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Restriction Requirements, Double Patenting, and Finding the Safe Harbor
Restriction requirements under 35 U.S.C. § 121 arise during examination at the U.S. Patent and Trademark Office (USPTO) when an examiner determines that an applicant is pursuing multiple, patentably distinct inventions within the same application. The examiner’s determination, however, may not always be in agreement with that of a court. In litigation, an accused infringer may assert that the patentee pursued the same or obviously similar inventions in multiple applications, one or more of which later issued as the patent-in-suit. [More](#)
Implicit Redefinition of Claim Scope

by Rebecca Harker Duttry

Although “the words of a claim are generally given their ordinary and customary meaning,” Thorner v. Sony Computer Entm’t Am. LLC, 669 F.3d 1362, 1365-67 (Fed. Cir. 2012), if the specification reveals “a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs,” Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). The Federal Circuit has recognized that determining when a patentee is acting as his own lexicographer can be difficult because “the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice.” Id. at 1323; see also Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). Recently, in SkinMedica, Inc. v. Histogen, Inc., No. 2012-1560 (Fed. Cir. Aug. 23, 2013), the Federal Circuit revisited many of its claim-construction principles, taking a close look at how to determine when a patentee has chosen to be his own lexicographer.

At issue in SkinMedica were U.S. Patent Nos. 6,372,494 (“the ’494 patent”) and 7,118,746 (“the ’746 patent”), owned by SkinMedica. The ’494 and ’746 patents contain claims related to methods for producing pharmaceutical compositions containing “novel conditioned cell culture medium compositions” and uses for those compositions. SkinMedica appealed the district court’s construction of the claim term “culturing . . . cells in three-dimensions.” The specifications of the ’494 and ’746 patents refer at several points to methods of culturing cells in two dimensions, using microcarrier beads, and in three dimensions. SkinMedica argued that the ordinary meaning of “culturing cells in three dimensions” includes growing cells using beads, which was the method allegedly used by the accused infringer Histogen, and that the district court should have interpreted the claim term according to this ordinary meaning. The district court, however, held that, based on statements made in the specification and during the prosecution history, the patentee acted as his own lexicographer and narrowed the scope of “culturing . . . cells in three-dimensions” by excluding the use of beads.

In order to determine whether a patentee has, in fact, chosen to be his own lexicographer and use terms in a manner other than according to their ordinary meaning, the court must examine the available intrinsic evidence. See Bell Atl., 262 F.3d at 1268. A court need not find an explicit redefinition of a claim term in order to hold that the ordinary meaning of the term does not apply. Id. Instead, a claim term may be clearly redefined by implication such that the meaning may be “found in or ascertained by a reading of the patent documents.” Id. (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 1584 n.6 (Fed. Cir. 1996)). The Court noted in Vitronics, for example, that when a patentee uses a claim term throughout the entire patent specification in a manner consistent with only a single meaning, he has defined that term “by implication.” Id. After a thorough analysis, that is precisely what the Court in SkinMedica concluded the patentees did through the consistent differentiation of beads from cells grown in three dimensions.

First, the Court analyzed the patentee’s use of disjunctives, such as “or” and “as opposed to,” to differentiate cells grown in three dimensions from cells grown on beads in several instances in the
The Court analyzed the following passages in the specification:

- “Cell lines grown as a monolayer or on beads, as opposed to cells grown in three-dimensions, lack the cell-cell and cell-matrix interactions characteristic of whole tissue in vivo.”
- “The cells are cultured in a monolayer, beads (i.e., two dimensions) or, preferably, in three-dimensions.”
- “The cells may be cultured in any manner known in the art including in monolayer, beads or in three-dimensions . . . .”

The Court found that the use of the disjunctive phrase “as opposed to” makes it clear that the patentee considered cells grown on beads to be different and distinct from cells grown in what is considered to be three dimensions. Similarly, relying on precedent, the Court found that the word “or” plainly designates that a series describes alternatives, and that SkinMedica’s use of the word “or” distinguishes beads from cells grown in three dimensions. See Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326 (Fed. Cir. 2001). Thus, the Court found that because these distinctions are consistent with the remainder of the specification, they constitute an implicit redefinition of the terminology.

Second, the Court analyzed language in the specification and prosecution history distinguishing beads from cells grown in three dimensions, such as:

- “Conventional conditioned cell culture medium, medium cultured by cell-lines grown as a monolayer or on beads, is usually discarded or occasionally used in culture manipulations such as reducing cell densities.”
- “Culturing cells in three-dimensions results in the production of a conditioned medium having a different chemical composition than that of cells cultured by conventional means.”

The Court relied upon prior precedent as it reasoned that emphasizing a particular attribute of the invention can operate as a disclaimer of claim scope. See, e.g., SafeTCare Mfg. Inc. v. Tele-Made, Inc., 497 F.3d 1262, 1269-70 (Fed. Cir. 2007). In SafeTCare, the Federal Circuit found that, because the specification repeatedly emphasized its invention as applying pushing forces, not pulling forces, the inventor made it clear that this attribute of the invention is important in distinguishing the invention over the prior art and, in effect, disclaims the use of pulling forces. Similarly, in Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322, 1333 (Fed. Cir. 2009), the Court emphasized that “[w]here the general summary or description of the invention describes a feature of the invention . . . and criticizes other products . . . that lack that same feature, this operates as a clear disavowal of these other products . . .” (citing Astrazeneca AB v. Mut. Pharm. Co., 384 F.3d 1333, 1340 (Fed. Cir. 2004)).

