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Double Trouble: The expanding application of the judicial doctrine of obviousness-type double patenting

The core principle of the patent system is that patent rights are a time limited asset. It is this policy reason, as well as the desire to prevent harassment of accused infringers by multiple parties asserting rights of exclusivity to the same invention, that justifies the judicially-created doctrine of obviousness-type double patenting (ODP). In recent years, ODP has been extended to a growing number of situations, which may catch patent owners off guard. Key administrative and judicial events in the past two years, as well as pending potential new legislation, are discussed below.

ODP doctrine extended to situation lacking common ownership and common inventorship

One scenario to which ODP has recently been applied is where there was not, and never had been, common ownership or common inventorship of an issued patent and a pending application. *In re Hubbell*, 709 F.3d 1140, 106 USPQ2d 1032 (Fed. Cir. 2013). In *Hubbell*, one of the key inventors, Dr. Hubbell, initially worked at Caltech, where an application was filed in 1997 naming him and three others as inventors. In 1998, Dr. Hubbell left Caltech and moved to another institution (Eidgenossische Technische Hochschule Zurich, or "ETHZ"), where another application was filed in 2002, naming Dr. Hubbell and two others as inventors. This later application, which issued as a patent in 2009, had two common inventors and a single non-common inventor as compared to the earlier application. All the while, the subject matter of the application from Dr. Hubbell's days at Caltech was still pending, through a series of continuation applications. One of those continuation applications eventually received an ODP rejection based on the issued patent owned by ETHZ.

From a subject matter perspective, the rejection was justified, since the Caltech application claimed a genus, and the ETHZ patent claimed a species within that genus. But, Caltech was stuck. They could not overcome the ODP rejection by filing a terminal disclaimer, because the pending application and the issued patent were not commonly owned, and no joint research agreement existed between the parties. Caltech challenged the double patenting rejection, on

the basis that an ODP rejection requires common inventorship, common ownership or a joint research agreement, none of which were present.

Ultimately, the CAFC maintained the ODP rejection. According to the panel, the doctrine of ODP exists to prevent undue extension of patent term, and to prevent harassment of potential infringers by different entities. Even though precedent cases (*Van Ornum*¹ and *Fallaux*²) involved situations where the inventors artificially created a scenario of non-common ownership seemingly in order to game the system, a situation not present here, the CAFC still maintained the ODP rejection based on similar policy reasons. Additionally, Caltech could not cure the rejection with terminal disclaimer, since there is no statutory basis for doing so where no common ownership or joint research agreement exists.

ODP doctrine extended to election of species

It is well established that 35 U.S.C. §121 provides Applicants a safe harbor from ODP rejections where an application is filed as a result of a restriction requirement. A recent case provided a situation where ODP extended to an election of species requirement, and precluded protection of the safe harbor where the applicant failed to maintain consonance at the species level. *St. Jude Medical, Inc. v. Access Closure, Inc.*, 592 F.3d (Fed. Cir. 2013).

In *St. Jude*, the Examiner required restriction between invention groups I and II in a grandparent application, and required election of species A, B or C. In the grandparent, the Applicants elected embodiment IB, and obtained a patent. The Applicants then filed a “divisional” child application with similar claims, and received a similar restriction/election requirement. The Applicants again elected embodiment IB, and obtained a patent, albeit with slightly different claim scope than the grandparent. Based on the parent application, the Applicants filed two grandchild continuations, both of which matured into patents. One of the grandchild patents claimed embodiments IC and IIC. The other grandchild patent generically claimed embodiment II. The validity of the grandchild patent claiming embodiments IC and IIC was challenged based on ODP in view of the grandchild patent generically claiming embodiment II.

The CAFC considered whether “demarcation” of claims for §121 safe harbor purposes is impacted only by restriction requirements, or whether it is also impacted by requirements for election of species. The court was guided by 37 CFR 1.146, which allows the Examiner to require the applicant to elect a species to which the claim “*will be restricted* if no claim to the genus is found to be allowable” (emphasis in the CAFC opinion). The court reasoned that in both the parent and grandparent, no generic claim was presented, and therefore, the demarcation analysis should look not just to inventions I and II, but also to species A, B and C. In other words, the lack of an allowable generic claim in the parent and grandparent applications converted the requirement for election of species into a restriction requirement.

¹ 686 F.2d 927 (CCPA 1982).

