UK IPO CONTINUES STRICT APPROACH TO MARKETING AUTHORISATIONS FOR SPC PURPOSES IN *ERBER AKTIEN-GESELLSCHAFT*

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There has been a recent run of case law, in particular before the CJEU, applying a restrictive approach to Supplementary Protection Certificates (SPCs). The case law has progressively excluded a number of technology areas from being able to benefit from these extensions. First it was medical devices (*Boston Scientific*), then it was new formulations of existing products (*Abraxis*) and then it was new therapeutic uses of existing products (*Santen*); all were found ineligible for an SPC. The latter in particular reversed the seminal decision in *Neurim*, which in 2012 arguably opened the door to many, if not all of the above possibilities, but which now appears firmly closed.

It was therefore interesting to see a new case at the UK Intellectual Property Office (UK IPO), *Erber Aktiengesellschaft*,[1] attempting to fight this restrictive trend in yet another field of technology, this time animal feed additives. The SPC application in question was made back in 2017 when these sorts of possibilities remained ripe for questioning. However, in the current environment, it may not now be surprising that the outcome has been unsuccessful. In December 2020, the UK IPO Hearing Officer issued a decision refusing the application on the ground that the marketing authorisation for an animal feed additive did not meet the requirements for SPC purposes, continuing the restrictive trend initially set out in relation to marketing authorisations for medical devices, which were refused under the same ground in earlier decisions of the UK IPO and confirmed by the CJEU. Pending appeal, this may be the end of another road for SPCs, at least in the United Kingdom. However, it is interesting to note that there is another parallel pending application, not for an SPC but for a plant protection certificate for the same product. While the laws are largely aligned (and in some areas overlap), we will need to wait to see if that application could survive where the present SPC application has not.

Legal Background

The intention behind the SPC system is to compensate for the regulatory delay needed to bring medicinal products to market, so that there is sufficient incentive to perform costly research in developing new medicines. As such, one of the requirements to be granted an SPC is that '*a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC*'.[2] Directive 2001/83/EC sets out the regulatory requirements for medicinal products for human use, whereas Directive 2001/82/EC concerns medicinal products for veterinary use.

1) BL O/610/20.

2) SPC Regulation Article 3(b) S; reflected also in Article 2.

In previous decisions related to medical devices (*Leibniz-Institut*, *Cerus Corporation*, and *Angiotech Pharmaceuticals Inc* of the UK IPO, and *Boston Scientific* of the CJEU), authorisations for medical devices under Directives 93/42/EEC, 90/385/EEC and 98/79/EC (now under transitional provisions of Regulations 2017/745 and 2017/746) have been found *not* to meet the requirements for an SPC, because the medical device regulatory regime was not considered equivalent to that of medicinal products for human or veterinary use.

The CJEU took a very hard line, focusing on the '*actual wording*' of the SPC Regulation, finding that '*a product may be the subject of an SPC only if it has been subject, as a medicinal product, to an MA procedure as laid down in Directive 2001/83* [or 2001/82/EC]'. Yet what was interesting about the decisions from the UK IPO, is that it did seem at least willing to consider, on a teleological view, that a marketing authorisation not formally under Directives 2001/83/EC or 2001/82/EC *might* potentially meet the requirements for an SPC, if found equivalent to these Directives. In the case of medical devices, the answer seems firmly 'no', but it did arguably leave open the question for other technology areas with their own marketing authorisation regime. This distinction between the CJEU and UK IPO approach may be relevant in light of Brexit, where the UK IPO will not be bound by future decisions of the CJEU.

Food for Thought: SPCs for Animal Feed Additives?

Erber Aktiengesellschaft's SPC application was directed to the product '*microorganism DSM 11798 of the Coriobacteriaceae family*', which was used as an animal feedstuff additive to destroy trichothecenes (a mycotoxin) that are produced by mould fungi. Animals exposed to trichothecenes can suffer from inhibited productivity and growth. The microorganism was authorised for the European market according to Implementing Regulations of Regulation EC No. 1831/2003 ('the Animal Nutrition Additives Regulation').

