Judgment of the Italian Supreme Court on the so-called Bolar Exemption

With its decision of 5 July 2024, a highest national court has for the first time in over a decade again ruled on the scope of application of the so-called Bolar Exemption. The Italian Supreme Court's decision marks a landmark moment and is the first of its kind on the interpretation of the European Bolar provisions. While the Italian court ruled in favour of applying the Bolar Exemption to contract manufacturers who are not directly involved in the authorisation procedure for medicinal products, at the same time it nevertheless imposed strict conditions and limits.

Background

The Italian Supreme Court of Cassation (*'Corte Suprema di Cassazione'*) in Rome recently ruled in *Boehringer Ingelheim* v. *Sicor* and its parent company *Teva* that *Sicor* had infringed a Boehringer Ingelheim patent and was therefore obliged to pay damages. The legal dispute was primarily about damages, as EP 716 and the related SPC 849 have already expired. Earlier, in July 2018[1], the Regional Court of Milan had already ruled that *Sicor* infringed *Boehringer Ingelheim's* patent EP 4 18 716 (active ingredient: "*tiotropium bromide*") and could not invoke the so-called Bolar exemption in that particular case. Following an unsuccessful nullity action brought by *Sicor*, the Milan Court of Appeal confirmed the first-instance infringement judgement in June 2021[2]. *Sicor's* subsequent appeal to the Supreme Court in Rome has now also been dismissed.

The Bolar Exemption and its significance

The Bolar regulation permits generics and, to a certain extent, biosimilar manufacturers to obtain marketing authorisation for medicinal products before expiry of a patent and to carry out the necessary trials or studies.[3] This is intended to enable generics companies to launch products immediately after expiry of the existing IP right(s) in respect of a medicinal product. The legal basis for this exemption under EU law is Art. 10 para. 6 of EU Directive 2001/83/EC.[4] This provision is formulated in very general terms and does not specify the activities covered by the exemption, their scope, or the parties benefiting from it, such as third-party suppliers of active substances. This and the fact that the provision, being an EU Directive, does not have direct effect for EU Member States, but must be implemented by the respective national legislatures, has in the past repeatedly led to differing interpretations in the individual EU Member States.

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[1] Tribunale di Milano, Judgment of 24.07.2018, No. 8273, cf. https://www.eplaw.org/blog/detail/it-teva-v-sicor-bolar-exemption/ [06.08.2024].
[2] La Corte d'Appello di Milano, Judgement of 08.06.2021, No. 1785, cf. https://www.eplaw.org/blog/detail/it-teva-v-sicor-bolar-exemption/ [06.08.2024].
[3] BT-Drs. 15/5316, 1, 31.
[4] EU Directive 2001/83/EC was amended by Directive 2004/27/EC

Judgment of the Italian Supreme Court

In its judgment of 05.07.2024[5], the Italian Supreme Court had to deal primarily with the question of whether the Bolar exemption also applies to third-party suppliers/contract manufacturers of active pharmaceutical ingredients (so-called APIs) who merely manufacture the corresponding medicinal product or only individual components thereof for the generics company applying for the marketing authorisation, but do not themselves initiate an authorisation procedure under the law governing medicinal products, which according to the wording of the provision is a prerequisite in order to qualify for the privilege.

The Polish Supreme Court ("*Sąd Najwyższy*") had already considered this issue in 2013 and ruled that the Bolar exemption does not apply to the activities of third-party providers or manufacturers.[6] A parallel judgment on this matter was also handed down in Germany in 2012 when the Düsseldorf Regional Court[7] ruled that an API provider such as *Polpharma* is only protected by the Bolar exemption if it is actively involved in the studies conducted by its customer. On appeal in 2013, however, the Düsseldorf Higher Regional Court[8] broadened the interpretation of the exemption and ruled that third-party API providers are protected if the supply serves a purpose that falls under the Bolar exemption. The Higher Regional Court also acceded to *Polpharma's* request to refer questions to the ECJ for a preliminary ruling.[9] However, the dispute was settled by the parties before the ECJ had a chance to make a ruling.