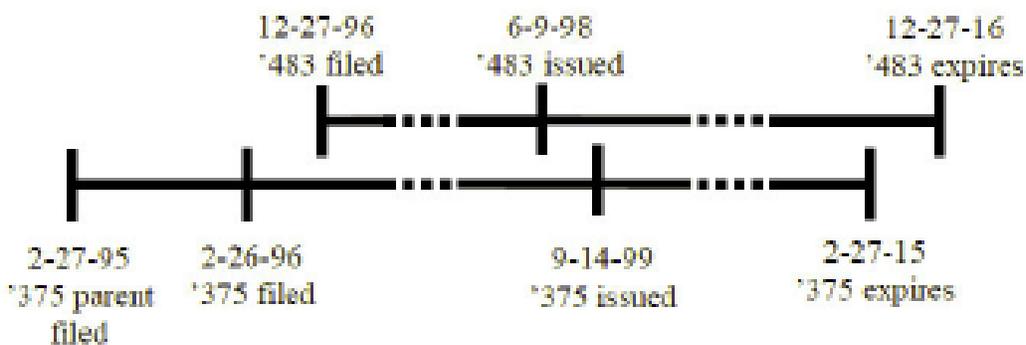
² 564 F.3d 131 (Fed. Cir. 2009).

Furthermore, the benefits of §121 safe harbor requires “consonance” between (i) the challenged patent, (ii) the reference patent, and (iii) the patent in which the restriction requirement was made, such that all three maintain the lines of demarcation from the restriction/election requirement. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683 (Fed. Cir. 1990). Due to the lack of a generic claim in the parent or the grandparent, the court divided the application into six groups, instead of the original two groups identified by the Examiner. The first grandchild patent (embodiments IC and IIC) and the grandparent and parent patents (embodiment IB) maintained consonance with the “six-way” restriction/election requirement. But according to the court, the second grandchild patent (embodiment II generally) did not maintain consonance. Therefore, the challenged patent (embodiments IC and IIC) was found to be invalid under the doctrine of obviousness type double patenting over the second grandchild application.

ODP doctrine can result in invalidation of earlier-issued patent

The doctrine of ODP has also recently been extended to a situation where a later filed but earlier issued patent was invalidated based on ODP with respect to an earlier filed but later issued patent. *Gilead Sciences, Inc. v. Natco Pharma Ltd.* (Fed. Cir. 2014). A full discussion of *Gilead* is omitted, since it was thoroughly covered in last month’s Biotech Buzz *here*.

The scenario of *Gilead* is summarized by the diagram below:



In short, the CAFC majority held that allowing the full term of the '483 patent would unduly extend the term of the '375 patent. Whereas much of the ODP precedent looked to the patent *issue* dates, the court here focused on the *expiration* date of the patents. Of course, in the pre-GATT days of 17-years-from-issue patent terms, the *issue* date and *expiration* date were essentially synonymous with respect to an ODP analysis, but this is not necessarily the case anymore. The majority explained that focusing on the expiration date not only avoids the potential for gaming the system by manipulating issue dates, but also that this is consistent with guidance in MPEP 804.I.B.1, which requires a terminal disclaimer in a later-filed copending application.

Gilead raises the question of how a situation like this might be handled during prosecution. Even though the precise scenario of *Gilead* appears to be an artifact of the changes in patent law that took place in 1995, it is still possible for a similar scenario to occur, albeit with a smaller gap in time between filing dates. It seems that the USPTO's analysis as to which application requires a terminal disclaimer would still focus on the earliest effective filing date, which according to MPEP 1490.VI.D, takes into account U.S. non-provisional applications and PCT applications to which the application in question claims benefit. The CAFC's focus on expiration dates creates an impossible burden on the USPTO, since it is impossible to determine the true expiration date of a patent until it is issued (and perhaps even not then, if §156 patent term extension applies). In the wake of *Gilead*, it appears that the USPTO may require terminal disclaimers in ***each*** co-pending ***unrelated*** application, in a similar manner to the situation discussed below with respect to two co-pending ***family*** member applications. However, this would appear to be in conflict with MPEP 804.I.B.1, and could unnecessarily eliminate some or all of the PTA in one of the co-pending unrelated applications.

