

# Intellectual Property & Technology Law Journal

Edited by the Technology and Proprietary Rights Group of Weil, Gotshal & Manges LLP

VOLUME 34 • NUMBER 7 • JULY–AUGUST 2022

## Collaborative Research and “Reverse” Obviousness-Type Double Patenting

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35 U.S.C. § 101 limits an inventor to only one patent per invention. Courts have extended this limitation by crafting the judicially created doctrine of obviousness-type double patenting (“ODP”),<sup>1</sup> which “prohibit[s] the issuance of the claims of a second patent that are not patentably distinct from the claims of the first patent.”<sup>2</sup>

Two policy rationales underlie ODP. The first is to prevent an unjustified time-wise extension of the right to exclude granted by a patent, while the second is to protect potential infringers from “harassment by multiple assignees” when the primary and reference patents or applications are owned by different parties.<sup>3</sup>

ODP can arise where there is at least one overlapping inventor but a lack of common ownership. If an applicant cannot overcome an ODP on the merits, then the typical fix is to file a terminal disclaimer. The challenge lies in the fact that it is enough for a single common inventor between

two patents or applications at issue to trigger ODP,<sup>4</sup> while common ownership is required to file a terminal disclaimer to obviate ODP. As such, without common ownership or a joint research agreement such that the Cooperative Research and Technology Enhancement (“CREATE”) Act applies, a terminal disclaimer is unavailable.

A traditional ODP challenge involves using the claims of an earlier-issued patent to invalidate the claims of a later-issued patent. However, over the years ODP has morphed into a formidable challenge to patent owners, as the courts have also allowed “reverse ODP” to truncate patent term irrespective of the original policy reasons.<sup>5</sup> Reverse ODP is particularly worrisome for life science innovators at companies and universities who often engage in partnerships and collaborative research to develop ongoing research.

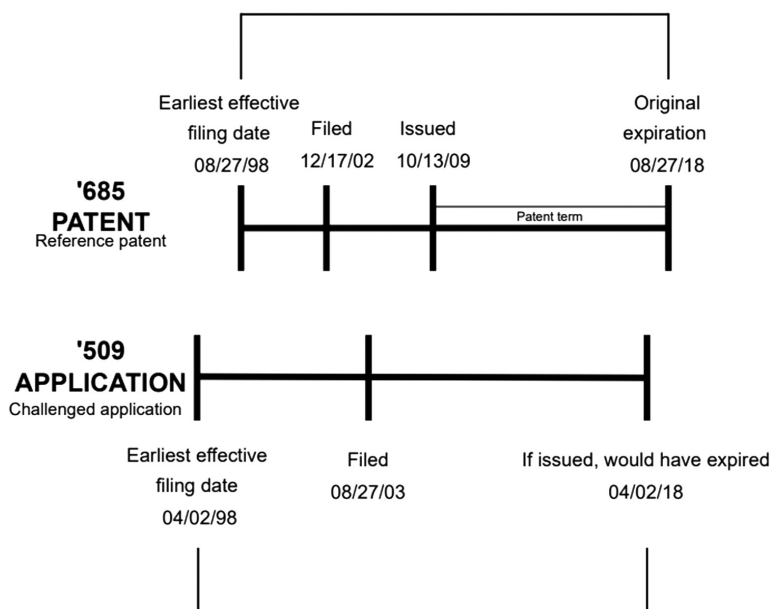
In this article, we discuss reverse ODP and the uncertainty surrounding whether it applies broadly, or only in special circumstances during *ex parte* prosecution.

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### CURRENT STATE OF THE LAW

ODP allegations rooted in preventing unjustified time-wise extension of the patent term are far more common than those intended to prevent harassment by multiple assignees. But, at least in certain



circumstances, the courts nonetheless recognize this second justification, standing alone, as a viable means to affirm invalidity based on ODP, regardless of whether the patent term is extended.

In *In re Hubbell*, the U.S. Court of Appeals for the Federal Circuit affirmed an ODP rejection of an application to prevent the possibility that multiple infringement suits could be brought by more than one party. In *Hubbell*, U.S. Patent Application No. 10/650,509 (the “’509 application”) was rejected for ODP over U.S. Patent No. 7,601,685 (the “’685 patent”).