Applying these principles in SkinMedica, the Court found that statements in the specification and prosecution history repeatedly distinguished the three-dimensional cultures from cell-lines grown using beads to demonstrate the novelty of the medium produced by three-dimensional cultures. Consistent with prior case law, the Court found that this emphasis on a particular mode of operation, especially to avoid prior art, operated as a disclaimer of the otherwise broad scope of the claim term at issue. See SafeTCare, 497 F.3d at 1270. The Court relied on SkinMedica’s consistent emphasis of this distinction between beads and three dimensions throughout the specification and prosecution history to find that the distinction was, in effect, a redefinition by implication of the claim term “culturing . . . cells in three dimensions.” See Bell Atl., 262 F.3d at 1271-73.

Lastly, the Court analyzed SkinMedica’s use of “i.e.” throughout the specification. The Court found that the inventors use of the phrase “i.e.” throughout the specification, about twelve times in total, to introduce an explanation or definition of a word or phrase, demonstrated the inventors’ intent to define “beads” when they wrote “beads (i.e., two dimensions).” This is consistent with the Court’s prior holding in Edwards Lifesciences, in which the Federal Circuit held that a patentee’s use of “i.e.” in the specification “signals an intent to define the word to which it refers.” 582 F.3d at 1334.¹
The *SkinMedica* case serves as yet another reminder that statements made both in the specification and during prosecution must be carefully considered so as not to later limit claim scope. Special attention should be paid to the use of words such as “or” and “as opposed to” when drafting specifications to ensure that they are only used when a distinction is required. The Federal Circuit has also reemphasized that “*i.e.*” is typically used to define a term, regardless of where in the specification it is used. Practitioners should use this term sparingly, and consciously, in patent applications, making sure to use it only when intended to provide a definition. Being aware of these potential pitfalls will assist in avoiding unintentional disclaimer of claim scope.

¹ Despite SkinMedica’s various arguments that the Court’s definition was inconsistent with references cited on the face of the patents or within the patents, and with its expert’s testimony, the Court declined to give much weight to this extrinsic evidence in light of the consistent and repetitive redefinition of the claim term through the intrinsic evidence, including the prosecution history and the specification.
Restriction requirements under 35 U.S.C. § 121 arise during examination at the U.S. Patent and Trademark Office (USPTO) when an examiner determines that an applicant is pursuing multiple, patently distinct inventions within the same application. The examiner’s determination, however, may not always be in agreement with that of a court. In litigation, an accused infringer may assert that the patentee pursued the same or obviously similar inventions in multiple applications, one or more of which later issued as the patent-in-suit. A finding of double patenting can invalidate the offending claims. To account for this possible anomaly, 35 U.S.C. § 121 includes a safe harbor against double patenting, whereby “[a] patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference . . . against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.”

Satisfying the safe-harbor provision requires that the divisional application maintain “consonance” with the parent and other reference patent. This judicially created consonance concept specifies that the “line of demarcation between ‘independent and distinct inventions’ that prompted the restriction requirement be maintained.” Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990). In other words, for the safe harbor to apply, a “divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention . . . elected and prosecuted in the parent application.” Id. at 687. While this concept seems clear in practice, its application can be complicated for more complex patent families.

The Court of Appeals for the Federal Circuit recently considered the scope of the safe-harbor provision for a family of four patents in St. Jude Medical, Inc. v. Access Closure, Inc., No. 12-1452 (Fed. Cir. Sept. 11, 2013). In the district court, St. Jude brought suit against Access Closure alleging patent infringement. The jury found that the claims-at-issue were invalid for double patenting.

The patent-in-suit was part of a family including a grandparent, parent, and one sibling. The examiner of the grandparent application had concluded that its claims were drawn to at least two patently distinct inventions, a device and a method. In addition, the examiner stated that the device and method claims included patentably distinct Species A, B, and C. The applicant elected device claims and Species B. The applicant then filed the parent application, a divisional of the grandparent, and the examiner imposed substantially the same restriction and election of species requirements. In response, the applicant again elected device claims and Species B. The applicant then filed a first continuation of the parent, and, in doing so, canceled the original claims and, notably, added new device and method claims. The applicant eventually filed a second continuation, a sibling, based on the parent application. All four of the patents issued. The first continuation application, called “Janzen,” was the patent-in-suit. The Janzen patent ultimately issued with claims directed to both devices and methods and to Species C, while its sibling patent issued with claims directed to methods.
With this history, the district court found the safe-harbor provision applied as between Janzen and its sibling (the second continuation), thus overturning the jury’s invalidity finding. ACI appealed.

On appeal, the Federal Circuit reversed, holding the safe-harbor provision did not apply between Janzen and its sibling. The Court found that, for the safe harbor to apply, the challenged patent (Janzen), the reference patent (the sibling), and the restricted patent (the grandparent) must not claim any of the same inventions identified by the examiner. Notably, the Court also held that, in addition to the device/method restriction requirement, the election of species requirement between Species A, B, and C also affected the line of demarcation.