ODP practice extended at the USPTO regarding co-pending patent family members

Since AIA implementation began, the USPTO has expanded its application of ODP, particularly with respect to co-pending applications in the same patent family. Specifically, in the 9th revision of the 8th edition of the MPEP (August 2012), MPEP 1490.V.D, which relates to terminal disclaimers in the context of two co-pending applications, was amended to add the following:

If both applications are entitled to the benefit of the same U.S. nonprovisional application under 35 U.S.C. 120,121, or 365(c), and (B)(ii) [describing a continuation/divisional vs. CIP situation] above does not apply, then the provisional ODP rejection made in each of the applications should be maintained until applicant overcomes the rejections by either filing a reply showing that the claims subject to the provisional ODP rejections are patentably distinct or **filing a terminal disclaimer in each** of the pending applications. Emphasis added.

The amendment remains in the recently published 9th edition of the MPEP. Previously, if provisional ODP rejections were made in two co-pending family member applications, the Examiner would continue to make the rejection until it was the only remaining rejection in one application. The provisional ODP rejection would then be withdrawn in the ready-to issue application that would pass on to issue. In the other application, the ODP rejection would no longer be provisional, and the Applicant would have to file a Terminal Disclaimer to overcome the now non-provisional ODP rejection, disclaiming any patent term beyond the expiration of the earlier-issued application.

Now, in view of the revised MPEP 1490.VI.D (which does not have the force of law, and has not been tested in the courts), the Examiner can maintain the provisional ODP rejection in the first application until a terminal disclaimer is filed, even if no other rejections are made. Whereas previously, the Applicant only had to file a terminal disclaimer in the second-issued application relative to the first-issued application, the Applicant now also may have to file a terminal

disclaimer in the first-issued application, relative to the second-issued application. Of course, since both applications claim priority to the same application, their “base” term is the same 20 years. However, it is possible that the two applications may have dramatically different amounts of Patent Term Adjustment. Due to this change in USPTO policy, the patent with fewer days of PTA effectively limits the terms of both patents. So, if one of the applications is mired in excessive USPTO delay while the other application sails through the USPTO with minimal delay, there is no remedy available to obtain an equitable extension of the second patent’s term.

Summary

How does one avoid this morass, and obtain the maximum patent term permissible? Generally speaking, the best advice may be to file claims with an eye to provoking restrictions and §121 safe harbor, maintaining the consonance of restriction requirements, and when in doubt, file a terminal disclaimer.

To avoid the situation in *Hubbell*, there are likely few options. Rather, the best advice may be to confer with inventors before, during and after their employment, so that the assignee is aware of all of their applications. Other options to avoid this situation may lie in careful drafting of employment agreements to require assignment of obvious variants of inventions made during employment, and/or reasonable time-based non-compete provisions. However, both of these options open up a variety of potential enforceability problems, particularly in academia.

To avoid the situation in *St. Jude*, the Applicant’s best bet is to monitor very carefully the entire patent family, to ensure that strict consonance is maintained to the demarcation of embodiments laid out by the Examiner in an initial restriction/election.

To avoid the situation in *Gilead*, the best advice may be to make sure that the Examiner is aware of all co-pending applications in a portfolio that may be relevant to an ODP rejection. Additionally, liberal filing of Terminal Disclaimers in scenarios lacking §121 safe harbor may be the most prudent action, although it may result in an undesirable surrender of some patent term in order to insulate against potential invalidation based on ODP.

Furthermore, if planning to file a continuation application including claims never previously presented and subjected to a restriction requirement, it may be prudent to file these claims first in a parent application to provoke a restriction requirement. This may help to avoid an Examiner requiring filing of multiple terminal disclaimers in light of the recently revised MPEP 1490.VI.D. If a restriction requirement is issued, §121 safe harbor is assured in the continuation, and the need for a PTA-killing terminal disclaimers in each application is eliminated.

However, Applicants should exercise caution when taking an allowance on narrow subject matter in conjunction with filing a continuation claiming rejected broader subject matter. In

such a scenario, the USPTO may issue an ODP rejection in the parent application after the continuation is filed. In view of the revisions to MPEP 1490.VI.D, it may necessary to file a terminal disclaimer in both the parent and the continuation application, thereby limiting PTA in patents maturing from both applications.

As the above examples demonstrate, the law surrounding ODP is a bit of a mess. It would seem that, if done right, codification of this judicially-created doctrine may help improve predictability. Although the Goodlatte “Innovation Act” in the House (H.R. 3309) is currently stalled, the most recent draft includes a proposed new 35 U.S.C. §106 codifying ODP. This most recent draft only addresses First-Inventor-To-File subject matter, and appears to only apply to two patents, rather than a patent and a pending application, or two co-pending applications. If this draft §106 ever becomes law, it would appear to only be a long-term solution, with plenty of uncertainty remaining for years.

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