EIP

High Court maintains status quo on SPCs: Combination patent cannot get extension using Marketing Authorisation of single active agent

Introduction

Newron Pharmaceuticals SPA (patentee) appealed a decision of the Comptroller General of Patents to refuse its Supplementary Protection Certificate (SPC) application on the ground that it did not meet the requirements of Article 3(b) of the SPC Regulation. The High Court dismissed the Appeal in a decision issued on 16 June 2003 ([2023] EWHC 1471).

Claim 1 of the patent in question relates to a combination of three active ingredients - safinamide, levidopa and Peripheral Decarboxylase Inhibitor (PDI) for use in treating Parkinson's disease. This combination represented "the product" protected by the patent and the SPC application was directed to this product. The Comptroller had held that the Marketing Authorisation (MA) was not an authorisation for this combination but for one or, at most, two of the active ingredients. The Court agreed.

Court's consideration of SPC Regulation and previous case law

The Court noted that the SPC Regulation aims to strike a balance between various interests at stake in the pharma sector and one way of doing that is by strictly confining protection to the product which obtained authorisation to be placed on the market as a medicinal product

. Article 1(b) of the SPC Regulation defines product as the active ingredient or combination of active ingredients of a medicinal product that has obtained MA and Article 3(b) requires a valid authorisation to place the product on the market as a medicinal product to have been granted for a SPC to be granted.

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The court cited and agreed with Arnold J comment in the previous decision in Abraxis that the SPC Regulation is a balance of competing interests and this means that some meritorious inventions do not qualify for extended protection. The correct approach, according to the Court, is to consider whether the requirements of the SPC Regulation are satisfied noting that these requirements go beyond the mere prevention of what the Appellant referred to as "evergreening".

A 2010 decision on Article 3(b) in Yeda Research & Development Company was considered the most relevant UK authority. In that case, a patent for a combination for Erbitux and another active ingredient could not be extended using a MA for Erbitux alone. The Court also confirmed that it was bound by decisions of the CJEU relating to SPCs (the SPC application in question was filed while UK was part of the EU) and referred to the CJEU decisions in Pharmacia Italia, MIT and Santen. The Pharmacia Italia decision held that what was important for the purposes of Article 3(b) was the product itself and not how it had been or was intended to be used and the MIT decision established that the definition of "product" does not include an excipient which did not have a therapeutic effect of its own even if it improved the performance of the active ingredient. Finally, the Santen decision emphasized that not all pharmaceutical research leading to patents will gain an SPC and the need for simplicity and predictability in the SPC system. Santen overruled the previous Neurim decision and held that a new therapeutic use for a previously authorised active ingredient did not confer on it the status of a distinct product for the purposes of the SPC Regulation.

Decision

Based on its consideration of the facts and case law discussed above, the Court held that the MA is specific to safinamide alone and not to a combination.

There was no mention of a combination of safinamide with anything in Article 1 of the MA and the Court made a passing comment that there is much to be said for the view that the product which is authorised by the MA is the product specifically identified in said Article 1. However, the Court went on to consider the remaining sections of the MA and noted one reference to "add-on therapy" and other references to levodopa. The Comptroller's essential conclusion was that the references to use of a PDI were too few, too deeply buried in the MA, and too equivocal to permit a conclusion that the MA was for safinamide in combination with both levodopa and a PDI. The Court found that existence

of such references, once found, does not mean that "the product" of the MA is the combination of safinamide with both levodopa and a PDI. It merely means that one possible use of safinamide is as part of such a combination.

The Court agreed with the Comptroller's analysis of the MA pointing one way: the product is safinamide, not a combination of safinamide with anything.

The Appellant argued that because safinamide is an add-on therapy, it would "always" be used in combination with levodopa/PDI. The Court considered this to be a way of seeking to import the therapeutic use into the definition of the product which was contrary to the case law analysed above, including in particular Pharmacia, MIT, Santen, and Yeda.

Conclusion

The decision by the High Court in this case is in line with the CJEU case law and this is not surprising given the SPC application was filed prior to UK's exit from the European Union so that case law is binding. There has been some speculation as to whether the Courts in England & Wales would diverge from CJEU case law for more recent SPC applications where CJEU case law is not binding. The reasoning and comments from the Court here provide no indication that this will be the case as the Court took great pain to highlight that the SPC Regulation is a) a balance of competing interests which means that protection granted should be strictly confined to the product which obtained authorisation, b) its requirements go beyond the mere prevention of evergreening and c) some meritorious inventions do not qualify for extended protection. It will be interesting to see if future decisions diverge from CJEU case law.