Competition Law Association
British Group of the
Ligue Internationale du Droit de la Concurrence
(International League for Competition Law)

Webinar: SPCs – Where Are We Now?

Date: Friday 16 July 2021

Speakers: Edward Oates, Carpmaels & Ransford
Natalia Wegner-Cribbs, Carpmaels & Ransford

1. INTRODUCTION

1.1. Chris Stothers was chairing the meeting and he introduced the viewers to the talk. He later introduced Edward Oates and Natalia Wegner-Cribbs as speakers.

2. EDWARD OATES – SPC INTRODUCTION

2.1. Edward Oates ("**EO**") started by covering the basics of Supplementary Protection Certificates (SPCs). He covered the requirement for SPCs to be for medicinal products and plant protection products, and he stated that they lie on the interface between regulatory law and intellectual property law. EO went on to describe the different EC regulations that govern SPCs but stressed that much of the law comes from case law.

2.2. EO then described the test for obtaining an SPC. The purposes of an SPC include: to provide compensation to companies that would lose patent time waiting for regulatory approval. An SPC can add an extra five years onto the patent, with the possibility of extending another 6 months. EO also talked about there being no centralised EU procedure for SPCs, so there can be a huge difference when applying for an SPC in different countries. He also briefly mentioned C-181/95 *Biogen* which shows that the patent holder does not have to be the same entity as the marketing authorisation holder, which has subsequently led to "SPC squatting".

3. EDWARD OATES – ARTICLES

3.1. EO gave a brief introduction into Article 1 and Article 3 of the SPC Regulation (EC) No 469/2009. Article 1 concerned the definitions of "medicinal product", "product" and "basic patent", which have been subject to recent case law. Article 3 set out the four criteria that need to be met to obtain an SPC. Case law has played a big role in the interpretation of this Article, and this has actually changed the law beyond what many may have originally thought based on the Article itself.

4. NATALIA WEGNER-CRIBBS – CASES AFFECTING ARTICLE 3(a)

4.1. Natalia Wegner-Cribbs ("**NWC**") began by looking at recent cases that have affected Article 3(a) SPC Regulation. She focussed mainly on the C-650/17 *Royalty Pharma* case. This gave further information about what is meant by a "product is protected by a basic patent". The question posed was whether a product could be protected if it only falls within the scope of a patent, rather than being specified or identified. In this case, sitagliptin was not identified in a patent but it did belong to the group of DP IV inhibitors which were mentioned in the patent claims. The CJEU decided that a product falling within the scope of a "general function definition" was protected by that patent. However, a skilled person must be able to identify the product in light of information in the patent, general knowledge, and prior art.

4.2. NWC described a further point that the CJEU needed to decide in *Royalty Pharma*. The CJEU stated that a product which was developed after the filing date of the patent, following an "independent inventive step", and which is not specified in the patent, cannot be protected under a general function definition. Royalty Pharma argued against this in the German national courts stating that the inventive step was dependent on previous work. However, the German courts rejected this as they interpreted "independent" as coming from another party. NWC also briefly covered the other cases in this area, including *Ono Pharmaceuticals* in France (18/10540 and 18/10522).

5. NATALIA WEGNER-CRIBBS – CASES AFFECTING ARTICLE 3(d)

5.1. NWC also spoke about *Santen* C-673/18 which has had a big impact on Article 3(d) SPC Regulation. This gave further information about the first market authorisation of a product. Originally, the case C-130/11 *Neurim* stated that earlier market authorisation of a product did not preclude the granting of an SPC for a different application of the same product. This applied only if the application was within limits of the protection of the patent. Despite this, NWC stated that *Santen* essentially reversed the decision in *Neurim* for most circumstances.

6. EDWARD OATES – OPEN ISSUES

6.1. EO went on to describe further issues that are still open to discussion in this area. This included a question about what is meant by an active ingredient of a medicinal product, as described by Article 1(b). EO described further developments of Article 3(a) following the Royalty Pharma case. There are also potential developments for Article 3(b) in relation to SPC squatting, and for Article 3(c) in relation to ownership of a patent and what happens if ownership is assigned to a different entity.

6.2. EO then explained the difficulty of the uncertainty described above, when considering competition law. He stressed that while companies and law firms are trying their best to comply with the regulations, the uncertainty of them can cause difficulty in assessing whether a company is in breach of competition law.

6.3. Finally, EO looked at the impact that Brexit has had on SPCs. The UK now has similar, but not identical, law to the EU SPC Regulation. As a result, you can now have different market authorisations that cover: Northern Ireland; Great Britain; Northern Ireland and Great Britain. There is now an asymmetry between the EU and UK regarding the manufacturing for export waivers. EO also mentioned that Unitary SPC regulations may be more likely now that the Unitary Patent Court appears to be back on track.