

FACTSHEET

The issue of divisional patent applications

April 2021

What are divisional patents?

The current framework allowing unlimited filing of divisional patents opens the door to a widespread misuse of the patent system to artificially delay generic and biosimilar competition.

Divisional patent applications are those deriving from an earlier patent application (the "parent"), which the applicant splits into a sequence of divisional applications each claiming a single element of the same claimed invention.

Divisional applications, themselves, can give rise to further multiple divisional applications, without any limitation. Each divisional patent lasts until the expiry date of the parent patent, but is subject to new examination procedures and, if granted, new opposition periods independently from the outcome of the parent application.

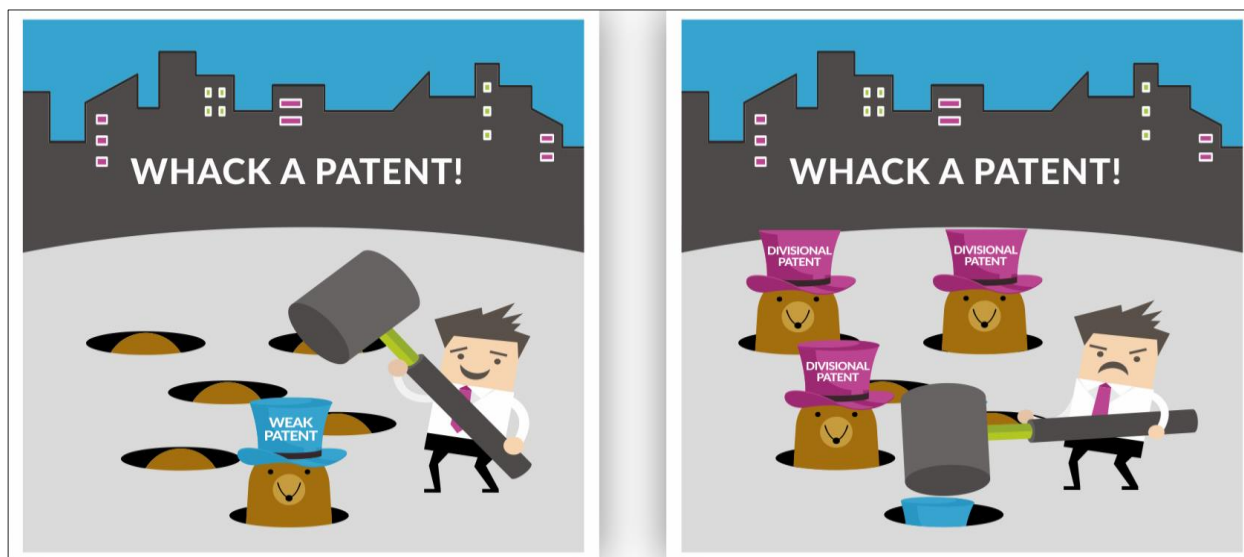
The issue

Divisional patent strategies are often pursued by originator pharmaceutical companies at the European Patent Office (EPO)¹ to create legal uncertainty for generic/biosimilar medicines developers seeking to launch competitor products, resulting in delayed launches and, consequently, delayed patient equitable access to medicines.

The "divisional patent game" is the following:

- (i) filing cascades of divisional patent applications at different times, related to the same weak parent application
- (ii) defending such divisional patents in (EPO) opposition proceedings
- (iii) enforcing such divisional patents in national courts, incl. via preliminary injunctions
- (iv) strategically withdrawing any earlier patent from the family, just before an EPO decision confirming it is invalid, thus avoiding the negative effects on the other divisional members of the family
- (v) even when a parent patent is invalidated in Courts, there will still be a divisional patent application covering substantially the same subject matter, replicating the legal uncertainty and the clock starts ticking again

Good-to-know: An opposition proceeding to invalidate a divisional patent can take 3-6 years until final resolution by EPO Technical Board of Appeal thus offering ample opportunity to artificially extend monopoly rights



¹ The EPO grants European patents, whose protection extends in the Member States picked by the patent owner. Such patents are then enforced and litigated in court at national level.

The EU competition law scrutiny of 2009

In 2009, in the [Pharmaceutical Sector Inquiry Report](#), the European Commission condemned the proliferation of divisional patent applications, noting that "*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.*"

Due to the anticompetitive effects of this practice, Rule 36 of the European Patent Convention was amended in 2009 to set deadlines for filing divisional applications. However, due to limited EPO resources and some effective lobbying, the policy was changed in 2014 and the deadline was removed.

What can be done: recommendations

In line with the findings of the 2019 EC Sector Inquiry and seen the very direct impact it has on competition and public health expenditure, Medicines for Europe recommends:

1. **Stricter requirements for filing and allowing new divisional applications.**
2. **Examination & opposition proceedings of patent applications from the same family should be heard together, incl. in relation to expedition of EPO procedures.**
3. **The withdrawal of a divisional application should be allowed only if duly justified and an EPO decision should be issued anyway.**
4. **Examination of divisional applications should be fast-tracked.**
5. **Divisional application/patent should not include any new experimental data or new facts that would overcome a patentability issue of an earlier application/patent.**
6. **The EPO should reaffirm the strict application of the prohibition of double patenting.**
7. **In addition, a 5-year deadline for the filing of any divisional applications should be re-introduced.**