The Court held that the claims of Janzen were not independent and distinct from those of its sibling. The Janzen application pursued claims directed to both devices and methods and Species C. The sibling application, however, contained method claims generic to Species A, B, and C. Thus, because of the overlap of Species C between Janzen and the sibling, the Court held that the safe-harbor provision did not apply and that the claims-at-issue in Janzen were invalid.

In a concurring opinion, Judge Lourie found the case should have been resolved by the failure of both the granted Janzen and sibling patents to maintain “consonance” with the original restriction requirement in the grandparent application. The restriction requirement required dividing claims to devices from claims to methods, and the Janzen patent contained both device and method claims.

In addition to clarifying application of the safe-harbor provision, St. Jude Medical highlights the distinction between divisional and continuation applications. Divisional applications only result from a restriction requirement, but continuation applications are voluntary. This distinction is important when planning a patent family and analyzing whether a child application will be subject to double patenting. Further complicating matters, St. Jude Medical clarifies that, in some cases, an elected species can affect the line of demarcation. Thus, in developing a patent strategy, it is important to consider the type of applications being filed, whether there is an election of species, and how that election can impact whether a patent qualifies for the safe-harbor provision of 35 U.S.C. § 121.

Patent practitioners should also note that, in the United States, unlike in some other jurisdictions, the double patenting is curable by filing a terminal disclaimer. A terminal disclaimer may be filed at any time during the patent term, including in preparation for litigation. Thus, prior to enforcing or licensing a patent family, practitioners should consider whether there could be double patenting found between any of the patents in the family and if terminal disclaimers should be filed to eliminate such double-patenting concerns. When the patents-at-issue have different patent terms, however, the filing of a terminal disclaimer in the patent with the longer term will shorten its term and can accordingly affect its enforceability and value. Thus, the effect of the terminal disclaimer on the patent’s enforceability should also be considered and balanced against the risk of a finding of double patenting.

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Among the many changes ushered in by the 2011 America Invents Act (AIA) is a new set of application filing procedures. The new procedures apply to all U.S. nonprovisional applications whose filing dates are on or after September 16, 2012, and to PCT national stage applications whose international filing dates are on or after September 16, 2012. The new procedures are important in part because they allow applicants greater flexibility, but also because failing to comply with some of the new requirements can have severe consequences, including a loss of priority rights.

Priority Claim Formalities
The U.S. Patent and Trademark Office’s (USPTO) previous formalities for claiming foreign and domestic priority were complicated and potentially confusing. Priority claims to non-U.S. patent applications were to be made in any of the following: an application transmittal letter, the inventors’ oath or declaration, or in an application data sheet. 37 C.F.R. §§ 1.55(d) (pre-AIA), 1.63(c); see also M.P.E.P. § 201.14(b). In contrast, priority claims to U.S. parent applications were required to be provided in the first paragraph of the specification, along with a statement as to whether the application is a divisional, continuation, or continuation-in-part of its parent. 37 C.F.R. § 1.78(a)(2) (pre-AIA).

The new rules require all priority claims to be made in one document: the application data sheet (ADS). Id. §§ 1.55(d), 1.78(a)(3), (c)(2). The USPTO has created a downloadable ADS form in fillable PDF format to make claiming priority simpler. The form is available to download at http://www.uspto.gov/forms/forms_alpha.jsp.

The time requirements for submitting a priority claim have not changed, however. All priority claims must be submitted within four months of filing the application (or within sixteen months of the first priority date being claimed, if that period is longer). 37 C.F.R. §§ 1.55(c)-(d), 1.78(a)(4), (c)(3); see also id. § 1.76. In addition, a certified copy of any foreign priority document (or its equivalent through the USPTO’s priority-document exchange program with certain foreign patent offices) must be submitted within that same four-month time period. Id. § 1.55(f), (h), (i).

Providing Power of Attorney
Prior to the AIA, the inventors of a U.S. application typically would give the U.S. counsel power of attorney to file and prosecute the application as part of the inventors’ oath or declaration. Accordingly,
the inventors were considered the “applicants.” An assignee could also provide power of attorney to its U.S. counsel to prosecute the application, but generally only by proving its ownership of the application, for example, through executed assignments from the inventors. \textit{Id.} §§ 3.71, 3.73(c) (pre-AIA).

Under the new law, any of the inventors, the assignee, an obligated assignee, or a party that otherwise shows proof of sufficient proprietary interest in the application may give the U.S. counsel power of attorney to file and prosecute the application. 35 U.S.C. § 118; 37 C.F.R. § 3.71. Accordingly, any of those individuals and entities may be considered “the applicant.” Furthermore, for the national stage of a PCT application, the USPTO will now treat the applicant of the PCT as the applicant for the U.S. national stage. 35 U.S.C. § 118.

The USPTO has also commented that it prefers the assignee to act as the applicant. The USPTO points out that “[o]therwise, the assignee may be paying the bill, while the inventor is providing the power of attorney, thereby possibly raising an issue as to who is the [patent] practitioner’s client. Additionally, relationships between an assignee and the inventors may deteriorate.” 77 Fed. Reg. 48776, 48783 (Aug. 14, 2012). The USPTO has made it simpler for an assignee to provide power of attorney by creating a one-page form in which an assignee provides power of attorney to its U.S. counsel to prosecute any future U.S. patent applications on its behalf. The form need only be signed once and may be used for any future application filings. The form is available from the USPTO Internet site at http://www.uspto.gov/forms/forms_alpha.jsp (form number PTO/SB/80). Patent applicants may wish to consider changing their U.S. filing strategies such that the power of attorney to U.S. counsel is given by the assignee rather than by the inventors.

