# Family matters: an empirical analysis of how divisionals and secondary patents extend legal uncertainty in life sciences

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**Family matters: an empirical analysis of how divisionals and secondary patents extend legal uncertainty in life sciences**

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**Abstract**

When a patent application is pending, it is uncertain whether a patent will be granted and, if so, what protection it will confer. If the validity of the patent is then challenged, uncertainty continues until a final decision in opposition is obtained. This uncertainty extends when multiple applications surround a single innovation, a phenomenon that is common in life sciences and can therefore have a great impact on healthcare systems and patients. This article examines whether examination duration, and therefore the period of uncertainty, at the European Patent Office (EPO) varies systematically with parent and divisional applications, secondary patenting, and the economic value of the associated drug. Using bulk EPO Register data and IQVIA Ark[5]/MIDAS®[6] data, 15,737 patent applications filed at the EPO between 1978 and 2026 Q1 are linked to a drug. Cox proportional hazards models show that parent applications and secondary patents are associated with significantly longer pendency than single applications, particularly for high-value drugs. Additional indicators trace where and how these delays arise. The findings suggest that delays are connected to the combined use of several procedural rights, both across a patent family and within individual applications, and are not limited to multi-generation families.

**Keywords**: life sciences; pharmaceutical patent; divisional application; secondary patent; patent family, European patent office; survival analysis

**JEL codes**: O34, O38, L65, I18, K11, C41

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[5] IQVIA Ark Patent Intelligence at March 2026 release, covering 130 countries. Mapping of 41 patent type categories for small molecules and biologic drugs.

[6] IQVIA MIDAS® quarterly value sales data (in USD) at Q4 2025 release for small molecules and biologics (including additional elements product name & ATC class) in US and EU**, reflecting estimates of real-world activity.  ***Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Netherlands, Norway, Poland, Romania, Slovakia, Spain, Sweden, Switzerland, UK, US*

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## 1. INTRODUCTION

Patents have always functioned as a trade-off mechanism between monopolistic incentives and competition as a means to drive innovation. In exchange for disclosing an invention, the applicant obtains a temporary right to exclude others (typically 20 years per granted patent). While patents have been linked to innovation and economic growth, research in life sciences is also considering the societal cost of that bargain and its implications for public health (Branstetter et al., 2011; Bacigalupo, 2023; Kesselheim, 2007; Amin & Kesselheim, 2012; European Commission, 2009).

In the pharmaceutical sector, this translates into a period during which generic or biosimilar competition cannot occur, during which time the originator company can charge monopoly prices. Once the initial compound patent (commonly referred to as the "primary" patent) expires, generic entry can deliver substantial savings. For example, comparative analyses by Dylst, Vulto & Simoens (2015) find that generic drugs are not only sold at a significant discount, >60% price reduction compared to originators, they also reach more patients, either through amendment of treatment guidelines, which enables patients to receive an effective drug earlier, or through treating previously untreated patients. Kirshner et al. (2024) also found that the Dutch healthcare system would have spent 178.5 million USD more over 2.5 years on Trastuzumab if biosimilars would not have been available. They estimate that cost to the healthcare system is 57% lower while the number of treated patients increased significantly, for every patient an additional 1.3 patients were treated. In 2009, the European Commission Pharmaceutical Sector Inquiry already estimated a 7-month delay in generic entry in the period 2000–2007, costing EUR 3 billion in foregone savings (European Commission, 2009). In 2024, a study by IQVIA outlined that the total originator value of biologics and small molecules which should see generic entry across 5 European markets over a 4-year period is nearly 23 billion USD (IQVIA, 2024). Combined with the >60% price decrease mentioned above, this means that at least 13.8 billion USD are at stake for European healthcare systems savings.

It can be argued that this is the price for innovation, especially considering that not every invention makes it to the market, so maximising the returns on the drugs that achieve market authorization could be seen as a justifiable argument to compensate for all the drug candidates that drop out during the development process (Foor, 2018). What is clear however, is that these figures show that there are significant financial stakes linked to the duration during which originators may maintain their monopoly, giving the design of patent prosecution systems a direct bearing on healthcare expenditure (Harhoff, 2016).

In pharmaceutical patents, two instruments are particularly relevant to address this topic: secondary patents and divisional applications.

Secondary patents protect subject-matter that emerges after the initial compound is identified. Drug development does not end with the discovery of an active ingredient; subsequent research on dosage forms, manufacturing processes, and new indications can be patented. Once granted, they confer the same legal rights as any other patent. However, the UNDP's 2016 Guidelines suggest a more restrictive, public-health-oriented approach to a number of secondary pharmaceutical claims (polymorphs, salts, ethers, formulations, dosage forms, and new indications). Such claims may address a specific way to

solve a problem in drug development, but that fact alone does not determine whether they satisfy the applicable requirements of patentability.[1]

Divisional patents also serve a distinct but equally legitimate way to protect different aspects of an invention[2]. Two scenarios can arise. First, when an examiner identifies a lack of unity of invention (i.e. when an application covers more than one invention), the applicant is required to file a 'mandatory' divisional(s) in order to split out those separate inventions into separate patents. Secondly, 'voluntary' divisionals filing is also possible under Article 76 of the European Patent Convention (EPC), allowing an applicant to pursue the initially filed subject matter in separate applications while retaining the same priority and filing date of the original parent. The parent and divisional applications are treated independently and are searched and examined in the same way (EPO Guidelines for Examination C-IX, 1.4). The two requirements for both types of divisionals are that all the content of the divisional should already be disclosed in the parent application, and the filing of divisionals can only be coming from an application that is still pending. It is worth noting that a divisional may itself serve as the basis for further divisionals, potentially giving rise to multiple generations from a single parent application.

To assess the potential adverse effects of these two instruments, it is necessary to introduce the concept of legal uncertainty. While a patent application is pending, it remains uncertain whether a patent will be granted and, if so, what scope of protection it will confer. Competitors may therefore be unable to determine whether, or when, they can lawfully enter the market. Legal uncertainty also persists after grant. A granted patent is not a guaranteed right but a probabilistic one - a legal right to try to exclude- whose strength and validity becomes apparent only if and when it is tested in opposition or litigation (Lemley & Shapiro, 2005; Lemley, 2001). This uncertainty may last for several years, from the filing of an application to a decision in examination and, if granted and opposed until a final decision in opposition proceedings and/or national litigation.

These strategies to extend protection beyond the primary patent are well documented as strategic accumulation of patents (Gurgula, 2016) aimed at a broader outcome of creating a dense web of overlapping rights and pending applications (divisionals) around a single product, which taken together, deter, delay or raise the cost of generic entry (Shapiro, 2001; FTC, 2003; Hemphill & Sampat, 2012).

Secondary patents and divisionals both contribute to this web, but through different channels. Secondary patents layer additional enforceable rights on top of the primary patent, creating different patent families, while divisionals multiply enforceable rights within one patent family. Because a generic competitor needs clearance of all relevant rights, uncertainty can persist until the last member of a family has completed examination and any opposition proceedings have concluded (European Commission, 2009; Pantelidis, 2024; WIPO, 2023).

Existing research by Gurgula (2016, 2022), Tyagi et al (2024) and Pantelidis (2024) focuses on the competition-law lens, where market power and anti-competitive intent need to be

[1] The guidelines state that "the identification of particular properties or physical forms of a known product does not amount to an invention, despite efforts involved in identifying such properties"

[2] In patent filing it is a standard practice for applicants to file claims that are broader than what may ultimately be granted considering that there are no consequences for doing so (Jacob, 2013, which gives applicants an opportunity in the first place to file divisionals.

established to determine an abuse. This is not the focus of this study. Rather, the paper addresses a distinct policy question: whether the established use of patenting practices and procedural rights is already systematically associated with a prolonged period of legal uncertainty. The antitrust literature demonstrates why features of the EPO procedural framework allowed these behaviours to occur.

The Copaxone decision provides a case-specific illustration of how the sequential filing of several divisionals can, in particular circumstances, prolong and increase legal uncertainty. The European Commission found that the staggered use of divisionals (filing, selectively withdrawing, and timing successive applications so that at least one pending or newly granted right always blocked entry) constituted an abuse of dominance (among other things), and fined Teva EUR 462.6 million (European Commission, 2024). The decision is under appeal. [3]

The fact that the use of divisionals concern only a minority of applications does not diminish their policy relevance. Out of all new filings at the EPO in the health sector (A61K and C07D) in 2024, 13.7% of applications are divisionals. Looking at all pending applications at the EPO in the health sector, 8.7% of applications had not received a decision at the end of 2024. Out of all pending applications at the EPO in the health sector (A61K and C07D) at the end of 2024, 8.7% of divisionals had not received a decision in examination and out of all new filings in the health sector, 13.7% were divisionals (EPO, 2025b). However, if divisionals are mostly filed for high-value drugs, their potential financial significance may exceed what their overall frequency suggests. A handful of applications protecting blockbuster medicines can create an extreme financial burden on healthcare systems and payers.

In this context, the paper has two complementary objectives. The first is to identify whether there is a pattern in the applications that exhibit significantly longer examination durations, considering divisional applications, secondary patents, and economic factors both individually and in the family context. The second is to explore whether the patterns observed are more consistent with the legitimate use of patenting practices and procedural rights than with strategic use to extend pendency. The two objectives are complementary: the first establishes the presence and scale of the delays, the second looks for evidence of strategic pendency management.

## 2. LITERATURE REVIEW

### 2.1. Examination duration

Time in examination has been linked to patent quality from two opposing directions. On the one hand, longer examination times have been associated with granting higher-quality patents and fewer revocations (Frakes & Wassermann, 2017; Kim & Oh, 2017). On the other hand, applicants can introduce delays and prevent timely prosecution in order to preserve strategic

[3] Teva held a secondary patent protecting a particular dosage regime of glatiramer acetate and filed two divisionals from it. The timing of when those divisionals were filed and prosecuted is what raised questions: while national invalidity proceedings against the first divisional were under way in the Netherlands, the second divisional in the same family received an intention to grant, and shortly afterwards Teva withdrew the Dutch country designation of the first divisional before a final judgment in the Netherlands could be reached. The effect was that, just as one divisional was being challenged, another was coming into force, forcing generic companies to start national proceedings afresh against the newly granted right and resetting the clock resolving the patent risk, while originator prices continued.

ambiguity around the patented invention and, subsequently, its validity (Harhoff & Wagner, 2005; Régibeau & Rockett, 2007; Mejer & van Pottelsberghe, 2011; Harhoff et al., 2015, Palangkaraya et al., 2008). Mejer and van Pottelsberghe (2011), comparing USPTO and EPO backlogs, conclude that the EPO's long pendency reflects strategic applicant behaviour at least as much as office-side capacity constraints. De Rassenfosse and Zaby (2016) formalise this concern in a queuing model of patent backlogs and, citing Harhoff (2016), note that the sharp rise in EPO divisional filings after the Office restricted the period during which divisionals can be filed in 2010 is itself suggestive of a general applicant interest in delaying examination outcomes. Palangkaraya et al. (2008) model examination request delays at patent offices and find that applicants delay request for examination when the quality of the application is low.

Harhoff and Wagner (2005) find that more complex applications, measured through claim counts, citations and IPC assignment, take longer to examine, and that examination duration is longer when a patent is ultimately not granted, which they interpret as consistent with applicants being unwilling to abandon applications they consider commercially valuable. Lazaridis and van Pottelsberghe (2007) identify a more specific mechanism: applications granted or refused contain, on average, 11 claims; without any office communication, a patent is granted around 30 months after filing, but two additional claims trigger, on average, a further communication and roughly one additional year of procedure, a pattern also observed for the US context by Popp, Juhl and Johnson (2004).

The strand of literature that speaks directly to the impact of family structure, however, is thin and not fully consistent. Van Zeebroeck (2011), evaluating overall patent life from filing to lapse at the EPO between 1980 and 2000, finds that patent life expectancy has increased, and attributes this to applicants' filing strategies.[4] Divisionals and their parent applications, specifically, live significantly longer than ordinary patents because of the delay induced during examination, which the author links to higher legal uncertainty and, in turn, reduced market competition. More recent aggregate evidence complicates this picture: the EPO (2025b) reports that divisionals filed in 2024 were processed faster than regular applications on average (3.6 years against 4.9 years), and an independent re-analysis of EPO bibliographic data for the period between 2016 and 2024 concludes that divisional applications are "no longer inherently associated with prolonged examination times" (patentepi.org, 2025), attributing earlier perceptions of a gap to changed filing behaviour following the 2010 restriction. This finding sits in tension with van Zeebroeck's (2011) result and with the broader assumption running through the literature above that family multiplication delays legal certainty.

Neither side of this disagreement, however, is measured on a fully comparable basis. The EPO's own "standard" timeliness statistics, including the 3.6- and 4.9-year figures above, exclude applications with more than one request for extension of time to reply, more than one late fee payment, or rescheduled oral proceeding (EPO, 2024). Since these excluded categories are themselves means by which pendency can be prolonged, restricting the comparison to "standard" cases may understate the scale of delay and any difference between family structures.

[4] Patent life in this context is not the fixed 20 years of statutory term, but rather the effective period during which a patent remains in force, ending when the right expires (after 20 years), lapses for non-payment of renewal fees, is surrendered, or is revoked (which can also occur after 20 years).

## 2.2. Secondary patenting

Feldman (2018), reviewing all US drugs on the market between 2005 and 2015, finds that 78% of the new patents filed on these drugs were secondary rather than primary patents. Research across Europe shows a similar picture: the European Commission's Pharmaceutical Sector Inquiry counts seven secondary patents for every molecule patent, rising to thirteen once pending applications are considered (European Commission, 2009), and Abud et al. (2015) report a comparable 1:5 ratio.

It is generally understood that secondary patents are used in the life sciences to extend the monopoly beyond the primary patent (Burdon & Sloper, 2003; Abud et al., 2015; Hutchins, 2003); Amin and Kesselheim (2012) show that they can extend a drug's monopoly by up to 12 years beyond the molecule patent's expiry. There are different types of secondary patents, such as polymorph, formulation and medical-use patents, and some are found to withstand national litigation better than others (Burdon & Sloper, 2003). Gurgula (2016) provides an extensive review of how secondary patents can delay generic competition in the market. As long as the invention meets the patentability requirements, secondary patents are per se not problematic under current patent law (Dwivedi et al., 2010).

Previous research has found that significantly more secondary patents are filed than primary patents, and that they tend to be filed later in a drug's life cycle (Feldman, 2018; Kapczynski et al., 2012; Horrow et al., 2024; Ullrich, 2013, in Gurgula, 2016). Kapczynski et al. (2012) show that secondary patents do not follow the same filing pattern as primary patents: secondary patent filings cluster after drug approval and filing density increases over time as a drug’s sales grow. Horrow et al. (2024) corroborate this pattern in a more recent sample, finding that 72% of secondary patents were filed after drug approval and that secondary-patent density peaked 13 years after approval. A resulting concentration of secondary patents toward the end of the compound patent's protection period is associated with delayed generic entry into the market (Gurgula, 2016; European Commission, 2009).

