

Position Paper

The Issue of Abuses of Divisional Patent Application

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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.* includes more than one invention and, 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 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 generation 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 independently from the outcome of the parent application.

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 weak parent application 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;
- (ii) defending such divisional patents in European Patent Office (EPO) opposition proceedings;
- (iii) enforcing such divisional patents in national courts, incl. via preliminary injunctions; and,
- (iv) 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, to avoid a decision confirming it is invalid.

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 Technical Board of Appeal of the EPO. Unless, as happens in some cases, the parent application is withdrawn at the oral hearing just before the Technical Board of Appeal announces a decision that could negatively affect the examination or opposition of the other divisional members of the family, and consequently the clock starts ticking again from the beginning.

In doing so, 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, so that 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 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.

All this results in:

- (i) undue 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;
- (iv) a risk for potential damages to be awarded by a national court, even if the divisional patent is later revoked in national proceedings or at the EPO.

This practice obviously defeats the check and balances of the system, frustrating the judicial and administrative procedures inherent in the patent system, thus prolonging the life of patents that, if reached judicial scrutiny, may not be able to stand up to it.

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

The EU Competition Law Scrutiny of 2009

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

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>

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

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.

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. There should be stricter requirements for filing and allowing new divisional applications:
 - i. only claims not previously included in the parent application (or other members of the family) should be allowed;
 - ii. the applicant should justify why it was not possible to include the claims from the beginning;
 - iii. when filing an application or defending the opposition of a divisional patent, the patentee should have a duty to disclose all relevant documents from any parent application's examination or opposition file and explain the differences and the reasons for filing such divisional
2. 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. All documents from the parent patent should be considered 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;
3. If there is pending litigation that gives ability to request expedition at EPO for one family member, the expedition should apply to the whole family, in coherence with point 2;
4. If a divisional application is withdrawn:
 - ✓ the applicant should
 - iv. provide the detailed reasons for such withdrawal;
 - v. specify in what way any pending divisional differs/overcomes the problem(s) of the withdrawn one;
 - vi. in case a subsequent new divisional application is filed, the applicant should specify in what way it differs and overcomes the problem(s) of the earlier one(s).
 - Failure to provide such detailed information should make the withdrawal or the application inadmissible;

✓ if there is a pending decision by the Opposition Division or Technical Board of Appeal on a divisional that is later withdrawn, a reasoned decision should be issued anyway, in coherence with point 2.

5. In order to mitigate any legal uncertainty, examinations of divisional applications should be fast-tracked and limited to a maximum of 6 months for the first divisional and 3 months for the subsequent ones;
6. It should not be allowed to file with the divisional application/patent any new experimental data or new facts that would overcome a patentability issue of an earlier application/patent. This would lead to an unallowable late filing of facts and evidence;
7. The EPO should reaffirm the strict application of the prohibition of double patenting.

Such a recommendation is 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.³

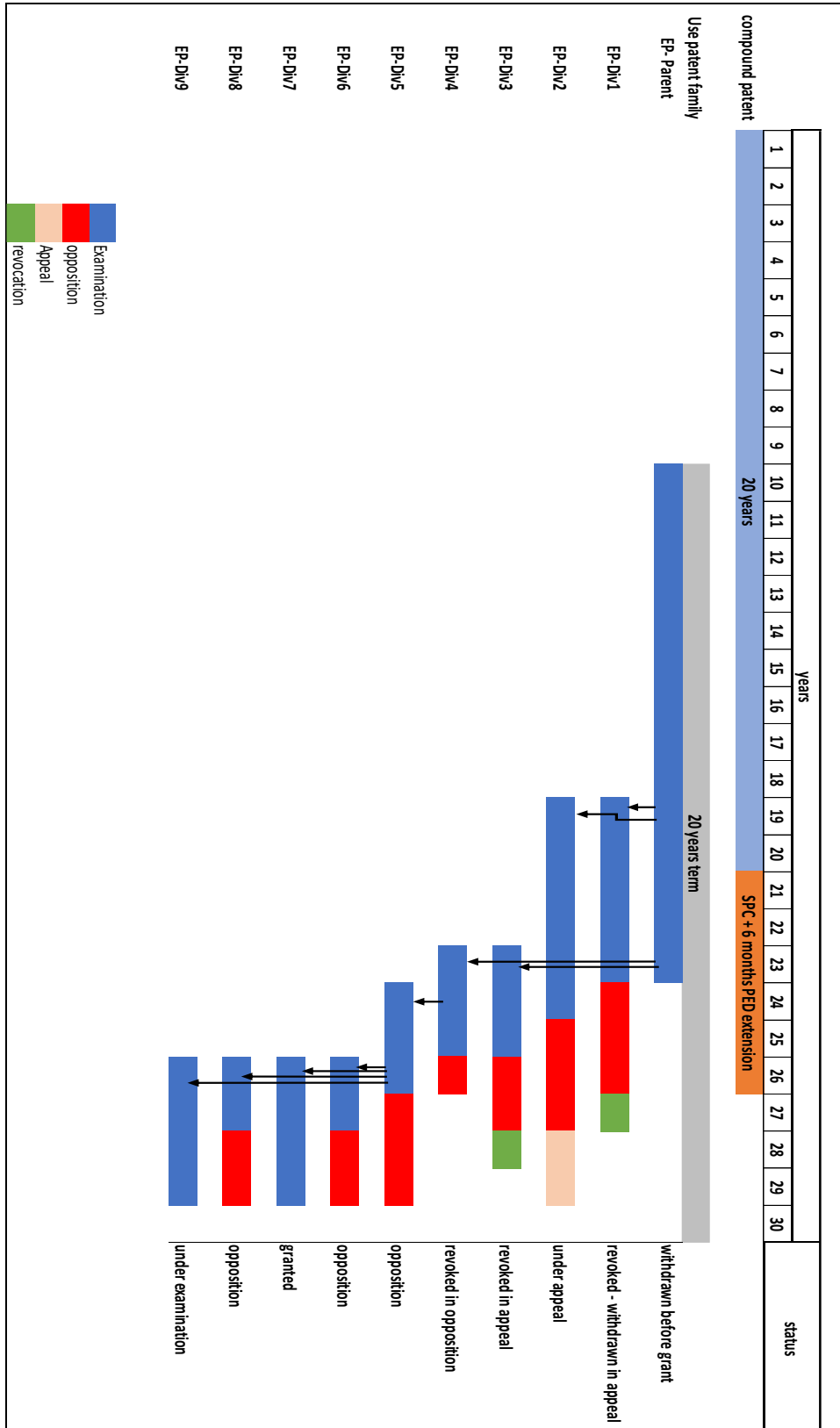
These changes may be introduced by amending the European Patent Convention (EPC) and issuing new EPO guidelines.

In addition to the solution described above, Medicines for Europe recommends the re-introduction of a 5-year deadline for the filing of any divisional applications that is not only dependent on the pendency of the relevant parent patent or its divisionals. This would provide a reasonable period of time for any divisional to be sought while limiting the potential for abuse. This should be accompanied by additional EPO resources to ensure the well-functioning of the EU patent system.

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

³ 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)

ANNEX ⁴



⁴ Company and product names have been omitted.