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Navigating through the Obviousness-Type Double Patenting Minefield

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Obviousness-type double patenting (ODP) is a judge-made doctrine intended to prevent a patentee from unfairly extending its patent term by obtaining different patents for essentially the same invention.[1] It also facilitates common ownership of affected patents, which helps to "prevent multiple infringement suits by different assignees asserting essentially the same patented invention."[2] ODP occurs where a claim in a later patent is patentably indistinct from (i.e., is either anticipated or rendered obvious by) a claim in an earlier patent.[3]

To prevent invalidation due to ODP, an applicant or patentee should file a terminal disclaimer either during examination or after patent issuance. The terminal disclaimer restricts the patent's term to the complete, statutory term of a second patent.[4] To obviate an ODP rejection received during examination or reexamination, the terminal disclaimer must also certify that the two patents will remain under common ownership throughout their enforceable lifetime.[5] A terminal disclaimer generally cannot be rescinded or amended.[6]

Recent Federal Circuit decisions have made it increasingly challenging to avoid double patenting. In particular, two related Federal Circuit appeals involving patents owned by Janssen Biotech, both argued in early October 2017, and the earlier Federal Circuit cases on which they are based, illustrate key issues that patent applicants who want to maximize the patent term should keep in mind: the types of patents that can give rise to double patenting and the extent to which restriction requirements during examination can protect against it.[7]

Patent Term and Terminal Disclaimers, from *Gilead* to *Janssen*

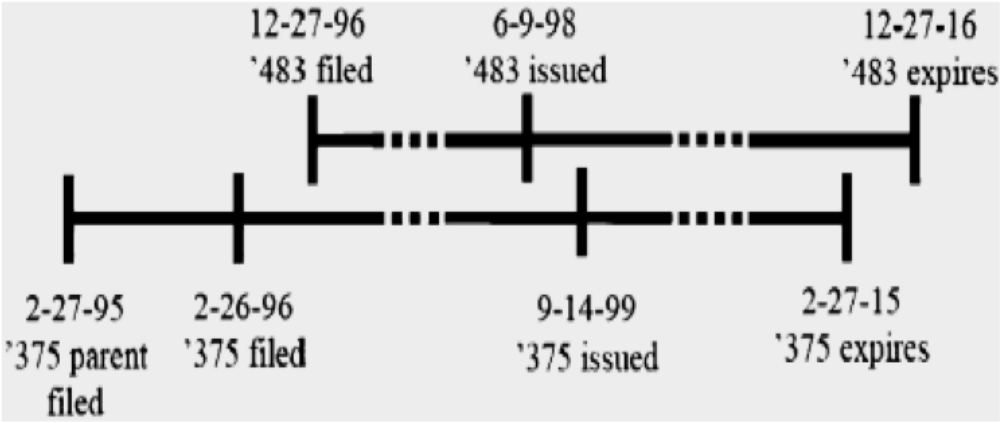
Traditionally, double patenting has been based on the respective issue dates of two patents rather than on their respective filing dates. Prior to June 1995 when the Uruguay Round Agreements Act (URAA) became effective, patent terms were 17 years from the issue date of each patent, meaning that the term of a later-issued patent was always longer than that of an earlier-issued patent. Typically, a court or patent examiner would consider whether the claims of a later-issued

patent were patentably distinct from those of an earlier-issued patent, and if not, a terminal disclaimer could avoid invalidity by restricting the term of the later-issued patent to that of the earlier-issued patent.[8]

The URAA altered the term of patents issued from applications filed before June 1995 to the longer of 17 years from the issue date or 20 years from the filing date, and set the terms of patents issued from applications filed after June 1995 to 20 years from the filing date.[9] At the same time, Congress introduced patent term adjustment (PTA), providing an additional patent term to make up for United States Patent and Trademark Office (USPTO) processing delays.[10] Accordingly, since 1995, US patent terms are no longer based on issue dates, and the term of a later-issued patent is not necessarily longer than that of an earlier-issued patent.

