Excessive extension of the Bolar clause in the 'pharmaceutical legislative package'

The extension of the Bolar clause is critically analysed (as it is considered excessive) in light of the agreement reached on 11 December 2025 by the Council and the European Parliament on the 'pharmaceutical legislative package'.

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1. Introduction

As is well known, the Bolar clause refers to the exemption from the exclusive rights conferred by patents and supplementary protection certificates for medicinal products, according to which the studies necessary for applying for marketing authorisation for a generic medicinal product are not considered to infringe those intellectual property rights. This exemption is currently set out in Article 10(6) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, following its amendment by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004. In this way, as highlighted in the fourteenth recital of

Directive 2004/27/EC, the aim is to facilitate access to the pharmaceutical market for generic medicines.

The name 'Bolar clause' comes from the ruling handed down by the United States Court of Appeals for the Federal Circuit in 1984 in the case of *Roche Products Inc. v. Bolar Pharmaceutical Co. Inc.* This U.S. ruling concluded that the so-called preparatory acts for product authorisation were not excluded from the scope of the patent holder's *ius prohibendi*. However, as a result of this court ruling, the Hatch-Waxman Act was passed, which expressly establishes the lawfulness of such preparatory acts.

According to the current wording of Article 10(6) of Directive 2001/83/EC, the Bolar clause extends to "[c]onducting the necessary studies" and "the consequential practical requirements" necessary to obtain a marketing authorisation for a generic medicinal product (studies and practical requirements referred to in Article 10(1) and (2)). It also provides that conducting the necessary studies with a view to the application of paragraphs 1, 2, 3 and 4 of Article 10 and the consequential practical requirements "shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products", which means that studies relating to a biological medicinal product that is similar to a reference biological product that does not meet the conditions in the definition of generic medicinal products are also covered by the exemption.

Directive 2004/27/EC also introduced the Bolar clause in relation to veterinary medicinal products, by adding it to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. However, Directive 2001/82/EC was subsequently repealed by the current Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products, Article 41 of which stipulates that "[c]onducting the necessary tests, studies and trials with a view to applying for a marketing authorisation in accordance with Article 18" (which regulates generic veterinary medicinal products) "shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for veterinary medicinal products and medicinal products for human use".

2. The amendment of the Bolar clause within the framework of the so-called 'pharmaceutical legislative package'

2.1. The 'pharmaceutical legislative package' is the name given to the texts amending European pharmaceutical law, a reform process initiated by two Commission proposals: a) the Proposal for a Directive of the European Parliament and of the Council laying down the Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC, - Document COM/2023/192 final, of 26 April 2023 -; and b) the Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules

for the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 - Document COM/2023/193 final, also dated 26 April 2023.

The amendment of Directive 2001/83 EC also affects the regulation of the Bolar clause, and in the course of this amendment, the exemption has been progressively extended to that we consider to be excessive.

2.2. Indeed, the aforementioned proposal for a directive presented by the Commission aims, as expressly recognised in its explanatory notes, to extend the scope of the 'Bolar exemption' and ensure its harmonised application in all Member States, adding in recital 63 of the proposal that the aim is to achieve harmonisation "both in terms of beneficiaries and in terms of activities covered".

With regard to the extension of the personal scope *(ratione personae)* of the Bolar clause, the new wording of the clause in the Commission's proposal (Article 85 of the proposal, entitled "Exemption to the protection of intellectual property rights"), it is provided that 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 is permitted"*.

As can be seen, express mention is made of the possibility of recourse to third parties, thus dispelling the debates raised in practice on this possibility, a preliminary ruling on this matter having been referred to the Court of Justice (Case C-661/13), which was not resolved because the parties reached an amicable settlement.

The same extension can be seen in relation to acts covered by the Bolar clause, as it expressly refers to studies, trials and other activities carried out to generate data for an application, not only for the purposes of marketing authorisation for medicinal products, but also *a*) for the purposes of health technology assessment, as defined in Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment, and *b*) for the purposes of pricing and reimbursement.

