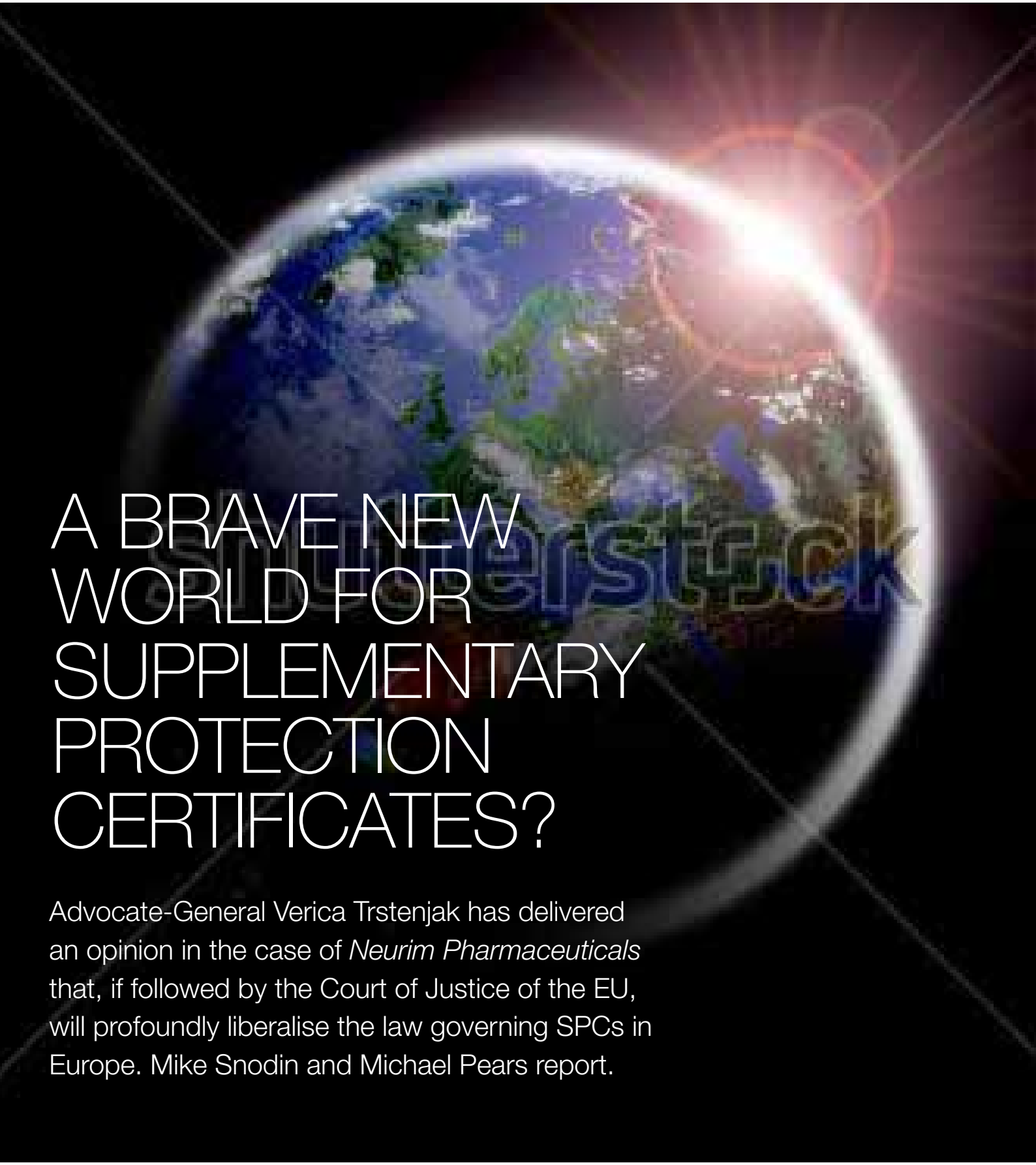

A BRAVE NEW WORLD FOR SUPPLEMENTARY PROTECTION CERTIFICATES?

Advocate-General Verica Trstenjak has delivered an opinion in the case of *Neurim Pharmaceuticals* that, if followed by the Court of Justice of the EU, will profoundly liberalise the law governing SPCs in Europe. Mike Snodin and Michael Pears report.

Supplementary protection certificates (SPCs) are a unique form of intellectual property that came into existence in Europe in 1993. They provide an extended period of monopoly to patent holders who experience substantially reduced effective patent terms due to the need to obtain regulatory approval prior to selling their patented medicinal or plant protection products.