Previous research has also evaluated the quality of secondary patents relative to compound patents and identified meaningful differences. Hemphill and Sampat (2011, 2013) find that 68% of secondary patents are invalidated when challenged in litigation, against only 8% for primary patents.[5] Sampat and Shadlen (2017) situate these findings globally, showing that secondary patenting is not a jurisdiction-specific phenomenon but tracks a low, and often permissively applied, inventive-step bar across countries.

## 2.3. Divisionals

An additional way to extend a drug's protection period is by filing divisionals (Gurgula, 2016). Divisional applications can be filed from any pending patent, whether primary or secondary, while inheriting the parent's filing and priority date. The divisional must share the parent's subject matter, though this is interpreted broadly, and a divisional is not limited to the parent's claims as long as the subject matter claimed in the divisional was disclosed in the parent.

[5] D'Agostino et al. (2023), investigating pharmaceutical and biotech patent oppositions, find that 52% of opposed patents are revoked and 30% amended, while Caviggioli et al. (2013), evaluating EPO oppositions across all industries, find lower rates (38% revoked, 28% amended) and identify a positive correlation between the likelihood of revocation and both the time spent in examination and the number of opponents. Frakes and Wasserman (2023) show that USPTO examiners given more time to review drug-patent applications grant fewer low-quality secondary patents.

(Foss-Solbrekk, 2022). As already noted, divisionals may be filed on an examiner's request, where an application is considered to include more than one invention, or voluntarily by the applicant (Foss-Solbrekk, 2022; Minn, 2016).

The policy underpinning for divisionals, whether mandatory or voluntary, is a reaction to the earlier concept of “unity of invention”; that is, that there should be only one invention per patent. Prior to the Paris Convention, national patent offices had required that there be only one invention per patent to stop applicants from paying one fee to patent multiple inventions and to ensure examination would be efficient and effective. That national practice was enshrined in the 1925 Hague Revision of the Paris Convention. Seen in that light, the policy objective underlying mandatory divisionals is clear dating back to Article 4G of the Paris Convention: to allow patentees to separately pursue multiple inventions that were disclosed in the original filing without losing the earliest priority date for those inventions.[6] The policy objective underlying voluntary divisionals also appears to be allowing separate inventions to be split into different applications, but at the initiative of the applicant, rather than in reaction to an office action. However, the conditions of exercise of such voluntary divisionals were left to national legislation. [7]

As recently as 2008, the EPO indicated that “The typical situation giving rise to a divisional application is where the examining division raises an objection of lack of unity under Article 82 EPC.” In practice, the vast majority of divisional filings are voluntary: the EPO reports that 84% of all divisional filings in the pharmaceutical sector in 2024 were voluntary (EPO, 2025b). Drawing an inference from search fee refunds, the vast majority of divisionals in the pharmaceutical sector also claim the same subject matter as the parent and hence no further search report is required. Of the 14,089 divisional applications filed in 2024 in the two IPC classes covering much of pharmaceutical chemistry (A61K, C07D), 82% received a full or partial refund of the search fee, indicating that the claimed subject matter had already been covered by the parent's search report (EPO, 2025b).

Pantelidis (2024) argues that the absence of any unified procedure for examining or opposing a parent together with its divisionals is structurally significant: even where a parent or one divisional is revoked, other pending divisionals on similar subject matter can still block competition, and a patentee can de-designate contested countries mid-proceeding to avoid an adverse national judgment. Tyagi et al. (2024) characterise divisionals, in this light, as "but the beginning of a strategic games story." Filler (2024), reviewing recent UK case law, reaches a comparable conclusion and proposes reintroducing a filing deadline for divisionals as a partial remedy, and WIPO (2023) similarly notes that a sequence of voluntary divisionals prolongs the period of uncertainty over the eventual scope of protection. [8]

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[6] See Article 4G (1) (as amended in Lisbon in 1958): “If *the examination reveals* that an application for a patent contains more than one invention, the applicant may divide the application

[7] Article 4G(2) states “The applicant may also, *on his own initiative*, divide a patent application and preserve as the date of each divisional application the date of the initial application.” (Guide to the application of the Paris Convention for the Protection of Industrial Property, as revised at Stockholm in 1967, by Professor G.H. C. Bodenhausen). The travaux preparatoires regarding Article 76 of the EPC do not provide significant insight into those conditions (see CA/145/08 Rev. 2).

[8] The same concern recurs outside Europe. Lemley and Moore (2004) argue, in the foundational law-review treatment of the topic, that US continuation practice, the closest analogue to EPO divisionals, is used to extend prosecution indefinitely and to "late-claim" rivals' products once they enter the market. Hegde, Mowery and Graham (2009) find empirically in the US context that some firms use continuations primarily to build patent thickets rather than to protect genuine follow-on invention, and Righi and Simcoe (2023) and Righi, Cannito and Vladasel (2023) confirm, in more recent USPTO data, that continuation filings are systematically associated with strategic late-claiming and prolonged prosecution. Carrier et al. (2024) note that only a limited number of technologies rely heavily on divisional-type filings, and that pharmaceuticals are foremost among them Evaluating a

### 2.4. Research question

To the best of our knowledge, no study has yet tested whether examination duration varies systematically with family structure, secondary patenting, or economic value of the protected invention. A further limitation of the existing literature is that it has largely examined individual applications in isolation rather than the patent family as a whole. Because divisional filings multiply the number of applications derived from a single invention, the cumulative pendency of a family, that is, the time elapsed until its last member reaches a final decision, may differ substantially from the duration of any single application within it, yet this family-level measure remains largely unexamined. This gap matters whether at the application or the family level since a longer examination prolongs legal uncertainty and imposes real costs on the systems. Moreover, no prior study has tested whether any resulting delay pattern is merely the legitimate exercise of procedural rights, or whether those delay strategies are strategically applied to a subset of all divisional applications to extend pendency. This paper addresses both questions: which applications and families take significantly longer to reach an outcome and whether the patterns observed reflect strategic use.

## 3. METHODOLOGY

### 3.1. Data

The dataset combines EPO procedural history with linked commercial data. EPO Patent Register data (Q1 2026 backfile) contain 4,728,387 patent applications filed between 1978 and Q1 2026, from which 690,171 life-science applications are identified using IPC classes associated with pharmaceuticals and biologic products (A61K, A61P, A61M, A61J, C07C, C07D, C12N, C07K, C07F, C12P, C12Q). To link applications to drugs, IQVIA Ark data (March 2026 download) are used to map patent applications to the International Nonproprietary Name (INN) of the drug product and to one of 41 patent-type categories (e.g., molecular, formulation, or dosing patents; see Annex 1 and 2). From the life-science subset, 20,226 applications are mapped to at least one INN, of which 15,737 are assigned to a primary- or secondary-patent classification and have a measure of time in examination[9]. Of this sample, 86.7% (13,646) are PCT applications and 13.3% (2,091) are EP direct filings.

Value sales information (in USD) for 1067 INN is obtained from IQVIA MIDAS® (quarterly sales data for the period Q4-2011 to Q4-2025). Each INN is mapped to a single originator company based on market-authorization data. Company revenues for 2025 are taken from Evaluate Pharma.

### 3.2. Stage 1

To estimate whether family structure, secondary patenting and economic value are associated with examination duration at the EPO, a survival analysis is carried out in which survival time corresponds to the duration in examination.

22-year period, they find that pharmaceuticals have the highest share of continuation-type filings of any sector (45% of Orange Book patents and 57% of Purple Book patents) and are also the most litigated, with 51% of litigated Orange Book patents and 58% of litigated Purple Book patents involving continuations.

[9] A time in examination requires both a filing date and a final examination outcome (grant, withdrawal, refusal) for the application.

At the application level, the unit of observation is the individual patent application. Examination duration is computed as the period starting from filing at the European Patent Office[10] until the publication of a final decision (grant, refusal, or withdrawal from the applicant[11]) on the EPO register. This definition is chosen because the policy concern is with the period during which the scope of protection remains unsettled, rather than with the probability of grant per se: an application that ends up refused or withdrawn has kept the surrounding legal position unresolved the same way as if it ended up granted. All three closing routes are therefore treated as the same event, and the application *survives* as long as it is pending.

At the family level, the unit of observation is the patent family, defined as the parent together with all its subsequent divisional applications (across all generations). Examination duration is computed as the period starting from the parent filing date until the final decision of the last pending family member: a family *survives* as long as at least one of its members is still pending. This level captures the true period of uncertainty attached to an invention.

Examination duration is modelled with the Cox proportional hazards model (Cox, 1972). The hazard of examination closure for observation *i* at time *t* is specified as

$$\lambda(t \mid x_i) = \lambda_0(t) \cdot \exp(\beta' x_i)$$

where $\lambda_0(t)$ is an unspecified baseline hazard common to all observations, $x_i$ is the vector of covariates for observation *i*, and $\beta$ is the vector of coefficients to be estimated. The baseline hazard is left unspecified because the shape of the examination duration distribution is unlikely to conform to a simple parametric form, and because the substantive interest lies in the relative effect of covariates rather than in the absolute level of the hazard. Under this model, the hazard ratio comparing two covariate values is

$$HR(x_1, x_0) = \lambda(t \mid x_1) / \lambda(t \mid x_0) = \exp[\beta(x_1 - x_0)]$$

A hazard ratio above one indicates a higher rate of examination closure, and thus a shorter examination duration; a hazard ratio below one indicates a lower rate of closure, and thus a longer duration. Because grant, refusal, and withdrawal are all treated as the same exit event, there are no competing risks in the baseline specification.

A key feature of the research design is that the estimation sample is restricted to closed applications, meaning that they have reached a final examination outcome (grant, refusal, or withdrawal) by the end of the observation window. This is necessary to fix each application's single/parent/divisional status: an apparently single application may still become a parent if a divisional is filed later, so the treatment variable is not fully observed while an application remains pending. The closed-cohort design therefore prioritizes correct classification of family structure over the use of right-censored observations.

At the family level, the treatment variable requires the full family structure, which is only final once every member of the family reached an examination outcome. To exclude such "open" scenarios, the family-level analysis is restricted to applications filed before 2006, or, for divisionals, to those whose original parent was filed before 2006. Allowing approximately a full

[10] For PCT application, the survival time starts at the entry into regional phase at the EPO
[11] An application that is deemed to be withdrawn for more than 3 months is considered as a final withdrawal.

patent-term window for subsequent divisional filings should ensure that, by Q1 2026, family structure is almost definitive. The family analysis (subsample E in Annex 9) comprises 3,966 single applications and 1,477 patent families (1,477 parent applications, associated with 2,753 divisionals). [12]

### 3.2.1. Family structure

Each patent application is assigned to one of three mutually exclusive categories: *single* (no divisional was filed; DIV=PAR=0), *parent* (at least one divisional was filed from the application; PAR=1, DIV=0), or *divisional* (the application is itself a divisional, filed from another application; PAR=0, DIV=1). Each family only has one parent, such that a divisional retains this status even if it later serves as the parent of further divisionals. This categorical variable enters the survival model as a fixed covariate.

At the family level, a binary indicator distinguishes families (FAM=1) from single applications (FAM=0), and family complexity is defined across five mutually exclusive categories: "0" for a single application, "D*1*" for a family with one parent and one divisional, "G1" for families with several first generation divisionals, "G2" for families that have two generations of divisionals, and "G3+" for families that have at least 3 generations of divisionals. The total number of divisionals filed within a family is denoted DIVC.

### 3.2.2. Secondary patenting

Based on IQVIA Ark data, each application is classified as *primary* (SEC=0) or *secondary* (SEC=1). A primary patent application aims to protect an active ingredient, while a secondary patent application covers subsequent stages of drug development (dosage forms, formulations, production methods, and so forth). Although this distinction has no formal basis in patent law, it is widely used in both industry practice and academic literature. All family members stay within the same category.

### 3.2.3. Economic value

Two variables capture the economic dimension: the commercial value of the drug the patent is protecting, and the financial resources of the company selling the product.

To measure drug value across heterogenous timelines, inflation-adjusted annual maximum observed sales (IAAMOS) over 2011-2025 are calculated from the IQVIA MIDAS® sales data. Following Grabowski & Kyle (2007), applications are classified as low-value (IAAMOS below USD 50 million; HV=MV=0), medium-value (IAAMOS between USD 50 million and USD 500 million; MV=1, HV=0), or high-value (IAAMOS above USD 500 million; HV=1, MV=1).

Based on 2025 revenues from Evaluate Pharma, applications are grouped as low company revenues (below USD 5 billion; HCR=MCR=0), medium company revenues (between USD 5 billion and USD 40 billion; MCR=1, HCR=0), or high company revenues (above USD 40 billion; HCR=1, MCR=1). Thresholds follow Hanlon & Hoopes (2024), who report that the largest foreign and US companies had average annual sales of USD 33.8bn and the average pharmaceutical company had reported average sales of 6.5bn USD. [13]

[12] Annex 9 outlines the samples used for different levels of analysis.
[13] The Pharmaceutical Industry: Effective Tax Rates Before and After the TCJA | Tax Notes

3.2.4. Control variables

*PCT*. Applications entering the EPO via the PCT route have 31 months from the earliest priority date (or from the filing date if no priority is claimed) to enter the European regional phase rather than 12 months for direct European filings, which can lengthen overall examination time. Survival time therefore starts at entry into regional phase for PCT applications. However, the prior search and examination work carried out by the International Search Authority may still influence subsequent EPO processing time (Petit et al, 2023).

*YEAR*. Filing year controls for time fixed effects such as changes in patent law or examination practices (e.g. the 2010–2014 Rule 36(1) EPC limiting divisional filings to two years after the parent's first examination report, or the examination-timeliness improvements reported in the EPO Quality report 2023. For PCT applications, the year of entry into the regional phase is used.

*CLAIMS*. A large number of claims is associated with a heavier examiner workload, which can prolong examination (Harhoff et al. 2005). To account for this, the number of claims filed in the patent application is measured. At the family level, the parent's claims are used as a proxy for family examination workload.

*OFCOM*. The number of office communications issued under article 94(3) during examination is collected. Models are estimated sequentially: first without OFCOM, capturing the total association between family structure and duration, and then with OFCOM, capturing the residual association. A persistent effect indicates that longer examination is not fully explained by a greater number of communications and may instead reflect applicant's response time. At the family level, office communications are summed up across all family members.

Two final family-level controls capture post-grant contestation: OPP is defined as the share of granted family members that were opposed; and REVAM is constructed as an indicator equal to one if any family member was opposed and subsequently revoked or amended.

3.3. Stage 2

Stage 1 survival models estimate whether divisional applications and secondary patents are associated with longer examination duration. Stage 2 explores where, when, and how such delays occur. Because it is very difficult to find a single statistic that can directly establish strategic intent, it is inferred from the accumulation of circumstantial evidence across four complementary indicators. Each indicator is examined descriptively, through means and standard deviations, compared across family structure, secondary patenting, and drug value to explore where signals are the strongest.