Regardless of who provides the power of attorney, however, the patent will actually be granted to the “real party in interest,” in other words, the true owner of the patent. 35 U.S.C. § 118. The real party in interest is the inventors until they execute the necessary assignments or contracts that transfer ownership of the patent. \textit{See id.} § 262. If there is a change in ownership, the applicant has a duty to notify the USPTO in reply to a Notice of Allowance so that the patent can be granted to the correct party. 37 C.F.R. § 1.46(e). This may be done, for example, in the Issue Fee transmittal form, which must be submitted three months after the Notice of Allowance is mailed.

\textbf{The Inventor’s Oath or Declaration}

The AIA also changed the statements required for the inventor’s oath or declaration. Specifically, under the new law, the inventor must (1) state that he/she is the original inventor or an original joint inventor of the claimed invention, (2) authorize the filing of the patent application, and (3) acknowledge the penalties under U.S. law for willful false statements. 35 U.S.C. § 115; 37 C.F.R. § 1.63. The inventor is no longer required to provide his or her citizenship, or to make certain other, previously required statements. \textit{See} 35 U.S.C. § 115; 37 C.F.R. § 1.63. Sample declaration forms may be found at the USPTO’s Internet site forms database given above.

The USPTO requires that every application with a U.S. filing date after September 16, 2012, must be filed with a declaration prepared under the new law, including all continuation, divisional, and continuation-in-part applications whose parent applications were filed before September 16, 2012, even if a declaration under the old law was provided in the parent application. 77 Fed. Reg. at 48802, cmt 18. This is certainly burdensome for the assignee. The new procedures, however, allow more time to submit the declaration. As long as an ADS listing the inventors’ names and contact addresses is provided, either when the application is filed or at a later point in response to a Notice of Missing Parts, the declaration may be provided at any time until the application has been allowed. 37 C.F.R. § 1.53(f)(3). Specifically, the latest time that the applicant may provide the executed declaration is with a response to a Notice of Allowability from the patent examiner, which will typically be the same date that the Issue Fee payment is due. \textit{See} 35 U.S.C. § 115(f). In practice, this may mean that an applicant may often have at least two to three years to submit the inventors’ declaration. In cases where inventors cannot be reached after reasonable efforts or refuse to sign the declaration, the assignee may provide a so-called “substitute
statement” in lieu of the declaration. *Id.* § 115(d).

In addition, there is no longer a patent term adjustment penalty in a PCT national stage application when the declaration is submitted after the national stage application is filed. *See* 78 Fed. Reg. 19416-21 (Apr. 1, 2013); *see also* 37 C.F.R. § 1.702(a)(1) (effective Apr. 1, 2013).

While the extra time will greatly assist assignees in tracking down inventors and obtaining the executed declaration, assignees should still promptly seek the inventors’ signatures upon filing the application. If problems arise in contacting the inventors, they could significantly delay issuance of the patent. Moreover, if the declaration is submitted after the application is allowed, the USPTO will not review it for compliance with the law.

**The Application Data Sheet (ADS) Form**

As noted earlier, the USPTO has provided a new ADS form in PDF format. Whenever possible, this form should be submitted when the application is first filed, and it may be amended and updated, if necessary, at a later time.

The ADS form is the location for all priority claims, and also allows the practitioner to state which party will act as applicant and give power of attorney, to list the inventors and their contact addresses, and to calculate the filing fees. The ADS form also provides a checkbox for the applicant to use in order to comply with the new “duty to flag” claims with priority dates on or after March 16, 2013, as described in the next section. Because the form is simple and easy to use, it will hopefully help to prevent omissions or errors in newly submitted applications.

**Filing Applications with Missing Parts**

It remains possible under the new procedures to initially file a patent application without paying the filing fees. 37 C.F.R. § 1.53(b), (f)(1). The fees may be paid upon response to a Notice of Missing Parts. *Id.*

If an application is initially filed without the fees, however, a small surcharge will be applied.

It is also possible to initially file the application without a claim for priority and/or without a list of the inventors. *Id.* An ADS with the priority claim may be submitted within four months of filing the application, while the inventor list may be provided in either an ADS or an inventors’ declaration upon response to a Notice of Missing Parts. 37 C.F.R. §§ 1.53(f)(3), 1.55(c)-(d), 1.78(a)(4), (c)(3). If only an ADS listing the inventors is provided in response to the Notice, then the inventors’ declaration is not due until a Notice of Allowability from the examiner is issued, as discussed earlier. *Id.* § 1.53(f)(3).

While the priority claim may be omitted upon initial filing, given the risk of inadvertently missing the four-month priority-claim deadline, practitioners should not omit a priority claim in an initial application filing unless it is absolutely necessary.

**The “Duty to Flag” Claims with Priority Dates on or After March 16, 2013**

One of the other new application filing requirements is the so-called “duty to flag” claims with priority dates on or after March 16, 2013. The purpose of the “duty to flag” is to inform the USPTO whether the application should be examined under the old, first-to-invent novelty law or under the new, first-inventor-to-file novelty law of the AIA, which took effect on March 16, 2013.