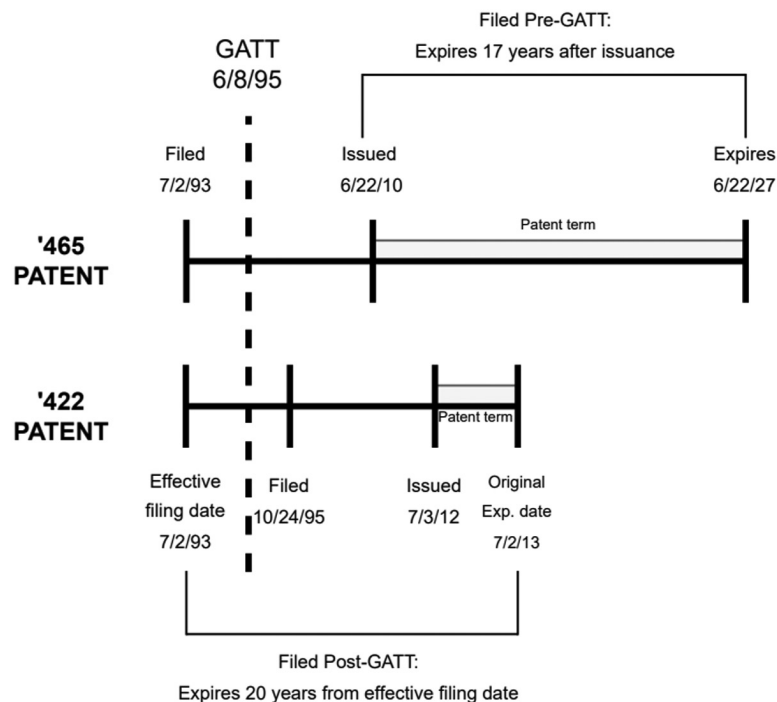
The ’509 application is based on Hubbell’s work as a professor at Caltech and named Hubbell as an inventor and Caltech as the assignee. Hubbell later left Caltech and joined the faculty at Eidgenossische Technische Hochschule Zurich (“ETHZ”) and the ’685 patent named Hubbell as an inventor and ETHZ and Universitat Zurich as the assignees. The ’509 application and the ’685 patent were never commonly owned, and Hubbell is the only common inventor between the two. As shown in the accompanying diagram, if the ’509 application was to issue, it would expire before the ’685 patent and so an unjustified time-wise extension of the patent term was not an issue here.

Hubbell argued that common ownership should be a requirement to trigger an ODP rejection, but the court dismissed this argument for the sole

reason that if the ’509 application claims were to issue, the potential for harassment by multiple assignees would exist. An infringer of the ’685 patent would also infringe the ’509 application claims. As such, a potential infringer could be subject to lawsuits from not only Caltech but also ETHZ and Universitat Zurich. For this reason, the Federal Circuit affirmed the decision to reject the ’509 application for ODP.<sup>6</sup>

Similarly, in *In re Fallaux*, the Federal Circuit upheld the rejection of an application in an effort to prevent multiple infringement suits. In *Fallaux*, Patent Application No. 10/618,526 (the “’526 application”) was rejected for ODP over U.S. Patent Nos. 6,340,595, and 6,413,776 (collectively, the “Vogel patents”). The ’526 application and the Vogel patents share a single common inventor, and were previously commonly owned, but no longer had common ownership. The court upheld the ODP rejection because of the risk of a potential infringer being subject to a multiplicity of suits because the ’526 application and Vogel patents are not commonly owned.<sup>7</sup>

The ex parte reexamination of U.S. Patent No. 7,741,465 (the “’465 patent”) also presents an interesting ODP situation. A third-party requestor filed a request for the reexamination of certain claims in the ’465 patent for reverse ODP over U.S. Patent No. 8,211,422 (the “’422 patent”). The



accompanying diagram shows the respective filing and issuance dates of each patent.

