



Global Patent Prosecution Newsletter

A U.S. Perspective on Global Strategy

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Double Patenting and Divisional Applications

Many countries allow an applicant to protect multiple inventions disclosed in a single application in one or more continuing applications. In most countries divisional applications are mandatory because in most, if not all jurisdictions, a single patent cannot claim more than one invention. Where potential issues come up is when an applicant may decide to file voluntary applications to obtain multiple patents protecting independent embodiments of the same invention. The January 2018 issue of Sterne Kessler's Global Patent Prosecution Newsletter includes information on double patenting, obviousness-type double patenting, and divisional practice worldwide.

Sterne Kessler's Global Patent Prosecution Newsletter is designed to help meet the needs of biotech/pharmaceutical companies regarding global patent prosecution strategies. For more information, please contact [Paul Calvo](#) or [John Covert](#). If you wish to unsubscribe from this and other newsletters, please click on the unsubscribe link below.

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Obviousness-Type Double Patenting Dangers in the U.S.

By: [Paul A. Calvo, Ph.D.](#) and [Miklos Gaszner, Ph.D.](#)

The Federal Circuit's decision in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*^[1] introduced even more confusion in an already confusing area of the law – namely obviousness-type double patenting. Obviousness-type double patenting (ODP) is a judicially created doctrine intended to prevent an improper timewise extension of patent rights by prohibiting the issuance, to a single entity, claims in a second patent which are not “patentably distinct” from the claims of a first patent. Claims are considered to not be patentably distinct from each other if one claim is anticipated or obvious in view of another claim in a separate patent. In *Gilead*, the Federal Circuit held that a later-issued patent can serve as an ODP reference against an earlier-issued patent where both patents issue from applications that are commonly owned and share common inventors. However, the rule handed down in *Gilead* appears deceptively simple – the determining factor whether a patent may be used as an ODP reference is the earliest expiration date. No weight is given to the filing dates, issue dates, priority claims, or patent term adjustment.

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Worldwide Divisional Strategy Considerations

By: [Paul A. Calvo, Ph.D.](#) and [Miklos Gaszner, Ph.D.](#)

Dividing a single patent application into multiple patents is often essential for deriving maximum economic benefit from the disclosed inventions. When an applicant wants to protect multiple inventions disclosed in a single application, one or more divisional applications are mandatory because in most, if not all jurisdictions a single patent cannot claim more than one invention. In other situations, an applicant may decide to file voluntary divisionals to obtain multiple patents protecting independent embodiments of the same invention. For example, separate patents protecting different applications of a platform technology can facilitate licensing deals by allowing the grant of exclusive licenses to multiple licensors. Or an applicant may want to file a divisional application to obtain claims that capture a specific competitor.

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Obviousness-Type Double Patenting Dangers in the U.S.

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The Federal Circuit's decision in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*^[i] introduced even more confusion in an already confusing area of the law – namely obviousness-type double patenting. Obviousness-type double patenting (ODP) is a judicially created doctrine intended to prevent an improper timewise extension of patent rights by prohibiting the issuance, to a single entity, claims in a second patent which are not “patentably distinct” from the claims of a first patent. Claims are considered to not be patentably distinct from each other if one claim is anticipated or obvious in view of another claim in a separate patent. In *Gilead*, the Federal Circuit held that a later-issued patent can serve as an ODP reference against an earlier-issued patent where both patents issue from applications that are commonly owned and share common inventors. However, the rule handed down in *Gilead* appears deceptively simple – the determining factor whether a patent may be used as an ODP reference is the earliest expiration date. No weight is given to the filing dates, issue dates, priority claims, or patent term adjustment.

To overcome an ODP rejection during prosecution, an applicant can either establish that the challenged claims are “patentably distinct” from the reference claims or file a terminal disclaimer to disclaim any portion of the 20-year statutory term of the challenged patent/application that extends beyond the expiration date of the reference patent. To file a terminal disclaimer, the reference patent and the rejected application must be commonly-owned at the time of filing of the terminal disclaimer, and throughout the term of both patents. However, a terminal disclaimer cannot cure every ODP issue. Conflicting patents that have at least one common inventor can be at risk for an ODP challenge, and a terminal disclaimer may not be feasible if the underlying patent is not commonly owned.^[ii]

Terminal disclaimers are not a panacea when it comes to ODP however, and this is especially true in the life sciences where many applications accumulate patent term adjustment (PTA) during prosecution. In *Magna Electronics, Inc. v. TRW Automotive Holdings Corp.*^[iii] the district court used an earlier-expiring patent (the patent without PTA) as an underlying ODP reference to invalidate the claims of the later-expiring patent (the patent with PTA). This, in effect, eliminated the statutory PTA of the “later-expiring” patent.