3.3.1. Procedural rights

After filing, either as a Europe-direct application or as a PCT application entering the European regional phase, the Search Division draws up the European search report (for PCT filings, as a supplementary search report under Article 153(7) EPC). The search report accompanied by a written opinion is communicated to the applicant under Rule 62 EPC. Euro-direct and Euro-PCT applicants may address any deficiencies identified in the European search opinion within the six-month periods provided under Rule 70a(1) EPC for requesting examination and Rule

70a(2) EPC for indicating whether they wish to proceed further with the application, respectively.

During examination, the applicant responds to each communication from the Examining Division (Article 94(3) EPC), typically by amending the claims or description and/or presenting arguments contesting the examiner's objections. Beyond this substantive exchange, the EPC also grants the applicant several procedural rights whose use may lengthen the examination process. Using several of these rights together, or using any one of them repeatedly, can be a sign of active management of pendency. This hypothesis is consistent with the EPO's own reporting practice on examination duration (EPO, 2024), which is based on what they refer to as “standard” applications (applications using more than one such procedural right are excluded). Practitioner guides also provide ample tips on how to optimize these rights to delay prosecution of an application [14]. The remainder of this section reviews each of these rights and how they can be used to prolong pendency.

**Extension to time limit**. Communications from the EPO always carry a fixed response deadline set under Rule 132 (EPC) (typically two to four months). To gain additional time, the applicant may file a request for extension of the time limit under Rule 132 EPC, which requires no justification and is usually granted for an additional two months where the total period does not thereby exceed six months (but can exceptionally be more if sufficient reasons are provided). Because an extension may be requested after every communication, the additional time can accumulate into substantial delays over the course of examination.

**Deemed to be withdrawn.** If the applicant does not respond to an EPO communication within the specified time limit, the office issues a loss-of-rights communication under Rule 112(1) EPC, notifying the applicant that the application is ‘*deemed to be withdrawn’*. Within two months of that communication, the applicant may request further processing under Article 121 EPC by paying the prescribed fee and completing the omitted act (Rule 115(1) EPC), e.g. responding to an examination report. This procedural right is also not capped in its number of uses throughout examination, as long as the requests for further processing relate to separate unrelated time limits, making it possible for applicants to extend pendency by repeatedly missing and then recovering deadlines.

**Intention to grant.** Once the patent application reaches the intention to grant stage, the office issues a communication under Rule 71(3) EPC including the text intended for grant and an invitation to the applicant to approve the text by paying the necessary fees for grant and filing a translation of the claims into the two other official EPO languages within a 4-month period. Alternatively, the applicant may disapprove the text and request amendments or corrections. In this case, the Examiner may either consent to the requested amendments or corrections and issue a further communication under Rule 71(3) EPC or otherwise resume the examination proceedings. If the applicant fails to either approve or disapprove the text within the time limit, the application will be ‘*deemed to be withdrawn’* (again with the possibility of requesting further processing under Article 121 EPC).

**Summons to oral proceedings**. After the applicant responds to the search opinion and requests examination, the Examiner generally issues at least one substantive examination

[14] For example: https://www.potterclarkson.com/news/how-to-gain-more-time-and-delay-the-prosecution-of-a-european-patent-application

communication under Article 94(3) EPC if the application cannot be granted directly. Oral proceedings may be scheduled at the applicant's request (Article 116(1) EPC), or where the Examiner consider them expedient to solve the case, particularly where no substantial progress has been achieved through the written proceedings. In this respect, a summons to oral proceedings marks the final stage available for resolving outstanding objections before a decision is reached.

### 3.3.2. Timing of examination delays and applicant's response time

Total time in examination is calculated from filing of the patent (for Euro- direct filings) or entry into regional phase (for PCT applications) until a final decision in examination.

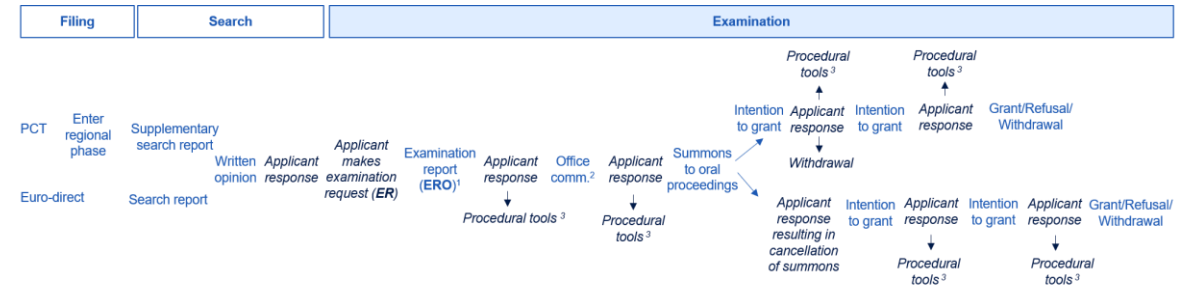
This period is then divided into two parts. Since there is no involvement of the applicant during the search phase, the first part starts once the applicant replies to the search opinion and files the request for examination (ER), under Rule 70 EPC, and ends with receipt of the examination report (ERO) the Examining Division's first substantive communication under Article 94(3) EPC. This period mainly reflects office workload and application complexity since no reply by the applicant is due and no procedural right can generally be invoked during that time.

The second part, from ERO to final decision grant, withdrawal or refusal covers the back-and-forth between the applicant and the Examining Division. This is the period during which the applicant can use the procedural rights mentioned in 3.3.1. to extend pendency.

Additionally, the time given to the applicant to reply is computed as the sum of the time allotted by the Office to respond to each communication. This metric is compared against the time taken by the applicant to reply to the office communications. A persistent gap is consistent with applicant-induced delays rather than office-side constraints.

Figure 1 is an illustration of the examination process with a specific focus on the different steps during examination. It should be noted that process flow during examination can have variations. It can be as fast as moving from examination report directly to an intention to grant or with many further iterations between the office and the applicant after summons to oral proceedings, with several intentions to grant. After each office communication applicants can either directly respond under the provided time limits or use the available procedural tools of non-response, resulting in a 'deemed to be withdrawn' communication or a request for time extension.

**Figure 1.** Examination process: key steps and procedural tools




Note: Applicant withdrawals can occur at any stage. Refusals by the office are rare (2-4%), hence not visualized.
[1] First substantiative communication, Art.94(3) EPC
[2] Office communication under Art 94(3) EPC
[3] Procedural tools available: no response to office communication resulting in "deemed to be withdrawn" status; extension to time limit

### 3.3.3. Examination and opposition outcomes

From the EP register bulk data, three examination outcomes are identified: grant, withdrawal or refusal. [15] Grant of a patent is not a necessary condition for a divisional to fulfil a purely defensive function: an application filed solely to keep contested subject-matter alive within the family can serve that purpose regardless of whether it is ultimately granted.

Withdrawal after an intention to grant is a distinct case, as it involves giving up a right already secured rather than failing to obtain one. Lazaridis and van Pottelsberghe (2007) and Petit and van Pottelsberghe (2026) show that a meaningful share of withdrawals occur before translation of the claims and grant fees are due and interpret this primarily as an economic reassessment of the application's value. Two alternative, non-exclusive explanations can be considered. First, withdrawing only at the last moment of examination pushes the ability to file a divisional from the application to the last possible moment. Second, since only a granted patent can be opposed and revoked, withdrawing before grant protects those claims from a public finding of invalidity.

Data regarding oppositions is also collected, along with the outcome of the opposition proceedings: maintained as granted, maintained in amended form, or revoked.

For opposed patents, the decision to revoke a patent is made by the Opposition Division or the Boards of Appeal. Applicants may also withdraw their approval of the granted text previously given in accordance with Rule 71(3) EPC, resulting in the revocation of the patent. [16]. In this case, the applicant could pursue the same claims again in a further divisional with no history of formal revocation in the patent family. In contrast, the Australian Patent Office recently indicated in pre-grant opposition proceedings related to AU2024203639 that it would agree to the withdrawal, only under the condition that the "applicant makes an undertaking to not pursue the same, or substantially the same, invention as has already been opposed in any further applications, whether already filed or not. Such an undertaking would require the

[15] Where applications have a status 'deemed to be withdrawn' for more than 3 months, these applications are considered withdrawn as a request for further processing can no longer be filed.
[16] Under Board of Appeal case law, if the applicant no longer approves the text, proceedings are terminated without a decision on patentability (Case Law of the Boards of Appeal, 10th edition, 2022, IV.D.2)

applicant to not pursue in any further application any claims overlapping in scope with the accepted claims of the present application".[17]

3.3.4. Divisional filing context

First, the time between the filing of the divisional and that of its initial parent is computed. Divisionals that are filed "early" are more consistent with ordinary claim-splitting, while a cluster of filings at the very end of the opportunity window is less likely to be a natural progression of the application process (for example, in the Teva case, divisionals were often filed the day before grant of the parent).

Second, the family context at the time of divisional filing is recorded: whether a family member was already granted, in opposition proceedings, or revoked/amended. A divisional filed once the parent's prospects have weakened could suggest that the applicant is using it to preserve claim options, restart examination on a fresh track, and/or maintain uncertainty.

## 4. RESULTS

The results are presented in three subsections. The first reports general descriptive statistics, including sample composition and Kaplan-Meier survival curves. The second presents the estimates from the Cox regression. The third reports statistics across the four indicators introduced in section 3.3. (procedural rights, time in examination, opposition outcome, and family context at the time of divisional filing). for the second stage analysis.

4.1. Descriptive statistics

Among the 15,737 INN-mapped applications with a final decision (filed 1978–Q1 2026), 42% are single applications (6,591), 25% are parents (3,960), and 33% are divisionals (5,186). These applications were further divided between primary and secondary and show a secondary-to-primary ratio of 3.7 Table 1. Among the 4,298 applications linked to high-value drugs (27% of the sample), single applications drop to 33%, divisionals rise to 40%, and the secondary-to-primary ratio reaches 4.9.

Table 1 shows that a larger share of secondary families have one divisional (54%), compared to primary families (49%), whereas in high-value drugs primary and secondary patents tend to have a higher share of G2 and G3+ families. The primary-side estimates rest on comparatively fewer observations and warrant caution.

[17] IP Australia. Patent examination e-dossier: https://ipsearch.ipaustralia.gov.au/patents/2024203639

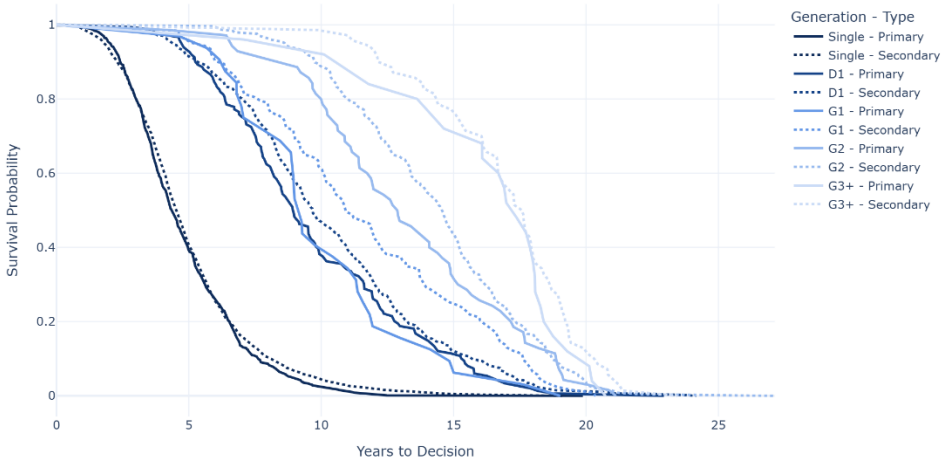
**Table 1.** INN-mapped applications with a decision in examination, filed in 1978 - 2026 Q1

| | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| **Full** | | 3371 | | | 12366 | | | 732 | | | 3566 | |
| Applications | 1188 | 924 | 1259 | 5403 | 3036 | 3927 | 146 | 202 | 384 | 1278 | 970 | 1318 |
| (% total) | 35 | 27 | 37 | 44 | 25 | 32 | 20 | 28 | 52 | 36 | 27 | 37 |
| **Restricted** | | 1484 | | | 5993 | | | 359 | | | 1610 | |
| Applications | 767 | 251 | 466 | 3199 | 987 | 1807 | 107 | 79 | 173 | 683 | 318 | 609 |
| (% total) | 52 | 17 | 31 | 54 | 16 | 30 | 30 | 22 | 48 | 42 | 20 | 38 |
| D1 (%) | | 124(49) | 124(27) | | 533(54) | 533(29) | | 29(37) | 29(17) | | 151(47) | 151(25) |
| G1 (%) | | 32(13) | 77(17) | | 114(12) | 255(14) | | 10(13) | 26(15) | | 26(8) | 54(9) |
| G2 (%) | | 69(27) | 172(37) | | 256(26) | 643(36) | | 27(34) | 73(42) | | 104(33) | 259(42) |
| G3+ (%) | | 26(10) | 93(20) | | 84(8) | 376(21) | | 13(16) | 45(26) | | 37(12) | 145(24) |
| D/P ratio for G1-G3+ | | | 2.7 | | | 2.8 | | | 2.9 | | | 2.7 |

The full sample corresponds to 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. The restricted sample consists of 7,477 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006. D1-G3+ describe the depth of the final family structure (respectively, D1: 1 divisional, G1: one generation of divisionals (> 1 divisionals), G2: two generations of divisionals, G3 +: three generations and more). Divisionals in G2, G3+ denote the number of divisionals in G2 and G3+ families, not the number of 2nd or 3rd + generation divisionals. S, P, and D respectively stand for single, parent and divisional applications.

Table 2 and Figure 2 show that total time to family resolution is already longer for families with a single divisional compared to single applications (from around 5 to 10 years, and it keeps increasing with the number of generations). Both secondary patents and high-value drugs show extended pendency (Kaplan-Meier estimates for high-value drugs are in Annex 3).

**Figure 2.** Kaplan-Meier survival curve at family level, by generation




Note: Years to decision represent the total time in examination (between filing of the parent and final examination decision of the last pending member). A family *survives* as long as at least one of its members is still pending, until they all reach a final examination decision (grant, refusal, or withdrawal). The estimates are carried out on the restricted sample of 3,966 single applications + 1,477 families with parents filed before 2006. D1-G3+ describe the depth of the final family structure (respectively, D1: 1 divisional, G1: one generation of divisionals, G2: two generations of divisionals, G3+: three generations and more). Divisionals in G2, G3+ denote the number of divisionals in G2 and G3+ families, not the number of 2nd or 3rd + generation divisionals.

