EIP

European Commission Proposals on Data Exclusivity and the Bolar Exemption

On 26 April, the European Commission published proposed legislation (specifically a new Regulation and a new Directive) aimed at reforming EU legislation in relation to pharmaceuticals. These proposals, if adopted, will affect pharmaceutical regulation in a number of ways. In relation to IP specifically, they will affect the periods of data exclusivity and bolar exemptions.

~~Data Exclusivity~~

Under the EU's current framework, a newly authorised pharmaceutical will benefit from 8 years of data exclusivity and 2 years of market exclusivity, i.e. "the 8+2 regime". The Commission is proposing to adjust this to a basic 6+2 regime, by reducing the period of data exclusivity by two years. However, there would be the possibility to extend this by up to four additional years, if certain criteria are met. Specifically:

- If the product addresses a "high unmet medical need", an additional six months will be available;
- For additional therapeutic indications with significant clinical benefit there will be a further 12 months' exclusivity;
- If, for new active substances, comparative clinical trials are conducted, this will result in an additional 6 month period of exclusivity; and
- Finally, in order to encourage the availability of pharmaceuticals in all member states, by sufficiently marketing the product in every authorised EU state, a further 24 months of exclusivity can be obtained.

There are also proposed changes to the regime in relation to orphan drugs:

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- The exclusivity period is reduced from 10 to 9 years...
- ...although 10 years of exclusivity will still be available where there is a "high unmet medical need";
- Well established orphan products will only be granted 5 years exclusivity;
- An additional 12 months' exclusivity will be available in return for marketing the product in every authorised EU Member State;
- An additional 12 months will also be available for obtaining additional authorisation for new orphan conditions; this 12 month extension of exclusivity will be available twice.

Also in relation to the orphan medicines regime, the two years additional market exclusivity on completion of a paediatric investigation plan is abolished, but a six month SPC extension would be available, in line with the paediatric extension currently available for non-orphan drugs.

Data exclusivity is also proposed to be used as an incentive to encourage new antibiotics. In return for seeking authorisation for a "priority antimicrobial", a transferable data exclusivity voucher will be awarded. This can be used to extend data protection of a product for 12 months. That product could be the priority antimicrobial but need not be; instead the voucher could be used for another product, provided that product is within the first four years of data protection. The voucher would also be transferrable for use by another company.

~~Harmonised EU Bolar exemption~~

Although EU law makes provision for bolar exemptions to apply under national patent law, EU member states have applied this exemption differently. The Commission has therefore sought to harmonise the position. The proposal to do so would mean that a patent or SPC would not be infringed by activities conducted to generate data for an application for:

(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products, and for subsequent variations;

(ii) health technology assessments (as they are defined in Regulation (EU) 2021/2282);

(iii) pricing and reimbursement.

The activities would have to be done exclusively for these purposes, but provided that is so, the exemption would apply to the submission of the application for a marketing

authorisation as well as activities by third party suppliers and service providers.

p3 This approach clarifies that wider regulatory processes, such as pricing, benefit from the exemption, and the fact that activities by third parties are also specifically exempted does clarify a point that was previously unclear. However, the proposal as drafted would apply not only to patents covering the medicinal product for which data is being generated, but potentially any patent used in the generation of the data, for example patents relating to research tools and devices. It is by no means clear if this was intentional (or even whether such an exemption would be compliant with TRIPS). This may be a point which the proposal is amended during the legislative process.

These proposals will now move to be considered by the European Parliament and Council before they can pass into law.