Courts have recently considered how ODP should be handled in light of changes to the patent term. For example, *Gilead Sciences, Inc. v. Natco Pharma Ltd.* addressed whether an earlier-filed but later-issued patent can act as a double patenting reference against an earlier-issued but later-filed patent.[11] Before 1995, a later-issued patent always had a longer term than an earlier-issued patent because the patent term was linked to the issue date.[12] Before the URAA, filing a terminal disclaimer in an earlier-issued patent against a later-issued patent had no patent term consequence. *Gilead*, however, involved two post-URAA patents with 20-year from filing date terms. As a result, the earlier-issued '483 patent had the longer term, as shown in figure 1.[13]

Figure 1

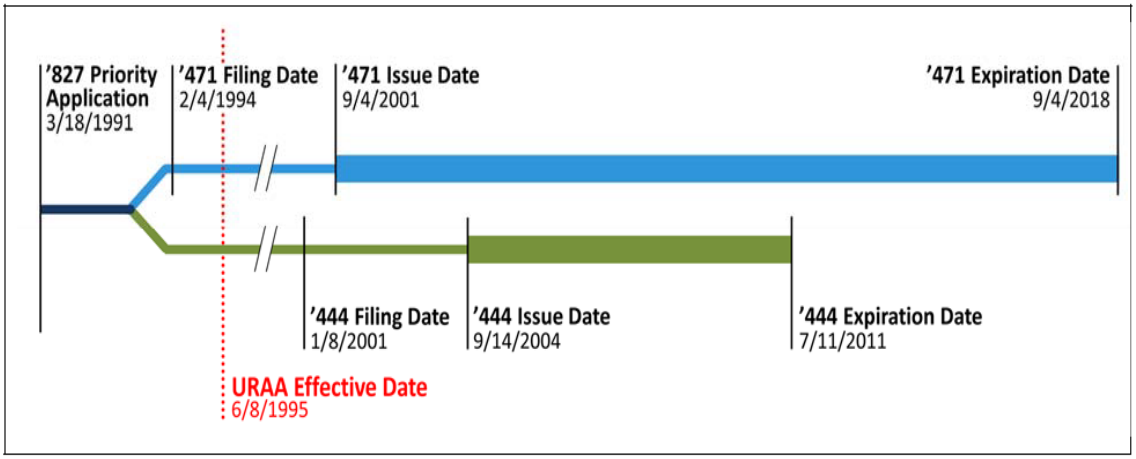


The panel majority in *Gilead* found that the later-issued but earlier-filed '375 patent could, in fact, be an ODP reference against the earlier-issued '483 patent. This resulted in an unexpected reduction in the patent term of the '483 patent to that of the '375 patent.[14] The panel majority pointed out that in prior cases where the expiration date was tied to the issue date, issue dates were used as stand-ins for expiration dates, but that, in this case, it did not matter which patent issued first.[15] In the court's opinion, a focus on the issue date could lead to "gamesmanship during prosecution" (e.g., arranging for applications with later filing dates to issue first).[16]

In *AbbVie Inc. v. Mathilda & Terrence Kennedy Institute of Rheumatology Trust*, the Federal Circuit affirmed that a later-issued patent can be a double patenting reference against an earlier-issued patent.[17] A related question not specifically addressed in *Gilead* or *AbbVie* is whether this reasoning applies to patents having the same effective filing dates, such as a parent and a continuation application where the difference in term is solely due to a PTA award and not due to any "gamesmanship" by the applicant. The US District Court for the Western District of Michigan has applied *Gilead* to this situation, effectively wiping away a 418-day PTA award in a parent patent due to issuance of a child patent with similar claims.[18]

The Federal Circuit is analyzing the scope of *Gilead* in *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*[19] The question in *Janssen*, as depicted in figure 2, is whether ODP restricts the term of an earlier-issued but later-expiring patent in the same family, where the earlier-issued patent was filed before the URAA took effect.[20] Not only do the terms of the '471 and '444 patents differ due to the URAA, but, unlike the *Gilead* patents, they also originate from the same priority application. Thus, this case allows the Federal Circuit to consider whether *Gilead* should apply to pre- and post-URAA patents as well as to patents in the same application family, whose terms differ due to a change in law.

Figure 2



The district court in *Janssen* found that ODP applies to this situation such that the earlier-issued '471 patent is now expired in view of the later-issued '444 patent, noting that Janssen "decided to take at least the risk that the '471 [patent] would be deemed invalid when the '444 [patent] expired."[21] On appeal, Janssen argues that the two patent terms differ merely due to changes in law, not because of the "gamesmanship" *Gilead* sought to prohibit.[22] According to Janssen, Congress did not intend to alter the existing ODP doctrine when enacting the URAA, and the district court's decision accordingly "departs from the well-established rule for pre-URAA patents that "'[a]ll proper double patenting rejections . . . rest on the fact that a patent has been issued and later issuance of a second patent will continue [patent] protection, beyond the expiration of the first patent" on the same invention or an obvious variation thereof.'"[23] Janssen distinguishes *Gilead* as specifically concerning patents that do not stem from a common application, but instead were purposely filed at different times and with different priority dates.[24]

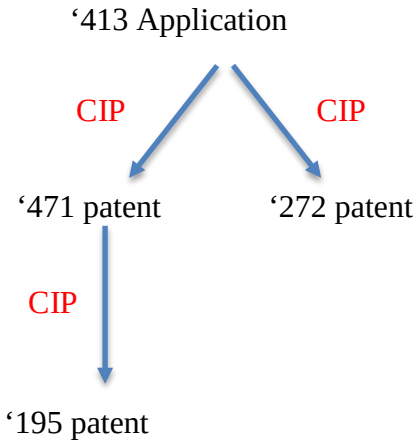
In view of these cases, applicants should take care in structuring claims among related patent applications, particularly if one or more applications achieve a significant PTA award. We discuss this in more detail below.

