Legal 500
Country Comparative Guides
Hot Topic | Intellectual Property

Navigating the Shift: A Comparative Analysis of the Bolar Exemption in Italy Under Current Law and the Proposed EU Pharmaceutical Package

Contributor

Jacobacci Avvocati

Navigating the Shift A Comparative Analysis of the Bolar Exemption in Italy Under Current Law and the Proposed EU Pharmaceutical Package

1. **Summary: The Evolving Landscape of the Bolar Exemption**

The “Bolar exemption” serves as a pivotal mechanism at the intersection of intellectual property protection and pharmaceutical regulatory law.

Designed to reconcile the patent holder's exclusive rights with the public interest in timely market access to medicines, the exemption shields specific regulatory testing and data generation activities from infringement claims relating to patent and Supplementary Protection Certificates (SPCs). In Italy, the traditional application of the Bolar clause has been relatively narrow, strictly tied to activities necessary for obtaining a Marketing Authorisation (MA). However, the European Commission's comprehensive reform of EU pharmaceutical legislation, specifically Article 85 of the draft Directive under the “Pharma Package,” is poised to radically reshape this framework by significantly expanding the scope of activities which are eligible for the exemption.

This article provides a comparative analysis of the current Italian legal regime governing the Bolar exemption and the forthcoming transformations under the EU Pharmaceutical Package, evaluating the strategic consequences for patent enforcement and market access.

2. **From a Narrow Safe Harbour to Universal Product Coverage**

Under current Italian law, the Bolar exemption is grounded primarily in Article 68(1)(b) of the Italian Industrial Property Code (IP Code) and Article 10(9) of the Italian Pharmaceuticals Code.

The IP Code states that the exclusive right conferred by a patent does not extend to studies and trials aimed at obtaining an authorisation to place a medicinal product on the market, nor does it extend to the consequential practical requirements, including the preparation and use of pharmacologically active raw materials strictly necessary for that purpose. This current framework is strictly teleological and narrow in scope. Italian courts have consistently interpreted this provision as covering only generic, biosimilar, and hybrid medicinal products, purposefully excluding innovative originator products. Originators seeking to conduct pre-registration trials for novel drugs cannot rely on the Italian Bolar clause and must instead turn to the distinct “experimental use exemption” under Article 68(1) (a-bis) of the IP Code, which permits genuine scientific research conducted on the patented invention itself to advance the state of the art.

The new EU Compromise Text for Article 85 upends this restrictive approach. The proposed directive explicitly broadens the exemption to encompass studies, trials, and activities that are necessary for obtaining a marketing authorisation for any medicinal product, thereby erasing the distinction between generics and innovative products. By bringing originators and subsequent variations within the Bolar safe harbour, the EU text eliminates the need for originators to rely solely on national experimental use provisions for pre-registration trials, creating a unified regulatory shield.

3. **Expanding the Scope: Market Access and Supply Chain Legalisation**

Beyond the types of products that are covered, the most profound comparative difference between the old and new regimes lies in the scope of activities which would fall under the Bolar exemption.

The current Italian Bolar exemption acts as a strict regulatory safe harbour focused almost exclusively on the preparation of the MA dossier. Activities that are primarily commercial in nature, or those relating to subsequent market access phases, fall clearly outside the exemption. The proposed EU Article 85, however, expands the safe harbour across the entire continuum of activities connected with market access prior to launch. The revised text explicitly protects data generation, and comparative clinical trials conducted for Health Technology Assessment (HTA) procedures, as well as administrative procedures and negotiations for obtaining Pricing and Reimbursement (P&R) approval.

This expansion into market access activities is further amplified by the new text's inclusion of broad supply chain acts within those permitted under the exemption. Currently, Italian law views manufacturing as covered only insofar as it is strictly necessary for MA clinical trials, treating the manufacture of finished products for commercial purposes, stockpiling, and offering for sale as clear acts of patent infringement. In stark contrast, Article 85 expressly legalises commercial-type supply chain steps when conducted for the exempted regulatory purposes. The proposed directive explicitly states that permitted activities may cover the offer, manufacture, sale, supply, storage, import, use, and purchase of medicinal products or processes. While paragraph 3 of Article 85 clarifies that the actual "placing on the market" of the medicinal products remains excluded and is thus infringing, the explicit inclusion of broad preparatory acts blurs the historical line between permitted regulatory conduct and prohibited commercial exploitation.

4. **The Third-Party Dilemma: National Case Law versus European Harmonisation**

The treatment of third-party suppliers further highlights the divergence between the current realities in Italy and the future European standard.