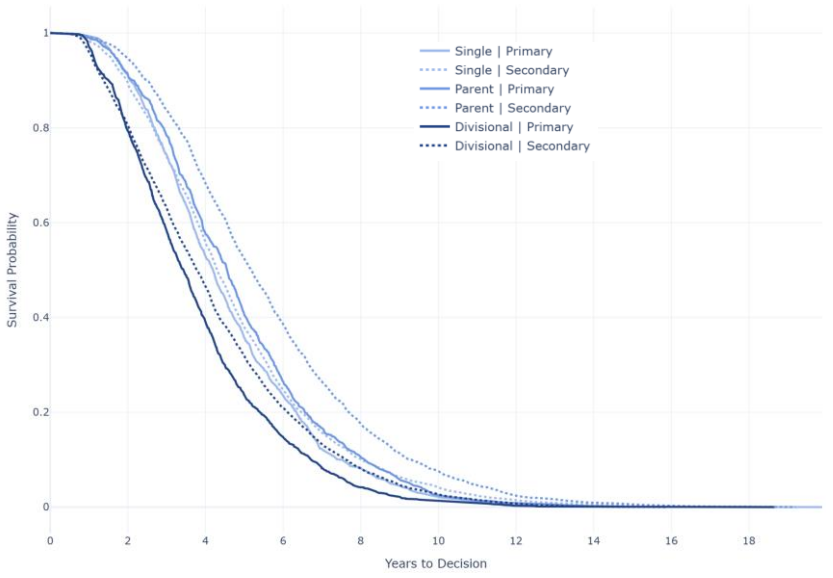
**Table 2.** Time in examination at family level

| Time months (stdev) | All | | | | High-value drugs | | | |
|---|---|---|---|---|---|---|---|---|
| | Primary | | Secondary | | Primary | | Secondary | |
| | S | FAM | S | FAM | S | FAM | S | FAM |
| Restricted | 58.6 (26.6) | | 59.0 (29.7) | | 57.1 (24.9) | | 56.4 (30.4) | |
| D1 | | 117.6 (43.8) | | 123.4 (47.1) | | 123.7 (50.3) | | 119.9 (45.4) |
| G1 | | 122.0 (38.4) | | 143.2 (51) | | 120.7 (54.9) | | 153.1 (52.9) |
| G2 | | 158.5 (46.6) | | 173.0 (42.0) | | 172.9 (50.0) | | 172.5 (44.2) |
| G3+ | | 192.1 (44.1) | | 203.9 (32.4) | | 209.4 (37.8) | | 203.4 (38.5) |

Time in examination provided as the average number of months between filing and final examination decision (standard deviation in parentheses). The statistics are carried out on the restricted sample of 3,966 single applications + 1,477 families with parents filed before 2006. D1-G3+ describe the depth of the final family structure (respectively, D1: 1 divisional, G1: one generation of divisionals, G2: two generations of divisionals, G3 +: three generations and more). S stands for single applications, FAM for patent families.

Independently of any aggregation across the family, the application-level analysis from Table 3 and Figure 3 show that the parent application itself has longer pendency than single or divisional applications (58 vs 46 months for primary parents vs divisionals and 67 vs. 50 months for secondary parents vs divisionals), and the differences are already striking for families with a single divisional (72 months for primary parents and 79 months for secondary parents). Overall, secondary patents only present longer pendency than primary ones for parents and divisionals.

**Figure 3.** Kaplan-Meier survival curve at application level




Note: Years to decision represent the time in examination (between filing and final examination decision). Survival represents the pendency of the application and stops as soon as a final examination decision is reached (grant, refusal, or withdrawal). The estimates are carried out on the full sample of 15,737 applications filed between 1978 and 2026 (Q1).

**Table 3.** Time in examination by family structure, secondary patenting, and drug value

| Time months (stdev) | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| **Full** | 54.8 (26.6) | 58.2 (28.1) | 45.7 (25.7) | 54.8 (30.1) | 67.4 (33.0) | 50.4 (29.6) | 55.3 (25.3) | 62.8 (29.5) | 51.0 (28.2) | 55.8 (31.2) | 67.4 (32.9) | 50.2 (29.9) |
| **Restricted** | 58.6 (26.6) | | | 59.0 (29.6) | | | 57.1 (24.8) | | | 56.4 (30.4) | | |
| D1 | | 71.9 (30.0) | 57.6 (33.7) | | 79.3 (38.2) | 56.2 (32.9) | | 69.8 (35.6) | 58.7 (32.8) | | 79.9 (36.1) | 54.0 (31.4) |
| G1 | | 79.8 (31.1) | 49.6 (29.2) | | 96.4 (46.7) | 59.9 (31.9) | | 76.7 (44.4) | 62.6 (40.0) | | 106.4 (49.4) | 66.5 (33.2) |
| G2 | | 69.1 (34.3) | 55.9 (28.2) | | 74.6 (29.9) | 63.2 (32.4) | | 79.2 (36.0) | 58.4 (29.2) | | 72.5 (28.7) | 63.2 (34.1) |
| G3+ | | 68.6 (25.2) | 50.3 (27.6) | | 69.7 (32.8) | 55.7 (29.8) | | 64.6 (17.9) | 60.6 (29.3) | | 80.2 (39.0) | 56.2 (30.8) |

Time in examination provided as the average number of months between filing and final examination decision (standard deviation in parentheses). The full sample corresponds to 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. The restricted sample consists of 7,477 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006. S, P, and D respectively stand for single, parent and divisional applications.

### 4.2. Stage 1

Table 4 presents Cox hazard ratio estimates for three sets of covariates. The unit of observation is the patent family, defined as a parent application together with all its divisional applications (for single applications, the application itself remains the unit of observation). Starting from the sample of 3,966 single applications and 1,477 patent families, 2,809 applications are excluded due to missing data on company revenues, drug value, or claim count, leaving a final sample of 2'634 observations, 1,816 single application and 818 families for the Cox regressions.

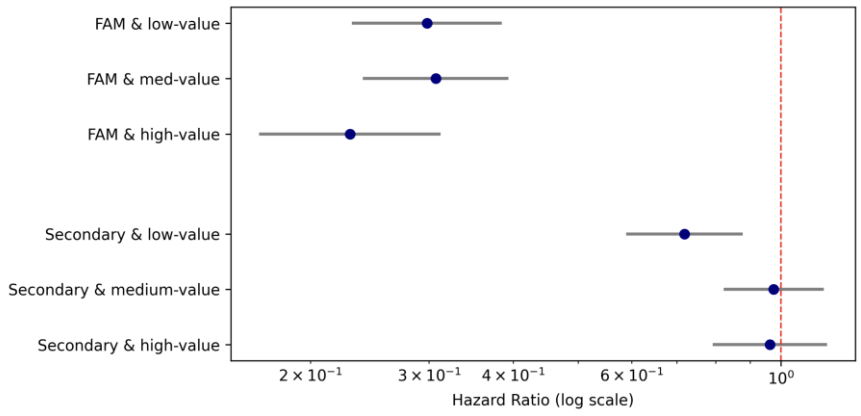
Results from Table 4 (with Model (2) illustrated in Figure 4) show that families take significantly longer to reach an outcome than single applications (HR=0.17), consistent with a family comprising multiple applications whose examination periods does not overlap completely. However, the effect remains significant (HR=0.29) after controlling for the total number of divisionals, indicating that family size alone does not explain the longer duration, and persists after further controlling for the total number of office communications (HR = 0.39). In this specification (Model (3)), the longer examination is still more pronounced for families linked to high-value drugs (HR=0.78) while company revenues show no significant effect. Finally, families related to secondary patents are on average slower than those related to primary patents (HR=0.89 in Model (1)), but this difference is reduced for high-value drugs (HR=0.75 for low-value, HR=0.75*1.2=0.9 for HV).

**Table 4.** Cox hazard ratio estimates at family level

| **Hazard ratios** | Model (1) | Model (2) | Model (3) |
|---|---|---|---|
| FAM | ***0.17(0.09) | ***0.29(0.14) | ***0.39(0.14) |
| SEC | *0.89(0.06) | ***0.73(0.10) | **0.75(0.10) |
| SEC*FAM | 1.05(0.10) | 1.09(0.06) | 1.14(0.10) |
| PCT | 0.94(0.06) | 0.94(0.06) | 0.96(0.06) |
| YEAR | *1.00(0.00) | *1.00(0.00) | 1.00(0.00) |
| CLAIMS | ***1.00(0.00) | ***1.00(0.00) | ***1.00(0.00) |
| MV | 1.03(0.06) | 0.88(0.10) | 0.88(0.10) |
| HV | 1.04(0.06) | 1.00(0.11) | 1.05(0.11) |
| FAM*MV | | 1.03(0.14) | 1.03(0.14) |
| FAM*HV | | ***0.76(0.09) | **0.78(0.09) |
| SEC*MV | | ***1.34(0.12) | 1.24(0.12) |
| SEC*HV | | **1.33(0.13) | ***1.20(0.13) |
| MCR | | *0.90(0.08) | 0.93(0.08) |
| HCR | | 0.99(0.09) | 1.00(0.09) |
| SEC*HCR | | 0.93(0.09) | 0.90(0.09) |
| FAM*HCR | | 0.93(0.12) | 0.94(0.12) |
| DIVC | | ***0.81(0.03) | ***1.10(0.03) |
| REVAM | | 0.87(0.11) | 0.96(0.11) |
| OPP | | 0.97(0.11) | 1.03(0.11) |
| OFFCOM | | | ***0.90(0.01) |

Hazard ratios estimates and standard errors in parentheses. Asterisks denote two-sided statistical significance at *10%, **5%, and ***1%. The estimates are carried out on carried out on the restricted sample of 1,816 single applications + 818 families with parents filed before 2006. A patent family *survives* as long as at least one of its members is still pending.

**Figure 4.** Forest plot for Cox-model (2) hazard ratios at family level




Note: Years to decision represent the time in examination (between filing and final examination decision). Survival represents the pendency of the application and stops as soon as a final examination decision is reached (grant, refusal, or withdrawal). The estimates are carried out on the restricted sample of 1,816 single applications + 818 families with parents filed before 2006. The red dotted line represents the baseline category: FAM = 0 vs 1, and Secondary = 0 vs 1.

Similarly to Table 4, Table 5 presents Cox hazard ratio estimates for three sets of covariates, this time with the patent application as the unit of observation. Starting from the full sample of 15'737 applications, 7'747 are excluded due to missing data on company revenues, drug value, or claim count, leaving a final sample of 7'990 observations for the Cox regressions.

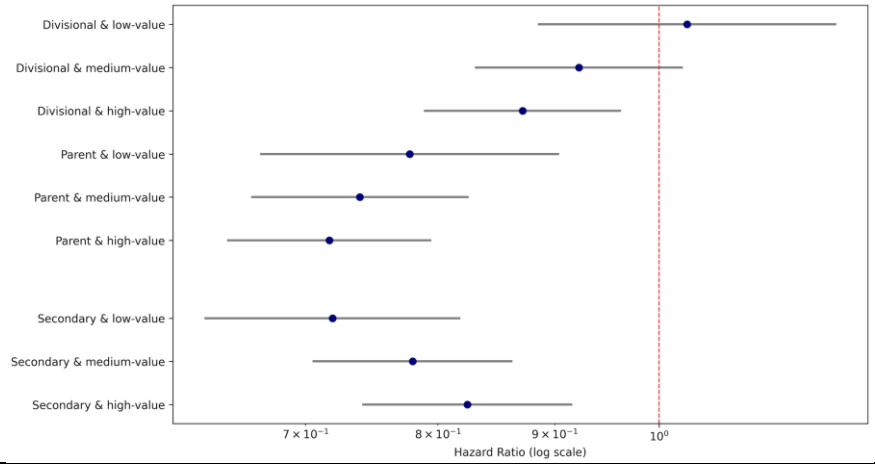
Results from Table 5 (illustrated for Model (2) in Figure 5) show that parent applications are associated with significantly longer examination duration (HR = 0.78) regardless of drug value or company revenues, while divisionals show significantly longer pendency only when linked to high-value drugs (HR = 1.03*0.84). Secondary patents are also associated with longer examination overall (HR=0.72). Once office communications are accounted for (Model (3)), divisionals show significantly shorter pendency overall (HR = 1.45), consistent with the EPO's objective of processing them quickly, though this reduction diminishes as drug value increases (HR = 1.45*0.82 for MV, HR = 1.45*0.87 for HV). In this specification (Model (3)), parent applications are only associated with significantly longer pendency for medium- and high-value drugs (HR = 1.03*0.85 for MV; HR = 1.03*0.76 for HV), an effect partly offset when they are filed by high-revenue companies (HR multiplied by 1.14). Secondary patents, by contrast, remain associated with significantly longer pendency (HR = 0.75) regardless of drug value or company revenues.

**Table 5.** Cox hazard ratio estimates at application level

| **Hazard ratios** | (1) | (2) | (3) |
|---|---|---|---|
| DIV | ***0.91(0.03) | 1.03(0.08) | ***1.45(0.08) |
| PAR | ***0.73(0.03) | ***0.78(0.08) | 1.03(0.08) |
| PCT | ***0.61(0.04) | ***0.61(0.04) | ***0.62(0.04) |
| CLAIMS | ***1.00(0.00) | ***1.00(0.00) | ***1.00(0.00) |
| YEAR | ***1.05(0.00) | ***1.05(0.00) | ***1.05(0.00) |
| SEC | ***0.83(0.03) | ***0.72(0.07) | ***0.75(0.07) |
| MV | **0.91(0.04) | 0.90(0.08) | 0.99(0.08) |
| HV | ***0.88(0.03) | **0.86(0.08) | 1.04(0.08) |
| DIV*MV | | 0.90(0.09) | **0.82(0.09) |
| PAR*MV | | 0.95(0.09) | *0.85(0.09) |
| SEC* MV | | 1.08(0.08) | 1.03(0.08) |
| DIV*HV | | **0.84(0.08) | *0.87(0.08) |
| PAR*HV | | 0.92(0.08) | ***0.76(0.08) |
| SEC*HV | | *1.15(0.08) | 1.02(0.08) |
| MCR | | 0.99(0.03) | 0.97(0.03) |
| HCR | | 0.94(0.06) | 0.94(0.06) |
| DIV*HCR | | 1.01(0.05) | 0.98(0.05) |
| PAR*HCR | | 1.00(0.06) | **1.14(0.06) |
| SEC*HCR | | 1.09(0.06) | 1.01(0.06) |
| OFFCOM | | | ***0.79(0.00) |

Hazard ratios estimates and standard errors in parentheses. Asterisks denote one-sided statistical significance at *10%, **5%, and ***1%. The estimates are carried out on 7,990 (3,034 singles, 2,116 parents + 2,840 divisionals) applications out of the 15,737 applications filed from 1978 to 2026 Q1.

**Figure 5.** Forest plot for Cox-model hazard ratios at application level




Hazard ratios represent the probability for the application to be pending at time t (rather than either granted, refused, or withdrawn). Dots represent the estimated hazard ratio, grey lines represent the 95% confidence interval around it. A hazard ratio above 1 indicates a shorter examination duration. The estimates are carried out on 7,990 (3,034 singles + 2,116 parents + 2,840 divisionals) applications out of the 15,737 applications filed from 1978 to 2026 Q1.

