DOI：10.6521/NTUTJIPLM.2015.4(2).6

SUPPLEMENTARY PROTECTION CERTIFICATE (SPC) FOR COMBINATION PRODUCTS: "PROTECTION OF INCREMENTAL INVENTIONS" IN PHARMACEUTICAL FIELD AFTER COURT OF JUSTICE OF EUROPEAN UNION (CJEU) RULING IN ACTAVIS CASE

Name of relevant case:

Actavis Group PTC EHF, Actavis UK Ltd V Boehringer Ingelheim Pharma Gmbh & Co. Kg, (C-577/13)

Single Sentence Summary:

In Actavis case, CJEU held that multiple Supplementary Protection Certificates (SPCs) are not possible relying on single basic patent wherein Article 3 (a) and (c) provisions are not met. But this ruling posed difficulties to Innovators as to how to protect the incremental inventions or add-on inventions.

Legal Context:

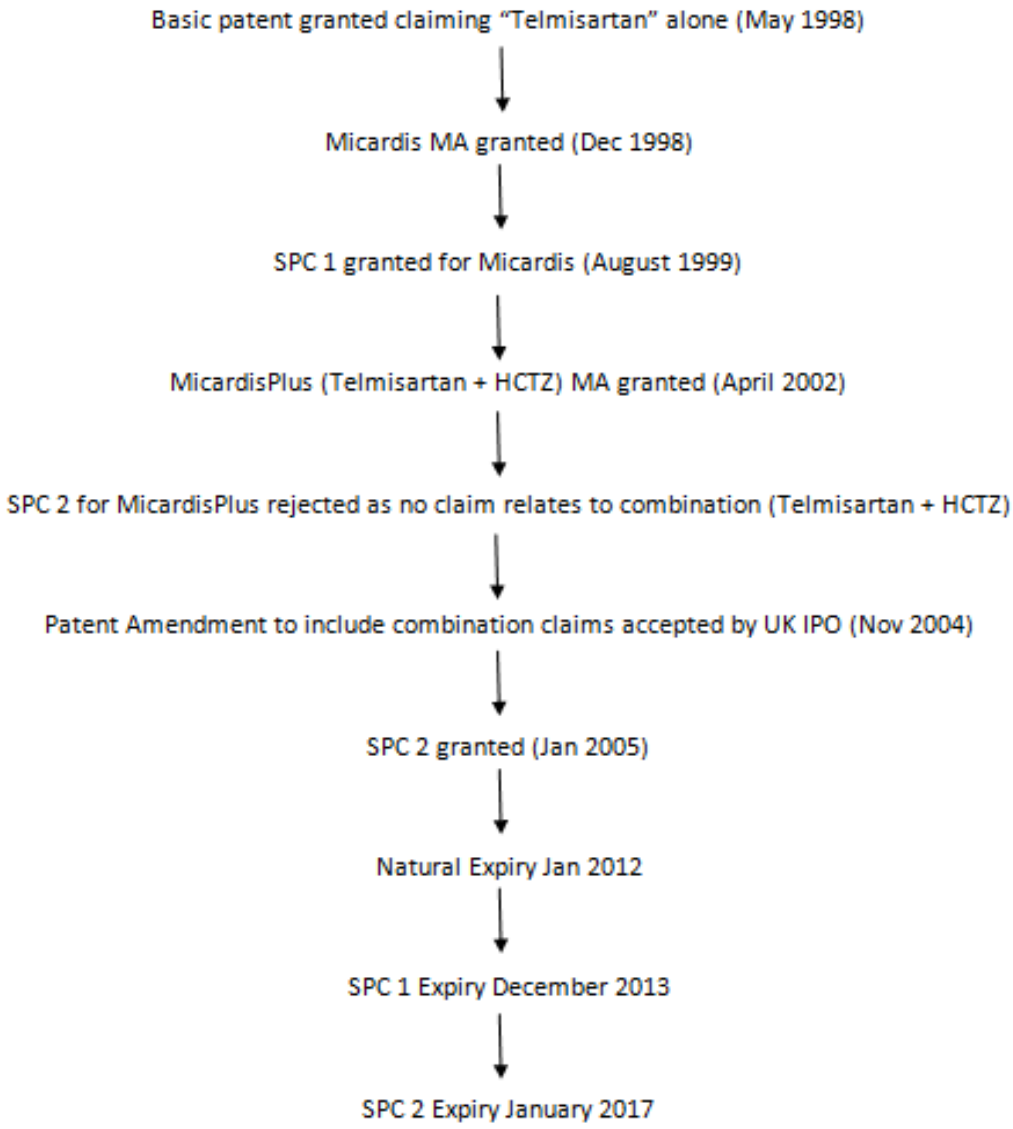
The Actavis case focused on the meaning of Article 3 (a) and (c) of Regulation (EC) No 469/2009 of European Parliament and of the Council of 6 May 2009 concerning the SPC for medicinal products.