SPCs sit at the interface between the patent and regulatory systems. That is, entitlement to SPC protection depends upon obtaining both a patent and a marketing authorisation for a regulated product. However, in order to provide a balanced system, the legislators stated their intention that SPC protection should be available only for new regulated products, with minor changes to those products (such as the use of a different salt, ester or pharmaceutical form) being barred from giving rise to additional SPCs.

For many years, the SPC legislation has been interpreted strictly with regard to the availability of protection for a specific 'product' (active ingredient or combination of active ingredients). This has resulted in the term of combined patent and SPC protection being capped to a maximum of 15 years (or 15½ years in some cases) from the date of the first authorisation in the European Economic Area for a medicinal product comprising the active ingredient(s) in question.

This strict interpretation of the legislation has led to some harsh results, with important medical innovations involving previously authorised active ingredients often being denied SPC protection. This is despite the fact that, in many instances, those innovations have been delayed in reaching the market for many years because of the regulatory burden imposed upon them. The companies sponsoring the clinical trials for these medical innovations have been particularly affected by the unfairness of this situation when they have not been the ones to have benefited from prior sales of medicinal products comprising the active ingredient(s) in question.

However, a non-binding opinion provided on May 3, 2012, by Advocate-General Verica Trstenjak in the case of *Neurim Pharmaceuticals* (case C-130/11) means that this situation could soon change, and that SPC protection could become much more widely available for medicinal products that contain previously authorised active ingredients.

Background

Case C-130/11 stems from a reference from the UK Court of Appeal, which had sympathy with the arguments presented by Neurim in its appeal against the refusal of the UK Intellectual Property Office (and the High Court) to grant an SPC for the 'product' melatonin.

The arguments from Neurim essentially related to the regulatory burden it had experienced prior to marketing the product Circadin® (as a treatment for insomnia, a therapeutic indication for melatonin patented by Neurim).

Although there had been earlier authorisations for medicinal products containing melatonin, these had been for unrelated veterinary uses (that did not fall within the scope of Neurim's patent). More importantly, those earlier authorisations did not lead to any significant reduction in the regulatory hurdles that Neurim needed to overcome in order to market Circadin®. As the European Medicines Agency (EMA) treated Circadin® as a new active substance, Neurim was obliged to provide a complete package of clinical data as specified in Article 8(3) of the Community code relating to medicinal products for human use (Directive 2001/83/EC).

> "THE AUTHORS OF THE ORIGINAL SPC LEGISLATION WERE CAREFUL TO STIPULATE THAT NOT ALL NEW PATENTS AND NEW MARKETING AUTHORISATIONS WOULD LEAD TO THE REWARD OF AN SPC."

In the view of the Court of Appeal, Neurim deserved the reward of extended protection (as provided by an SPC) because it had invented a new clinical application for melatonin, but could not commercially exploit its invention until after it had obtained, submitted and waited for the EMA to review a complete package of clinical data.

Although it seemed to the court that Neurim should be awarded an SPC, prior case law of the Court of Justice of the EU (CJEU) stood in the way. Specifically, prior case law meant that:

- An earlier veterinary marketing authorisation for an active ingredient is prejudicial to the grant of an SPC application based upon the first ever human marketing authorisation for the same active ingredient (*Pharmacia Italia SpA*, case C-31/03); and
- A new (patented) use of an active ingredient cannot be taken into account for the definition of the 'product' in an SPC application (*Yissum Research and Development Company*, case C-202/05).

Nevertheless, the Court felt strongly enough in Neurim's favour to refer questions to the CJEU in order effectively to ask it to reconsider this established case law. The Court of Appeal was able to do this because Neurim could point to differences in the facts and/or law relating to its case that provide distinctions over the previously decided cases.

The first and broadest of the questions referred by the court essentially asked whether the grant of a SPC is precluded when:

- The SPC application is for active ingredient A;
- The SPC application is based upon authorisation MA2 and patent X;
- There is an earlier authorisation, MA1, to a medicinal product containing A; and
- Selling, for the use specified in MA1, the old medicinal product containing A would not infringe patent X.

The Advocate-General's opinion

To our surprise, the Advocate-General is of the opinion that the answer to the above question is 'no'.

On the face of it, the legislation clearly stipulates that all SPCs for a particular active ingredient must be based upon the first marketing authorisation (for either human or veterinary use) for a product comprising that active ingredient. However, the Advocate-General believes that the phrase 'first authorisation' should now be interpreted to mean the first authorisation that is within the scope of protection conferred by the patent upon which the SPC application is based.

