The SPC Year in Review – Politics rather than Litigation

There have been no Court of Justice of the European Union (CJEU) referrals decided this year. The main activity on supplementary protection certificates (SPC) has been political with changes considered on a European Union level as part of the pharmaceutical legislation review and the much vaunted appearance of the Unified Patent Court (UPC) on the horizon at the end of the year.

On a legislative level the last changes made to the SPC Regulation were to introduce a manufacturing waiver. This manufacturing waiver properly kicks in at the beginning of July 2022 and only a handful of notifications (if that) have been made under the waiver at national patent offices. The process is fairly formalistic but initial experience is that generic manufacturers are not rushing ahead at the opportunities afforded to export European made generics. The only notification seen so far with details of an export market seeks to send product to Australia, another highly-advanced economy.

The opportunity to stockpile before European launch seems likely to prove more interesting, though limiting the location of where product can be stored to the country of manufacture will dampen use of the system. That said, generics have long had processes in place to bring blockbuster products rapidly into major markets once exclusivities expire.

In complying with the waiver generics would do well to use the registered address for service for an SPC to ensure notification actually occurs.

The last extension of SPC rights occurred with the paediatric legislation providing the carrot of a six month extension to SPCs as a reward for completing a paediatric investigation plan. A requirement for the reward is that there is a marketing authorisation (MA) present in all EU member states. Early beneficiaries of the extension sometimes had to scramble to achieve this when a product was authorised under the mutual recognition procedure. Now that most products receive centralised authorisations it would be rare to be in a situation where there is not an MA in an EU state.

The pharmaceutical legislation review is wide in scope in considering whether the rewards framework for orphan medicines and paediatric medicines is achieving desired outcomes. Whether the current SPC extension requirements are sufficient is being considered. Might there, perhaps, be a requirement that a product be actively marketed in each member state to obtain the reward? It is not clear how this might be demonstrated as evidence would be needed from each member state, considerably complicating a procedure that currently relies on centrally available and applicable documentation.

By the time this column is written next year the Unified Patent Court might be in operation and the first Unitary Patents (UP) may have been granted. As a consequence the unavailability of unitary SPCs becomes acute. It is assumed that national SPCs may be obtained under a UP in the same way as under a European patent (EP) but such SPCs will fall within the inherent jurisdiction of the UPC by virtue of being based on a UP. The prosecution of those SPCs may also have varying outcomes, both as to grant and in terms of the product description. Whilst the UPC deals with European patents, all

having the same wording in the claims, it seems unsatisfactory that any SPCs that fall within their jurisdiction are very likely to have differences in their product descriptions, however slight, as a result of the individual grant of these rights by each national patent office.

European industry associations in the fields of pharmaceuticals, veterinary products and crop protection products are all in favour of setting up a virtual EU SPC office, perhaps attached to the European Patent Office (EPO), that would operate either on a Patent Cooperation Treaty (PCT) or European Patent Convention (EPC) model, and that this office could handle unitary SPC applications once appropriate legislation for them has been adopted. Under a PCT model the initial stage of national applications could be made, avoiding the wasteful duplication of supplying the same information to each national patent office. A non-binding opinion on allowability could be produced by examining divisions made up of national patent office examiners experienced in SPCs. An application would then convert into a bundle of national applications for grant or continued prosecution. Under an EPC model the office would grant the SPC which would then turn into a bundle of national SPCs. There would need to be a route for references to the CJEU if the office has authority to grant SPCs. This could be achieved either by a *de novo* appeal tribunal which can refer or a protocol on jurisdiction so that appeals from the office go to the courts of the country where the applicant is domiciled or, if that is outside the EU, to the country where the marketing authorisation holder is domiciled, since this will always be in the EU.

The year ahead will contain considerable advocacy opportunities in order to ensure any legislative proposals are efficient and deliver benefits both to European industry and society as a whole. SPCs have become a key incentive for pharmaceutical development and it is important to maintain and enhance their benefits to ensure new medical treatments are developed for patients.

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