Position Paper

The Issue of Abuses of Divisional Patent Applications – A Way Forward

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Executive Summary

This position paper addresses the issues around misuses of divisional patent applications taking place through certain divisional patent strategies put in place in procedures before the European Patent Office (EPO). These strategies, also described as "divisional patent game", create legal uncertainty for generic/biosimilar medicines developers seeking to launch competitor products, with subsequent delayed competition.

This concern is reinforced by the increasing focus of competition authorities on "misuse of the patent system" in the pharmaceutical sector, where the assessment turns on the overall exclusionary effects of a strategy rather than the formal permissibility of each individual procedural step.

This practice defeats the checks and balances of the system, frustrating the judicial and administrative procedures inherent in the patent system, and thus prolonging the enforceable life of invalid patents.

The distortion of the patent system, described in detail below, has a very negative impact on timely patient access to generic and biosimilar medicines, on national healthcare budgets and on competition more generally, ultimately frustrating the prominent purpose of the patent system, which is to incentivise genuine innovation.

Medicines for Europe reiterates the importance of ensuring the highest quality of the EU patent system and proposes the following recommendations in relation to divisionals:

1) Stricter requirements for filing and allowing new divisional applications
2) Optimise and expedite procedures for divisionals
3) Prohibition of withdrawal of patents if there is a further divisional
4) Limit the filing of divisional applications to the 1st generation of divisionals
5) A 5-year deadline from the filing date of the 1st patent application for the filing of divisionals

Medicines for Europe is fully committed to constructively supporting these important systemic changes in the interest of timely patient access and competition, genuine innovation and sustainability of healthcare systems.

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Divisional Patents

Divisional patent applications are those deriving from an earlier patent application referred to as the "parent". Divisional applications can be used in case the parent application lacks unity of invention, *i.e.* it includes more than one invention. Therefore, the applicant splits the parent into one or more divisional applications each claiming only a single invention. The subject matter of a divisional application cannot extend beyond the scope of the earlier application. However, no limitations exist for new voluntary (i.e. not due to a lack of unity) divisional applications and applicants may file as many divisional applications as they wish, without any justification required. A European patent application may give rise to multiple divisional applications, which, themselves, may give rise to multiple divisional applications leading to several generations of divisional patent applications.

Divisional patents are deemed to have the same date of filing as the parent, *i.e.* they are considered protected retroactively from the filing date of the parent patent, but will be subject to new examination procedures and, if granted, new opposition periods independent from the outcome of the parent application.

While divisional filings do not extend the formal patent term, the multiplication of independent grant and opposition cycles can prolong uncertainty about the effective scope and enforceability of the overall patent family, making it difficult for third parties to predict when all relevant barriers will be resolved.

The Issue: the “divisional patent game”

Certain divisional patent strategies put in place in procedures before the European Patent Office (EPO) create legal uncertainty for generic/biosimilar medicines developers seeking to launch competitor products, with subsequent generic/biosimilar delayed launch. This can manifest in the practice of:

(i) **filing cascades of divisional patent applications**, with each divisional patent application filed subsequently, at different times, all related to the same parent application (which itself may be weak) and claiming in slightly different ways the same product, salami-slicing second medical uses or trying to block any alternative option to design around the claims of the parent application. A key feature of these cascades is the “moving target” effect: within the confines of the original disclosure, claim scope can be reshaped over time, so that a design-around developed against one granted claim set may later be confronted by a differently formulated divisional targeting the same commercial product pathway;

(ii) **defending such divisional patents in separate EPO opposition** proceedings;

(iii) **enforcing such divisional patents in national courts**, including via preliminary injunctions;

(iv) **blocking or delaying pricing and reimbursement procedures** for generics/biosimilars, thus triggering *unlawful* patent linkage;

(v) eventually, **strategically withdrawing any earlier patent** from the family, **just before it is due to be considered** by the Opposition Division or Technical Board of Appeal of the EPO (TBA), to avoid a decision confirming it is invalid; and,

(vi) whether invalidated or withdrawn, l**ater-filed divisional patent applications covering the same product replace the barrier**, triggering a new cycle.

To describe what it means in concrete terms, suffice to say that, at the EPO, the grant of every divisional patent triggers a new opposition deadline (9 months) and a minimum of 4 months is given to the patentee to reply to a notice of opposition. Although acceleration is possible, an opposition can take between 3 and 6 years until final resolution by the TBA. If the parent application is withdrawn at the oral hearing just before the TBA announces a decision that could negatively affect the examination or opposition of the other divisional members of the family, the clock starts ticking again from the beginning. In practical terms, this means competitors may be compelled to initiate and maintain multiple separate opposition and/or invalidity tracks across successive family members to achieve legal certainty—costly parallel proceedings that can materially deter timely market entry even where underlying claims appear weak.