The CJEU will now consider that opinion when reaching its final judgment later this year.

A step too far?

At first sight, the opinion of the Advocate-General seems to represent excellent news for the innovative pharmaceutical industry. This is because it offers the first possibility of suitable rewards and incentives for those companies that develop important medical innovations using old active ingredients.

However, the opinion could have hidden dangers as, inadvertently, it breaks an important link in the legislation that is key to producing a balanced and sustainable system of rewards and incentives.

The authors of the original SPC legislation were careful to stipulate that not all new patents and new marketing authorisations would lead to the reward of an SPC. For example, a relevant section of the Explanatory Memorandum for the original legislation (Point 36 of "Proposal for a Council Regulation [EEC] concerning the creation of a supplementary protection certificate for medicinal products"; COM[90] 101 final – SYN 255) states that:

- "Although one and the same product may be the subject of several patents and several authorisations ... the SPC will only be granted for that product on the basis of a single patent and a single authorisation to be placed on the market, namely the first chronologically given in the state concerned."

The same section also states that:

- "If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product (use of a different salt, different excipients, different pharmaceutical presentation, etc)."

Dr Mike Snodin specialises in handling pharmaceutical and chemical patent matters. He has particular expertise on SPCs and has authored various influential articles, including one proposing the concept of negative term SPCs, which concept has now been accepted by the CJEU in case C-125/10.

> "IN THIS RESPECT, THE ADVOCATE-GENERAL'S INTERPRETATION OF THE LEGISLATION DOES NOT APPEAR TO DISTINGUISH BETWEEN THOSE APPLICANTS WHO HAVE CONDUCTED FULL CLINICAL TRIALS AND THOSE WHO HAVE NOT."

The purpose of this stipulation appears to have been to link the availability and duration of SPC protection to only those authorisations requiring submission of a complete package of (pre-)clinical data for the active ingredient(s) concerned. Unlike later marketing authorisations for the same active ingredient(s), the first marketing authorisation is guaranteed to have required the submission of such a complete package of clinical data.

Before the Advocate-General's opinion, this link had been relatively firm. That is, it had been weakened only by Recital (14) of a later piece of legislation (Regulation 1610/96, creating SPCs for plant protection products and amending the earlier legislation). However, the practical effects of that recital are essentially limited to SPCs for new salt forms of active ingredients. On the other hand, the opinion of the Advocate-General now appears effectively to sever this important link almost completely. This is because it is common for a new marketing authorisation for an old active ingredient to be the first to fall within the scope of a particular patent. More importantly, the interpretation of the legislation proposed by the Advocate-General does not appear to prevent (either directly or indirectly) the authorisation and patent pertaining to the kind of changes to a medicinal product that were expressly mentioned in the Explanatory Memorandum as not qualifying for fresh SPC protection.

In this respect, the Advocate-General's interpretation of the legislation does not appear to distinguish between those applicants who have conducted full clinical trials and those who have not. This could make SPC protection available to applicants whose marketing authorisations rely either in whole or in part upon clinical data submitted by others (including even authorisations for generic medicinal products), as the patentability of modifications to an authorised medicinal product is often judged upon criteria that are completely unrelated to regulatory concerns.

Many observers will believe that because Neurim has been obliged to supply a complete package of clinical data, it should not count against it that there was an earlier authorisation for the same active ingredient. Indeed, were it to count against the company, a majority of observers would probably concur with the UK Court of Appeal's comment that "the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose".

The 'fix' proposed by the Advocate-General that would allow Neurim to be awarded an SPC is therefore appealing in many ways. However, that fix appears likely to throw the SPC system inadvertently out of balance in a way that, through enabling a proliferation of SPCs based upon almost any kind of marketing authorisation (including even an authorisation for a generic medicinal product), could be detrimental to the long-term interests of the innovative industry. In this regard it is possible that, when delivering its final judgment, the CJEU might ultimately settle upon an alternative solution that grants Neurim an SPC but does not produce such undesired side-effects. ■

The views expressed in this article are the personal views of the authors and are not intended to reflect the views of Potter Clarkson LLP or its clients.

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Dr Michael Pears handles a wide range of biotechnological patent matters. In recent years he has developed experience in SPCs and has been involved in coordinating the prosecution of high profile SPC portfolios throughout Europe, and in taking a case to the CJEU (*Georgetown University et al*, C-422/10).