

Healthcare & Life Sciences - Germany

Generic drug and API producers deal with the Bolar exemption

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Introduction

The business strategies of generic drug companies are influenced by the patents owned by major pharmaceutical companies. In order to allow generic drug companies to enter the market as seamlessly as possible after the expiration of patent rights, certain actions are permitted while the patent is still in force. This privilege arises from the Bolar exemption. While it is undisputed that the companies are allowed to produce the protected substance in order to obtain marketing authorisation, it is unclear whether active pharmaceutical ingredient (API) producers or contract manufacturers can also invoke this privilege. Many generic pharmaceutical companies depend on their work as they do not have their own production capacity. In December 2013 in *Solifenacin* the Dusseldorf Higher Regional Court – a prominent German court for patent matters – was confronted with that question.⁽¹⁾ The court referred legal questions to the European Court of Justice (ECJ) regarding the conditions under which a third party may deliver a protected substance to a generic company which intends to use it for tests in order to obtain a marketing authorisation. At the same time, the court outlined a possible solution which is already likely to be important in practice for the generic industry.

Starting point

A new Bolar exemption (Section 11(2)b of the Patent Act) was inserted into the Patent Act during the transposition process of the EU Medicinal Products Directives. It enables a generic drug company to take necessary measures in view of obtaining a market admission before expiration of a patent, so that it can begin marketing the generic drug immediately after the patent expires. This privilege covers the production and use of patent-protected substances and APIs, which are required for bio-equivalence studies in the context of abridged applications – so-called generic applications which cross-refer to the data of the clinical dossier in support of a market authorisation granted for a reference product (ie, the branded drug). These studies are intended to document that an already admitted branded drug and a generic drug can be exchanged without risk to the patient. The generic application significantly lowers the regulatory thresholds for generic drug companies, since it permits a simple reference to the clinical dossier of the branded drug without having to repeat expensive clinical studies. This form of admission benefiting generic drug companies is flanked by the Bolar exemption. Under the exemption, the patent holder must generally tolerate all measures necessary to obtain an admission of the respective generic drug.

Issue

It is unclear whether and under what conditions third parties other than generic drug companies may also invoke the privilege. Are API suppliers permitted to produce patent-protected substances and supply generic drug companies which will use these to carry out their studies in connection with a generic application? The Dusseldorf Higher Regional Court addressed this question in its decision of December 5 2013. It considered it necessary to send the case to the ECJ because the German Bolar exemption is based on an EU rule,⁽²⁾ the wording of which permits several possible interpretations. Previously, at first instance the Dusseldorf Regional Court generally rejected any extension of the exemption to third parties. It included in the circle of privileged companies only those suppliers considered to be so-called 'co-

organisers' of the studies. This relatively contourless term left various ambiguities. However, the Dusseldorf Higher Regional Court disregarded this narrow and impractical interpretation.

Business approaches

Generic drug manufacturers with their own API production capacities would not have been affected by a narrow interpretation of the Bolar exemption. However, there are many small or medium-sized generic drug companies whose business models do not provide for in-house API production. Even larger companies often do not produce all of the APIs for their drugs themselves, instead using third-party suppliers. The API supplier is also often used for the subsequent commercial distribution. Changing the producer would involve additional regulatory measures and cost. The API supplier selected for the regulatory phase is usually also used for the commercial phase which follows the market admission. If the privilege was interpreted restrictively, excluding third parties from its scope of application, generic companies without production capacity would be forced to buy APIs produced in patent-free foreign countries. If no suitable suppliers could be located there, even this route would be blocked.

This would not encourage the marketing of generic drugs as soon as the patents of branded companies expire, which is generally desired by the EU legislature. Further, it does not support its interest in bringing the generic drug business into the European Union.

Even though the Dusseldorf Higher Regional Court referred the case to the ECJ, it clearly expressed its opinion that companies without their own production capacity which depend on external sources shall not be discriminated against in comparison to self-producers. The local procurement of materials required for the regulatory phase in order to obtain market admission shall also be privileged.

Requirements

The court established certain requirements in regard to APIs:

- The API supplier must take suitable measures to ensure that the protected ingredients will be "used reliably only for privileged admission purposes".
- When making offers, it must regularly be pointed out in a "highly visible manner" that the willingness to supply is confined to privileged studies only. Thus, an internet offer must contain a corresponding disclaimer.
- Before delivery, the supplier must actively obtain assurance (eg, through inquiries) that the active ingredient to be supplied will be used exclusively for privileged purposes. There should be no reasonable doubt at the time of the delivery that the generic drug company will stay within the legal boundaries of the Bolar exemption. The court set out the following relevant criteria for this assessment:
 - orientation of the supplied company as a generic drug company;
 - quantity of the supplied active ingredients;
 - expiration of the patent protection in the near future; and
 - a positive or negative experience in respect to the reliability of the generic drug company.
- The API supplier must take specific protective measures which effectively counteract any unlawful use of the provided active ingredients. This duty may be fulfilled through, for example, an agreement containing an obligation subject to a contractual penalty to use the provided active ingredient only for admission purposes.

Comment

In *Solifenacin* the Dusseldorf Higher Regional Court provided the Bolar exemption with new contours. In order to enjoy the privilege, the supplier must overcome high but not insurmountable hurdles. It remains to be seen what scope the ECJ will give to the Bolar exemption, but taking an overall perspective of EU law into account, a generous interpretation is expected. Thus, the pharmaceutical industry may already be considering the guidelines established by the Dusseldorf Higher Regional Court.

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Endnotes

⁽¹⁾ December 5 2013, I-2 U 68/12.

⁽²⁾ Article 10(6) of EU Directive 2001/83/EC

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