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Courts Are Unsettled On Obviousness-Type Double Patenting

By **Rachel Elsby, Brooks Kenyon and Svetlana Pavlovic**
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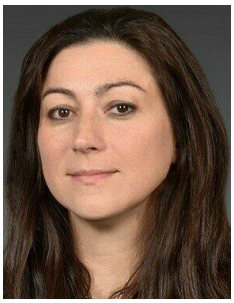

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The judicially created doctrine of obviousness-type double patenting, or ODP, can be a potent defense in litigation. Under the ODP doctrine, patent claims that are not patentably distinct from those in a commonly owned, earlier-filed patent are subject to invalidation.

Grounded on the principle that each invention should be limited to one patent term, the ODP doctrine was created to deter parties from procuring sequential patents with different expiration dates claims to the same invention, or obvious variants of the same invention,[1] the primary concern being that a patentee who obtains such patents could:

- Engage in serial litigation; or
- Sell the patents to different entities only to have both entities separately sue an alleged infringer for effectively the same thing.[2]

On its face, the ODP analysis may seem relatively straightforward, but its application has proven to be confounding. In general, when two patents are alleged to claim the same invention, but one has a later expiration date, a court must determine whether differences between the claims render them patentably distinct — whether the later claims are obviously over or anticipated by the earlier claims.

If the claims are not patentably distinct, then the later-expiring patent can be invalidated. In some circumstances, however, a patentee may file a terminal disclaimer to overcome that basis of invalidity.[3] The terminal disclaimer statutorily disclaims "any terminal part of the term" of the later-expiring patent so that both patents expire on the same date.[4]

Doing so may eliminate concerns over gamesmanship by the patentee to extend its patent rights.

Adding complexity, there are some instances in which the expiration dates of related or similar patents have different terms as a result of statutorily provided patent term adjustments or extensions. The question has thus arisen as to how the ODP doctrine should apply when patent terms are extended

through permissible means and by statutory grant. On this question, courts and the Patent Trial and Appeal Board are divided.

Modifications to Patent Terms

A patentee is generally provided 20 years of patent exclusivity from the filing date of the first non-provisional application from which priority is claimed.[5] However, Congress has provided two mechanisms by which that term can be extended.

First, when a patent's issuance is delayed during prosecution, the patent's term can be adjusted under Title 35 of the U.S Code, Section 154(b) to account for those delays. Notably, filing a terminal disclaimer limits the availability of patent term adjustment, or PTA.[6]

Second, because certain inventions, such as pharmaceutical compositions, are subject to lengthy regulatory review periods prior to commercial marketing that can effectively reduce a patent's term, Congress provided a mechanism to recover patent term lost as a result of that review.

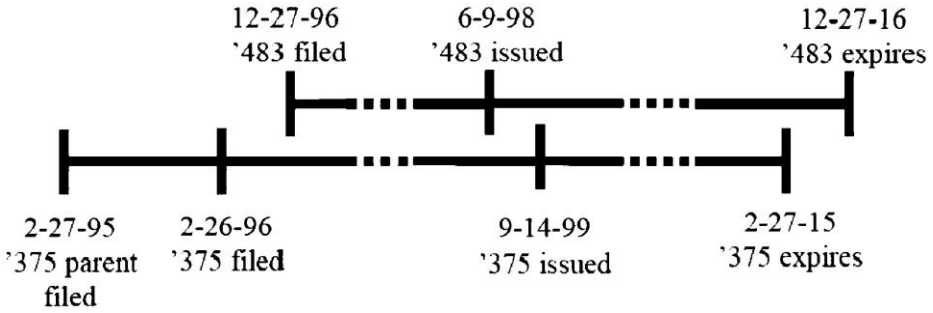
Specifically, when a patent claims an invention related to a product subject to regulatory approval by the U.S. Food and Drug Administration, its term may, under certain circumstances, qualify for a patent term extension, or PTE, under Title 35 of the U.S. Code, Section 156 if there are delays in the approval process at the regulatory agency.

Unlike PTA, PTE grants are not limited by the filing of terminal disclaimers.

Both PTA and PTE extensions are common and can be particularly important to the pharmaceutical and biotechnology industries. It is often the case that parties in these industries will file patent applications early in the research and development process, but not launch products until long after patents issue due to the extensive preclinical research and clinical trials that must be performed before a drug can be sold to the public.

