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The new Bolar provisions and their potential impact on European PI landscape

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As is well known in the life sciences community in Europe, both the Commission and the Parliament have proposed reforms to the Medicines Directive which, if implemented, would serve to broaden the ambit of the Bolar exemption in the European Union. It is understood that the European Council is now considering these reforms and it is expected that consensus at this level will be reached during the Danish presidency in the second half of 2025. Once the European Council adopts its position, tri-party negotiations will take place between the Commission, the Parliament and the Council. Although the present timing is uncertain, it is expected that the new legislation will be adopted in 2026 and thereafter, there will be an 18-month implementation period.

In a previous post on this blog (link), Miquel Montana has pointed out, in his characteristically convincing manner, that some aspects of such proposals may be outside of the limited exceptions to patent infringement permitted by TRIPS.

This post considers a different angle.

Anyone who is experienced in the co-ordination of the defence and enforcement of patents for important medicines in Europe will know that the ability to get a preliminary injunction can be crucial for patentees. This is because if the generic has launched (or even worse has become established in the market) the patentee can rarely adequately recoup the damage incurred subsequently. Those experienced in this field will therefore also be familiar with two issues which invariably arise:

The first is that, although the procedures for the granting of marketing authorisations in Europe are harmonised to a large extent, the mechanisms for pricing and reimbursement are not. In some countries, the application for pricing and reimbursement can trigger steps being taken which lead to an immediate and irreparable impact on the originator when the generic product is launched.

The second is that so-called “trigger-point” – that is the point at which a patentee must commit to enforcing its patents or else risk not being able to obtain preliminary injunctive relief i.e. the point at which there is an “imminent threat” of infringement – varies considerably from country to country. The table below summarises the typical position in some of the larger European markets.

Country	Trigger Point for Applying for a PI

Germany	Publication in the Lauer-Taxe
France	Reimbursement Price Grant plus either declaration to the French Pricing Committee of intended launch or other evidence of pre-marketing activity
Italy	Reimbursement Price Grant plus evidence of pre-marketing activity
Spain	Reimbursement Price Grant plus failure to provide suitable reassurances to a notice letter or other evidence of imminent launch
United Kingdom	MA Grant plus the failure to provide suitable reassurances to a notice letter
Netherlands	Publication in the G-Standaard database
Belgium	Reimbursement Price Grant
Denmark	Reimbursement Price Grant
Sweden	Reimbursement Price Grant plus pre-launch activity

By necessity, this short tabular summary omits granularity and nuance. However, it is clear that in many countries, the obtaining of a reimbursement price is a necessary and in some instances sufficient act for the patentee to instigate an application for a preliminary injunction to protect its position in court. And in many countries, if a patentee delays in taking such steps for a significant period, this could impact adversely on its chances of obtaining preliminary injunctive relief from the court.

The implementation of the new Bolar provisions as they currently stand will inevitably bring uncertainty to all stakeholders as to the appropriate moment to instigate legal proceedings and seek a preliminary injunction. Whilst patentees will be likely to continue to argue that the same steps should remain as acts of "imminent infringement", it will surely be argued by generics companies that if the act of obtaining pricing and reimbursement is always exempt from infringement, these steps can no longer be seen as acts of imminent infringement and therefore cannot justify an application for preliminary relief. This will be particularly galling for patentees if those acts can even directly result in harm to the patentee due to an impact on their own price or reimbursement. The new regime will bring uncertainty and whilst this is good for lawyers, it is sub-optimal for industry.

The situation regarding threatened patent infringement and when to bring an application for preliminary relief has already been made more complex in much of Europe with the overlaying of the UPC on top of national systems and traditions. This is a topic that the Düsseldorf Local Division of the UPC had to grapple with last summer in a dispute between Novartis and Genentech, on the one hand, and Celltrion, on the other, regarding the latter's biosimilar omalizumab product. Omalizumab is marketed in Europe by Novartis as Xolair®. The Local Division had to decide whether certain pre-launch activities undertaken by Celltrion in various countries amounted to an imminent threat of patent infringement. Ultimately, the Court considered that the law of the UPC took precedence over national law and provided a new yardstick by which infringement was to be adjudged. When it came to the assessment of imminent infringement, the court took an holistic approach stating : "*In order for an infringement to be imminent, in the present case means that all pre-launch preparations must have been completed in such a way that an offer can be made at any time*." An holistic approach is obviously commendable in principle but problems may arise in practice when what counts as the completion of pre-launch activities can vary considerably from country to country. The new Bolar provisions, if implemented, may add

to the complexity. In view of this post, it is hoped that those legislators working on the revised Bolar exemption ensure that the current balance between the interests of originators and generics is maintained in order to avoid increased uncertainty for all.

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