This duty only applies in certain applications called “transition applications.” These are applications filed on or after March 16, 2013, but claiming priority to at least one application of any type (U.S. or foreign, provisional or nonprovisional) filed before March 16, 2013. In other words, a transition application has filing and priority dates that straddle the March 16, 2013, effective date for the new AIA novelty law.

If any transition application contains, *or contained at any previous point in time*, a claim that is not fully supported by the application disclosure until March 16, 2013, or later (an “AIA claim”), then the *entire*
application will be examined under the AIA novelty law. 35 U.S.C. § 100 (note). To assist the USPTO in determining which law applies to the application, the applicant has a duty to inform the USPTO if the applicant reasonably believes that a transition application contains or previously contained any AIA claims. Specifically, the applicant must “flag” the application within four months of the application filing date if the application already contains or contained AIA claims, or on the date that AIA claims are first introduced by amendment, if the claims are introduced at a later time. 37 C.F.R. §§ 1.55(j), 1.78(a)(6), (c)(6). There are no extensions of time allowed. id. §§ 1.55(l), 1.78(g). As the duty to flag is part of the requirements for claiming priority, failing to flag applications that contain AIA claims may result in the complete loss of the right to priority. See id. §§ 1.55(j), (l), 1.78(a)(6), (c)(6), (g). Thus, it is important for practitioners to determine before filing an application and before every claim amendment if the application is a transition application and if it contains or previously contained any AIA claims. Further information from the USPTO regarding this new requirement may be found at the following link: http://www.uspto.gov/blog/aia/entry/message_from_janet_gongola_patent2.

The new ADS form includes a checkbox to flag a transition application that includes or previously included one or more AIA claims. Otherwise, the application may be flagged in a claim amendment.

Claim Amendments in Continuation and Divisional Applications
One of the concerns raised by practitioners when the duty to flag was first proposed by the USPTO was how it would affect continuation and divisional applications whose parent applications were filed before the March 16, 2013, transition date, given that these applications contain the same disclosure as their parent but often include amended or new claim sets. For example, practitioners were concerned that if a new or amended claim were rejected for alleged new matter or lack of written description, this might cause a continuation or divisional application to be examined under the new AIA novelty law rather than the old law. Practitioners were also concerned that the applicant in such a case might be found to have violated the duty to flag the application and, accordingly, might lose all priority rights.

To remedy this concern, the USPTO has noted that as long as any claim amendments in a continuation or divisional application whose parent was filed before March 16, 2013, are submitted after the continuation or divisional application is filed, then the application will continue to be examined under the old novelty law. 78 Fed. Reg. 11024, 11043 (Feb. 14, 2013). The take home message to practitioners, therefore, is to refrain from submitting claim amendments in continuations or divisionals until after filing the application. For example, a preliminary amendment may be submitted the following day. In fact, to avoid any concerns whatsoever, it may be best practice to submit all amendments to the disclosure after filing the application.
The enactment of the America Invents Act (AIA) two years ago established new types of patent validity challenges in the U.S. Patent and Trademark Office (USPTO), namely, post-grant review (PGR) and inter partes review (IPR). Post-grant oppositions have been available at the European Patent Office (EPO) since 1978. While PGRs and EPO oppositions both must be filed within nine months of a patent’s issue date and may address many different invalidity grounds, the procedures have more differences than similarities.

Although PGR has been possible since September 16, 2012, no PGR petitions have been filed yet, because PGR is available only for patents issued under the AIA’s first-inventor-to-file (FITF) regime, which took effect on March 16, 2013. Nevertheless, such patents have now begun to issue in the United States. The first FITF patent issued on July 2, 2013, and with each new FITF patent that issues, PGRs are increasingly possible.

As PGR practice becomes more active, it is important for practitioners both in the United States and abroad to understand the similarities and differences between PGRs and opposition procedures available at the EPO and in other jurisdictions. This article addresses several of the basic differences between the two types of proceedings. While other writings have explored the history and nuances of the proceedings, this article is intended to provide practical guidance to practitioners.

**Timing**

Two key timing considerations are relevant to both PGRs and EPO oppositions: the deadlines of each proceeding and the typical duration of each proceeding. Timing can be particularly important when the patent-at-issue is in litigation or there is a threat of litigation.

PGRs and EPO oppositions are similar in terms of the deadline they set for parties to initiate a validity challenge. A PGR petition must be filed within nine months of a patent being granted, and an EPO opposition must be requested within nine months of the publication of the “mention of the grant” in the European Patent Bulletin.

One difference, however, is that the EPO does not even look at oppositions until the nine-month period has elapsed, because the party that filed the opposition has until the end of the nine-month period to address any deficiencies without the opposition being deemed untimely. PGR petitions, by contrast, may not be substantively changed after filing. A further difference is that the EPO will hear multiple oppositions challenging the same patent simultaneously, whereas the USPTO is more reluctant to do so for post-grant proceedings. The USPTO can consolidate or stay proceedings, as well as deny petitions (in whole or part) for raising “redundant” grounds. Thus, petitioners in the United States have an incentive to file early, to ensure that their petition will be fully considered on the merits. For parties seeking an EPO opposition, filing early is usually counterproductive, because it merely gives the patentee more time to plan its response.
Because no PGR petition has yet been filed, the typical duration of a PGR cannot be determined. Nevertheless, PGR proceedings are required by statute to be complete within one year of their institution date. Accordingly, PGR proceedings are expected to be significantly quicker than EPO oppositions, which have a typical duration of approximately thirty-four months.