Taken together, these results point to three main findings. First, examination delays are not only significant at the family level, but also at the application level. Second, these delays hold even after controlling for procedural factors such as the number of claims or office communications. Third, the delays vary both with drug value and primary vs secondary patents. Secondary parent applications for high-value drugs take longer in examination than primary single low-value drugs. These findings reinforce the importance of exploring how delays arise, and whether they are an inevitable consequence of legitimate use of patenting practices and procedural rights or a sign of strategic use to extend pendency from the applicant.

## 4.3. Stage 2

To explore where, when, and how examination delays occur Table 6-9 present statistics across the four complementary indicators (procedural rights, time in examination, opposition outcome, family context at the time of divisional filing). As laid out in section 3.3., it is the accumulation and convergence of signals across those indicators (by family structure, secondary patenting, and drug value) that can suggest strategic pendency management by the applicant.

Table 6 reports the use of procedural rights. Applicants request time extensions and summons to oral proceedings most often for parent applications (up to 68% of secondary patents linked to high-value drugs use at least one time extension, and 23% schedule oral proceedings. Parent applications also show a higher share of cases with two or more intentions to grant (up to 25% for parents of a primary patent compared to 8% for singles). Divisionals show a different profile: among applications that received an intention to grant, divisionals have the highest share of withdrawals. They also use the procedural tool of '"deemed to be withdrawn" at a higher rate, with up to 58% for those linked to high-value drugs compared to 16-38% for singles and parents.

**Table 6.** Procedural rights usage by family structure, secondary patenting, and drug value

| | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| **Applications** | 1188 | 924 | 1259 | 5403 | 3036 | 3927 | 146 | 202 | 384 | 1278 | 970 | 1318 |
| **"Extension to time limit"** | | | | | | | | | | | | |
| % applications with ≥ 1 | 42 | 57 | 47 | 44 | 64 | 50 | 56 | 65 | 59 | 48 | 68 | 52 |
| **"Deemed to be withdrawn"** | | | | | | | | | | | | |
| % applications with ≥ 1 | 16 | 23 | 49 | 30 | 28 | 54 | 25 | 26 | 54 | 38 | 31 | 58 |
| % granted with ≥ 1 | 9 | 19 | 28 | 12 | 23 | 30 | 17 | 21 | 34 | 17 | 25 | 36 |
| **"Intention to grant" (IG)** | | | | | | | | | | | | |
| % applications with ≥ 2 | 8 | 25 | 18 | 6 | 17 | 13 | 3 | 22 | 18 | 7 | 17 | 14 |
| % withdrawn (from all applications with ≥ 1 IG) | 2 | 1 | 7 | 3 | 2 | 7 | 2 | 2 | 7 | 4 | 3 | 7 |
| **"Summons to oral proceedings"** | | | | | | | | | | | | |
| % applications with ≥ 1 | 4 | 14 | 10 | 7 | 22 | 16 | 3 | 15 | 13 | 8 | 23 | 17 |

The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. S, P, and D respectively stand for single, parent and divisional applications.

**Table 7.** Timing of examination delays by family structure, secondary patenting, and drug value

| | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| **Time in months (stdev)** | S | P | D | S | P | D | S | P | D | S | P | D |
| Total examination duration | 54.8 (26.6) | 58.2 (28.1) | 45.7 (25.7) | 54.8 (30.1) | 67.4 (33.0) | 50.4 (29.6) | 55.3 (25.3) | 62.8 (29.5) | 51.0 (28.2) | 55.8 (31.2) | 67.4 (32.9) | 50.2 (29.9) |
| Taken by applicant to reply | 8.6 (6.8) | 11.1 (7.9) | 9.0 (8.0) | 8.7 (7.0) | 12.3 (8.6) | 8.8 (8.2) | 9.3 (7.2) | 12.3 (8.8) | 10.7 (9.5) | 9.0 (7.6) | 12.6 (8.5) | 9.1 (8.5) |
| Given by applicant to reply | 8.8 (5.9) | 10.8 (6.6) | 8.2 (6.4) | 8.6 (6.2) | 11.7 (7.3) | 8.2 (6.8) | 9.2 (6.0) | 11.7 (7.0) | 9.5 (7.4) | 8.6 (6.5) | 11.8 (7.2) | 8.3 (6.9) |
| From ER to ERO | 24.5 (16.0) | 25.2 (17.2) | 17.2 (13.3) | 27.7 (19.1) | 27.6 (18.6) | 16.1 (16.1) | 25.1 (16.1) | 28.3 (19.3) | 13.7 (14.5) | 28.1 (19.3) | 27.1 (17.9) | 21.5 (22.2) |
| From ERO to IG | 19.4 (17.4) | 26.2 (20.0) | 17.5 (17.2) | 21.6 (19.7) | 31.4 (24.2) | 21.5 (21.6) | 20.2 (16.0) | 27.8 (20.6) | 19.8 (19.3) | 23.4 (22.1) | 31.9 (23.6) | 48.2 (27.4) |
| From ERO to refusal | 36.4 (22.7) | 56.4 (29.5) | 47.0 (22.9) | 48.1 (31.2) | 62.2 (30.4) | 47.6 (25.9) | 19.0 (n/a) | 63.0 (22.9) | 50.8 (31.2) | 48.6 (30.7) | 66.8 (31.7) | 48.2 (33.6) |
| From ERO to withdrawal | 28.4 (28.7) | 34.1 (26.5) | 27.8 (26.6) | 25.9 (26.5) | 38.9 (29.2) | 26.9 (25.6) | 27.5 (22.3) | 35.5 (19.7) | 35.6 (30.6) | 24.2 (25.7) | 42.2 (29.4) | 25.1 (24.2) |

Time provided in average number of months (standard deviation in parentheses). Time taken to reply represents the aggregated time taken by the applicant before replying to office communications. Time given to reply represents the aggregated allotted time provided to the applicant to reply to office communications. ER stands for examination request, and ERO examination report. The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. S, P, and D respectively stand for single, parent and divisional applications.

Table 7 presents a more detailed picture of where delays occur during the examination process, following the two-stage split between examination request (ER) and examination report (ERO) described in section 3.3.2. The extended pendency of parent applications is driven mainly by the time between the examination report (ERO) and the final decision rather than by the initial examination request (ER) to examination report stage (ERO), which is consistent with applicant-induced delays. Table 6 shows that applicants take up to almost 1 additional month to reply than they are formally given, especially for parent and divisional applications, and even more so for high-value drugs.

Table 8 reports examination and opposition outcome. Divisionals are granted less often than singles or parents (55-65% vs. 66-92%) and are withdrawn during examination far more

frequently (32-40% vs 6-31%). Parents of high-value drugs have a much higher proportion of withdrawals despite having received an intention to grant compared to singles and divisionals.

Parents and single applications have the highest grant rate (66-92%) compared to divisionals (55-65%). Once granted, parents are opposed most often (9-39%), followed by divisionals (6-36%) and secondary parents have the highest opposition rates (30-39%). The outcome in opposition shows that divisionals have a substantially higher revocation rate (50-52%) than parents (16-44%) or singles (7-36%). Over 30% of revoked divisionals result from withdrawal of the approval to the text.

**Table 8.** Examination and opposition outcome by family structure, secondary patenting, and drug value

| | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| **All applications(count)** | 1188 | 924 | 1259 | 5403 | 3036 | 3927 | 146 | 202 | 384 | 1278 | 970 | 1318 |
| ↳withdrawn | 9 | 6 | 32 | 25 | 10 | 40 | 12 | 8 | 33 | 31 | 13 | 40 |
| ↳↳despite an intention to grant | 16 | 11 | 14 | 10 | 17 | 11 | 11 | 19 | 14 | 10 | 20 | 10 |
| ↳granted | 90 | 92 | 65 | 72 | 87 | 56 | 86 | 90 | 63 | 66 | 84 | 55 |
| ↳↳ opposed | 4 | 9 | 6 | 15 | 30 | 26 | 9 | 20 | 11 | 24 | 39 | 36 |
| ↳↳↳revoked or amended | 66 | 58 | 67 | 75 | 70 | 65 | 55 | 64 | 70 | 75 | 68 | 62 |
| ↳↳↳revoked | 7 | 16 | 52 | 36 | 42 | 51 | 0 | 17 | 52 | 36 | 44 | 50 |
| ↳↳↳↳applicant withdrew approval | 33 | 33 | 33 | 11 | 24 | 30 | 0 | 50 | 29 | 16 | 24 | 38 |
| ↳↳↳↳↳has pending family members | 0 | 50 | 88 | 0 | 81 | 51 | 0 | 67 | 75 | 0 | 76 | 47 |

↳ Each arrow indicates that the value is a percentage calculated relative to the preceding category, not to the total. The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. S, P, and D respectively stand for single, parent and divisional applications.

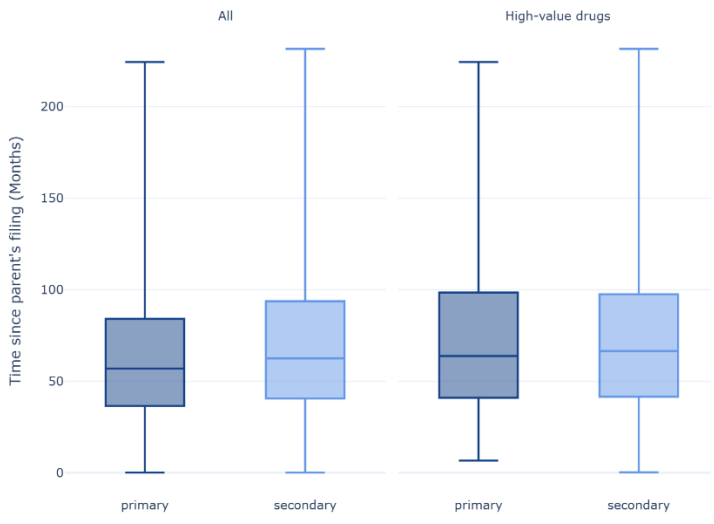
Table 9 reports the family context at divisional filing. On average, divisionals are filed 5-6 years after their parent application. However, Figure 6 shows a distribution that is strongly right-skewed: although 75% of divisionals are filed within 8 years of the parent application, the upper tail is long and extends to 20 years. For 12% of secondary divisionals, rising to 15% for those linked to high-value drugs, filing occurred while at least one family member had already been opposed.

**Table 9.** Family context at filing of divisional, by secondary patenting, and drug value

| | All | | High-value drugs | |
|---|---|---|---|---|
| | Primary | Secondary | Primary | Secondary |
| **Time since parent's filing in months (stdev)** | 64.68 (39.36) | 70.32 (39.84) | 73.8 (41.52) | 73.32 (41.28) |
| **Applications** | 1259 | 3927 | 384 | 1318 |
| At least one family member in opposition prior to filing | 59 | 488 | 32 | 201 |
| % applications | 4.7 | 12.4 | 8.3 | 15.3 |
| At least one family member revoked/amended prior to filing | 15 | 100 | 8 | 44 |
| % applications | 1.2 | 2.6 | 2.1 | 3.3 |
| At least one family member granted prior to filing | 379 | 1049 | 142 | 372 |
| % applications | 30.1 | 26.7 | 37.0 | 28.2 |

The sample consists of 5,186 divisionals out of 15,737 applications filed between 1978 and 2026 (Q1),

**Figure 6.** Boxplots of time since parent's filing by secondary patenting, and drug value




The sample consists of 5,186 divisionals out of 15,737 applications filed between 1978 and 2026 (Q1). Time since parent's filing represent the number of months between the parent's filing and the filing of the divisional.

Taken together, these results show that parent applications take a longer time in examination but are ultimately most often granted, while divisionals show the opposite profile. Parent applications repeatedly draw on the procedural rights, extending time limits and filing amendments after intention to grant. While they mostly proceed to grant (84-92%), they are opposed at the highest rate and only survive as granted 3 out of 10 times.

Divisionals are generally filed 5-6 years after their parent, although 25% are filed more than 8 years later, extending to 20 years. Often, divisionals are filed while the validity of another family member is already being contested in opposition. When in examination, divisionals are more often left 'deemed to be withdrawn' during the examination process or withdrawn from examination shortly after an intention to grant. When divisionals are granted and opposed, they are revoked at a much higher rate than parents or singles, and a substantial share of these revocations are due to the applicant's withdrawal of the approval to the text rather than a formal revocation decision by the Office.

The fact that many of these patterns are amplified for high-value drugs is particularly telling, since there is no obvious procedural reason why examination should take longer when the underlying drug is more valuable.

## 5. Discussion and limitations

### 5.1. Heterogeneity issues

The average effects reported in the results section can mask considerable heterogeneity. Even if strategic use of the patent system were limited to a limited number of cases, it could still matter substantially: a few high-value drugs protected by extended chains of divisionals that prolong monopoly by even a few months can generate substantial costs to healthcare

systems. At the same time, it is worth checking whether less extreme cases already present meaningful issues on their own. Two complementary checks are carried out to capture this heterogeneity.

First, reproducing the analysis by generation depth yields consistent results (see Annexes 3b, 4-7). Notably, the patterns identified are already visible when comparing single applications to families with a single divisional and tend to be exacerbated as family complexity increases.

Second, the sample is split into two types of applications based on procedural rights (extension to time limit, deemed to be withdrawn, intention to grant, and summons to oral proceedings) use: applications using at most one procedural right are classified as "one and done" (not one of each type but one in total), while those using more than one are classified as "drag and delay." Since this distinction is directly correlated with examination duration, it is applied to the stage 2 analysis only. This is similar to the EPO's own reporting of separating cases that are not "standard" applications.

In Table 10, one can see that parents are not the only applications that use several/multiple procedural rights. While a large majority of single applications use maximum one procedural right (73% primary, 67% secondary), the proportion reaches 44-51% for parents and 52-56% for divisionals.

**Table 10.** Procedural rights by family structure, secondary patenting, and applicant behaviour

| | One & done | | | | | | Drag & delay | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| **Applications** | 866 | 469 | 701 | 3614 | 1350 | 2054 | 322 | 455 | 558 | 1789 | 1686 | 1873 |
| % of total primary/secondary applications by category | 73 | 51 | 56 | 67 | 44 | 52 | 27 | 49 | 44 | 33 | 56 | 48 |
| **"Extension to time limit"** | | | | | | | | | | | | |
| % applications with ≥ 1 | 23 | 26 | 13 | 19 | 28 | 13 | 93 | 90 | 89 | 94 | 94 | 91 |
| **"Deemed to be withdrawn"** | | | | | | | | | | | | |
| % applications with ≥ 1 | 6 | 5 | 29 | 16 | 6 | 35 | 42 | 42 | 73 | 56 | 47 | 75 |
| % granted with ≥ 1 | 2 | 3 | 8 | 3 | 4 | 9 | 31 | 37 | 60 | 36 | 41 | 61 |
| **"Intention to grant" (IG)** | | | | | | | | | | | | |
| % applications with ≥ 2 | 6 | 19 | 12 | 4 | 11 | 7 | 13 | 31 | 27 | 11 | 21 | 18 |
| % withdrawn (from all applications with ≥ 1 IG) | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 1 | 10 | 8 | 3 | 9 |
| **"Summons to oral proceedings"** | | | | | | | | | | | | |
| % applications with ≥ 1 | 1 | 4 | 3 | 2 | 9 | 5 | 11 | 24 | 18 | 18 | 33 | 28 |

The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. Applications using at most one procedural right are classified as "one and done". S, P, and D respectively stand for single, parent and divisional applications.