With potential landmines at each turn, what should patent practitioners do to best protect against ODP issues? Perhaps most important is to obtain safe harbor protection from ODP challenges. Thus, practitioners should draft their claims in parent applications to trigger a robust restriction requirement since 35 U.S.C. § 121 protects claims in a divisional application from ODP rejections.

Continuation applications should then be filed, or even allowed to issue, only when all of the ramifications are taken into account. This is especially important if one (or more) patents at risk for an ODP challenge has significant PTA.

Another scenario that comes up frequently during prosecution in biopharma is timing of prosecuting narrow versus broader scope claims. Timing here is important because broad claims may be at risk for an ODP challenge based on the narrow scope claims. Therefore, applicants should consider filing strategies where narrow claims in the first patent of a family are pursued, and broader claims are pursued in a subsequent continuation. Pursuing narrow claims in the first (parent) application may act as a safeguard because the second (continuation) application may not be applicable as an ODP reference against the parent because those broader claims may not anticipate or render obvious the narrower claims.

While ODP was originally created to safeguard against patents that were mere obvious variants of one another, the growing body of precedent in this area further limits a patent owner's ability to adequately protect their invention. It will be interesting see if the Federal Circuit addresses the *Magna Electronics* question and determines whether the judicially-created doctrine of ODP should take precedence over the statutory grant of PTA.

[\(i\)](#) 753 F.3d 1208 (Fed. Cir. 2014)

[\(ii\)](#) *In re Hubbell* 709 F.3d 1140, 1145 (Fed. Cir. 2013)

[\(iii\)](#) No. 1:12-cv-654 (W.D. Mich., 10 December 2015)

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Worldwide Divisional Strategy Considerations

By: [Paul A. Calvo, Ph.D.](#) and [Miklos Gaszner, Ph.D.](#)

Dividing a single patent application into multiple patents is often essential for deriving maximum economic benefit from the disclosed inventions. When an applicant wants to protect multiple inventions disclosed in a single application, one or more divisional applications are mandatory because in most, if not all jurisdictions a single patent cannot claim more than one invention. In other situations, an applicant may decide to file voluntary divisionals to obtain multiple patents protecting independent embodiments of the same invention. For example, separate patents protecting different applications of a platform technology can facilitate licensing deals by allowing the grant of exclusive licenses to multiple licensors. Or an applicant may want to file a divisional application to obtain claims that capture a specific competitor.

A separate reason for divisional filings is to maintain pendency of the application family. This is particularly important in industries with a long development cycle, such as biopharma. There are several reasons to keep biopharma applications pending throughout their 20-year term given that the majority of economic benefits, if any, will accrue late in the term. Perhaps most important, it is easier to defend an originator drug against a generic challenge when the option of obtaining a new patent specifically targeting the generic challenger is available. In most jurisdictions divisional practice is the only way for keeping an application family pending in the long term.

As opposed to the distinction between continuations and divisionals in the U.S., the term divisional application or divisional, as applied to ex-US jurisdictions, is generally used to describe a patent application filed after the filing of a first or parent application that claims subject matter disclosed but not claimed in the initial or parent application. A divisional is accorded the priority benefits of the parent application provided it does not claim subject matter not disclosed in the parent application. While in a few jurisdictions, e.g., Australia, a divisional may also include claims directed to subject matter not disclosed in the parent application, the discussion below is limited to divisionals that do not claim new matter.^[1]

Mandatory vs. voluntary divisionals

The right to file a divisional was established by the Paris Convention, and consequently is available throughout the world.^[2] The Paris Convention discusses both mandatory and voluntary divisional applications. Mandatory divisional applications are filed after the parent application has been found to disclose more than one invention, and applicant is required to split the parent application into one or more divisional applications, each claiming only a single invention. Voluntary divisional applications on the other hand are filed based on choice. While the Paris Convention requires that the right to file mandatory divisionals is granted to applicants, it allows signatory countries to set conditions under which voluntary divisionals can be filed. Consequently, the regulation of voluntary

divisionals significantly differs among various jurisdictions.

Time Limits of Divisional Filing

One area of difference is the time period during which voluntary divisional applications can be filed. Some jurisdictions, for example, United States, Australia, Canada, China, and the European Patent Convention allow the filing of a divisional any time during the pendency of the parent application.^[3] One must be aware that the definition of pendency may also differ among jurisdictions. For example, if an application is allowed, in the United States, Australia, Canada, and Europe a divisional can be filed any time before the issuance or grant of the patent. In contrast, in China and Russia a divisional can only be filed before payment of the final fees. And if a parent application is finally rejected, a divisional must generally be filed before the expiry of the jurisdiction specific time period for filing a response.