2.3. Subsequently, the European Parliament — when approving the proposal at first reading by means of its Legislative Resolution of 10 April 2024 [P9_TA(2024)0220] — further broadens the scope of application. In fact, with regard to marketing authorisations for medicinal products, the Commission's proposal was limited to "generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations". However, the European Parliament at first reading (amendment 211) removes the reference to these specific types of medicinal products, so that the clause applies when it comes to "obtaining a marketing

authorisation and subsequent variations". This deletion thus allows studies, trials and other activities conducted to generate data for an application for a marketing authorisation of any type of medicinal product, including innovative medicinal products, to be included in the exemption. In fact, although Directive 2001/83/EC does not provide for the Bolar clause in relation to acts relating to the obtaining of marketing authorisation for any type of medicinal product, several Member States had already introduced the general clause without limiting it to generic or biosimilar medicinal products, with the result that in those States the exemption applies to any type of medicinal product, including innovative ones. This is the case, for example, in Germany (s. 11(2)(b) of the *Patentgesetz*), France (Art. L. 613-5 of the *Code de la propriété intellectuelle*) and Spain (Art. 61(c) of the 2015 *Ley de Patentes*).

Extending the exemption to cover bids in public tenders may constitute a violation of TRIPS

2.4. In turn, the Council of the European Union, in document published on 2 June 2025 (OR. en - 9285/25), further broadened the scope of the Bolar clause by extending the exemption from patent rights to acts consisting of "submitting an application on procurement tenders, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale or marketing of the medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate".

This extension is maintained in the agreement reached on 11 December 2025 by the Council and the European Parliament on the 'pharmaceutical legislative package'. Although the agreed texts have not yet been made public (which must be endorsed by both the Council of the European Union and the European Parliament before being formally adopted and entering into force after publication in the Official Journal of the EU), a press release has been issued highlighting that the co-legislators "have maintained the Council's extension of the scope to include submissions for procurement tenders"[1].

3. Critical considerations

In this analysis, we will focus specifically on the extension of the exemption to cover submissions in public tenders, as this may constitute a breach of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"),

[1] See the following ***link***.

contained in Annex 1C of the Marrakesh Agreement establishing the World Trade Organisation of 15 April 1994.

It should be noted that, although Article 30 of the Agreement allows Member States to provide for exceptions to the exclusive rights conferred by a patent, these must be *"limited"* and *"not unreasonably conflict with a normal exploitation of the patent and [...] not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"*.

Participation in a public tender to sell medicines essentially involves making an 'offer to sell'

In fact, the European Union itself filed a complaint with the World Trade Organisation ("WTO") against the Bolar clause regulation approved by Canada, considering that it exceeded the exceptions permitted by TRIPS, as it allowed the manufacture and storage of products during the last six months of the patent's validity, for sale immediately after its expiry. And in the decision of 18 August 2000 adopted by the WTO Panel that heard the case (WT/DS114/13), a series of considerations were established that we believe are equally applicable to the extension of the Bolar clause to tendering acts.

Thus, after recalling that *"the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others"*, the Panel noted, with respect to *"manufacturing for commercial sale,"* that this is *"a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward"* (para. 7.35 of the report). In other words, the Panel noted that it would be an unjustified limitation of the exclusive rights of a patent to seek to allow, in the six months prior to its expiration, the manufacturing of the patented product, even if its marketing were not to take place, and therefore not become effective, until after its expiration. The Panel also noted that Canada's argument for agreeing to such an extension of the Bolar clause, namely that *"the right to exclude sales to consumers during the patent term is the essential right conveyed by a patent, and that the rights to exclude "making" and "using" the patented product during the term of the patent are in some way secondary"*, cannot be accepted and is contrary to the TRIPS Agreement. As stated in the report: *"The Panel does not find any support for creating such a hierarchy of patent rights within the TRIPS Agreement"*.In fact, all the rights conferred on the patent holder under Article 28 of the TRIPS Agreement *"are considered a meaningful and independent part of the patent owner's rights"* (para. 7.33 of the decision).

We understand that this same reasoning would apply, *mutatis mutandis*, to another of the rights conferred by the patent under Article 28 of the TRIPS Agreement, namely that of *"offer for sale"*. Indeed, although the *"sale"* or *"marketing"* could in some way be

postponed to a later date, once the patent or supplementary protection certificate has expired, we find it difficult to argue that participation in a public tender does not constitute an *"offer for sale"*. This is because participation in a public tender to sell medicines essentially involves making an "offer to sell".

That being the case, the clarification that participation in such a public tender should in no case mean the sale, offering for sale or marketing of the medicinal product in question during the period of protection conferred by the patent rights may not be sufficient, given the reasoning followed by the Panel in the aforementioned decision.