From Table 11, an interesting estimate can be done: using several/multiple procedural rights adds roughly 1.9-2.3 years to examination, which can add an estimated 5-7 years to total family pendency with 2.7-2.9 divisionals per family on average. Interestingly, one-and-done applicants reply before the office deadlines, while drag-and-delay applicants take 0.8-1.8 additional months.

**Table 11.** Timing of examination delays by family structure, secondary patenting, and applicant behaviour

| Time (months) | One & done | | | | | | Drag & delay | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| Total | 47.6 (21.6) | 47.2 (24.1) | 34.7 (19.3) | 48.1 (23.4) | 54.0 (28.0) | 37.3 (22.8) | 74.3 (29.0) | 69.7 (27.4) | 59.8 (26.0) | 74.5 (33.5) | 78.1 (32.9) | 64.7 (29.5) |
| Taken to reply | 6.0 (3.7) | 7.0 (4.3) | 5.0 (3.9) | 5.8 (4.2) | 7.4 (5.0) | 4.9 (4.2) | 14.1 (8.4) | 14.7 (8.5) | 12.0 (8.9) | 12.9 (8.2) | 15.7 (8.9) | 11.5 (9.2) |
| Given to reply | 6.7 (3.5) | 7.8 (4.4) | 5.5 (3.6) | 6.5 (4.2) | 8.1 (4.7) | 5.6 (4.2) | 13.3 (7.2) | 13.5 (7.2) | 10.2 (7.2) | 11.8 (7.1) | 14.2 (7.8) | 9.9 (7.5) |
| ER to ERO | 22.8 (15.0) | 24.6 (16.4) | 12.1 (12.5) | 26.2 (17.6) | 27.1 (18.0) | 14.9 (14.5) | 29.0 (17.6) | 25.8 (17.9) | 14.8 (14.2) | 30.5 (21.1) | 28.1 (19.1) | 17.0 (17.5) |
| ERO to IG | 14.3 (12.7) | 16.6 (14.3) | 10.8 (11.8) | 15.5 (14.3) | 20.5 (17.6) | 13.1 (15.8) | 36.7 (20.2) | 39.2 (19.3) | 33.0 (17.9) | 39.0 (22.3) | 43.3 (24.7) | 38.0 (21.8) |
| ERO to R | 23.0 (3.8) | 34.8 (22.1) | 54.0 (26.0) | 30.2 (21.6) | 49.8 (28.0) | 36.5 (21.2) | 46.2 (26.8) | 62.6 (29.0) | 44.6 (21.7) | 54.8 (31.7) | 66.0 (30.1) | 50.0 (26.3) |
| ERO to W | 16.4 (15.8) | 16.1 (13.1) | 13.8 (19.2) | 12.5 (13.8) | 28.7 (24.0) | 14.9 (20.0) | 33.2 (31.2) | 37.6 (27.1) | 31.4 (27.1) | 32.8(2 8.8) | 40.4 (29.5) | 30.7 (25.9) |

Time provided in average number of months (standard deviation in parentheses). Time taken to reply represents the total time taken by the applicant before replying to office communications. Time given to reply represents the allotted time provided to the applicant to reply to office communications. ER stands for examination request, ERO examination report, communication under 94(3) EPC, IG intention to grant, R rejection, and W withdrawal. The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. Applications using at most one procedural right are classified as "one and done". S, P, and D respectively stand for single, parent and divisional applications.

Table 12 shows that the two categories differ systematically in grant rates, less so in opposition rates. Primary parents and divisionals in the drag-and-delay category are more often revoked in opposition. Revocation rates for secondary parents and divisionals are high, regardless of category.

Finally, divisional filing after the parent does not strongly differ between the two categories (see Table 13).

**Table 12.** Examination and opposition outcome by family structure, secondary patenting and applicant behaviour

| | One & done | | | | | | Drag & delay | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| **All applications (count)** | 866 | 469 | 701 | 3614 | 1350 | 2054 | 322 | 455 | 558 | 1789 | 1686 | 1873 |
| ↳ withdrawn | 6 | 3 | 26 | 21 | 4 | 35 | 16 | 9 | 39 | 33 | 14 | 45 |
| ↳↳ despite an intention to grant | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 1 | 10 | 8 | 3 | 9 |
| ↳ granted | 94 | 96 | 72 | 78 | 95 | 64 | 82 | 87 | 56 | 62 | 80 | 47 |
| ↳↳ opposed | 3 | 7 | 4 | 14 | 29 | 25 | 6 | 11 | 9 | 18 | 31 | 27 |
| ↳↳↳ revoked or amended | 56 | 44 | 56 | 74 | 68 | 64 | 82 | 68 | 75 | 77 | 72 | 67 |
| ↳↳↳ revoked | 7 | 9 | 39 | 34 | 41 | 50 | 6 | 20 | 60 | 40 | 43 | 54 |
| ↳↳↳↳ applicant withdrew approval to the text | 50 | 67 | 14 | 9 | 29 | 27 | 0 | 22 | 41 | 15 | 19 | 33 |
| ↳↳↳↳↳ with pending family members | 0 | 50 | 100 | 0 | 79 | 47 | 0 | 50 | 86 | 0 | 83 | 55 |

↳ Each arrow indicates that the value is a percentage calculated relative to the preceding category, not to the total. The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1), linked with a primary or secondary subject-matter, with a final examination outcome. Applications using at most one procedural right are classified as "one and done". S, P, and D respectively stand for single, parent and divisional applications.

**Table 13.** Divisional filing context by secondary patenting and applicant behaviour

| | One & done | | Drag & delay | |
|---|---|---|---|---|
| | **Primary** | **Secondary** | **Primary** | **Secondary** |
| | D | D | D | D |
| **Time since parent's filing** months(stdv) | 64.8(38.4) | 70.8(40.8) | 64.8(37.2) | 67.2(38.4) |
| Applications | 701 | 2054 | 558 | 1873 |
| At least one family member in opposition prior to filing | 28 | 276 | 31 | 212 |
| % applications | 4 | 13 | 6 | 11 |
| At least one family member revoked/amended prior to filing | 6 | 60 | 9 | 40 |
| % applications | 1 | 3 | 2 | 2 |
| At least one family member granted prior to filing | 231 | 601 | 148 | 448 |
| % applications | 33 | 29 | 27 | 24 |
| The sample consists of the 5,186 divisional out of 15,737 applications. Applications using at most one procedural right are classified as "one and done" and otherwise "drag & delay". | | | | |

## 5.2. Trend over time

While the Cox models from the results section control for filing year, they do not capture whether the intensity with which divisional applications and procedural rights are used has itself evolved over time. A marked increase in such behaviour over a period without a comparable increase in the underlying volume of applications would be consistent with a shift in applicant strategy.

Table 14 shows that the number of patent families increased and divisionals in each family increased for both primary and secondary families across all generations between the 1991–1995 and 2001–2005 cohorts, with primary families appearing to develop more complex generational structure over time (but the growth rates are computed from small base counts). There is no striking difference for high-value drugs. Notably, secondary divisionals are filed later than primary ones at every generation for every cohort.

**Table 14.** Trend in family structure, divisional filings (count and timing)

| | | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Primary | | | Secondary | | | Primary | | | Secondary | | |
| Filing year | | FAM count | DIV count | DIV filing | FAM count | DIV count | DIV filing | FAM count | DIV count | DIV filing | FAM count | DIV count | DIV filing |
| 91-95 | D1 | 20 | 20 | 69.5 (26.0) | 85 | 85 | 79 (37.8) | 3 | 3 | 61.7 (35.5) | 26 | 26 | 88.9 (35.9) |
| 96-00 | | 45 | 45 | 61.1 (34.5) | 191 | 191 | 68.2 (31.8) | 12 | 12 | 53.1 (33.9) | 46 | 46 | 61.0 (28.2) |
| 01-05 | | 68 | 68 | 61.2 (25.9) | 314 | 314 | 61.4 (30.4) | 15 | 15 | 68.9 (42.6) | 101 | 101 | 64.6 (30.3) |
| 91-95 | G1 | 3 | 6 | 78.1 (27.5) | 16 | 35 | 87 (41.1) | 0 | 0 | 0.0 | 3 | 6 | 58.4 (25.5) |
| 96-00 | | 8 | 20 | 50.8 (20.0) | 32 | 82 | 51.8 (36.1) | 2 | 5 | 40.6 (24.5) | 4 | 10 | 53.2 (55) |
| 01-05 | | 23 | 63 | 64.6 (25.8) | 72 | 181 | 68.4 (29.0) | 9 | 23 | 61.1 (29.5) | 21 | 45 | 79.9 (28.1) |
| 91-95 | G2 | 3 | 6 | 80.6 (35.9) | 39 | 96 | 94.5 (39.5) | 2 | 4 | 67.3 (53.2) | 14 | 31 | 102.6 (37.0) |
| 96-00 | | 20 | 48 | 92.7 (4.0) | 85 | 221 | 96.2 (37.1) | 11 | 28 | 112.6 (37.3) | 38 | 95 | 88.2 (35.3) |
| 01-05 | | 45 | 128 | 74 (39.1) | 137 | 398 | 81.1 (36.3) | 15 | 47 | 76.3 (38.6) | 55 | 164 | 81.8 (39.6) |
| 91-95 | G3+ | 1 | 3 | 100 (38.4) | 16 | 80 | 124.4 (54.7) | 1 | 3 | 100.0 (38.4) | 6 | 28 | 132.8 (56.0) |
| 96-00 | | 5 | 18 | 122.3 (55.5) | 20 | 115 | 95.3 (40.4) | 3 | 11 | 120.9 (62.4) | 7 | 29 | 104.8 (40.1) |
| 01-05 | | 20 | 81 | 101.1 (50.5) | 45 | 213 | 99.6 (47.7) | 9 | 34 | 105.7 (51.7) | 22 | 103 | 101.1 (48.1) |

The sample consists of 1,313 parents and 2,187 divisional applications whose parent was filed between 1991 – 2005 out of 15,737 applications. Filing year is that of the parent. FAM count represents the number of patent families whose parent was filed during that period, DIV count represents the number of divisionals filed for those patent families. DIV filing represents the average number of months (stdv) between the parent and the divisional filings in that year span.

### 5.3. Limitations

One limitation of the analysis is that it includes applications that are later withdrawn or refused. These outcomes may be related to applicant behaviour and may affect the relationship between application characteristics and examination duration. Estimating the Cox proportional hazard models using only applications that were granted provides consistent results.

Further limitations concern the thresholds used to classify drugs by sales value and companies by revenue, as well as the descriptive nature of the Stage 2 analysis. The present study does not test whether the findings change under alternative value or revenue cut-offs. In addition, the differences observed across family structures, subject-matter types, and procedural-behaviour categories in Stage 2 have not been tested for statistical significance. Future research could test alternative classification thresholds, and estimate the Stage 2 indicators in a formal regression framework. It would also be interesting to explore whether the patterns identified in this study exist in other jurisdictions or technology sectors.

## 6. Conclusion

This paper set out to establish whether different patent types, by family structure, subject-matter and value of the product protected, take systematically longer in examination, and whether such delay can be explained as legitimate exercise of procedural rights or reflects their strategic use to prolong legal uncertainty.

Results confirm the hypothesis that patent families take significantly longer in examination than single applications, but there is more to that story. First, the effect is stronger for high-value drugs. This could reflect strategic behaviour around high-stakes drugs, at the very least; it also points to a greater significant impact on healthcare systems. Second, the effect remains significant after controlling for family size and office communications, indicating it is not simply a matter of patent complexity. The application-level analysis confirms these results and highlights that the delays are mainly driven by parent applications. Throughout all levels and specifications, secondary patents take consistently longer in examination. This result is particularly relevant since around 4-5 secondary patents are filed for every primary patent.

On average, divisionals are filed 5 to 6 years after the parent, but 25% of divisionals filings occur between 7 to 20 years after the parent. Divisionals are frequently filed after another family member has already been granted (27% of cases), is in opposition (10%), or has even been revoked or amended (2%). The parent of a single divisional stays in examination for one to two additional years compared to single applications. These delays are induced by the use of several or multiple procedural rights such as requests for time extensions, summons to oral proceedings, letting the application be deemed withdrawn then reviving it, and so forth. With an estimated 1.9 to 2.3 additional years per application that uses more than one procedural right, and with around 2.7 to 2.9 divisionals per family, one could expect an average of 5-7 years of additional pendency at the family level (hence on a single invention). Once granted and opposed, secondary parents and divisionals are revoked at much higher rates than singles (42 and 51% vs 36%), and 30% of these revocations during opposition follow the applicant's withdrawal to the approval of text rather than an adverse decision, usually while another family member remains pending.

Two considerations follow from this, and they are not mutually exclusive. First, the delay itself carries a cost: in the multi-generation patent families, total examination can exceed 20 years, leaving the scope and validity of protection unresolved for the entire statutory life of a patent. Second, several patterns identified here, such as the family and secondary-patent effect that are seen even after controlling for procedural and communication factors, look more like deliberate pendency management than something complexity alone would produce. This analysis cannot establish whether there is any broader intent behind those delays and does not claim to. Even if applicants are using these tools strategically, this does not necessarily equate to misconduct: they are lawful and equally available to any applicant. The same evidence can just as reasonably be read as a rational response to the system's incentives. On this view, scrutiny should extend beyond individual applicants to the procedural framework that makes such conduct available in the first place.

This distinction has implications for how a policy response should be framed. Competition law, as discussed by Gurgula (2016, 2022) and Pantelidis (2024), acts on individual conduct after the fact. It can address the accumulation of patent rights around a single product, but only once that accumulation has occurred and its abusive character has been established. Furthermore, antitrust law can only intervene if the party engaging in that abusive conduct also has market dominance at the time of abuse. When competition authorities don’t intervene, healthcare systems typically cannot recover the excess expenditure incurred paying monopoly

prices, even where the patents sustaining it are later found invalid. [18] A response limited to competition law therefore leaves most of that cost unaddressed. Patent-law reform, along the lines proposed by Foss-Solbrekk (2022) and Tyagi et al. (2024), operates instead on a prospective basis. Measures such as capping the number of generations a family can reach, limiting the repeated use of procedural rights, or establishing a public register of family and subject-matter structure at filing would change the rules for every applicant going forward, rather than judging conduct after the fact. Whether such measures, alone or combined with competition-law intervention, would strike an adequate balance between procedural flexibility and timely resolution of legal uncertainty is a question this analysis cannot settle. It does suggest that amending the use of procedural tools could speed up examination, and that this deserves closer attention than it has so far received.

