Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 183 - 184 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.087
Short communication

Pharmaceutical patent protection in Europe: Challenges and alignment of national practices

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Introduction

A patent is a tool that serves two distinct purposes: it protects an invention from unauthorized third-party commercial use while also disseminating knowledge of new innovations in different fields of technology. In the pharmaceutical industry, originator companies are the primary driver of innovation which often requires substantial investments in research and development (R&D). Accordingly, these companies are expected to account for a large share of patent application and patent ownership. According to 2024 statistics from the European Patent Office (EPO), 7 out of 10 applicants that filed the highest number of patent applications in the pharmaceutical field were originator companies. Generic companies by contrast, must develop and launch their products without infringing any valid third-party patent rights, often by designing around key patent-protected aspects of the originator product. Given the contrasting approaches of these two types of companies, originator companies may seek to protect multiple aspects of an invention in order to delay generic product entry and maintain market exclusivity. Generic companies may, in turn, respond to such strategies by challenging the validity of relevant patents through opposition proceedings before patent offices and revocation actions before national courts.

Although patent law is substantially harmonized across EPO member states, national courts may differ in their interpretation and application of the relevant legal standards. Consequently, the outcomes of patent validity challenges before national courts and Intellectual Property Offices may vary from one country to another. Such divergence can lead to differences in availability of generic medicines in different countries, ultimately affecting patients' access to more affordable therapies.

This paper examines how divergent national decisions in pharmaceutical patent validity disputes may affect the timing of generic market entry and explores whether the Unified Patent Court can contribute to greater consistency within the participating European framework.

Comparative case study of Rivaroxaban and Apixaban

This study examines two pharmaceutical patent disputes in which challenges to key originator patents led to divergent outcomes across European jurisdictions. In the case of Xarelto® (rivaroxaban), an antithrombotic Xa inhibitor, its originator, Bayer held a patent covering once-daily dosing regimen of the product, which was valid until 19.01.2026. The

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validity of this patent was challenged in several European countries on the grounds of lack of inventive step. While courts in UK and France, revoked the patent, courts in the Netherlands and Belgium upheld its validity. This divergent outcome enabled earlier generic market entry in some jurisdictions than in others, illustrating how national decisions on the same patent family may affect the timing of access to generic therapy. (Richter, K. 2025). A similar divergence can be observed in the case of Eliquis® (apixaban), another antithrombotic factor Xa inhibitor. The compound patent was challenged in relation to plausibility, in the context of insufficiency of disclosure and inventive step. This patent is due to expire on 20.05.2026 in the countries where Supplementary Protection Certificate is in force and 20.11.2026 in the countries that have pediatric extension. However, in 2022 the patent was revoked in United Kingdom, whereas courts in Netherlands and France among other countries upheld its validity (England and Wales High Court, 2022; The Hague Court of Appeal, 2023). As a result, patients from UK could have access to less expensive, generic products even 4 years before patients in the rest of the countries.

Taken together, these cases demonstrate that divergent national decisions in pharmaceutical patent validity disputes can have direct impact on the timing of generic market entry and, consequently, on patients' access to more affordable medicines. A system of centralized adjudication, such as that offered by the Unified Patent Court for participating states, may help reduce such divergence within its territorial scope.

Unified Patent Court

As an active measure for reducing these inconsistencies, the European Union introduced the Unitary Patent system on 1 June 2023. The Unitary Patent enables a simplified validation and maintenance process in 18 participating member states through the payment of a single annual renewal fee. An additional advantage to this system is the Unified Patent Court, which offers centralized decision-making process on the validity and infringement of unitary patents. The transitional period for implementation is 7 years and currently is expected to end on 1 June 2030. During this period, proprietors of classic European patents may opt-out of the jurisdiction of the UPC, meaning that disputes concerning those patents may continue to be handled by national courts. However, it should be noted that this transitional period may be extended by up to another 7 years by the decision of the Administrative Committee of the UPC, potentially by 1 June 2037. It is expected that this system could play an important role in reducing differences in court outcomes within the participating states, thereby limiting negative impact of divergent national decisions on end-users, including patients.

Conclusion

The analysis of selected cases shows that divergent national patent court decisions can significantly affect the timing of generic market entry and, consequently, patients' access to more affordable therapies. The Unitary Patent System and the Unified Patent Court represent important steps towards greater consistency within the participating states. However, during the transitional period, which may last up to 14 years, proprietors of classic European patents may still opt out of the UPC system and rely on national court proceedings. Therefore, while the new system may reduce fragmentation, divergent outcomes may continue to occur during the transitional phase.

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