What Is a Divisional Application under 35 U.S.C. § 121 Safe Harbor?

A further question in *Janssen* is whether Janssen's '471 patent is also invalid for ODP over two other later-issued patents, both of which are continuations-in-part (CIPs) in relation to the '471 patent (see fig. 3). Janssen has argued that the '471 patent is protected by the safe harbor of 35 U.S.C. § 121, which protects parent and divisional applications whose claims were separated due to a restriction requirement from findings of ODP over each other. The policy behind the § 121 safe harbor is to avoid penalizing a patentee with an ODP rejection when the USPTO required the patentee to divide its original claims.

Both the district court and the USPTO's Patent Trial and Appeal Board (PTAB), following a reexamination of the '471 patent, found that Janssen's '471 patent does not qualify for the § 121 safe harbor because the '471 patent is not a "true" divisional application as defined in § 121.[25]

Figure 3



Janssen had, in its '413 application, received a restriction requirement separating composition and method-of-use claims. Janssen pursued the composition claims in the application leading to the '471 patent, filed as a CIP of the '413 application. Then Janssen pursued the method-of-use claims in applications leading to the '272 and '195 patents, filed as CIPs of the '413 application and the application leading to the '471 patent, respectively.[26]

Janssen argues on appeal that the § 121 safe harbor applies to these patents because, even though they are CIPs in name, they are divisionals in operation.[27] Specifically, says Janssen, (1) the USPTO issued a restriction requiring multiple applications, (2) the claims of the applications were amended to be consonant with the restriction, (3) Janssen advised the USPTO that the CIP leading to the '471 patent was submitted in response to the restriction, and (4) Janssen did not rely on any newly added subject matter to support its claims.[28] Janssen also argues that the patent examiner withdrew an ODP rejection over the application leading to the '195 patent, reasonably believing that the § 121 safe harbor protected the '471 patent.[29] Furthermore, in a reexamination, the USPTO permitted Janssen to delete the subject matter from the '471 patent that had been newly added and to redesignate the '471 patent as a divisional.[30] Nonetheless, the district court and the PTAB each decided that the § 121 safe harbor does not apply.[31]

The district court in *Janssen* commented that the Federal Circuit had previously addressed whether applications not *labeled* as divisionals during examination at the USPTO can nonetheless benefit from § 121 protection. For example, in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit held that the § 121 safe harbor did not apply to a patent filed as a CIP rather than as a divisional.[32] The *Pfizer* court noted that Congress drafted the statutory language of § 121 to refer only to divisionals even though CIPs were also known and available.[33] In the court's opinion, "[i]f the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so."[34] In addition, the court in *Pfizer* noted that, to obtain the § 121 safe harbor, a patent applicant must also "maintain the line of demarcation between the independent and distinct inventions that prompted the restriction requirement."[35] In other words, the claims must remain consonant with the restriction, and an applicant should not "amend[] the claims in the divisional application in a way that would violate the originally

imposed restriction requirement" because that would "impermissibly extend the patent term as to that subject matter."[36]

Subsequently, the Federal Circuit in *Amgen Inc. v. F. Hoffman-La Roche Ltd* held that the § 121 safe harbor did not apply to an application designated as a continuation.[37]

In its appeals against the USPTO and district court rulings, Janssen contends that, unlike in *Pfizer* and *Amgen*, Janssen had specifically advised the USPTO that the application leading to the '471 patent was filed in response to the earlier restriction, that its claims did not rely on the subject matter added in the CIP, and that its claims maintained consonance with the restriction.[38] Thus, Janssen argues that the '471 patent is a divisional of the '413 application in operation even if not in name.[39]

Janssen also distinguishes *G.D. Searle LLC v. Lupin Pharmaceuticals, Inc.*, which addressed whether a reissue application can be used to redesignate a CIP application as a divisional for purposes of the § 121 safe harbor.[40] The court in *Searle* found that the patentee could not in fairness redesignate its patent as a divisional because its originally issued claims relied in part on new subject matter added in the CIP.[41] On appeal, Janssen asserts that, in contrast to *Searle*, the claims of its '471 patent never relied on any newly added subject matter.[42] Furthermore, according to Janssen, there is no statutory requirement that an application be designated as a divisional before examination for § 121 purposes, and neither *Pfizer* nor *Amgen* addressed that issue.[43]

The Janssen appeals and their predecessor cases show that courts and the USPTO may narrowly interpret the meaning of a "divisional application" under § 121. *Janssen* also shows that courts may find ODP between groups of claims that patent examiners often consider patentably distinct: compositions and methods of their use.