This requires more transparent and granular EPO bulk data, capable of linking family members, procedural events, and examination outcomes. Average examination durations and standard cases alone can obscure the relevant patterns. Policy attention should therefore focus on the upper tail: the relatively few, high-value patent families in which unusually long pendency, repeated procedural activity, and multiple related applications converge.

[18] see *Menzis Zorgverzekeraar N.V. and Anderzorg N.V. v AstraZeneca B.V. and AstraZeneca AB*, Hoge Raad, 3 November 2023, Case No. 22/01071

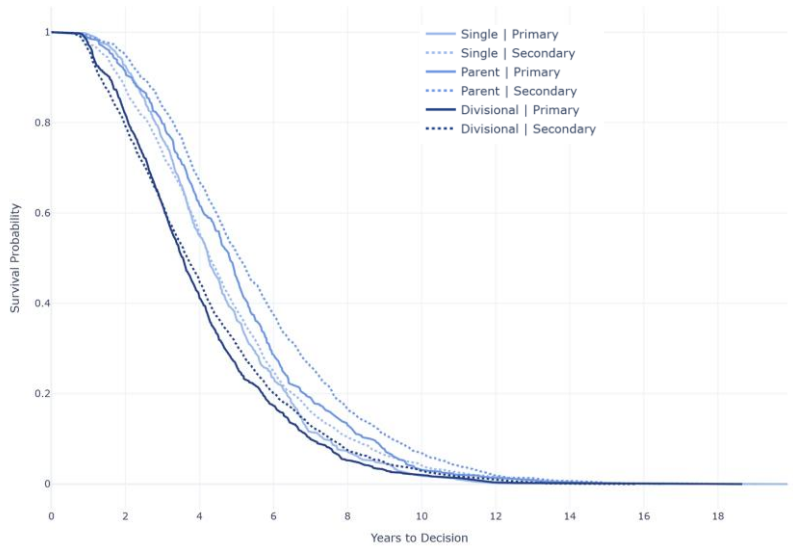
**Annex 1:** Life-science IPC classes

| IPC | Description |
|---|---|
| A61K | Preparations for medical, dental or toiletry purposes |
| A61P | Specific therapeutic activity of chemical |
| A61M | Devices for introducing media into, or onto, the body |
| A61J | Containers specially adapted for medical or pharmaceutical purposes; devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms; devices for administering food or medicines orally; baby comforters; devices for receiving spittle |
| C07C | Acyclic or carbocyclic compounds |
| C07D | Heterocyclic compounds |
| C12N | Microorganisms or enzymes; compositions thereof; propagating, preserving, or maintaining microorganisms; mutation or genetic engineering; culture media |
| C07K | Peptides |
| C07B | General methods of organic chemistry; apparatus therefor |
| C07F | Acyclic, carbocyclic, or heterocyclic compounds containing elements other than carbon, hydrogen, halogen, oxygen, nitrogen, sulfur, selenium or tellurium |
| C12P | Fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optical isomers from a racemic mixture |
| C12Q | Measuring or testing processes involving enzymes, nucleic acids or microorganisms (immunoassay g01n 33/53); compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes. |

**Annex 2.** List of patent types and category

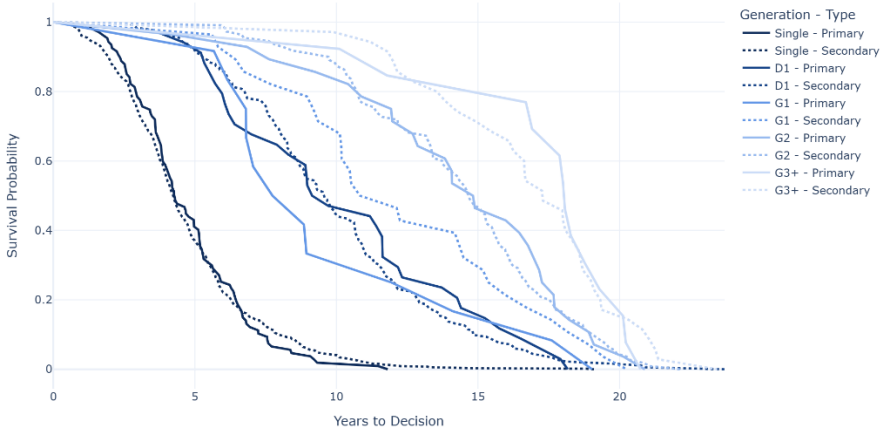
| Patent Type | Category |
|---|---|
| molecule patents | primary |
| new use related to main indication | secondary |
| other molecular forms | secondary |
| general formulations & methods | secondary |
| salts, hydrates & solvates | secondary |
| polymorphic forms | secondary |
| inhalation formulations | secondary |
| respiratory devices | secondary |
| dosing regimen & administration conditions for combinations | secondary |
| use of combinations | secondary |
| transdermal patch | secondary |
| intermediates & preparation thereof | secondary |
| dosing regimen/administration conditions | secondary |
| oral formulations | secondary |
| complete synthesis | secondary |
| injection devices | secondary |
| injectable formulations | secondary |
| assaying methods | secondary |
| biotechnology | secondary |
| purification methods | secondary |
| final synthetic stages | secondary |
| ophthalmic formulations | secondary |
| topical formulations | secondary |
| administration of a drug with a device | secondary |
| ophthalmic devices | secondary |
| kits & packaging | secondary |
| fermentation methods | secondary |
| diagnostic devices | secondary |
| administration of a drug combination with a device | secondary |
| administration of a drug with a medical procedure | secondary |
| energy-dependent devices | secondary |
| excipients | secondary |
| methods of determining patient suitability | secondary |
| oral-administering devices | secondary |
| penile formulations | secondary |
| vaginal formulations | secondary |
| nasal formulations | secondary |
| implants | secondary |
| rectal formulations | secondary |
| optic formulations | secondary |
| intra-cardiovascular devices | secondary |

**Annex 3a**. Kaplan-Meier survival curve at application level for high-value drugs




Note: Years to decision represent the time in examination (between filing and final examination decision). Survival represents the pendency of the application and stops as soon as a final examination decision is reached (grant, refusal, or withdrawal). The estimates are carried out on the sample of 4,298 out of 15,737 applications filed between 1978 and 2026 (Q1) that are linked to high-value drugs.

**Annex 3b**. Kaplan-Meier survival curve at family level for high-value drugs, by generation




Note: Years to decision represent the total time in examination (between filing of the parent and final examination decision of the last pending member). A family *survives* as long as at least one of its members is still pending, until they all reach a final examination decision (grant, refusal, or withdrawal). The estimates are carried out on the restricted sample of 1,217 out of 5,443 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006, and that are linked to high-value drugs.

**Annex 4**. Procedural rights by family structure, secondary patenting, and drug value.

| | | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | | S | P | D | S | P | D | S | P | D | S | P | D |
| **Restricted** | | 767 | 251 | 466 | 3199 | 987 | 1807 | 107 | 79 | 173 | 683 | 318 | 609 |
| % of total primary/secondary applications by category | | 52 | 17 | 31 | 53 | 17 | 30 | 30 | 22 | 48 | 42 | 20 | 38 |
| **"Extension to time limit"** | | 48 | | | 46 | | | 55 | | | 51 | | |
| % applications with ≥ 1 | D1 | | 84 | 60 | | 76 | 57 | | 79 | 59 | | 79 | 57 |
| | G1 | | 84 | 53 | | 82 | 68 | | 70 | 73 | | 88 | 78 |
| | G2 | | 78 | 65 | | 80 | 65 | | 78 | 71 | | 81 | 64 |
| | G3+ | | 96 | 66 | | 77 | 56 | | 100 | 80 | | 78 | 58 |
| **"Deemed to be withdrawn"** | | | | | | | | | | | | | |
| % applications with ≥ 1 | | 14 | | | 26 | | | 18 | | | 35 | | |
| | D1 | | 27 | 55 | | 28 | 63 | | 21 | 38 | | 28 | 61 |
| | G1 | | 31 | 52 | | 36 | 64 | | 30 | 42 | | 38 | 70 |
| | G2 | | 26 | 53 | | 27 | 54 | | 37 | 59 | | 24 | 57 |
| | G3+ | | 42 | 60 | | 24 | 55 | | 38 | 71 | | 30 | 63 |
| % granted with ≥ 1 | | 8 | | | 11 | | | 10 | | | 15 | | |
| | D1 | | 23 | 20 | | 24 | 28 | | 12 | 16 | | 25 | 30 |
| | G1 | | 25 | 33 | | 31 | 23 | | 14 | 25 | | 32 | 44 |
| | G2 | | 24 | 24 | | 25 | 32 | | 35 | 31 | | 22 | 37 |
| | G3+ | | 36 | 41 | | 21 | 40 | | 36 | 56 | | 25 | 55 |
| **"Intention to grant"** | | | | | | | | | | | | | |
| % applications with ≥ 2 | | 1 | | | 1 | | | 0 | | | 1 | | |
| | D1 | | 2 | 3 | | 2 | 5 | | 0 | 3 | | 0 | 5 |
| | G1 | | 3 | 4 | | 5 | 5 | | 10 | 4 | | 8 | 9 |
| | G2 | | 4 | 9 | | 1 | 9 | | 4 | 11 | | 2 | 9 |
| | G3+ | | 4 | 24 | | 1 | 9 | | 0 | 22 | | 3 | 17 |
| % withdrawn (from all applications with ≥ 1 IG) | | 1 | | | 2 | | | 1 | | | 2 | | |
| | D1 | | 0 | 5 | | 2 | 5 | | 0 | 0 | | 2 | 1 |
| | G1 | | 0 | 3 | | 1 | 3 | | 0 | 0 | | 0 | 2 |
| | G2 | | 0 | 9 | | 0 | 6 | | 0 | 8 | | 0 | 6 |
| | G3+ | | 0 | 5 | | 0 | 3 | | 0 | 7 | | 0 | 3 |
| **"Oral summons"** | | | | | | | | | | | | | |
| % applications with ≥ 1 | | 3 | | | 6 | | | 1 | | | 6 | | |
| | D1 | | 11 | 10 | | 23 | 11 | | 7 | 7 | | 23 | 12 |
| | G1 | | 28 | 8 | | 35 | 24 | | 40 | 12 | | 31 | 35 |
| | G2 | | 17 | 10 | | 22 | 20 | | 15 | 12 | | 24 | 19 |
| | G3+ | | 19 | 12 | | 26 | 25 | | 23 | 16 | | 41 | 31 |

The restricted sample consists of 7,477 (3966 singles + 1238 parents + & 2273 divisionals) out of 15,737 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006.

**Annex 5**. Procedural rights by family structure, secondary patenting, and drug value.

| Time Months (stdev) | | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | | S | P | D | S | P | D | S | P | D | S | P | D |
| **Total** | | 58.56 (26.64) | | | 59.04 (29.64) | | | 57.12 (24.84) | | | 56.40 (30.36) | | |
| | D1 | | 71.88 (30.00) | 57.60 (33.72) | | 79.32 (38.16) | 56.16 (32.88) | | 69.84 (35.88) | 58.68 (32.76) | | 79.92 (36.12) | 54.00 (31.44) |
| | G1 | | 79.80 (31.08) | 49.56 (29.16) | | 96.36 (46.68) | 59.88 (31.92) | | 76.68 (44.40) | 62.64 (39.96) | | 106.44 (49.44) | 66.48 (33.24) |
| | G2 | | 69.12 (34.32) | 55.92 (28.20) | | 74.64 (29.88) | 63.24 (32.40) | | 79.20 (36.00) | 58.44 (29.16) | | 72.48 (28.68) | 63.24 (34.08) |
| | G3+ | | 68.64 (25.20) | 50.28 (27.60) | | 69.72 (32.76) | 55.68 (29.76) | | 64.56 (17.88) | 60.60 (29.28) | | 80.16 (39.00) | 56.16 (30.84) |
| Taken to reply | | 9.00 (7.14) | | | 8.78 (7.02) | | | 9.04 (7.31) | | | 8.80 (7.48) | | |
| | D1 | | 13.60 (8.17) | 8.81 (7.46) | | 14.14 (9.43) | 8.21 (7.72) | | 12.30 (9.00) | 10.49 (8.20) | | 14.10 (8.63) | 7.42 (7.05) |
| | G1 | | 14.63 (7.76) | 9.01 (7.83) | | 17.30 (10.42) | 9.57 (10.41) | | 13.85 (5.35) | 11.11 (7.73) | | 19.05 (12.71) | 12.32 (11.76) |
| | G2 | | 13.62 (9.23) | 11.11 (8.86) | | 14.23 (8.51) | 11.17 (8.93) | | 17.08 (12.09) | 13.46 (10.34) | | 13.45 (8.77) | 11.77 (9.59) |
| | G3+ | | 13.95 (7.63) | 9.92 (8.94) | | 13.83 (9.13) | 9.44 (7.77) | | 12.24 (5.99) | 12.05 (10.85) | | 16.39 (9.81) | 10.16 (8.23) |
| Given to reply | | 9.17 (6.11) | | | 8.79 (6.14) | | | 9.06 (6.18) | | | 8.52 (6.31) | | |
| | D1 | | 12.93 (7.14) | 8.31 (6.19) | | 13.45 (8.17) | 7.50 (6.48) | | 12.14 (7.98) | 9.96 (6.51) | | 13.54 (7.69) | 6.59 (5.63) |
| | G1 | | 13.59 (6.37) | 8.27 (6.58) | | 16.39 (9.02) | 8.14 (7.71) | | 13.60 (4.70) | 11.27 (7.60) | | 17.76 (11.40) | 10.47 (8.60) |
| | G2 | | 12.89 (7.47) | 10.17 (7.03) | | 13.57 (7.47) | 10.30 (7.53) | | 14.81 (9.55) | 11.41 (7.73) | | 12.93 (7.69) | 10.82 (7.92) |
| | G3+ | | 12.73 (7.18) | 8.45 (7.35) | | 13.38 (7.79) | 8.76 (6.31) | | 10.92 (4.80) | 10.38 (8.89) | | 15.31 (7.37) | 8.87 (6.24) |
| ER to ERO | | 23.88 (16.08) | | | 27.60 (18.96) | | | 24.96 (15.36) | | | 28.44 (18.60) | | |
| | D1 | | 27.84 (19.32) | 19.68 (19.20) | | 32.64 (22.08) | 20.40 (20.88) | | 30.36 (21.96) | 24.36 (21.48) | | 33.60 (20.04) | 20.76 (20.04) |
| | G1 | | 35.52 (18.24) | 14.16 (15.96) | | 31.68 (21.60) | 19.44 (19.20) | | 30.36 (22.68) | 18.00 (24.24) | | 35.76 (22.92) | 18.00 (21.12) |
| | G2 | | 29.04 (20.64) | 16.32 (15.84) | | 31.08 (19.08) | 17.16 (16.92) | | 37.68 (24.24) | 14.28 (14.52) | | 29.04 (17.64) | 18.12 (17.16) |
| | G3+ | | 26.76 (15.84) | 10.20 (10.92) | | 27.48 (17.52) | 18.00 (19.56) | | 27.84 (12.60) | 11.16 (12.48) | | 27.96 (17.64) | 16.56 (20.88) |
| ERO to IG | | 21.00 (17.40) | | | 21.60 (18.24) | | | 19.32 (14.28) | | | 23.04 (20.76) | | |
| | D1 | | 34.44 (21.24) | 25.80 (22.32) | | 35.64 (25.08) | 25.80 (22.80) | | 32.40 (27.96) | 18.84 (18.36) | | 37.08 (24.84) | 23.88 (18.96) |
| | G1 | | 34.32 (20.16) | 17.88 (16.20) | | 53.16 (36.96) | 22.68 (20.64) | | 35.04 (24.00) | 24.72 (20.40) | | 55.68 (41.64) | 18.72 (18.60) |
| | G2 | | 28.20 (20.40) | 25.68 (15.72) | | 33.96 (20.28) | 30.36 (25.32) | | 29.76 (24.00) | 27.12 (20.40) | | 34.68 (19.92) | 29.16 (27.48) |
| | G3+ | | 31.08 (18.00) | 23.88 (21.72) | | 30.84 (22.32) | 26.76 (21.60) | | 29.04 (12.12) | 33.48 (24.60) | | 36.96 (25.68) | 28.08 (23.88) |
| ERO to R | | 43.20 (23.64) | | | 47.64 (33.24) | | | 18.96 (0.00) | | | 39.72 (19.08) | | |
| | D1 | | 48.96 (35.88) | 44.88 (20.04) | | 69.72 (32.88) | 48.00 (22.56) | | 0 (0) | 42.72 (16.56) | | 70.80 (35.28) | 30.84 (19.08) |
| | G1 | | 55.80 (0.00) | 67.20 (2.28) | | 68.40 (25.20) | 57.12 (32.52) | | 55.80 (0.00) | 67.20 (3.24) | | 0 (0) | 71.88 (32.04) |
| | G2 | | 70.68 (0.00) | 49.56 (29.52) | | 76.68 (25.56) | 47.28 (26.64) | | 0 (0) | 54.84 (34.20) | | 99.84 (42.36) | 47.52 (29.28) |
| | G3+ | | 62.40 (31.32) | 26.16 (6.72) | | 48.36 (0.00) | 47.16 (27.60) | | 45.24 (13.68) | 26.16 (6.72) | | 0 (0) | 46.20 (29.28) |
| ERO to W | | 33.36 (32.40) | | | 25.92 (28.68) | | | 34.92 (25.56) | | | 24.00 (27.24) | | |
| | D1 | | 49.32 (41.76) | 27.84 (32.52) | | 43.32 (28.80) | 25.08 (26.64) | | 33.48 (25.20) | 36.24 (39.96) | | 41.88 (26.16) | 20.64 (23.88) |
| | G1 | | 41.88 (31.56) | 31.80 (35.52) | | 68.40 (44.04) | 29.16 (25.32) | | 24.60 (14.04) | 73.56 (45.48) | | 83.76 (51.84) | 38.28 (25.44) |
| | G2 | | 53.16 (0.00) | 36.84 (27.60) | | 39.12 (28.92) | 39.48 (32.16) | | 53.16 (0.00) | 44.64 (29.04) | | 29.28 (21.72) | 39.96 (32.04) |
| | G3+ | | 22.68 (0.00) | 29.52 (27.36) | | 72.24 (44.16) | 28.32 (26.76) | | 0 (0) | 36.72 (32.04) | | 85.44 (33.72) | 21.12 (18.12) |