Other jurisdictions limit filing of a divisional to certain periods of the parent application's pendency. For example, in Japan, a divisional application can be filed before the mailing of the first office action or during a fixed time period after the mailing of each new office action, the length of which varies depending on the nature of the office action.^[4] In other jurisdictions, for example, in Malaysia, a divisional application can be filed before the mailing of the first office action or during a fixed time period after the mailing of the first office action on the merit. After expiry of this time period, only mandatory divisionals, i.e., ones triggered by a unity rejection, can be filed. In yet another set of jurisdictions, a voluntary divisional can only be filed within a fixed time period after the filing date of the original application. For example, New Zealand regulations require that examination must be requested for any divisional application within five years of the parent's original complete specification filing date.^[5]

The time periods for divisional filings can and do change over time. For example, Japanese regulations were changed a few years ago to allow the filing of a divisional after the mailing of a Notice of Allowance. The changes, however, only affected applications that were filed on or after April 1, 2017. The EPO also changed its rules for divisional filing in 2013. Under the current rules, which apply to applications filed on or after April 1, 2014, a divisional can be filed any time during the pendency of the parent applications. Under the old EPO rules, which are still in force for some of the earlier filed applications, voluntary divisionals had to be filed during the period of reply to the first examination report.

Subject Matter of Divisional

Divisional applications are directed to subject matter that is disclosed but not claimed in the parent application. However, the prohibition against double patenting further limits the subject matter that can be claimed in a divisional. Double patenting is assessed under different standards, including "same invention" double patenting, "obviousness-type" double patenting, "overlap" double-patenting, or some combination thereof. Given that different jurisdictions assess double patenting under different standards, the scope of subject matter available for claiming in a divisional varies between jurisdictions. Mandatory divisionals generally cannot be rejected for double patenting because they are filed in response to a finding that the parent application disclosed more than one distinct invention.

The least restrictive jurisdictions are the ones that assess double patenting under a "same invention" standard. They include, for example, Australia, Japan, and China.^[6] In these jurisdictions a divisional is generally not objected to for double patenting unless the divisional and the parent claim identical, or substantially identical, inventions. In other words, overlap between the subject matter of parent and divisional claims is allowed provided the claims do not have identical scopes.

The most restrictive jurisdictions are the ones that assess double patenting under both a "same invention" standard and an "obviousness-type" standard. They include, for example, the United States and Canada.^[7] In such jurisdictions a divisional must claim subject matter that is patentably distinct from the subject matter claimed in the parent.^[8] In other words, a divisional must claim subject matter that is not anticipated or rendered obvious by the claims of the parent. Thus, an applicant must ensure that all commercially relevant embodiments are claimed in the first Canadian application because a divisional cannot be used to secure additional claims directed to the same

invention. Note that even in Canada mandatory divisionals claiming different inventions are allowed.

Europe occupies a middle ground between the above discussed extremes. Double patenting is assessed based on a "same invention" standard, with the additional prohibition against divisional claims with a scope that completely overlaps with that of the parent or vice versa.^[9] Partial overlap in claim scope is acceptable, provided the subject matter claimed in a divisional application is not wholly encompassed within, or wholly encompasses, the claims of its parent. In practical terms, claims covering the same invention can be obtained in successive European divisionals by using claims directed to different categories, such as compound and a composition comprising the compound.

As discussed above, the rules governing divisional practice varies greatly among different jurisdictions. Therefore, to maximize the value extracted from a patent application, a global patent prosecution strategy must include country specific plans for divisional filings.

[1] http://manuals.ipaustralia.gov.au/patents/Patent_Examiners_Manual.htm

[2] Paris Convention for the Protection of Industrial Property, Article 4G

[3] <https://www.uspto.gov/web/offices/pac/mpep/s201.html>; http://manuals.ipaustralia.gov.au/patents/Patent_Examiners_Manual.htm; https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01581.html#n14_09; http://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_d_viii.html

[4] https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/5_1.pdf

[5] <https://www.iponz.govt.nz/about-ip/patents/apply/>

[6] http://manuals.ipaustralia.gov.au/patents/Patent_Examiners_Manual.htm; https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/5_1.pdf

[7] <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01610.html>;

<https://www.uspto.gov/web/offices/pac/mpep/s804.html>

[8] United States patent law provides a unique mechanism for overcoming an "obviousness-type" double patenting over a reference patent by disclaiming divisional patent term that would extend beyond the expiry of the reference patent. <https://www.uspto.gov/web/offices/pac/mpep/s804.html>

[9] http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iv_5_4.htm

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