Facts:

The case involved basic patent claiming "Telmisartan" as an active ingredient. The claims of patent are directed to Telmisartan alone and salt form thereof. Boehringer was granted two marketing authorizations (MAs) for Telmisartan (Miacardis®) and Telmisartan in combination with hydrochlorthiazide (HCTZ) (MicardisPlus®). Two separate SPCs were granted for the same patent in respect of both the authorization by national office.

Actavis challenged the SPC granted for combination product MicardisPlus in High Court of Justice (England and Wales), Chancery Division (Patent Court). The High Court decided to refer four questions to CJEU for preliminary ruling.

Table 1: Chronology of Telmisartan and Telmisartan/Hydrochlorthiazide



SPCs

*MA – Marketing Authorization

The CJEU only answered the question relating to Article 3(a) and (c) of Regulation (EC) No 469/2009 as follows:

"Article 3(a) and (c) must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that

patent has already obtained a supplementary protection certificate, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second supplementary protection certificate for that combination."

Analysis:

The Actavis case poses important questions to Innovator Pharmaceutical Industry and one of it is:

"How to protect the combination products (A+B) which are researched after the SPC granted to the single active ingredient (A) to basic patent which has claims for both A as well as A+B ?"

These rulings before Actavis case also had similar scenarios where CJEU decided to invalidate SPC for combination products for almost similar reason.

This case also raises question on "How patent amendment may be used after grant to include the inventions which are not initially covered by claims of basic patent?" Since CJEU decided not to answer these questions, the authors have attempted to analyze the situation and give some recommendations.

"Basic patent in force" –

In Actavis case, the basic patent which was originally granted did not contain claim directed to combination product of Telmisartan and HCTZ. It was in April 2002, which was almost four years from the grant of basic patent, when Boehringer received the MA for combination product. SPC application for this incremental invention was made then.

United Kingdom Intellectual Property Office (UK IPO) objected the application on the basis that patent fails to claim as such combination product. Hence, Boehringer suspended the SPC application and applied to UK IPO to amend its basic patent to include new claim for combination of Telmisartan and HCTZ combination.

UK IPO granted amendment in basic patent. After insertion of new claim for combination, Boehringer requested UK IPO to recommence the grant of SPC application for combination on the basis of amended patent. Finally, SPC application was granted for combination on the basis of amendment.

Actavis raised precisely that question about whether such amended patent can be qualified as "basic patent in force" pursuant to Article 3(a) of Regulation No 469/2009/EC.

This indeed is vital question for Innovator pharmaceutical companies who always make attempts to extend the product life cycle by researching add-on inventions or incremental inventions which are better in performance compared to previous products. If such incremental inventions would be denied from protection, then it will discourage them from research. In Telmisartan case,

Boehringer failed to include combination claim for Telmisartan and HCTZ in original patent and hence, they lost monopoly over combination product.

The authors recommend that patent should be drafted with care to include the claims which will cover all possible products which may be researched in future as incremental inventions.

"Patent amendment after grant of SPC" –

In Actavis case, another issue was the grant of SPC application for amended patent which was initially suspended by UK IPO on the basis that the patent fails to claim the combination product.

SPC regulation (169/2009) does not provide any clear indication about power of competent industrial property office to allow suspension of SPC application in order to allow amendment to basic patent. Further, the regulation is not clear about recommencement of SPC application on the basis of amended patent.

The authors believe that this question requires interpretation of SPC regulation by CJEU to confer the role of competent industrial property offices like UK IPO in allowing suspension of SPC application for patent amendments to the granted patents. In addition, CJEU should clear the air revolving around revival of suspended SPC application based in amended patent.

Innovator companies need answers from CJEU in future about this question because an issue arises frequently.

"Six Months deadline to file SPC application from date of valid MA" -

In Actavis, another issue was the timeline to file SPC application. Article 7(1) of SPC regulation (No 469/2009) requires that the application should be made within six months of the date on which valid MA to place that product on the market as a medicinal product has been granted. In Actavis case, although original application for combination SPC was made within six months from the date of MA for combination product, the SPC application was objected by UK IPO. Finally, SPC application was suspended until patent amendment decision was pending with UK IPO.

After amended patent was granted, SPC application was revived. By that time, the six months window to file SPC application was expired, and till the application was granted.

The authors believe that CJEU should have answered whether such practice by competent Industrial property office, in this case, UK IPO is acceptable as per SPC regulation.

Had CJEU answered this question, it would have clarified the Article 3 provision in better way for both Generics & Innovators.

Practical Significance:

Although, Actavis case clarified Article 3 (a) and (c) of Regulation (EC) 469/2009, authors believe that CJEU should have answered the Questions relating to patent amendments after grant of patent to cover incremental inventions like in this case. Further, the questions relating to grant of SPC for amended patent would have been helpful for innovator companies to formulate effective strategy to protect such type of inventions.

The caselaw around combination products continues to be evolving. Authors are optimistic that more questions will be referred to CJEU about issues involving patent amendments and SPC for combination products. The more clarity by CJEU will help Innovator companies to craft their strategies well in advance right from the drafting basic patent which effectively will cover all possible combination products.

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