Time provided in average number of months (standard deviation in parentheses). Time taken to reply represents the total time taken by the applicant before replying to office communications. Time given to reply represents the allotted time provided to the applicant to reply to office communications. ER stands for examination request, ERO examination report, IG intention to grant, R refusal, and W withdrawal. The restricted sample consists of 7,477 (3966 singles + 1238 parents + & 2273 divisionals) out of 5,737 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006.

## **Annex 6**. Outcome distribution by family status, secondary patenting and drug value

| | | All | | | | | | High-value drugs | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | | S | P | D | S | P | D | S | P | D | S | P | D |
| **Applications** | | 767 | | | 3199 | | | 107 | | | 683 | | |
| | D1 | | 124 | 124 | | 533 | 533 | | 29 | 29 | | 151 | 151 |
| | G1 | | 32 | 77 | | 114 | 255 | | 10 | 26 | | 26 | 54 |
| | G2 | | 69 | 172 | | 256 | 643 | | 27 | 73 | | 104 | 259 |
| | G3+ | | 26 | 93 | | 84 | 376 | | 13 | 45 | | 37 | 145 |
| **Average number of divisionals per parent G1-G3+** | | | | 2.7 | | | 2.8 | | | 2.9 | | | 2.7 |
| % **granted** (%) | | 92 | | | 77 | | | 90 | | | 69 | | |
| | D1 | | 93 | 48 | | 87 | 43 | | 90 | 66 | | 86 | 46 |
| | G1 | | 88 | 66 | | 85 | 37 | | 70 | 62 | | 73 | 33 |
| | G2 | | 96 | 51 | | 89 | 54 | | 96 | 48 | | 89 | 58 |
| | G3+ | | 85 | 63 | | 92 | 58 | | 85 | 60 | | 86 | 57 |
| % withdrawn during examination | | 7 | | | 21 | | | 9 | | | 30 | | |
| | D1 | | 5 | 46 | | 8 | 53 | | 10 | 28 | | 9 | 51 |
| | G1 | | 9 | 30 | | 12 | 55 | | 20 | 31 | | 23 | 52 |
| | G2 | | 3 | 44 | | 7 | 40 | | 4 | 44 | | 9 | 37 |
| | G3+ | | 4 | 34 | | 7 | 33 | | 0 | 36 | | 14 | 32 |
| % withdrawn that had received an intention to grant | | 18 | | | 9 | | | 10 | | | 7 | | |
| | D1 | | 0 | 11 | | 19 | 9 | | 0 | 0 | | 21 | 3 |
| | G1 | | 0 | 9 | | 7 | 5 | | 0 | 0 | | 0 | 4 |
| | G2 | | 0 | 20 | | 6 | 14 | | 0 | 19 | | 0 | 16 |
| | G3+ | | 0 | 16 | | 0 | 9 | | 0 | 19 | | 0 | 9 |
| % granted that were **opposed** | | 5 | | | 15 | | | 10 | | | 22 | | |
| | D1 | | 10 | 2 | | 23 | 19 | | 19 | 0 | | 28 | 32 |
| | G1 | | 4 | 2 | | 36 | 23 | | 14 | 6 | | 42 | 28 |
| | G2 | | 26 | 9 | | 42 | 28 | | 38 | 20 | | 51 | 33 |
| | G3+ | | 27 | 8 | | 52 | 39 | | 36 | 11 | | 53 | 46 |
| % opposed that were **revoked or amended** | | 74 | | | 78 | | | 50 | | | 78 | | |
| | D1 | | 36 | 0 | | 85 | 79 | | 40 | 0 | | 83 | 77 |
| | G1 | | 0 | 0 | | 91 | 82 | | 0 | 0 | | 100 | 80 |
| | G2 | | 82 | 88 | | 86 | 80 | | 80 | 86 | | 85 | 76 |
| | G3+ | | 100 | 80 | | 83 | 72 | | 75 | 67 | | 82 | 71 |
| % opposed that were revoked | | 8 | | | 36 | | | 0 | | | 41 | | |
| | D1 | | 9 | 0 | | 52 | 63 | | 0 | 0 | | 53 | 59 |
| | G1 | | 0 | 0 | | 66 | 73 | | 0 | 0 | | 63 | 60 |
| | G2 | | 29 | 50 | | 40 | 60 | | 40 | 57 | | 47 | 58 |
| | G3+ | | 33 | 80 | | 43 | 52 | | 0 | 67 | | 59 | 53 |

Withdrawn = during the examination process (not the opposition process). The restricted sample consists of 7,477 (3966 singles + 1238 parents + & 2273 divisionals) out of 15,737 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006.

**Annex 7**. Pendency-extending procedural tools by family status, innovation type and INN value.

| | | All | | High-value drugs | |
|---|---|---|---|---|---|
| | | Primary | Secondary | Primary | Secondary |
| | | D | D | D | D |
| **Time since parent's filing** | D1 | 62.8 (29.0) | 67.7 (33.7) | 62.4 (37.4) | 67.3 (31.7) |
| | G1 | 62.0 (25.4) | 67.4 (35.9) | 57.1 (29.3) | 73.2 (39.2) |
| | G2 | 81.0 (40.8) | 88.8 (38.6) | 88.9 (41.8) | 87.8 (40.3) |
| | G3+ | 106.1 (51.4) | 105.8 (48.5) | 110.6 (52.9) | 107.4 (49.2) |
| Applications | D1 | 124 | 533 | 29 | 151 |
| | G1 | 77 | 255 | 26 | 54 |
| | G2 | 172 | 643 | 73 | 259 |
| | G3+ | 93 | 376 | 45 | 145 |
| % with at least one family member in opposition prior to filing | D1 | 0 | 0 | 0 | 0 |
| | G1 | 0 | 0 | 0 | 0 |
| | G2 | 11.0 | 19.3 | 13.7 | 19.7 |
| | G3+ | 17.2 | 42.6 | 24.4 | 35.9 |
| % with at least one family member in revoked/amended prior to filing | D1 | 0 | 0 | 0 | 0 |
| | G1 | 0 | 0 | 0 | 0 |
| | G2 | 1.2 | 1.7 | 0 | 3.1 |
| | G3+ | 8.6 | 10.6 | 13.3 | 10.3 |
| % with at least one family member granted prior to filing | D1 | 0 | 0.2 | 0 | 0 |
| | G1 | 0 | 0.4 | 0 | 0 |
| | G2 | 11.0 | 6.7 | 9.6 | 4.6 |
| | G3+ | 4.3 | 4.3 | 6.7 | 2.8 |

The restricted sample consists of 7,477 (3,966 singles + 1,238 parents + 2,273 divisionals) out of 15,737 applications either filed before 2006 or, for divisionals, whose parent was filed before 2006.

## **Annex 8**. Average time in examination by application, subject-matter type, high-value INN

| Time months | One & done | | | | | | Drag & delay | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary | | | Secondary | | | Primary | | | Secondary | | |
| | S | P | D | S | P | D | S | P | D | S | P | D |
| Total (std) | 45.7 (19.2) | 50.5 (26.2) | 35.8 (20.6) | 45.4 (25.1) | 53.6 (28.6) | 36.1 (22.0) | 69.2 (26.5) | 72.5 (28.6) | 64.0 (27.4) | 72.8 (32.5) | 77.0 (32.2) | 63.5 (30.4) |
| Taken to reply | 5.2(3.1) | 6.7(4.0) | 4.9(3.1) | 5.2(3.8) | 7.2(4.1) | 4.8(4.3) | 13.8(7.9) | 16.4(9.0) | 13.6(10.3) | 13.1(8.6) | 15.6(8.9) | 11.5(9.4) |
| Given to reply | 6.1(2.9) | 7.7(4.1) | 5.6(3.3) | 5.8(4.0) | 8.0(4.2) | 5.6(4.4) | 12.6(6.7) | 14.6(7.2) | 11.4(8.2) | 11.6(7.3) | 14.0(7.7) | 9.8(7.6) |
| ER to ERO | 22.3 (13.2) | 28.0 (19.0) | 12.8 (15.6) | 26.9 (18.4) | 27.2 (18.5) | 14.4 (14.2) | 28.7 (18.8) | 28.7 (19.8) | 14.3 (13.8) | 30.0 (20.6) | 27.1 (17.4) | 16.0 (16.9) |
| ERO to IG | 12.6 (9.2) | 17.6 (12.1) | 10.0 (10.3) | 15.0 (15.7) | 20.0 (17.3) | 11.5 (15.0) | 32.4 (17.0) | 38.9 (22.2) | 34.8 (20.2) | 41.5 (23.0) | 43.3 (23.4) | 37.3 (22.6) |
| ERO to R | 19.0 (n/a) | 35.5 (n/a) | 62.8 (38.6) | 47.3 (35.4) | 75.2 (21.2) | 35.8 (21.6) | n/a (n/a) | 69.8 (19.6) | 47.0 (23.3) | 48.8 (30.7) | 65.3 (33.2) | 50.9 (28.0) |
| ERO to W | 12.1 (11.9) | 4.3 (n/a) | 15.8 (18.0) | 12.7 (13.4) | 46.8 (28.9) | 12.7 (16.9) | 31.6 (23.0) | 37.9 (18.4) | 38.0 (31.0) | 32.0 (28.9) | 41.6 (29.5) | 28.9 (24.8) |

Time provided in average number of years / months (standard deviation in parentheses). Time taken to reply represents the total time taken by the applicant before replying to office communications. Time given to reply represents the allotted time provided to the applicant to reply to office communications. ER stands for examination request, ERO examination report, communication under 94(3) EPC, IG intention to grant, R rejection, and W withdrawal. The sample corresponds to the full 15,737 applications filed between 1978 and 2026 (Q1).

**Annex 9**. Overview of sample selection for different types of analysis

| | Total | Singles | Parents | Divisionals |
|---|---|---|---|---|
| **A) Total applications** mapped to INN and primary and secondary patents, all time 1978-Q1 2026; applications have a time in examination (filing date and decision date) | 15,737 | 6,591 | 3,960 | 5,186 |
| **B) Family analysis**<br>Based on total applications under A); excluding patents where singles and parents filed after 2006; excluding divisionals where respective parent was filed after 2006 | 5,443 | 3,966 | 1,477* | n/a |
| **C) Family analysis Cox regression**<br>Based on family analysis under B); excluding patents for which the respective INN does not have a sales value, where no company name could be connected to the INN or where claim count is missing | 2,634 | 1,816 | 818 | n/a |
| **D) Application-level Cox regression analysis**<br>Based on total applications under A), excluding patents where the respective INN does not have a sales value, where no company name could be connected to the INN or where claim count is missing | 7,990 | 3,034 | 2,116 | 2,840 |
| **E) Application-level generation analysis**<br>Based on total applications under A), excluding patents where singles and parents filed after 2006; excluding divisionals where respective parent was filed after 2006, if divisional is missing time in examination (filing or decision date), the respective parent is also excluded from the analysis. | 7,477 | 3,966 | 1,238* | 2,273 |

*For the family analysis under B), divisionals were included for which no filing date, but decision date was available. For the application-level analysis under E) the divisional filing and decision date had to be available. The higher count of parents under B) is explained by the inclusion of parents, for which connected divisionals did not have a filing date.

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