The examiner objected to the SPC application on the ground that a marketing authorisation under the Animal Nutrition Additives Regulation was not a valid authorisation to place the product on the market as a medicinal product granted in accordance with Directive 2001/82/EC ('the Veterinary Medicinal Products Directive'), as required under Articles 2 and 3(b) of the SPC Regulation. Moreover, even if the marketing authorisation under the Animal Nutrition Additives Regulation could be considered, the SPC application had not been filed within six months of the date of the earliest authorisation, as required by Article 7 of the SPC Regulation. Furthermore, during the course of proceedings the *Santen* judgment of the CJEU was issued, and the applicant invited to give its views on the relevance of this decision as to whether the authorisation was the first authorisation to place the product on the market as a medicinal product, as required by Article 3(d) of the SPC Regulation.

The applicant clearly had its work cut out, but ultimately the case hinged on whether the authorisation under the Animal Nutrition Additives Regulation was a valid authorisation for SPC purposes, with the UK IPO concluding that it was not. The remaining objections were then not relevant.

Comparing the Veterinary Medicinal Products Directive and Animal Nutrition Additives Regulation

While it is clear that a marketing authorisation under the Animal Nutrition Additives Regulation is not formally one under the Veterinary Medicinal Products Directive, the case considered if these authorisation regimes are sufficiently equivalent that a product authorised under the Animal Nutrition Additives Regulation could still be granted an SPC.

According to the Veterinary Medicinal Products Directive, a veterinary medicinal product is '*any substance or combination of substances presented as having properties for treating or preventing disease in animals*', where a substance includes '*medicated feeding stuffs*'. However, the Directive specifically excludes '*any additives covered by Council Directive 70/524/EEC … concerning additives in feeding stuffs where they are incorporated in animal feeding stuffs and supplementary animal feeding stuffs in accordance with that Directive*'.

According to the Animal Nutrition Additives Regulation, feed additives are '*substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to … favourably affect the characteristics of feed … [or] favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs*'. However, the Regulation excludes '*veterinary medicinal products as defined in Directive 2001/82/EC*'.

Thus, while the scopes of the Veterinary Medicinal Products Directive and Animal Nutrition Additives Regulation appear similar in some respects, they are explicitly defined to be mutually exclusive.

Where the Veterinary Medicinal Products Directive applies, a marketing authorisation is required before a person can place the veterinary medicinal product on the market. Applications are assessed by the European Medicines Agency (EMA), with particular importance put on the results of tests done on the veterinary medicinal product, such as pharmaceutical tests, safety tests, residue tests, pre-clinical and clinical trials and tests assessing the potential risks posed by the medicinal product for the environment. The purpose of this assessment is to provide a risk-benefit profile for the use of the medicinal product in animals to achieve a clinical outcome, namely the cure or prevention of disease.

Where the Animal Nutrition Additives Regulation applies, a marketing authorisation is also required before a person can place the product on the market. The feed additive must satisfy the requirements of the Regulation, including that it '*favourably affect[s] the characteristics of feed … [or] favourably affect[s] animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs*' amongst other benefits, but that it does not '*have an adverse effect on animal health, human health or the environment*'. Applications for authorisation are assessed by the European Food Safety Authority (EFSA) to determine the '*benefits for animal health and welfare and for the consumer of animal products*'.

Thus, while the assessment procedures of the Veterinary Medicinal Products Directive and Animal Nutrition Additives Regulation are somewhat similar, there appeared to be differences, in at least their intended purpose.

No SPCs for Animal Nutrition Additives

Considering the purpose and objectives of the SPC Regulation, the UK IPO Hearing Officer concluded that the system for granting approvals for animal feed additives is not comparable to the system for granting authorisation for veterinary medicinal products.