Therefore, the patent applicant, whilst being aware of the weakness of its patent, can maintain legal uncertainty by keeping a series of divisional patent applications pending for an extended period of time. Even when a parent patent is invalidated before a patent office or court, there will still be a divisional patent application covering substantially the same subject matter, replicating the legal uncertainty. Divisional applications can be applied for until the day of publication of the grant of the parent patent. Therefore, every time one patent application in the family approaches grant, a new divisional may be applied for, thus restarting the lengthy examination/grant/opposition process and creating an interminable version of a legal 'Whack-A-Mole'. This dynamic is exacerbated where earlier rights are strategically withdrawn shortly before a substantive EPO decision, because the absence of a reasoned validity outcome makes it easier to re-introduce closely related claim sets via remaining or newly filed divisionals. This may even result in divisional applications being granted close to the expiry date (*i.e.* almost 20 years from the parent application filing) and with no material time for filing oppositions before the actual expiry.

The uncertainty is even higher, with increased risk of patent infringement, in scenarios where a patent thicket has been generated and divisional applications are filed from numerous secondary patents.[1]

This practice defeats the checks and balances of the system, frustrates the judicial and administrative procedures inherent in the patent system, and prolongs the life of patents that, if allowed to reach scrutiny, would not stand up to it at EPO or court proceedings.

The Impact of the "divisional patent game"

The distortion of the patent system described above results in:

(i) unjustified prolongation of the enforceable life of invalid patents

(ii) unnecessary and costly oppositions and litigation against multiple members of the same patent family;

(iii) delayed generic/biosimilar entry, as the launch is blocked by the granting of injunctions and/or costs of litigation. The deterrent effect for competitors is reinforced by the procedural asymmetry between the speed of interim enforcement and the slower pace of definitive validity decisions across multiple related rights: even a short-term market

[1] Specific examples and additional details are included in the Whitepaper: *Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy*, 5 Nov. 2020, available at: https://www.medicinesforeurope.com/docs/2020.11.04-Medicines-for-Europe-Whitepaper.pdf

exclusion can be commercially decisive, while full resolution of validity may come only after extended multi-stage proceedings; resulting in

(iv) huge economic impact on national healthcare budgets due to delays to more affordable medicines being made available.

(v) a concrete risk for potential damages to be awarded by a national court or the Unified Patent Court (the "UPC"), even if the divisional patent is later revoked in national or UPC proceedings or at the EPO;

Competition Law Aspects

Already in 2009, in the Pharmaceutical Sector Inquiry Report, the Commission condemned the proliferation of divisional patent applications, noting that the "*examination of divisional applications continues even if the parent application is withdrawn or revoked, which can add to the legal uncertainty for generic companies*", adding that: "*filing divisional applications for the same secondary patent... can… be used strategically to create further uncertainty and delays for new entrants*."[2]

Due to the anticompetitive effects of this practice, in 2009, Rule 36 of the European Patent Convention (which governs divisional applications) was amended to limit the time period within which a divisional application could be filed to two years from the Examining Division's first communication to the applicant (with limited exceptions). However, this led to an initial influx of divisional applications that stretched the EPO's limited resources and, after a consultation and some effective lobbying, the deadline was removed in 2014.

In the absence of a deadline, this initial increase of divisional filings receded. However, over time the number of divisionals per patent family has risen again, and these divisionals were filed increasingly late, thereby escalating the anticompetitive effects already identified in 2009.

Today, this continues being a widespread issue.[3] From a competition-law perspective, the key point is that a strategy can be considered exclusionary based on its objective market effects even where the underlying steps are formally 'legitimate', as compatible with sector-specific patent procedures. This strengthens the case for targeted procedural safeguards that reduce the scope for strategies whose primary function is delay rather than resolution.

The ongoing glatiramer acetate case recently brought by the European Commission shows greater attention by European institutions to the divisional patent system and its potential effects on competition, further highlighting the importance of the issues and recommendations discussed herein.

Moreover, the availability of preventive certainty tools against future or pending rights is not uniform across Europe, which further supports the need for EPO-level procedural safeguards that reduce strategic uncertainty at its source.

