Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 205 - 206 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.098
Short communication

The impact of originator patent strategies on generic drug entry in Europe

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Introduction

The European pharmaceutical market operates within a complex legal and economic framework designed to balance public health protection with incentives for pharmaceutical invention. Patent protection is a key mechanism for encouraging investment in research and development by granting originator companies time-limited patent protection and a temporary monopoly on the market. However, in practice, deficiencies in patent examination especially in assessing the inventive step often undermine this balance, as patents may be granted without a genuine technical contribution or protection may be extended through strategies such as divisional applications. This creates significant barriers to generic entry, patent protection for a prolonged period, delays competition, and leads to high prices of medicines. At the same time, the resulting legal uncertainty pushes generic manufacturers into costly and lengthy opposition and litigation proceedings, delaying generic drug market entry (Elizee T., 2024).

Weaknesses in the patent opposition procedure before the European Patent Office

According to Article 99 of the European Patent Convention (EPC), any patent granted by the European Patent Office may be opposed within nine months from the publication of the mention of the grant in the European Patent Bulletin. Oppositions may be based on the grounds set out in Article 100 EPC, such as lack of novelty, lack of inventive step, lack of industrial applicability, etc. According to Article 101 EPC, the outcome of opposition proceedings may result in the maintenance of the patent as granted, the maintenance of the patent in amended form, or the complete revocation of the patent.

One of the most common problems faced by the European Patent Office (EPO) is the slow resolution of patent opposition and appeal proceedings. These procedures are often used strategically by originator companies to delay the entry of generic medicines, thereby maintaining high prices and limiting access. In many cases, patent holders intentionally prolong opposition and appeal proceedings when the market situation is favorable, as the originator product remains the sole option during the proceedings, allowing continued profits. This practice may contribute to the extension of market exclusivity beyond the original purpose of patent protection. Notably, the revocation of patents through proceedings may take several years, considerably longer than the patent granting process itself. An additional challenge in opposition proceedings is that the burden of proof lies with the opponents, who must demonstrate the lack of novelty or inventive step, an inherently more complex process than proving patentability. This significantly increases the

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difficulty of successfully challenging and revoking disputed patents (Pinsent Masons, 2020)

Analysis of Novartis' Patent Strategy through the Antineoplastic Case

Structural weaknesses in patent law may be strategically used to sustain market monopoly beyond the expiration of the basic compound patent. This case concerns an antineoplastic drug developed by Novartis, whose patent was ultimately revoked by the Boards of Appeal of the European Patent Office (EPO) due to a lack of inventive step, despite having acted as a long-term barrier to generic entry. The compound patent, for which the patent application was filed in 1993, expired in 2013, and additionally, a Supplementary Protection Certificate (SPC) was granted, extending protection until 2018. In order to further prolong patent protection, Novartis filed a divisional patent application in 2002, claiming the medical use of the same active substance in combination with an aromatase inhibitor for the treatment of hormone-receptor-positive breast cancer. This patent was granted in 2019 and further extended by an SPC until 2027, allowing continued market monopoly even after the expiry of the compound patent. Multiple oppositions were filed, challenging the divisional patent on grounds of lack of novelty, lack of inventive step, insufficient disclosure, and added subject matter. Although the Opposition Division initially rejected these oppositions, the Boards of Appeal revoked the patent in July 2023. The decision was based on the loss of priority rights and the lack of an inventive step, as the claimed combination therapy was already suggested in the scientific literature and showed no unexpected or synergistic therapeutic effect. Despite its eventual revocation, this divisional patent successfully delayed generic competition for several additional years. This case illustrates how divisional patents and procedural delays can be strategically used to extend patent protection, even when the underlying invention lacks inventive step.

Conclusion

Patent strategies used by originator pharmaceutical companies play a decisive role in shaping the conditions for generic entry into the European market, with significant economic, legal, and public health implications. Strategies to extend patent protection, delay the entry of generic medicines, allowing originator products to remain dominant and maintaining high prices for extended periods. This increases healthcare costs for public systems and patients, while limiting access to affordable treatment options, particularly for patients with chronic or rare diseases. At the same time, generic manufacturers face substantial legal uncertainty, financial obstacles, and regulatory complexity, which increase the costs and risks associated with market entry. The cumulative effect of these barriers is reduced competitive pressure, fewer therapeutic alternatives, and prolonged financial strain on healthcare systems. Overall, these dynamics illustrate how patent strategies may significantly influence market outcomes, often prioritizing extended monopoly positions over competition and timely access to lower-cost medicines (Gambardella, A., 2023).

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