Strategies for Avoiding Patent Term Landmines

The above decisions show how the patent term effects of ODP can be unforeseeable, especially while applications are pending. Will an earlier-issued patent lose its PTA if a later patent in the same family issues with similar claims? Are longer terms in pre-URAA patents at risk due to later issuing post-URAA filings? Because applicants cannot fully control examination speed, it can be difficult to foresee how to arrange claims between different applications during examination. Nonetheless, there are some practices that may help in avoiding losses of previously awarded patent terms due to ODP.

How to Split Claims between Applications

Generally, it is helpful to be aware of which types of applications in a portfolio tend to have longer examinations, and thus longer terms due to PTA. Often the longest examinations occur in the first-issued case in a family, in part because the USPTO may not quickly begin examination. Also, in a first case, the examiner and applicant may spend more time searching for the right claim scope and language to confer patentability. In contrast, an examiner might quickly consider later-filed cases that rely on claim language and scope agreed upon in the parent.

A first patent in a family with a long PTA can be a problem if the applicant later wishes to file a continuation application with similar claims. If the parent's claims are, to maintain validity, later terminally disclaimed over those of a continuation, the parent may lose most or all of its PTA. Thus, applicants might wish to consider filing foreseeable further claims, and particularly additional narrow claims, in a first application instead of in a continuation. And applicants may wish to focus continuing examination on divisional applications where possible.

Watch Out for Appeals

A successful appeal decision on at least one claim can lead to lengthy PTA because of backlogs at the PTAB.[44] If the successfully appealed patent contains claims found patentably indistinct from those of a continuation or improvement patent, that lengthy PTA could be at risk. Thus, it may be helpful to carefully review the claims of an application to be appealed against those in other co-pending and intended future applications. For example, adding narrow claims to the case on appeal rather than submitting them in a continuation may allow the additional claims to enjoy a longer term afforded to the successfully appealed patent.

Yet Another Reason Not to File a CIP

As seen above, ODP cannot occur between divisional and parent patents protected under the § 121 safe harbor. But the Federal Circuit might continue to narrowly define the scope of a "divisional application" under § 121 to exclude CIPs and continuations even if they are explicitly filed in response to a restriction requirement with claims consonant with that restriction. Thus, applicants should be diligent in initiating restriction requirements in parent applications and in filing new applications, before examination, as divisionals (in name) with claims amended to be consonant with the restriction. Consider also telephoning the examiner to ensure that demarcation lines in restrictions are clear and maintained.

While the CIPs in the *Janssen* appeals were filed before the URAA, there are, since the URAA, few reasons to file a CIP in lieu of a stand-alone improvement application. For example, the 20-year term of a CIP is the same as that of its parent. And a previously published parent disclosure acts as prior art to the newly added subject matter, regardless of whether it is filed in a CIP or a new, stand-alone application. Cases such as *Pfizer*, *Searle*, and *Janssen* also make clear that a CIP may not protect against double patenting the way a divisional does.

Learn to Love Restriction Requirements

Patent examiners have wide discretion to issue restriction requirements. While applicants often dislike having original claim sets broken up, filing various types of claims in an original application may provoke restriction by claim type. Thus, if examination on one set of subject matter takes a long time or requires appeal, resulting in a long PTA, there is less chance of that PTA award being disturbed by later patent issuances in the family. Moreover, applicants should consider initiating further restrictions in subsequently filed applications so that lines between claim groups remain clear.

Consider Patent Ownership

Finally, applicants should consider ownership issues. If an ODP rejection is made during examination or reexamination on a patent with overlapping inventors, it can be obviated by a terminal disclaimer. But the applicant must agree to keep the two patents or applications under common ownership.[45] Collaborators may help avoid later delays in issuance by reaching early agreement on how they will handle patent ownership in the event of a terminal disclaimer.

