusive jurisdiction over all infringement and validity issues with regard to SPCs in civil matters, will follow the FIIP if there is no decision of the Swiss Federal Supreme Court that moves the Swiss SPC practice away from established case law towards the practice in the EU. It remains to be seen whether the Swiss Federal Supreme Court will back the FIIP's change of practice. Finally, it is unclear to what extent the proposed change in the FIIP's granting practice will be able to affect existing SPCs.

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