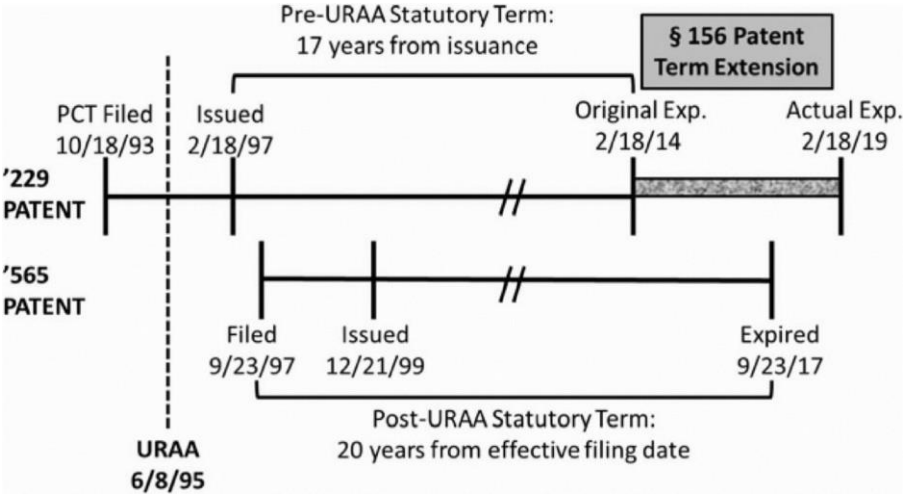
The Impact of PTA and PTE on the ODP Doctrine

In years past, the U.S. Court of Appeals for the Federal Circuit has addressed whether a later-issued, earlier-expiring patent can be used as an ODP reference — It can. In the Gilead Sciences Inc. v. Natco Pharma Ltd. decision, the Federal Circuit held that although the reference patent (the '375 patent below) issued after the challenged patent (the '483 patent below), its earlier expiration dated qualified it as prior art for ODP purposes based on the timeline below.



In contrast, the Federal Circuit has also found that a later-filed, later-issued patent that expires before an earlier-filed, earlier-issued patent due to PTE cannot act as an ODP reference.[8] In this situation, the

extended expiration date does not open the door to ODP even though the alleged reference patent (the '565 patent below) expires earlier than the challenged patent (the '229 patent below) because the difference in expiration dates was the result of validly obtained PTE.



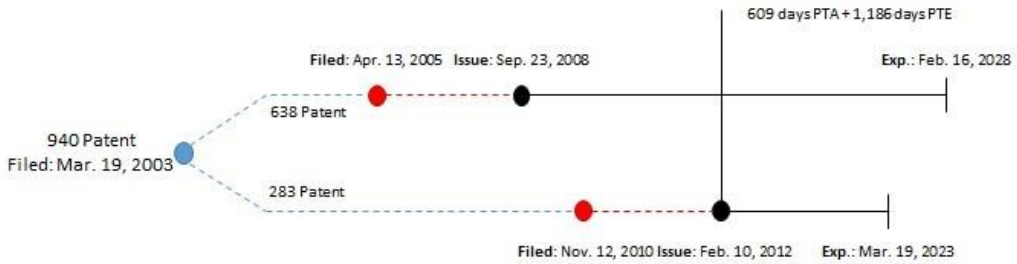
The Federal Circuit has not, however, ruled on whether the same is true for a patent whose term is extended by PTA. Such a scenario was presented to the Federal Circuit last year in Mitsubishi Tanabe Pharma Corp. v. Sandoz Inc. but the case was settled before any decision could be made.[9]

Different District Courts, Different Outcomes

With no controlling precedent from the Federal Circuit, district courts and the Patent Trial and Appeal Board have reached different conclusions on how PTA impacts the ODP analysis.[10]

For example, in last year's Amgen Inc. v. Sandoz Inc. decision in the U.S. District Court for the District of New Jersey, an ODP challenge was raised based on two patents claiming the same priority date that differed in expiration dates by nearly five years.[11] As illustrated below, the challenged patent was filed and issued before the reference patent, but had a later expiration date due to 609 days of PTA and 1,186 days of PTE.[12] The district court rejected the defendants' ODP challenge, finding that because both the PTA and PTE were statutorily authorized extensions, neither could form the basis for an application of ODP in view of the Federal Circuit's 2018 Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceuticals decision.

