

5 Ways To Avoid Obviousness-Type Double Patenting

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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 of claims in a second patent which are not "patentably distinct" from the claims of a first patent.[1] Claims are not patentably distinct from each other if one claim is anticipated or obvious in view of another claim in a separate patent.[2] ODP is a ground for invalidating the claims of a patent and is an affirmative defense against patent infringement.[3] Additionally, ODP often arises during patent prosecution.[4]

ODP has several characteristics. First, ODP usually involves two or more patents owned by the same entity, or subject to a joint research agreement, or have at least one common inventor,[5] that claim similar subject matter but have different expiration dates. Second, the patent used as an ODP reference does not need to be prior art. Rather, an ODP analysis involves comparing the claims of the two patents.

Third, the safe harbor under 35 U.S.C. § 121 protects a patent from an ODP challenge.[6] If patents can trace their lineage back to a common parent that was subject to a restriction requirement and consonance is maintained, then the safe harbor prevents a double-patenting rejection or challenge.[7]

Fourth, ODP may be overcome by filing a terminal disclaimer (TD).[8] Patents that have the same earliest effective filing date may nonetheless have different patent term due to different patent term adjustment (PTA).[9] And filing a TD to obviate ODP can reduce the term of a patent by eliminating or limiting PTA.[10] ODP is of particular importance in the pharmaceutical and biologics industry because patents covering biopharma products are often quite profitable during the last few years of patent term.

Courts and the U.S. Patent and Trademark Office have considered ODP important to preserve the public's right to use an invention claimed in a patent and obvious modifications of that invention once the patent expires. In view of recent case law, it is important to remember the basics to avoid ODP pitfalls during prosecution or when alleged in litigation or post-issuance. Below, we provide the top five considerations for achieving that goal.



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1. Avoid ODP Over Patents or Applications Sharing Only Common Inventors

ODP may arise between patents and/or applications that share only common inventors.[11] Under this situation, a patent owner cannot overcome ODP by filing a TD because common ownership and/or joint research agreement between assignees are prerequisites for filing a TD. In the Hubbell case, Hubbell's patent application was rejected for ODP over a patent that had a common inventor and Hubbell could not file a TD to overcome the ODP rejection.[12]

To avoid a Hubbell situation, investigate whether any inventor of an application is a co-inventor of patents or applications directed to similar subject matter in previous employment(s). If such patents or applications are identified, devise a suitable strategy. For example, prepare patent applications with claims that are distinct from that of the prior patents/applications. Alternatively, a patentee can explore acquiring the prior patents/applications such that a TD may be filed to overcome a possible ODP rejection or challenge.

2. Obtain Safe Harbor Protection

The safe harbor protects an application or patent from an ODP rejection or challenge. There are two prerequisites for safe harbor: (1) the USPTO issued a restriction requirement during prosecution,[13] and (2) consonance was maintained.[14] We will discuss these requirements in turn.

Draw a Restriction Requirement

The USPTO sets out criteria for determining whether claims are subject to a restriction requirement and has discretion in making such requirements.[15] According to the Manual of Patent Examination Procedure, the USPTO deems the following inventions independent and distinct and typically imposes a restriction requirement: process and apparatus used in the practice of the process; composition and process in which the composition is used; or process and product made by such process.[16] For example, the USPTO typically deems claims to a compound or a composition and claims to methods of using the compound or composition distinct inventions and imposes a restriction requirement.[17]

On the other hand, courts have consistently held the opposite regarding compound or composition claims and method of use claims in the absence of safe harbor protection. In *Geneva v. GlaxoSmithKline PLC* (2003) and *Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Company* (2010), the Federal Circuit held claims to a method of using a composition patentably indistinct from an earlier claim to the identical composition in a patent that discloses the uses in the specification. In both cases, the court found the method claims invalid for ODP over the claims to the compound or composition.

In view of the USPTO's restriction requirement practice and case law, an applicant should file an initial application with claims directed to different types of inventions to draw a restriction requirement and obtain safe harbor protection. For example, if an applicant files an initial application with claims directed to a new compound, a composition comprising the compound, methods of using the compound or composition, and methods of making the compound or composition, the USPTO typically will impose a restriction requirement between the different types of claims. Then the applicant can elect one group of claims and file one or more divisional applications claiming the unelected inventions. If the application discloses multiple utilities of the new compound, claims to each of the disclosed uses should be included.[18] Importantly, the application should avoid merely listing various potential uses of the new compound; rather, it should disclose sufficient data to enable each of the uses.[19] Following this approach, an applicant can procure a family of patents with different scope of protection and safe harbor protection. These patents also may have different expiration dates due to the availability of PTA.