Initiation
Another key difference is that PGRs have a substantive threshold that must be met for the USPTO to institute a review, while an EPO opposition effectively has no threshold (only a check that formalities have been met). Thus, the challenger in the United States must have its best arguments assembled and make them in its initial petition or it may risk the USPTO deciding not to hear some or all of the grounds for challenge. There have already been several IPR requests that the USPTO has denied (in whole or part) on the ground that the threshold for institution was not met. We can expect the same for PGRs, which have a higher threshold for institution than IPRs.

Filing Fees
There is a significant disparity in cost between a PGR proceeding and an EPO opposition. The filing fee for an EPO opposition is only € 745 (about US $1,000). For a PGR, the initial filing fee (for up to twenty challenged claims) is US $12,000 and the post-institution fee is US $18,000 (for up to fifteen challenged claims), totaling US $30,000 (approximately € 22,630). Of course, these are only the official filing fees. Attorneys’ fees and other costs are additional, and can be significant, particularly in the case of a PGR, which allows for certain limited discovery among the parties. EPO oppositions, by contrast, do not permit the parties to engage in any discovery.

Win Rates
Both PGRs and EPO oppositions allow for claim amendments during the proceedings. Accordingly, there are three main results possible in each proceeding: claims will be confirmed as patentable, claims will be cancelled as unpatentable, and/or claims will be confirmed in amended form. For practitioners, it is important to understand the win rates in each type of proceeding, given these three possible outcomes.

In EPO oppositions, all claims are confirmed in approximately 26% of cases, all claims are cancelled in approximately 44% of cases, and claims are confirmed in amended form in approximately 30% of cases. Of course, comparable win rates are not yet available for PGRs. Nevertheless, it is worth noting that the historical win rate for patentees in inter partes reexamination (which was replaced by IPR and PGR under the AIA) is less favorable for patentees: all claims were confirmed in 11% of cases, all claims were cancelled in approximately 42% of cases, and claims were confirmed in amended form in approximately 40% of cases.

Types of Invalidity Grounds Considered
PGRs and EPO oppositions both allow for a wide variety of invalidity attacks. In both a PGR and an EPO opposition, a validity challenge may be based on prior art, such as patents, printed publications, public uses, and oral information, as well as on grounds of ineligible subject matter, introduction of new matter (i.e., lack of basis), and inadequate written description or enablement (i.e., lack of sufficiency). One important difference, however, is that lack of claim clarity may not be used as a ground of invalidity in an EPO opposition, while lack of claim definiteness is a permitted ground in a PGR. Nevertheless, claim clarity is considered in an EPO opposition if a claim is amended during the proceedings.

The broad spectrum of potential invalidity attacks available in PGRs and EPO oppositions raises the important question of how evidence of invalidity will be obtained. Discovery might not be critical for invalidity challenges based on patents or printed publications. But for challenges based on oral information or public uses, discovery can be crucial to the success of the challenge. As discussed below, the limited availability of discovery in PGRs can help patent challengers in such situations.

Discovery


In addition to the situations mentioned above, discovery can also be helpful in addressing highly fact-based questions, such as inherency in a novelty attack, or whether claims are obvious or not enabled.

In a PGR, two types of discovery are available: "routine" and "additional." Routine discovery must be provided by the parties in a PGR, even if not requested by the opposing party. Routine discovery includes any exhibit cited in a paper or in testimony that has been filed but not yet served on an opponent, cross-examination of affidavit testimony (e.g., cross-examination of experts who provide an expert declaration), and information that is inconsistent with a position argued by a party during the proceeding. "Additional" discovery is available if the parties agree to it, or if the USPTO grants a motion for it. Additional discovery is available only if "the interests of justice" permit it, unless the discovery "is limited to evidence directly related to factual assertions advanced by either party in the proceeding."12

Accordingly, if the strongest case of a challenger to a U.S. patent and/or a European counterpart requires something other than a patent or printed publication, or requires expert testimony, careful consideration and planning will be critical. Challengers should seek out and hire experts who can provide a supporting declaration and who are prepared to be cross-examined on that declaration as early as possible.

Estoppel
The prospect of estoppel is another important difference between PGRs and EPO oppositions. While PGRs have a strong estoppel effect for petitioners (with respect to further USPTO proceedings and litigation), EPOs have no estoppel.

The event that triggers estoppel in a PGR is a “final written decision,” which is the written order issued by the presiding panel at the conclusion of a PGR trial. Once the final written decision issues, the petitioner is barred from raising in another USPTO proceeding “any ground that the petitioner raised or reasonably could have raised” during the PGR.13 The petitioner is similarly barred from raising such grounds of invalidity in court.14 By contrast, a party may in theory lose an EPO opposition and then argue invalidity in litigation in a national court involving the same patent.

The strong estoppel provisions for PGRs effectively require parties to decide where to fight the issue of validity: in court or at the USPTO. Parties in Europe generally have both options and may pursue both. Even with the estoppel issues in the United States, however, validity challenges in the USPTO can be desirable for the challenger for several reasons, including the broader standard for claim construction and the reduced cost compared to litigation.