In particular, the Hearing Officer noted different overall objectives in the two regulatory systems. On the one hand, the Animal Nutrition Additives Regulation is about ensuring that the additives have a beneficial effect on food and do not have an adverse impact downstream on the animals that eat the feed or animals (including humans) that eat the animals that eat the feed. On the other hand, the Veterinary Medicinal Products Directive is about ensuring the effective cure and prevention of disease or diagnosis in animals. While potentially related, the purposes of these systems are different such that they cannot be considered equivalent. There was, in the Hearing Officer's view, an important issue of degree in the level of testing that has to be carried out to establish clinical benefit for a veterinary medicinal product, that was considered to be of a greater and more significant degree than testing needed to establish safe use of a feed additive.

For the microorganism of the SPC application, safety and efficacy tests were summarised in two scientific opinions by the EFSA. Both opinions related to the safety and efficacy of the microorganism when used as a feed additive for pigs and chickens. It was therefore clear that the opinions were given in the context of approving a feed additive and the standards for compliance were set in that same context. The Hearing Officer could not ignore the context in which the marketing authorisation for the microorganism of the SPC application had been made. While the efficacy of the microorganism had been assessed and had been shown effective in detoxifying mycotoxins in animals, it had not in the Hearing Officer's opinion been tested for its effectiveness in treating or preventing disease in animals, or in restoring, correcting or modifying physiological functions in sick animals. Thus, the authorisation of the microorganism under the Animal Nutrition Additives Regulation was not considered equivalent to an authorisation under the Veterinary Medicinal Products Directive, such that the requirements for an SPC were not met.

As a consequence, it was not necessary for the Hearing Officer to give a decision on the timing of filing the SPC application in relation to the marketing authorisation, or what constituted the first marketing authorisation, because there was no relevant marketing authorisation for SPC purposes.

Conclusion

The SPC application was refused, which is perhaps unsurprising given the number of other negative decisions following a similar argument in the context of medical devices. Indeed, it is interesting to note that when comparing *Erber Aktiengesellschaft* against the earlier decision for drug-device combination products in *Boston Scientific*, the Hearing Officer stated '*even if a substance has undergone a highly similar authorisation process – which [in Boston Scientific] is even more closely matched that the two we are looking at in the present case – it would still not fulfil the conditions of Article 2 of the SPC Regulation*'. In *Boston Scientific*, the regulatory regime for drug-device combination products explicitly required that the quality, safety and usefulness of the drug substance had to be verified by analogy with the methods for a medicinal product, and yet the authorisation for the drug-device combination product was still not enough to justify an SPC. It is therefore hard to imagine a scenario where products authorised as anything other than a strict medicinal product or veterinary product could be granted an SPC.

The decision in *Erber Aktiengesellschaft* could be appealed to the UK Patents Court (albeit there is no sign of this yet and the deadline fell in January 2021). Given that the hearing took place in June 2019, during the Brexit transition period, it would have been open for the applicant (or UK IPO) to make a case for a referral to the CJEU. However, there is no sign in the decision that this was argued or considered. If the UK case does continue on appeal, following 1 January 2021, there is now no chance of a CJEU referral from this case. Moreover, given that the United Kingdom is no longer bound by CJEU decisions, there is potential for divergence moving forward. Either the United Kingdom could seek to introduce additional protection for non-medicinal products by means of new legislation, or an EU Member State could refer a question to the CJEU seeking additional clarity on SPC protection for such products. While this may be unlikely in the short term, it does illustrate how the United Kingdom could depart from the rest of Europe and the CJEU, if one were to be more restrictive and the other more relaxed.

Finally, it should be noted that a second UK application for Erber Aktiengesellschaft is still pending for the same product, but authorised under the Plant Protection Product Regulation. In this respect, there is an interesting reference in the decision to a decision from the first instance court in Hungary, which is said to have concluded that an SPC could be granted for the active substance in a plant protection product even though there was an earlier SPC for the same active substance in a veterinary medicinal product. While the present decision makes it unlikely that such overlap will need to be considered in the United Kingdom, it suggests that further applications and/or disputes may arise in this field. Thus, there may be more developments to come on whether there is equivalence between animal nutrition additives and plant protection products in terms of the relevant authorisation.