Consider Obviousness-Type Double Patenting as a Basis for Invalidity

ODP also merits consideration when conducting diligence relating to, for example, licensing, acquisition, or financing. For instance, one should consider whether any earlier-issued, later-expiring patents in a family could be found invalid for ODP in view of later-filed, earlier-expiring family members or other applications having nondistinct claims. Licensing negotiations, in particular, can be greatly impacted by concerns regarding the patent term.

Conclusion

As of the drafting of this article, practitioners remain in a state of uncertainty about the scope of ODP and how it will impact patent terms. The Federal Circuit's decisions in *Janssen* may greatly impact future prosecution strategies.

Endnotes

1. *See, e.g.*, *In re* Hubbell, 709 F.3d 1140, 1145 (Fed. Cir. 2013).
2. *Id.*
3. *See In re* Longi, 759 F.2d 887, 892 (Fed. Cir. 1985).
4. 35 U.S.C. § 253(b); 37 C.F.R. § 1.321.
5. 37 C.F.R. § 1.321(b)–(d).
6. *See, e.g.*, Bayer AG v. Carlsbad Tech., Inc., 298 F.3d 1377 (Fed. Cir. 2002) (allowing amendment of a terminal disclaimer because relevant changes in law were unforeseeable when the disclaimer was filed); Japanese Found. for Cancer Research v. Rea, No. 1:13-cv-412, 2013 WL 3894156 (E.D. Va. July 26, 2013) (allowing withdrawal of a terminal disclaimer because the applicant had not properly authorized filing); President & Fellows of Harvard Coll. v. Rea, No. 1:12-cv-1034, 2013 WL 2152635 (E.D. Va. May 15, 2013) (prohibiting withdrawal of terminal disclaimer where the applicant had not paid the required filing fee).
7. Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd., No. 17-1120 (Fed. Cir. filed Jan. 26, 2017); *In re* Janssen Biotech, Inc., No. 17-1257 (Fed. Cir. filed Feb. 28, 2017).
8. *See, e.g., In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985); *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001).
9. 35 U.S.C. § 154(a)(2) (providing that the term of a continuing application is 20 years from the filing of the first priority application filed under 35 U.S.C. § 120, 121, or 365(c)).
10. *Id.* § 154(b).
11. 753 F.3d 1208 (Fed. Cir. 2014).
12. Under 35 U.S.C. § 156, delays in regulatory approval may separately extend the patent term.
13. *Gilead*, 753 F.3d at 1210.
14. *Id.* at 1217.
15. *Id.* at 1215.
16. *Id.*
17. 764 F.3d 1366 (Fed. Cir. 2014).
18. Magna Elecs., Inc. v. TRW Auto. Holdings Corp., No. 1:12-cv-654, 2015 WL 11430786 (W.D. Mich. Dec. 10, 2015).
19. No. 17-1120 (Fed. Cir. filed Jan. 26, 2017).
20. *See* Brief for Plaintiffs-Appellants at 10, *Janssen*, No. 17-1120 (Fed. Cir. Jan. 26, 2017).
21. Janssen Biotech, Inc. v. Celltrion Healthcare Co., 210 F. Supp. 3d 278, 279–280, 281 (D. Mass. 2016).
22. Brief for Plaintiffs-Appellants, *supra* note 20, at 2–3.
23. *Id.* at 12.

24. *Id.* at 37–44.

25. Janssen Biotech, Inc. v. Celltrion Healthcare Co., 211 F. Supp. 3d 364 (D. Mass. 2016); *Ex parte* Janssen Biotech, Inc., No. 2016-006590 (P.T.A.B. Nov. 4, 2016).

26. *See Janssen*, 211 F. Supp. 3d at 368.

27. *See* Brief for Plaintiffs-Appellants, *supra* note 20, at 15–18.

28. *See id.*

29. *Id.* at 17.

30. *Ex parte Janssen*, No. 2016-006590.

31. *See id.*; *Janssen*, 211 F. Supp. 3d 364.

32. 518 F.3d 1353 (Fed. Cir. 2008).

33. *Id.* at 1361–62.

34. *Id.* at 1362.

35. *Id.* at 1359.

36. *Id.*

37. 580 F.3d 1340 (Fed. Cir. 2009).

38. Opening Brief for Janssen Biotech, Inc. & New York University at 28–31, *In re* Janssen Biotech, Inc., No. 17-1257 (Fed. Cir. Feb. 28, 2017).

39. *See id.*

40. 790 F.3d 1349 (Fed. Cir. 2015).

41. *Id.* at 1354–55.

42. Opening Brief for Janssen Biotech, Inc. & New York University, *supra* note 38, at 30–33.

43. *Id.* at 26–29.

44. *See* 35 U.S.C. § 154(b)(1)(C).

45. 37 C.F.R. § 1.321(b)–(d).