[2] European Commission, *Final Report: Pharmaceutical Sector Inquiry* (8 July 2009), para. 275

[3] The International Generic and Biosimilar Medicines Association (IGBA) 2025 Report "Gaming the system: An overview of originator companies' evergreening strategies used to hinder access to generic and biosimilar products" shows the issue of misuses of divisional patent applications is particularly problematic in Europe but also in other jurisdictions worldwide.

Recommendations

In line with what was highlighted by the EU Commission in 2009, Medicines for Europe reiterates the importance of ensuring the highest quality of the EU patent system, notably in view of the very direct impact it has on competition and public health expenditure.

To this aim, Medicines for Europe makes the following recommendations in relation to divisionals:

1) Stricter requirements for filing and allowing new divisional applications

a) When filing an application, the applicant must

i) Justify why it was not possible to include the claims from the beginning, confirming it does not add matter and that the claims were not already considered;

ii) Explain the differences from any application claiming common priority and the reasons for filing such divisional;

iii) Have a duty to disclose all relevant documents from the examination or opposition of any application claiming common priority.

b) When receiving an application, the examiner should reject the application unless:

i) The examiner is satisfied with the justification as to why it was not possible to include the claims from the beginning and with the confirmation that it does not add matter and that the claims were not already considered;

ii) The examiner is satisfied with the explanation on the differences from any application claiming common priority and the reasons for filing such divisional;

iii) The examiner is satisfied with the documents disclosed from the examination or opposition of any application claiming common priority.

Should the examiner not be satisfied with any of the points above, the application should be rejected. These requirements would operationalise a clear expectation of claim differentiation, ensuring that divisionals are used to pursue genuinely distinct subject matter (e.g., to address unity or specific objections), rather than to re-file substantially the same claim set and thereby prolong uncertainty through repetitive re-examination.

2) Optimise and expedite procedures for divisionals

a) Without creating delays, examination proceedings of patent applications from the same family (parent/divisionals) should be heard together (in combination) whenever these applications overlap, where possible by the same examiner (*e.g.* a "patent family manager"). The same should apply to opposition (incl. appeals) proceedings of parent/divisional patents. A family-based approach also reduces opportunities to exploit fragmentation of proceedings (and inconsistent visibility of the relevant file history) as a delay tactic, and it supports coherent, timely decision-making on overlapping claim scope across the patent family;

b) The applicant must disclose all relevant documents from any national or UPC proceedings related to any patent applications or granted patents claiming common priority. The EPO must consider all such disclosed documents and all documents from any patent applications or granted patents claiming common priority as part of the

examination/opposition of any related divisional in order to give continuity to the arguments and evidence used in each patent family;

c) If there is pending litigation that gives the ability to request expedition at EPO for one family member, the expedition should apply to the whole family, in coherence with point 2)a);

d) In order to mitigate any legal uncertainty, examinations of divisional applications should be fast-tracked and limited to a maximum of 12 months until a final determination is adopted, when no additional search is needed.

3) Prohibition of withdrawal

a) No withdrawal should be allowed of any patent under opposition when there is a pending application or granted patent claiming common priority, in harmony with the provisions of Art 105a EPC, to assure issuance of a reasoned decision. Ensuring that opposition proceedings culminate in a reasoned decision is essential to preserve the integrity of the EPO's checks and balances and to prevent "drop-and-switch" patterns in which a negative decision is avoided while parallel family members remain available to continue the barrier through closely related claims.

4) Limit to 1st generation of divisionals

a) The filing of a divisional patent application should be limited to the first generation of divisionals, *i.e.*, only divisionals of the original European application should be permitted, in line with a similar rule in another IP5 (China). In this way, applicants are assured of the opportunity to explore the legitimate scope of protection during the prosecution of their first application, and guaranteed an opportunity to file divisionals in order to pursue strategically important subject matter not granted during those proceedings. A first-generation limitation directly targets the serial "chain" dynamic that enables repeated re-starting of grant and opposition cycles, and it therefore supports earlier certainty as to the final scope and viability of the patent family relevant to market entry.

5) 5-year deadline

a) Introduction, for the filing of any divisional application, of a 5-year deadline from the filing date of the first patent application. This would provide a reasonable period of time for any divisional to be sought while limiting the potential for abuse, and should be accompanied by additional EPO resources to ensure the well-functioning of the EU patent system.