The challenged '465 patent lists inventors Eschhar, Waks, and Gross. The reference '422 patent lists inventors Eschhar, Waks, Gross, Schindler, Rosenberg and Hwu. Thus, the two patents share common but not identical inventorship. The overlap in inventors opened the door to an ODP challenge.

During prosecution, the '422 patent was rejected for ODP over the '465 patent. There was no unjustified time-wise extension of patent rights because the 1995 General Agreement on Tariffs and Trade ("GATT")<sup>8</sup> is the reason why the patents expire on different days. Legislative change, not the patent owner's actions, led to the difference in term duration. Despite this, the USPTO used the '422 patent as the reference patent to reject the claims of the '465 patent in the reexamination, in a surprise reverse ODP.

As demonstrated in *Hubbell*, *Fallaux*, and the '465 reexamination, ODP rejections for reasons other than the goals initially advanced by courts to prevent an unjustified time-wise extension can arise during ex parte prosecution and reexaminations where an investigator is involved in ongoing research and collaborations.

## TERMINAL DISCLAIMERS

Generally, to obviate ODP the applicant or patent owner can file a terminal disclaimer if the challenged application or patent and the reference patent are commonly owned.<sup>9</sup> A terminal disclaimer obviates an ODP rejection by disclaiming the portion of the patent term of the second patent that extends past the term of the first patent, that is, it removes the extended right to exclude with claims in a later patent that are not "patentably distinct" from claims in an earlier patent.

When a terminal disclaimer is filed to overcome an ODP rejection during prosecution, it must include a provision that any patent granted on that application shall be enforceable only for and during the period that the patent is commonly owned with the application or patent that formed the basis for the ODP rejection.<sup>10</sup> As such, a terminal disclaimer cannot overcome ODP when the challenged patent or application and the reference patent are not commonly owned.

The MPEP defines common ownership to require 100 percent common ownership.<sup>11</sup> This requirement presents significant issues in cases where the challenged and reference patents share a common owner but do not have 100 percent common ownership. In those situations, a terminal

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disclaimer will not overcome an ODP rejection. For example, in both *Hubbell* and *Fallaux*, the patents at issue could not be saved because the challenged and reference patents lacked common ownership and a terminal disclaimer was unavailable.

## PROBLEMS FOR COLLABORATIVE RESEARCH

While the presence of one common inventor is sufficient to raise ODP, absent 100 percent common ownership, that common inventor is insufficient to support filing a terminal disclaimer that will overcome the ODP rejection. In this common inventor scenario, the patentee's hands are effectively tied. The risk of triggering ODP with one overlapping inventor often comes into play where a primary investigator makes an initial discovery and then collaborates with individuals at different institutions or companies to further develop the technology. This common scenario routinely occurs, for example, between principal investigators at a University and a spin-out company and between smaller biotech companies and big pharma.

The CREATE Act provides some relief from ODP rejections in these scenarios but the CREATE Act only applies if a joint research agreement is in place prior to the filing date of the application under rejection. In other words, the CREATE Act only operates in one direction. It is unavailable for applications filed prior to the date of the joint research agreement.<sup>12</sup>

The “genus first/species second” situation is a perfect illustration of the reverse ODP concern. An application filed directed to a genus invention prior to a collaboration, and thus prior to the date of a joint research agreement, would be at risk from a reverse ODP rejection based on a later-filed patent claiming a species that includes one overlapping inventor and a lack of 100 percent identity in ownership. In the *Hubbell* and *Fallaux* scenarios, the researchers continued the work that formed the basis for their first filed patent at their new place of employment, which led to the issuance of a second patent. Both cases were appeals from reverse ODP rejections that had been made during ex parte prosecution. Thus, in *Hubbell* and *Fallaux*, a patent to the later-filed species invention issued while the earlier-filed application, directed the genus, was still pending.