The Corte Suprema di Cassazione now also supports a broad interpretation of the Bolar exemption, but has set strict limits on its application: thus, although third parties not directly involved in the authorisation procedure should in principle also be allowed to invoke the Bolar exemption and manufacture APIs and medicinal products before expiry of the respective patent protection, this should only be done in response to a specific request from the generic manufacturer applying for the authorisation, and both parties should commit to the objective that the manufacture and supply should serve the (sole) purpose of pursuing an authorisation under medicinal product law.[10] In its judgment, the Italian Court of Justice stated that a manufacturer who does not itself file the application for authorisation, but merely supplies the medicinal product or components thereof to other companies pursuing the authorisation procedure, must act clearly on behalf of the applicant in order to itself be able to invoke the Bolar exemption. One consequence of this is that, according to the Italian court, (third-party) manufacturers may not advertise the supply of patented active ingredients, even if they are only to be used in clinical trials, as they are only permitted advertise their own competencies.

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[5] La Corte Suprema Di Cassazione, Judgment of 05.07.2024, No. 18372.
[6] Sąd Najwyższy, Judgment of 23.10.2013, Az. IV CSK 92/13.
[7] Düsseldorf Regional Court, judgment of 26/07/2023, ref. 4a O 282/10.
[8] Düsseldorf Higher Regional Court, judgment of 5 December 2013, case no. I-2 U 68/12.
[9] https://www.lexology.com/library/detail.aspx?g=c593c17f-cdaf-48c6-a057-e18ca685b23d.
[10] See also: https://www.juve-patent.com/cases/italian-supreme-court-rules-on-bolar-exemption-boehringer-ingelheim-sicor-teva/.

Impact and significance of the judgment

This judgment could have considerable significance for the interpretation of the (Italian) Bolar exemption by other European courts in the future.

The Bolar Regulation was introduced in the EU in 2004 to reduce the existing competitive disadvantages of the European generics industry in international competition and at the same time lower the price of medicines. Even though this goal has been at least partially achieved, the trend that Europe sources most of its active pharmaceutical ingredients (APIs) and medicines from China and India continues to this day, and production is increasingly being outsourced to China and India.[11] Besides the associated loss of jobs, this will increase Europe's dependence on pharmaceutical supplies from China. This should not be overlooked when interpreting the Bolar privilege. Apart from this teleological and global and domestic public health policy argument, a narrow interpretation ultimately penalises smaller generics manufacturers who, due to limited in-house manufacturing resources, are forced to outsource the manufacture of the respective medicinal product or API to contract manufacturing companies, which then cannot invoke the Bolar exemption, or can only do so to a limited extent if they wish to avoid exposing themselves to the risk of a patent infringement action being brought against them.

The Italian judgment once again highlights the need for further discussion on the harmonisation of this Regulation within the EU, primarily in order to create more legal certainty for generics manufacturers. Last year, and as part of the so-called pharmaceutical package,[12] the EU Commission also submitted a proposal for a new Bolar regulation. Under the Commission's proposal, trade in and use of patented medicinal products or processes, including by third-party suppliers and service providers, would also fall under the Bolar exemption. Art. 85 b) of the draft states: *"the activities conducted exclusively for the purposes set out in point (a), may cover the submission of the application for a marketing authorisation 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 implementation of this proposal would (at least in the author's opinion) remove the restrictions imposed by the Italian court. At the same time the new wording would ensure greater clarity and legal certainty in the Member States when interpreting the Bolar exemption. However, it remains to be seen whether this proposal will be adopted and, if so, with what amendments.

[11] European Parliament (2020): Report on the shortage of medicines: how to address an emerging problem (2020/2071(INI)). https://www.europarl.europa.eu/doceo/ document/A-9-2020-0142_EN.pdf.
[12] European Commission, Proposal for a Directive Of The European Parliament And Of The Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, 26.4.2023, COM(2023) 192 final 2023/0132(COD).