Maintain Consonance

To obtain safe harbor protection, consonance must be maintained.[20] Consonance requires that the patent being challenged under ODP, the reference patent, and the patent in which the restriction requirement was imposed do not claim any of the same independent and distinct inventions identified by the examiner in a restriction requirement.[21]

Election of species requirements imposed by the USPTO may also affect consonance. In *St. Jude Medical Inc. v. Access Closure Inc.* (2013), the Federal Circuit held that the requirement for an election of species creates a restriction if no generic claim is found allowable.[22]

Thus, in building up a patent family after the USPTO imposes a restriction requirement in a parent application, an applicant should ensure that the claims of each subsequent patent in the family do not claim the same independent and distinct invention set forth in the restriction requirement. Also, if there is an election of species requirement, an applicant should analyze whether the species election requirement imposes a restriction, and if yes, make sure there is no overlap of the species between the claims of the patents in the family. Furthermore, it is important that a restriction requirement is clearly documented in the prosecution history; otherwise it would be difficult to analyze whether or not consonance is maintained.[23]

3. File Divisional Applications

Because Section 121 explicitly refers to "divisional applications," the safe harbor protects only divisional applications and patents issued from such applications.[24] Consequently, an applicant should file divisional applications to claim the restricted-out inventions following a restriction requirement. An applicant can either pursue those inventions in the same divisional application, or file a separate divisional application for each invention in the restriction requirement.[25]

However, filing a continuation or continuation-in-part application (CIP) immediately following a restriction requirement will lead to loss of safe harbor protection. In *Pfizer v. Teva* (2008), the Federal Circuit held that the safe harbor protection does not apply to a patent issued from a CIP application.[26] The court reached the conclusion despite Pfizer's argument that even though the patent was termed a CIP, the patent was a divisional for purposes of section 121, because the statute explicitly calls for divisional applications.

In *Amgen Inc. v. F. Hoffman-La Roche Ltd.* (2009), the Federal Circuit denied safe harbor protection of patents issued from continuation applications even though substantively the applications could be divisional applications.[27] Amgen urged the court to look to an application's substance — not its designation — to determine whether it qualifies as a divisional application under the safe harbor.[28] The court found that the challenged patents did not receive safe harbor protection because they issued from applications that were filed as continuation applications instead of divisional applications.[29]

Thus, courts put the burden on an applicant to properly file and name an application to receive safe harbor protection. Therefore, an applicant should strictly adhere to the practice of filing divisional applications to claim the restricted subject matter and designating the applications as "divisional" applications.

4. Conduct Thorough Analyses Before Filing a Terminal Disclaimer

An applicant or patent owner may file a terminal disclaimer to overcome an ODP rejection or challenge. TDs

are authorized by 35 U.S.C. § 253. Because ODP prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a patentably indistinct variant, a TD restricts the variant to the term of the original patent and cures the ODP rejection.[30]

An applicant may file a terminal disclaimer to overcome an ODP rejection during prosecution, during litigation, or even after a finding that the challenged patent is invalid for ODP.[31] A situation where a terminal disclaimer is not effective against an ODP challenge is when the reference patent already expired.[32]

However an applicant should avoid filing a terminal disclaimer without a thorough analysis of the relevant claims. Filing a TD may shorten the term of a patent issued from the application because it disclaims "any terminal part of the term of a patent" over the reference patent such that both patents expire at the same time.[33] The statute does not allow disclaimer of only the rejected claims.[34]

Typically only certain claims of an application are rejected for ODP during prosecution. In this situation, an applicant may consider splitting the claims: e.g. canceling the rejected claim(s), allowing the nonrejected claims to issue without filing a terminal disclaimer, and pursuing the rejected ones in a later application. This is particularly important if filing a TD would shorten patent term significantly.

If a patent is challenged on the basis of ODP during litigation, a patentee generally would have to file a terminal disclaimer to overcome the challenge because claim(s) of an issued patent may not be canceled.