Anonymity
A further difference between PGRs and EPO oppositions is the potential for the challenger to remain anonymous. In an EPO opposition, the challenger may be a "straw man," i.e., a party hired to file the opposition while the real party interested in invalidating the patent remains undisclosed. A PGR, by contrast, requires the petitioner to identify each "real party-in-interest."15

The main reason an identification of real parties-in-interest is important for PGRs is the estoppel that attaches upon a final written decision. Estoppel applies not only to the petitioner, but also to any real parties-in-interest and any privies of the petitioner.16 Because EPO oppositions have no estoppel effect, there is less need for real parties-in-interest to be identified.

Reviewing Bodies
Both EPO oppositions and PGRs are handled by three-person panels, and in both procedures one panel member typically takes the lead in managing the proceeding. One difference, however, is that EPO opposition panels are comprised of experienced patent examiners, while PGRs are heard by a panel of administrative patent judges at the USPTO Patent Trial and Appeal Board (PTAB). Most PTAB judges have substantial patent litigation experience. In an EPO opposition, unlike in a PGR, it is possible that
one of the panel members was also involved in the original examination of the patent at issue.

Appeals of PGR and EPO opposition decisions also differ. An adverse EPO opposition decision may be appealed to the EPO Board of Appeal. Generally, no further appellate review is possible. By contrast, adverse PGR decisions may be appealed directly to the U.S. Court of Appeals for the Federal Circuit. Thus, while EPO opposition appeals are heard by a higher-level panel within the same organization, PGR appeals are heard by federal appeals court judges.

Conclusion

PGRs and EPO oppositions share several basic common features. Both must be filed within nine months of a patent’s issuance, both are *inter partes* in nature, both allow for a wide range of invalidity attacks, both are heard by three-person panels, and both allow for claim amendments. Nevertheless, the differences between the proceedings are significant.

Many of the differences result from the nature of the two proceedings. PGRs are administrative trials on validity, whereas EPO oppositions are an extension of the original examination procedure. As discussed above, PGRs are expected to be much faster than EPO oppositions. PGRs will also be significantly more expensive, both because of the required filing fees and the possibility of discovery. In addition to this time and cost pressure on the parties in PGRs, the threshold for instituting a PGR and the prospect of estoppel are further concerns for the challenger. These factors all force the challenger in a PGR to carefully plan out its invalidity attack, including what its best grounds of challenge are and what evidence it will need to support them.

1 Of course, many requests for covered business method (CBM) review have been filed pursuant to the transitional program for CBM patents, which became available on September 16, 2012. CBM review is akin to PGR, but limited to patents for business methods. The same standards and procedures apply in both types of proceedings, with certain exceptions.

2 The patent is design patent D685,381. The patent application was filed on April 1, 2013, and issued to Bluelounge Pte. Ltd.


6 35 U.S.C. § 326(a)(11). The USPTO has discretion to extend this time period by six months.


8 The threshold for institution of an IPR is that there must be a “reasonable likelihood that the petitioner would prevail” on at least one challenged claim. 35 U.S.C. § 314(a). A PGR requires that it is “more likely than not” that at least one challenged claim will be found unpatentable. *Id.* § 324(a).

9 Unlike the USPTO, the EPO does not consider individual claims, as such, but rather “requests,” i.e., sets of claims. The opposition division will make a decision on the independent claims of a request. If they are not allowable, the request fails, irrespective of whether or not any of the dependent claims might be allowable. If a patentee wants the opposition division to consider the subject matter of a dependent claim, it has to present it as an independent claim in a specific request.

10 There are many situations where a novelty or obviousness challenge is supported by an expert’s declaration, however. Discovery tools such as depositions can be used to support or attack the credibility of an expert.

11 37 C.F.R. § 42.51(b)(1).

12 *Id.* § 42.51(b)(2).
A prosecution disclaimer is a statement or amendment made during prosecution of a patent application that can limit the scope of the resulting patent claims. A prosecution disclaimer may limit the range of equivalent structures that fall within the scope of a means-plus-function limitation. J&M Corp. v. Harley-Davidson, Inc., 269 F.3d 1360, 1367 (Fed. Cir. 2001). In addition, with respect to any claim term, a disclaimer made during the prosecution of a parent application may, in some instances, operate as a disclaimer with respect to later patents of the same family. Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1306 (Fed. Cir. 2007).

In Regents of the University of Minnesota v. AGA Medical Corp., 717 F.3d 929, 934 (Fed. Cir. 2013), the University filed a parent application covering “septal occluders,” which are devices used to block holes in a thin wall of muscle and tissue dividing two chambers of the heart. In particular, the parent claimed a type of septal occluder that can be delivered and positioned within the heart using a catheter threaded through a vein (a “transcatheter septal occluder”). During prosecution, the examiner rejected independent claim 1 as anticipated by a prior art patent to King et al. (“King”). King was mentioned in the specification of the parent application and described a transcatheter septal occluder with an umbrella-like radial frame.

In responding to the rejection, the University distinguished its claims over King, arguing that the claimed device did not have a radial frame, but rather a frame extending along the periphery of the membrane of a disk. The University also amended the claim to expressly exclude the devices described in King. The parent application was then abandoned. Four divisional patents claiming priority to the parent application eventually issued, including the two patents-at-issue in the lawsuit. The issue of the prosecution disclaimer arose during litigation of one of the patents (“the child patent”).