Such recommendations are perfectly in line with the stated objective of the EPO to improve timeliness in substantive examination and opposition as well as streamline the patenting process.[4]

While some of these changes may be introduced by issuing new EPO guidelines, others require the amendment of the European Patent Convention (EPC). These proposals are designed to preserve the legitimate role of divisionals (e.g., addressing unity issues and pursuing distinct inventions) while

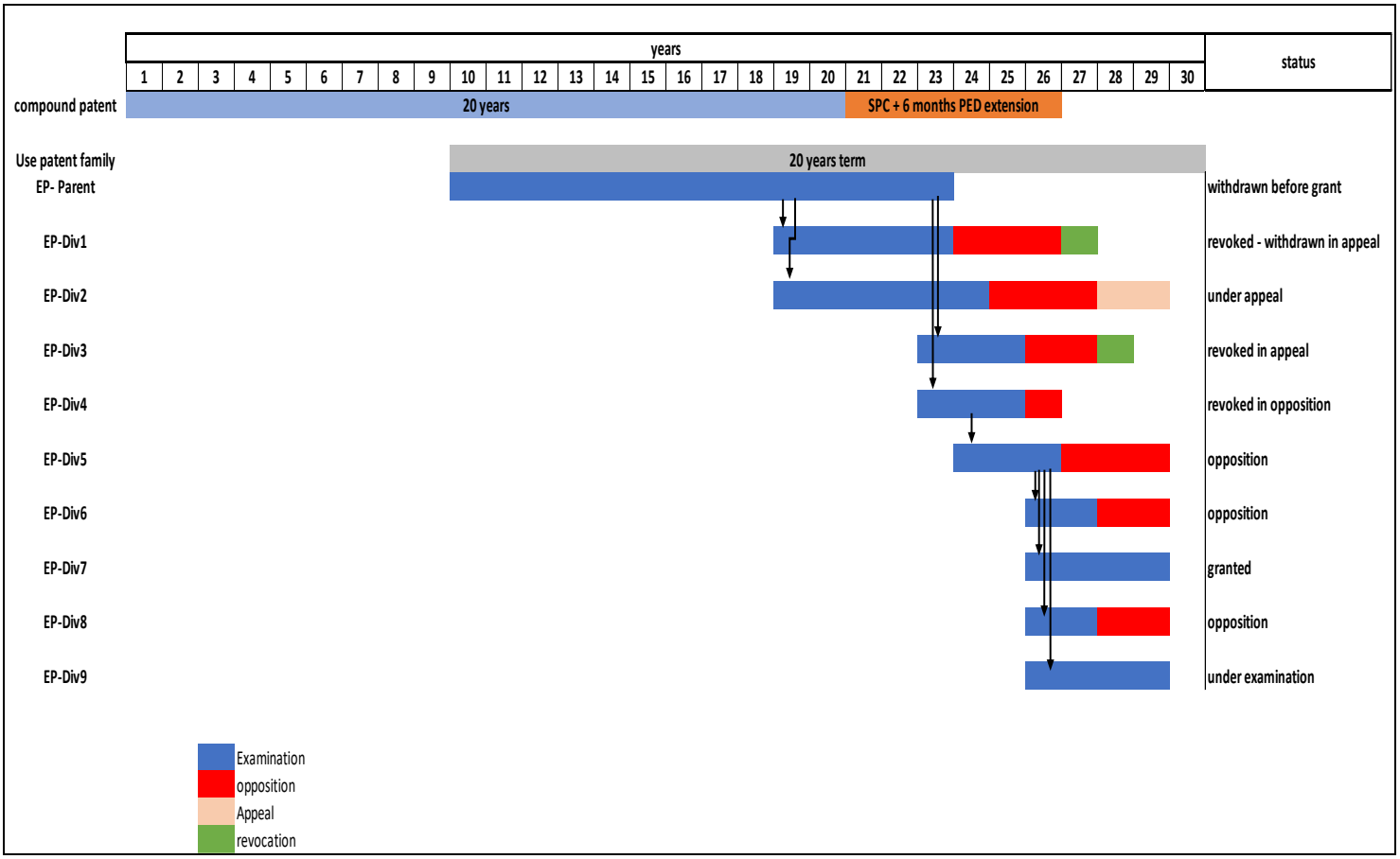
[4] For example, the Rules of Procedure of the Board of Appeals leave to the discretion of the Board the admittance of any amendment of the case after the grounds have been filed and the party has to provide reason for filing the amendment at late stage of the procedure (Art. 12.4 and Art. 13.1)

preventing procedural repetition that functions primarily as a tool to extend uncertainty and delay effective competition.

The table below provides a real example of a “divisional patent game”.

Medicines for Europe remains fully committed to constructively supporting these important systemic changes.

TABLE 1 [5]



[5] Company and product names have been omitted.