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ADVISORY

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# UPDATE ON THE UK VIEW ON SPC TERM EXTENSIONS FOLLOWING COMPLIANCE WITH A PAEDIATRIC INVESTIGATION PLAN

## BACKGROUND

Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, now consolidated into Regulation EC/469/2009 (the SPC Regulation), allows for patent term extensions of up to five years, if certain conditions are met.

In addition to this, Regulation EC/1901/2006 on medicinal products for paediatric use (the Paediatric Regulation) creates a reward of an additional six-month term on supplementary protection certificates (SPCs) if certain conditions relating to an agreed Paediatric Investigation Plan (PIP) are met.

Whilst the legislation is European and is implemented directly into Member States' national laws, SPCs are national rights, operated by national intellectual property offices (IPOs) and are granted following an application made to the particular IPO.

Both the SPC and Paediatric Regulation contain within them certain ambiguities and these have resulted in inconsistent interpretations and case law across Europe. The most recent example of such a case in the English Courts is the judgment of the Court of Appeal, made public on 6 October 2009, in *E I Du Pont Nemours & Co* v. *UKIPO* [2009] EWCA Civ 966. The Court of Appeal (in particular Lord Justice Jacob) has provided some detailed guidance to the UK IPO about how certain of the ambiguities should be resolved.

## *E I DU PONT NEMOURS & CO* v. *UKIPO*

This decision follows an initial decision of the UKIPO and an appeal to the High Court in which the requested six-month extension to the Losartan SPC was refused on the grounds that certain of the provisions of the SPC Regulation and the Paediatric Regulation had not been complied with.

The result of Lord Justice Jacob's detailed judgment is that the Losartan SPC extension can now be granted in the UK. This will bring the UK position into line with that in the Netherlands and also the majority of countries in Europe where Du Pont hold an SPC and where they had applied for the extension (13 in total, although we understand the decision is still pending in some countries). However, as Jacob LJ points out, the reasons for grant seem to differ from country to country.

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Three main issues were addressed in the judgment:

## 1. REQUIREMENT FOR THE EXTENSION APPLICATION—ARTICLE 8(1)(d)(i) OF THE SPC REGULATION

*Must the application for an extension include a marketing authorisation (MA) containing a statement of compliance with the PIP, pursuant to Article 28(3) of the Paediatric Regulation?*

At the application date for the UK SPC the MA containing the Article 28(3) statement of compliance was not available. However, an email did exist from the Dutch authorities (the Reference Member State) confirming compliance with the PIP.

Relying on the wording of Article 36(2) of the Paediatric Regulation that such a statement "shall be used," and also relying on the uncertainty that would exist if patent authorities were expected to review such emails indicating compliance with PIPs (rather than being presented with the MA containing the appropriate wording), Jacob LJ found that it is necessary for an application for an SPC extension to contain an MA which has the PIP compliance wording contained within it. Detail of the particular areas of the Paediatric Regulation and its Recitals that were relied upon to draw this conclusion are set out in some detail in the judgment.

Whilst this aspect of the decision means that the English Court's interpretation of this particular provision appears to be strict, it should be set against the somewhat more lenient approach which has been taken in relation to requirements which are necessary *at the time* that the initial application is made and those that can be completed prior to grant of the extension. In relation to the latter, the timing for providing the relevant deliverables appears to be at the discretion of the UK IPO.

## 2. REQUIREMENT FOR THE EXTENSION APPLICATION—ARTICLE 8(1)(d)(ii) OF THE SPC REGULATION

*What is meant by the requirement of Article 8(1)(d)(ii) of the SPC Regulation which relates to the existence of "authorisations to place the product on the Market of all other Member States?"*

This also relates to Article 36(3) of the Paediatric Regulation, which states that the reward for an extension *"shall be granted only if the product is authorised in all Member States."*

At the application date for the SPC in the UK, certain Member States had not yet granted marketing authorisations containing a statement confirming compliance with the PIP. MAs do now exist in all Member States. However, at the time of the original application, Du Pont argued that its central authorisation for products containing the same active ingredient as the formulation which was subject to the PIP was enough to comply with the requirements of Article 8(1)(d)(ii). This argument was based on the narrow definition of "product" within the SPC Regulation which relates only to a product with a particular "active ingredient" or "combination of active ingredients."

This argument was rejected by Jacob LJ as he considered that supporting such a narrow definition would undermine the purpose of the Paediatric Regulation. He stated that applicants "would not get [a] reward unless product carrying the information generated by carrying out the agreed PIP are authorised EU wide." In other words, the ambiguity of the Paediatric Regulation is best resolved, in Jacob's eyes at least, by relying on the purpose of the Regulation, rather than the definition of "product" in the closely linked SPC Regulation.

Again, the implication of this seemingly tough interpretation of the Regulation is somewhat softened by the approach which Jacob LJ has taken to the issue of irregularities at the time of the application for the SPC extension.

## 3. CURING DEFICIENCIES IN THE APPLICATION—ARTICLE 10(3) OF THE SPC REGULATION

*To what extent can the UK IPO exercise discretion in setting time limits for correction of an application containing "irregularities?"*

Article 10(3) of the SPC Regulation sets out a procedure whereby the relevant IPO may provide details of irregularities within an application to the applicant and provide a time limit for compliance. In this case, the

irregularities discussed above existed at the date of the application but were subsequently rectified such that, prior to the expiry of the original SPC, the conditions for the granting of an SPC extension were met.

The question which arose was whether irregularities at the time of the application constitute a fundamental failing of the application as a whole, or the IPO could take into account the various circumstances surrounding the irregularities in setting a time limit for compliance. Jacob LJ held that the answer to this later question is "yes" stating that the IPO should use discretion and knowledge of the surrounding circumstances to set the time limit for compliance with all the requirements of Article 8. Jacob LJ suggests that, provided the applicant has not behaved unreasonably, time should be extended for as long as necessary for the paperwork to be completed.

On this point Jacob again considered the underlying objective of the Paediatric Regulation and concluded that: "[the Recitals and Explanatory Memorandum] are all about the reward of an extension being made available if the applicant complies with its PIP and gets the necessary MAs. The reward is not for doing all of that before the application is made."

## CONCLUSION

This decision does seem to have brought some clarity to the way in which the issues relating to the availability of the six-month SPC reward under the Paediatric Regulation may be dealt with by the UK IPO. For Du Pont, it also seems to have brought the grant of the extension into line with other countries in Europe, all before the underlying SPC lapses. A lapse of the SPC in the UK would, of course, have allowed generic entry in the UK six months ahead of the other 12 countries in Europe, where Du Pont seems to have been treated as entitled to this reward.

*We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:*

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