The footnotes in *Hubbell* recognized that the two-way test of obviousness analysis applies in cases where a later filed improvement application issues before the first-filed basic application due solely to delays at the USPTO. The two-way test – a test more favorable to the applicant – compares the patentable distinction between both the later patent claim over the earlier patent claim, and the earlier claim over the later claim. This contrasts with the default one-way test, which looks at whether the claim at issue is patentably distinct from the earlier reference claim. *Hubbell* noted that, even in cases where the invention could not have been filed in a single application, if the applicant controlled the relative rate of prosecution for the applications and the USPTO was not solely the cause for the order of prosecution, the two-way test does not apply.<sup>13</sup>

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Can the *Hubbell* and *Fallaux* holdings be avoided if the applications are prosecuted in order? At least at the ex parte examination level, the answer appears to be yes. Where two applications are pending directed to patentably indistinct inventions, Section 1490 of the Manual of Patent and Examination Procedure (“MPEP”) instructs examiners to withdraw a provisional ODP rejection against the earlier-filed application and permit it to issue and then reject the later-filed application for ODP.<sup>14</sup> However, prosecuting different patent application families “in order” becomes quite difficult when continuation and divisional applications are filed and/or the same party does not control prosecution of both families. In practice, it is reasonably likely that a patent will issue out of the second “species-family” while at least one continuation or divisional application out of the first “genus-family” is still pending.

Moreover, even for patents issued “in order” to avoid reverse ODP at the ex parte examination level, it is possible that the Central Reexamination Unit (“CRU”) might nonetheless entertain a reverse ODP rejection in an ex parte reexam. Indeed, in the reexamination of the '465 patent described above, the '465 patent was filed first and issued before the '422 patent. Despite this, the USPTO allowed the

'465 patent to be rejected for ODP over the '422 patent.

Another consideration is what limits courts will place on reverse ODP challenges raised for the first time in litigation. As *Hubbell* and *Fallaux* arose during ex parte prosecution, there is at least some uncertainty concerning the reach of these decisions into a district court dispute.<sup>15</sup>

## CONCLUSION

ODP and reverse ODP can present significant obstacles for protecting inventions that both pre-date, and arise out of, collaborative research. ODP challenges can be raised in several scenarios with different justifications, and without common ownership or a joint research agreement in place, terminal disclaimers are not available to overcome a rejection. Researchers (as well as IP counsel) should be aware of the potential issues associated with being named as an inventor on multiple patents, where the patents do not share common ownership.

## Notes

1. *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985).
2. *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1318 (Fed. Cir. 2018).
3. *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013).
4. *Id.* at 1147.
5. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1216 (Fed. Cir. 2014).
6. *In re Hubbell*, 709 F.3d 1140, 1147 (Fed. Cir. 2013).
7. *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009).
8. See 35 U.S.C. § 154. GATT went into effect on June 8, 1995. For patents filed pre-GATT (before June 8, 1995), patents are granted a term of 17 years from the issuance date. For patents filed post-GATT (on or after June 8, 1995), patents are granted a term of 20 years from filing date.
9. *In re Hubbell*, 709 F.3d 1140, 1148 (Fed. Cir. 2013).
10. See 37 CFR §1.32(c)(3).
11. See MPEP 706.02(I)(2). “The term ‘commonly owned’ is intended to mean that the subject matter which would otherwise be prior art to the claimed invention and the claimed invention are entirely or wholly owned by the same person(s) or organization(s)/business entity(ies) at the time the claimed invention was made. If the person(s) or organization(s) owned less than 100 percent of the subject matter, which would otherwise be prior art to the claimed invention, or less than 100 percent of the claimed invention, then common ownership would not exist. Common ownership requires that the person(s) or organization(s)/business entity(ies) own 100 percent of the subject matter and 100 percent of the claimed invention.”
12. See 35 U.S.C. § 102(c).
13. *In re Hubbell*, 709 F.3d 1140, 1150 (Fed. Cir. 2013).
14. MPEP 1490.VI.D.2(a).
15. The scenario of a first-filed genus patent and a later-filed species patent is quite frequent in pharma and biopharma. Sometimes the scenario involves ongoing research by an individual who is an overlapping inventor of both patent families. But often, the later species patent is invented by completely different individuals at different institutions, which renders ODP rejections inapplicable. Selectively subjecting individuals engaged in ongoing research to such reverse ODP rejections seems to be an unintended consequence of the “harassment by multiple assignee” policy concern.

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