SPCs not available for animal feed additives

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The fundamental question which types of products are amenable to SPC protection and which types of marketing authorizations allow the filing of SPCs has aroused much controversy in Europe, and reached a climax when the CJEU in its judgment *Boston Scientific* (C-527/17) of 25 October 2018 denied the grant of SPCs on the basis of CE-mark approvals for medical devices, as previously reported on this blog.
The series of disappointments to SPC applicants continues as the German Federal Patent Court in a recent decision denies SPC protection for animal feed additives.

While the SPC Regulation (EC) 469/2009 establishes in Article 2 that SPCs are available for the active ingredients of medicinal products approved in accordance with Directive 2001/82/EC (on veterinary medicinal products) or Directive 2001/83/EC (on human medicinal products), feed additives are explicitly excluded from the scope of Directive 2001/82/EC and are instead approved under Regulation (EC) 1831/2003 (on additives for animal nutrition).

It should therefore not come as a surprise that the German Federal Patent Court in its recently published decision in 14 W (pat) 1/18 of 18 December 2018 – *Futtermitteladditiv* (feed additive) confirmed the rejection of an SPC application (12 2012 000 055.1) filed for the product "6-phytase preparation (EC 3.1.3.26), produced in *Pichia pastoris*" which was approved as an additive in animal nutrition, specifically as a digestibility enhancer, with Commission Implementing Regulation (EU) 98/2012 of 7 February 2012.

The Federal Patent Court found that the 6-phytase preparation at issue had not been approved as an active ingredient of a medicinal product and was therefore not amenable to SPC protection. The Court further held that the scope of the SPC Regulation had been purposively limited to medicinal products and that, in line with the CJEU's findings in *Boston Scientific* (C-527/17), there was no room for an analogous application of the SPC Regulation to other products including feed additives.

It is also noteworthy that the German Federal Patent Court rejected the argument that an analogous application of the SPC Regulation to feed additives should be mandated by Article 27(1) of the TRIPS Agreement, which stipulates that patents shall be available for any inventions in all fields of technology and that patent rights shall be enjoyable without discrimination as to the field of technology, as well as Article 33 TRIPS which prescribes a corresponding minimum term of protection. According to the Federal Patent Court, however, Articles 27(1) and 33 TRIPS refer exclusively to patents and do not extend to SPCs. While the Court provided no further justification for this conclusion, it will be known to readers of this blog that the implications of the TRIPS Agreement for SPCs can inspire intense discussions (see here and here).

It may be added that parallel SPC applications filed for this same animal feed additive in other EU member states have likewise been rejected, including the parallel French SPC (12C0047) which was rejected by the French patent office with decision of 19 November 2014, and the parallel Dutch SPC (300544) which was rejected by the Dutch patent office with decision of 27 March 2014.

The question whether SPCs should be made available for products other than medicinal products and plant protection products is currently not subject of any legislative initiatives, but it may well resurface if and when a fundamental reform of the European SPC system will eventually be tackled, possibly in the context of the future creation of a unitary SPC title based on the (still elusive) unitary European patent.

Dr. Alexa von Uexküll *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the handbook "European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe" published by Wolters Kluwer in November 2018.*