Because the statutory text of the Italian IP Code is framed objectively around the nature of the acts rather than the identity of the actor, third parties such as Contract Development and Manufacturing Organisations (CDMOs) and active pharmaceutical ingredient (API) suppliers have sought Bolar protection. The Italian Supreme Court, in its recent landmark decisions in the *Teva v. Boehringer Ingelheim* cases (Decision No. 18372 of 2024 and Decision No. 20074 of 2025), affirmed that third parties can rely on the Bolar exemption, but imposed severe restrictions. The Court ruled that API suppliers are protected only if the manufacturing activity is initiated upon the explicit, prior request of a generic applicant, insofar as the production is guided by the initial need to fulfil regulatory requirements and the contract expressly restricts the use of the API solely to exempt regulatory purposes.

In contrast, the new EU text expressly covers activities conducted by third-party suppliers and service providers, but it does not explicitly articulate these strict *ex-ante* contractual prerequisites. It remains highly uncertain whether Italian courts will maintain this rigorous three-part test, or whether the new EU directive will be interpreted as loosening these national contractual requirements, thereby granting remote actors in the supply chain greater freedom.

5. **The Impact on Patent Enforcement and Preliminary Injunctions**

Perhaps the most critical consequence of shifting from the old Italian Bolar framework to the new EU model is the profound impact on the assessment of imminent infringement and the granting of preliminary injunctions (PIs). Under established Italian judicial practice, the mere filing or grant of an MA application does not constitute an imminent threat of patent infringement. However, Italian courts adopt a holistic approach to pre-launch activities. To date, acts such as participating in public procurement tenders, executing pre-launch distribution arrangements, applying for P&R approval, and commercial stockpiling have been viewed as concrete evidence of an imminent threat, readily triggering the issuance of a PI before the patent expires.

The revised EU text fundamentally alters this enforcement dynamic. Because Article 85 explicitly exempts P&R approvals, HTA evaluations, pre-launch storage, and crucially, submitting applications to participate in procurement tenders (provided no supply occurs during the patent term), these activities will no longer support a finding of an imminent threat. Consequently, the enforcement window for patent holders will compress significantly. The threshold for engaging enforcement measures will move away from early indicators of launch and shift drastically closer to actual market entry. Patent holders will be forced to wait for clearer evidence of intended commercialisation, such as post-expiry delivery commitments or actual offering for sale, before they can successfully petition an Italian court for pre-launch injunctive relief.

6. **Procedural Complexities: SPC Waivers and Article 56a Access Obligations**

These reduced options for enforcement are further complicated by the interplay between the expanded Bolar exemption and the SPC Manufacturing Waiver. The existing waiver allows generic companies to manufacture for export to third countries and to stockpile for an EU Day-1 launch during the final six months of the SPC term. Because the revised EU Bolar text will also allow generic companies to manufacture and store batches during the protection period if strictly necessary for the newly expanded MA, HTA, P&R, or tender compliance purposes, distinguishing between “Bolar-exempt storage” and “SPC Waiver stockpiling” will present massive evidentiary challenges. The risk of mixed stocks will be incredibly high, making ex-post monitoring and the enforcement of statutory limits exceedingly difficult for patent owners.

Furthermore, the introduction of Article 56a in the draft Directive provides new complexities for patent enforcement. This article allows Member States to request an MA holder to place a product on the market to meet patient needs, failing which the product's regulatory market protection may be suspended, allowing generic competitors earlier regulatory access. While this affects regulatory exclusivity rather than the underlying patent rights, the removal of the regulatory barrier introduces a strong public-interest signal in favour of patient access. When an originator files for a PI based purely on patent rights after losing regulatory protection under Article 56a, Italian courts evaluating the balance of hardship and urgency will face strong public interest arguments, potentially further reducing the likelihood of granting pre-launch injunctions.

7. **Conclusion: Adapting to a Broadened Regulatory Horizon**

In conclusion, the proposed EU Pharmaceutical Package represents a paradigm shift from a narrow, MA-focused safe harbour to an expansive, market-access-oriented exemption. For Italy, a jurisdiction where

the Bolar clause has historically been construed to exclude commercial and pre-launch preparatory acts, this reform will require legislative amendments to the national IP Code. The transition will fundamentally alter patent enforcement dynamics, severely reducing early enforcement opportunities, delaying the timing for seeking injunctive relief, and eliminating key PI triggers such as participation in public tenders and P&R approval applications.

As the boundary of imminent infringement shifts ever closer to actual market entry, both originators and generic manufacturers will need to profoundly adapt their litigation and supply chain strategies to navigate this newly broadened regulatory landscape.

