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The "Bolar" Exemption in Europe

By Dr. Holger Tostmann[15]

In Europe, in essence, two mechanisms for exemption of medicinal products from patent protection exist. First, the so-called "*research exemption*" permits the use of a patented invention (e.g., a process or a compound) for *research purposes* (e.g., to determine specific properties or effects of a protected medicinal products). For example, in Germany, a research exemption is codified by German national law since 1981, exempting from the effects of a patent all "*acts done for experimental purposes relating to the subject-matter of the patented invention*". This or a similar

[15] Dr. Holger Tostmann is a German and European Patent Attorney and a Partner at the Wallinger Ricker Schlotter Tostmann Law Firm in Munich, Germany

research exemption can also be found in the national law of all other relevant European jurisdictions.

The second mechanism, termed the "*Bolar exemption*" allows generics manufacturers to perform *activities related to market authorization or approval* under local pharmaceutical law before a patent expires, thus enabling market entry immediately after expiration of an originator's patent. This exemption also applies to biosimilars. The following remarks are focused on the Bolar exemption aspect (and not on the specifics of the research exemption mentioned above).

In the end, both exemptions are governed by national law in each jurisdiction. However, at least for the member states of the European Union (EU), the Bolar exemption is based on EU Directive 2001/83/EC as last amended by EU Directive 2004/27/EU (for a proposed further amendment see the discussion below).

The basic "mechanism" of an EU directive is that a directive does not become law directly, in each jurisdiction, but that the directive needs to be transposed into local law by the legislative of each member state. Not surprisingly, this generally leads to substantial differences in implementation and results in a lack of harmonization.

The stated aim of the presently valid Directive 2004/27/EU is to not unnecessarily delay the arrival of generic medicinal products on the market. The most relevant passage of the Directive is Art. 10(6), which reads:

> *Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3, and 4 [referring to reference medicinal products, generic medicinal products and biological medicinal products] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.*

The language of Art. 10(6) of the Directive leaves at least the following questions open:

- While generic medicinal products and biological medicinal products are explicitly mentioned, the development of *new* drugs or "variants" of existing drugs is not addressed.
- It is not clear whether the exemption only covers the Applicant for market authorization or also Third Parties involved in the process.
- It is not clear whether only EU market authorization is covered or also activities directed at jurisdictions outside of the EU.
- It is not clear what is meant by "*consequential practical requirements*" (pricing? marketing? …)

To discuss some divergent aspects, in **Germany** the Bolar exemption applies to any activities to obtain marketing approval, also in jurisdictions outside of the EU. In the **UK** (presently not a member of the EU) "*any activity*" carried out for the purposes of "*medicinal product assessment*" is deemed to fall under the "Bolar" privilege. By contrast, according to the **French** Bolar exemption, the privileged acts must be "*necessary*" for the performance of clinical trials *as required by*

the regulatory authorities. In **Italy**, the legislator did not seem to have the intention to limit the Bolar exemption to generic products, i.e. the exemption could also apply to other drugs. Also, Italian law seems to include as exempt activities related to authorization outside the EU. By contrast, it seems that **Dutch** courts apply the research exemption restrictively and that the Dutch Bolar provision is limited to generics.

As mentioned above, the Directive related to the Bolar exemption has been last modified in 2004. However, significant new developments were initiated on April 26, 2023, when the EU Commission published the so-called "***EU Pharma Packaging***" proposal, which aims to clarify the concept of the Bolar exemption under EU law and to thereby address the lack of harmonization. In fact, the Commission's proposal for a new Directive confirms in its recitals that the current Bolar exemption is "*fragmented across the Union and it is considered necessary in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products, to clarify its scope in order to ensure a harmonized application in all Member States* […]".

Specifically. Art. 85 of the Draft Directive stipulates that the following activities are not to be regarded as infringement of patent rights or SPCs [underlining added]:

> *(a) studies, trials and other activities conducted due to generate data for an application for:*
> *(1) a marketing authorization of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent regulations;*
> *(2) health technology assessment as defined in regulation (EU) 2021/2282;*
> *(3) pricing and reimbursements;*
>
> *(b) the activities conducted exclusively for the purposes set out in point (a), may cover the submission of the application for a marketing authorization and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.*
>
> *The exception shall not cover the placing on the market of the medicinal products resulting from such activities.*

The type of medicinal products covered by the Bolar exemption now also includes "hybrid" (or biohybrid) medicinal products [defined by the European Medicines agency (EMA) as follows: "*a medicine that is similar to an authorized medicine containing the same active substance, but where there are certain differences between the two medicines such as in their strength, indication or pharmaceutical form*"].

Standard health technology assessment such as pricing and reimbursement activities are now expressively included under Art. 85 as exempted, which is more specific than the ambiguous concept of "*consequential practical requirements*" in the 2004 Directive.

Importantly, the Bolar exemption is expanded to explicitly include third party suppliers and service providers (CMOs etc.).

While all of this may be seen as a potential concern for innovator/originator pharmaceutical companies, the last sentence reproduced above (re)emphasizes that the Bolar exemption does *not* extend to the actual entering onto the market. Overall, the new Draft Directive clarifies that the Bolar exemption is confined to conduct studies and trials and other activities needed for the regulatory approval process and strives to balance the interests of generic/biosimilar companies to enter the market directly once patent protection expires with the innovator's/originator's interest to obtain a return on their significant investment.

This "*pharma package*" including the new Directive is at an early stage and the proposal first must be discussed by the European Parliament and the Council. No timeline has yet been adopted, but experience shows that it will be several years before a final draft can be adopted.

In another recent development relevant for the European market, the Bolar exemption is also codified in the new **Unified Patent Court** Agreement (UPCA), namely in Art. 27(b) UPCA, which simply "re"-cites Art. 10(6). No court decision related to this exemption is on record yet, which is no surprise since the UPC has only started taking cases in June of 2023. Since the entry of the UPCA into force, several EU Member States have (further) amended their national laws to implement the UPCA provisions.