SPCs under friendly fire

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Why would anyone want to have their own supplementary protection certificate (SPC) revoked? – The answer is, quite simply, Article 3(c).
Under Article 3(c) of Regulation (EC) 469/2009 on SPCs for medicinal products (and, likewise, under Article 3(1)(c) of Regulation (EC) 1610/96 on SPCs for plant protection products), an SPC shall be granted only if "the product has not already been the subject of a certificate" in the respective EU member state. In practice, this requirement effectively means that different holders of basic patents can each be granted one SPC for the same product, while the same holder of several patents cannot be granted more than one SPC for the same product. This has become known as the "one SPC per product per patent holder rule".

So, what can patent holders do if they wish to obtain an SPC for an active ingredient X on the basis of their recently issued patent P2 even though they have already obtained a prior SPC for this same active ingredient X on the basis of an earlier granted patent P1? Could the patent holder have its prior SPC revoked with retroactive effect (*ex tunc*) and thereby clear the way for a new SPC filing? Similarly, if the basic patent underlying an SPC is revoked and the SPC is consequently rendered invalid (with retroactive effect), can this give the SPC holder a "second chance" to file a new SPC for the same active ingredient on the basis of a different patent?

In Germany, the case law of the Federal Patent Court suggests that this may indeed be possible. Thus, in the case underlying the Federal Patent Court's decision in 15 W (pat) 51/05 of 2 October 2014 (clothianidin), the SPC applicant had already been granted an earlier SPC for the same product clothianidin on the basis of the same patent but relying on an emergency marketing authorization for this plant protection product. The earlier SPC was revoked in invalidation proceedings about 4.5 years after it entered into force (German Federal Patent Court, decision in 3 Ni 60/06 of 24 June 2014). Following the revocation of the earlier SPC, the Federal Patent Court in 15 W (pat) 51/05 accepted the grant of a new SPC for the same product (clothianidin) to the same rights holder, relying on the same basic patent but a new provisional marketing authorization; the Court explained that the earlier SPC had been revoked with retroactive effect and did therefore no longer preclude the grant of the new SPC. A similar conclusion was also drawn by the Federal Patent Court in an *obiter dictum* in its decision 3 Ni 16/08 of 28 April 2009 (iodosulfuron). While in these decisions the new SPC was based on a different marketing authorization rather than a different basic patent, they nevertheless suggest that the revocation of an SPC with retroactive effect can indeed remove the obstacle that such an SPC poses under Article 3(c) to the grant of a new SPC for the same product to the same rights holder. Moreover, the Federal Patent Court in its decision 15 W (pat) 22/14 of 7 December 2016 (trifloxystrobin) also acknowledged that the revocation of an SPC can be requested by the SPC holder itself, given that Article 15(2) of the SPC Regulation allows "any person" to file an invalidation action or request, which the Court understood to also include the rights holder.

An instructive example of a self-induced SPC revocation, followed by the filing of a new SPC for the same active ingredient on the basis of a different patent (of the same rights holder) has recently been provided by pharmaceutical giant Novartis.

Specifically, Novartis Pharma filed an SPC for the antihypertensive combination of valsartan with amlodipine in a number of European countries in September/October 2007, relying on its European patent EP-B-1 096 932 granted in August 2007 and a centralized EU marketing authorization for the valsartan/amlodipine combination Exforge® (EU/1/06/370/001-024) issued in January 2007. The corresponding SPCs were granted, *inter alia*, in Germany in 2010 (DE122007000055.3), in France in 2008 (FR07C0042), and in the United Kingdom in 2009 (SPC/GB07/056), and were supposed to come into force upon the expiry of the basic patent in July 2019.

It should be noted, however, that Novartis obtained a centralized marketing authorization for the same valsartan/amlodipine combination not only under the proprietary name Exforge® (EU/1/06/370/001-024) but also under the proprietary names Dafiro® (EU/1/06/371/001-024), Copalia® (EU/1/06/372/001-024) and Imprida® (EU/1/06/373/001-024). While the approvals of Exforge® and Imprida® were issued on 17 January 2007 and notified on 19 January 2007, the approvals of Dafiro® and Copalia® had already been issued on 16 January 2007 and had been notified on 18 January 2007 – i.e., one day before the approval of Exforge®. This would obviously seem to affect the validity of the Novartis SPCs relying on the later-notified marketing authorization for Exforge®, given that Article 3(d) of the SPC Regulation requires, simply put, that the marketing authorization underlying an SPC must be the first authorization for that product in the respective EU member state.

The basic European patent underlying Novartis' SPCs for valsartan/amlodipine underwent opposition proceedings and was finally revoked by the EPO with the Technical Board of Appeal decision T 1121/11 of 7 October 2015. In fact, Novartis withdrew all their requests and thereby effectively renounced their patent shortly before the oral proceedings at the appeal stage. It can be safely assumed that this was done for strategic reasons.

Indeed, Novartis had in parallel pursued a divisional application which was granted as EP-B-2 322 174 in September 2015 – i.e., shortly before the self-inflicted revocation of the parent patent EP-B-1 096 932 in October 2015. Novartis proceeded to file new SPCs for the valsartan/amlodipine combination based on the divisional patent EP-B-2 322 174 and – in contrast to their initial SPC filings – relied on the centralized EU marketing authorizations for Dafiro® (EU/1/06/371/001-024) and Copalia® (EU/1/06/372/001-024), rather than the later-notified marketing authorization for Exforge®. So, one may wonder, how have these new SPC applications fared?

In Germany, Novartis filed the corresponding new SPC (DE122016000016.1) in March 2016 and subsequently requested the revocation of their own earlier SPC (DE122007000055.3) in April 2018. The German Patent Office revoked the earlier SPC with decision of 30 May 2018 and, following this, granted the new SPC with decision of 18 July 2018.

In France, the new SPC (FR16C0008) was filed in March 2016 and was initially granted with decision of 20 June 2016. Novartis' competitor Teva, however, appealed the grant of this SPC before the Appeal Court of Paris on 22 July 2016 and pointed to the formally still existing earlier SPC (FR07C0042) held by Novartis for the same combination product. This prompted the French Patent Office to cancel the grant decision on 26 September 2016 (which is possible under French law within four months from issuing the grant decision) and to raise an objection under Article 3(c) of the SPC Regulation in view of Novartis' earlier SPC (FR07C0042). The earlier SPC had to be revoked to overcome this objection: Novartis Pharma SAS (a French subsidiary of Novartis Pharma AG) filed a revocation action against the earlier SPC held by Novartis Pharma AG, which gave rise to a judgment of the High Court of Paris of 5 April 2018 (RG no. 18/02118) revoking this earlier SPC (this judgment was recently reported on the recommendable Patent my French blog). Only then did the French Patent Office grant the new SPC to Novartis Pharma AG with decision of 4 June 2018.

In the United Kingdom, the position of the UK IPO is that an SPC based on a revoked patent is invalid as a matter of fact (with retroactive effect), and that this does not require applying for a declaration of invalidity. Thus, Novartis' new SPC (SPC/GB16/012) filed in March 2016 was granted in October 2016 without further ado.

What these cases illustrate is that the self-initiated revocation of one's own SPC may indeed be advantageous under certain circumstances. This also begs the further question whether an SPC that was granted in violation of Article 3(c) can later be "rescued" if the SPC holder arranges for the revocation of its earlier SPC with retroactive effect. As a note of caution, however, the feasibility of such approaches is certainly not beyond controversy and might eventually be referred to the CJEU.

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