To address infringement and validity, the district court construed the means-plus-function limitation of claim 1 of the child patent shown below:

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a self-expanding structure exhibiting a spring-like behavioral component for moving the member between a compressed orientation . . . and an expanded orientation.
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The district court considered “moving the member from a compressed orientation to an expanded orientation” to be the functional part of the limitation. The specification disclosed two corresponding structures for carrying out that function: “a frameless membrane made of a thin piece of a superelastic material,” and “a flexible elastically deformable frame carried around the periphery of the member” (“the peripheral frame structure”).

To challenge the validity of the patent, the accused infringer AGA relied on an article cited in the specification (“the Lock article”). The specification described the Lock occluder as a modified version of
the King device with a similar umbrella-like structure mounted on a radial frame. Accused infringer AGA argued that Lock’s device anticipated claim 1 under the court’s construction. The district court agreed with AGA and held that the structure of the Lock device was an equivalent of the peripheral frame structure of the claimed device. Therefore, claim 1 was held as anticipated by Lock.

On appeal, the University argued that the district court’s finding was improper because, during prosecution of the parent application, the University had disclaimed the use of a radial frame as an equivalent of the peripheral frame. Specifically, the University argued that the disclaimer was made when the University amended claim 1 in response to the rejection over King, which, as mentioned above, the University had characterized as disclosing a radial frame occluder. The amendment in the parent application is shown below:

<table>
<thead>
<tr>
<th>Original Claim</th>
<th>Claim Amendment (to overcome King)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A septal defect closure device comprising first and second occluding disks, each disk comprising a flexible, biologically compatible membrane having a periphery and an elastically deformable frame carried about the periphery of the membrane . . . .</td>
<td>1. A septal defect closure device comprising first and second occluding disks, each disk comprising a flexible, biologically compatible membrane having a periphery and an elastically deformable frame extending along and attached adjacent to the periphery of the membrane . . . .</td>
</tr>
</tbody>
</table>

Neither the accused infringer nor the district court disputed that the University’s disclaimer in the parent patent was clear and unambiguous. Nor was there a dispute over the fact that the University’s disclaimer of King’s radial frame was also applicable to the similar radial frame of the occluder disclosed in Lock. Thus, the question on appeal was only whether the disclaimer also applied to claim 1 of the child patent.

In general, statements made during the prosecution of a parent application may operate as a disclaimer in a child application. Nevertheless, in University of Minnesota, the Federal Circuit reiterated that when a disclaimer made in a parent prosecution is directed to claim terms that are missing or materially changed in a child application, the disclaimer will not apply to the child application’s claims. See Univ. of Minn., 717 F.3d at 943 (citing Saunders Grp., Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1333 (Fed. Cir. 2007)). In other words, for a disclaimer in a parent to apply to a claim of a child patent, the language of the claim limitation must be the same or closely related.

The Court also pointed out that when evaluating claim limitations for similarity, the appropriate focus is on the scope of the claim element as a whole, not on the meaning of individual words in isolation. See id. at 944. Thus, for example, where the scope of the two claims is materially the same, the disclaimer may apply even if the claims are not word-for-word identical. See id. (citing, e.g., Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999)). The requirement for a “limitations in common,” the Court noted, is not a mere technicality, but rather necessary to find that the patentee’s arguments in the parent application are also applicable to the child. Id. at 945. Without claim language that clearly shows how the two claims are linked, neither the USPTO nor the patentee’s competitors know the true scope of the claims. Id.

The Court determined that claim 1 of the child patent and claim 1 of the parent patent were materially different and captured different subject matter. Thus, King and Lock were relevant in different ways to the parent patent’s “frame carried about the periphery” requirement and the child patent’s functional “self-expanding structure” requirement. Id. During prosecution of the parent patent, the University did not tell the USPTO that the radial frame in King and Lock was ineffective in fulfilling the function of expanding the occluder’s disks. Instead, the University simply criticized the King device as being too difficult to assemble and keep in position, and redrafted its claims to explicitly exclude King’s radial frame. See id. Thus, without the “frame around the periphery” recitation of the parent patent, and in the absence of explicit disclaimers during prosecution of the child patent, the radial frame disclosed in Lock
was a suitable equivalent structure for use in performing the function of the claim in the child patent. \textit{Id.}

The Court also rejected the University’s alternative argument that, even if the prosecution disclaimer over King did not apply to the claims of the child patent, the specification disclaimed the radial frame of Lock’s device. \textit{Id.} at 945 n.9. The specification merely expressed concern about using radial arms to hold the expanded occluder. \textit{Id.} The Court concluded that such a statement of concern about the function of Lock’s device, without more, did not amount to a clear disavowal of the use of a radial frame to expand the occluder upon deployment. Thus, the Court agreed that Lock anticipates the asserted claims of the child patent, and affirmed the district court’s grant of summary judgment of invalidity to AGA.

The Federal Circuit’s holding is a welcome reminder of the importance of a coordinated prosecution strategy for related applications that use similar terminology. If a claim limitation-related disclaimer was made in one application but is not necessary for patentability of claims in a related application, using different claim terms in the two applications, if possible, is one strategy that might help avoid a narrow construction of the child patent claims in litigation. In contrast, if the patentee hopes to continue to benefit from a disclaimer made in one application to overcome prior art in a related application, the safest route to preserve the disclaimer is to expressly make the same disclaimer arguments in both cases.

\footnote{But claim 1, as amended, later issued in a child patent that was not at issue in the case.}