5. Review Patent Portfolios for ODP Issues

In *Gilead Sciences Inc. v. Natco Pharma Ltd.* (2013), the Federal Circuit appears to have shifted the policy ground for ODP to preserving "the public's right to use not only the exact invention claimed by an inventor when his patent expires, but also obvious modifications of that invention that are not patentably distinct improvements." [35] The court held that a patent that issues later but expires earlier than another patent can serve as an ODP reference against that other patent. At least one lower court has interpreted *Gilead* to stand for the proposition that a court should look to the expiration dates to determine if a patent can be used as a prior art patent under ODP.[36]

Gilead will likely increase ODP challenges as all patents or applications directed to related subject matter but having different expiration dates can potentially be used as reference patents for ODP. Thus, patent owners should carefully review patent portfolios covering important drug products for ODP issues and determine whether and when a terminal disclaimer should be filed if such issues are identified. If a patent owner delays filing a TD until the reference patent expires, and a court ultimately finds ODP, it could be incurable through a TD.

Conclusion

For patents covering important pharmaceutical or biological products, patent term is quite valuable. A successful ODP challenge typically reduces patent term, leading to significant loss to the patent owner. Courts, on the other hand, have intensified scrutiny on patents claiming similar subject matter and have stated that the public should be free to practice an invention as well as its obvious variants once a patent claiming the invention expires. Patent owners will be well served by implementing patent prosecution and portfolio management strategies that minimize ODP rejections or challenges.

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[1] *In re Lonardo*, 119 F.3d 960 (Fed. Cir. 1997).

[2] *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985).

[3] *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991); *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003)

[4] 35 U.S.C. § 103(c)(2) (3), MPEP § 804, and *In re Hubbell*, 709 F.3d 1140 (Fed Cir. 2013)

[5] MPEP § 804 and 35 U.S.C. § 103(c)(2) (3).

[6] 35 U.S.C. § 121.

[7] *Id.* see also *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347 (Fed. Cir. 2004).

[8] 35 U.S.C. § 253(b); *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985).

[9] For a patent filed on or after June 8, 1995, the term of the patent is twenty years from the earliest effective filing date. 35 U.S.C. § 154(a)(2).

[10] 35 U.S.C. §§ 154(b)(2) and 253(b).

[11] MPEP § 804, *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013).

[12] *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013).

[13] 35 USC 121, *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347 (Fed. Cir. 2004)

[14] *Symbol Techs.*, 935 F.2d at 1579 (Fed. Cir. 1991); *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).

[15] MPEP §§ 802 and 806; 35 U.S.C. § 121.

[16] MPEP §§ 802 and 806.

[17] MPEP § 806.

[18] *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Company*, 611 F.3d 1381, 1388 (Fed. Cir. 2010).

[19] *Rasmussen v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005) (holding that to obtain a valid

method of use claim, the application needs to disclose sufficient data demonstrating that the compound is enabled unless one skilled in the art would accept without question the stated use.).

[20] *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).

[21] *Symbol Technologies, Inc.*, 935 F.3d at 1354 ("what consonance requires is that the claims prosecuted in two or more applications having common lineage in a divisional chain honor, as between applications, the lines of demarcation drawn by the examiner to what he or she considered independent and distinct inventions in the restriction requirement.").

[22] *St. Jude Medical, Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1379 (Fed. Cir. 2013).

[23] *Geneva*, 349 F.3d. at 1379-1380.

[24] 35 USC § 121; *Pfizer v. Teva Pharmaceuticals, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008)

[25] *Boehringer Ingelheim Int'l GmbH v. Barr Labs, Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010) ("The safe harbor is provided to protect an applicant from losing rights when an application is divided. The safe harbor of § 121 is not lost if an applicant does not file separate divisional applications for every invention or when independent and distinct inventions are prosecuted together.").

[26] *Pfizer*, 518 F.3d at 1363.

[27] *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1352 (Fed. Cir. 2009).

[28] *Id.*

[29] *Id.*

[30] MPEP 804.02; *In re Longi*, 759 F.2d at 892.

[31] See e.g., *Geneva Pharms., Inc.*, 349 F.3d at 1378; *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005) (noting that there is no "prohibition on post-issuance terminal disclaimers" and that "[a] terminal disclaimer can indeed supplant a finding of invalidity for double patenting.").

[32] *Boehringer Ingelheim*, 592 F.3d 1340, 1324 (2010).

[33] *Id.*

[34] 35 U.S.C. § 253(b) and MPEP § 804.02.

[35] *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014)

[36] *Magna Electronics Inc. v. TRW Automotive Holdings Corp.*, case 1:13-cv-00324 (W. D. Mich. Dec. 10, 2015).