Amgen Timeline



The district court also noted that even if ODP could apply in such a situation, it would exercise its equitable discretion not to apply it. Citing the Federal Circuit's Gilead decision, the district court reasoned that because the difference in expiration dates was not the result of improper gamesmanship

and the extensions were properly awarded for delays outside the patentee's control, the equitable doctrine of ODP should not be used to invalidate the claims.

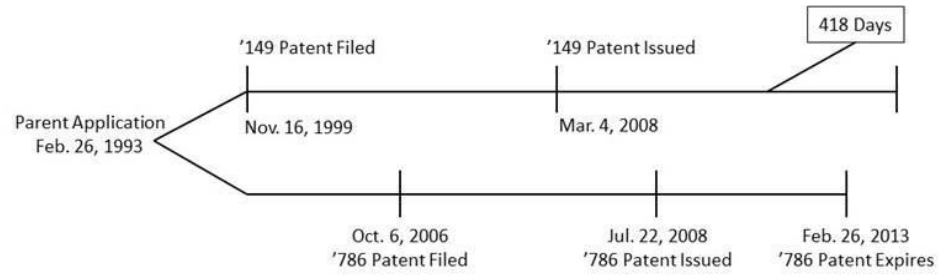
Faced with a similar situation in Magna Electronics Inc. v. TRW Automotive Holdings Corp., the U.S. District Court for the Western District of Michigan found the opposite and in 2015 held that a later-filed, later-issued patent that expires before an earlier-filed, earlier-issued patent due solely to PTA could serve as an ODP reference.[13]

As shown in the timeline below, the two patents at issue both shared a common parent and were set to expire on the same date, but the earlier-filed '149 patent received 418 days of PTA. The district court found the Federal Circuit's Gilead decision to be decisive.[14]

According to the district court, Gilead stands for the simple proposition that courts should look to the expiration dates, not the issuance dates, to determine whether ODP applies. As a result, the district court held that the '786 patent could serve as an ODP reference to the '149 patent because the '786 patent expires first.

It did not matter that both patents would have expired on the same day but for the PTA.

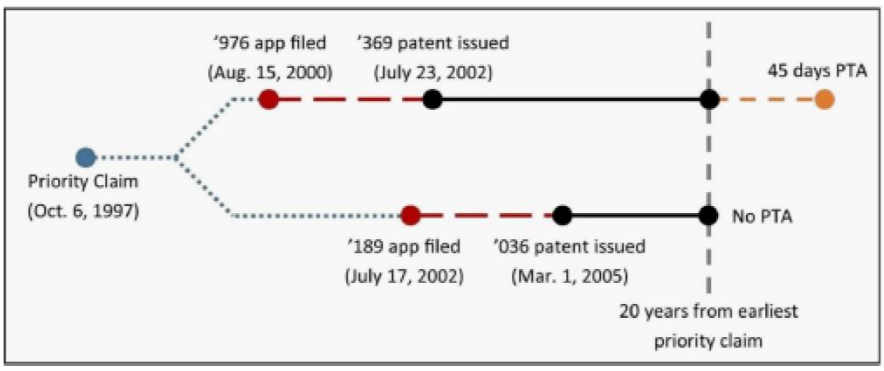
Magna Timeline



The PTAB Weighs In

More recently, the PTAB agreed with Magna in an ex parte reexamination — Ex Parte Cellect LLC.[15] As depicted in the graphic below, when confronted with the same scenario in Magna, the PTAB found that a later-filed, later-issued patent that expires before an earlier-filed, earlier-issued patent due to PTA could serve as an ODP reference.

Cellect Timeline



In its decision, the PTAB specifically distinguished PTA from PTE, explaining that the statutory language of Section 154(b) is limited where a terminal disclaimer has been filed, whereas Section 156 contains no such limitation. Because terminal disclaimers are applied after PTA to prevent the extension of a patent term beyond that which has been disclaimed, so too must ODP—they are "two sides of the same coin."[16]

According to the PTAB, its decision was consistent with Novartis because the Federal Circuit held "if a patent, under its original expiration date without [] PTE, should have been (but was not) terminally disclaimed because of obviousness-type double patenting, then this court's obviousness-type double patenting case law would apply, and the patent could be invalidated."[17]

What's Next?

Until further guidance is provided by the Federal Circuit, questions about the interaction between ODP and PTA will continue to appear. Patentees, especially those in pharmaceutical and biotechnology industries, should weigh the risk of ODP issues arising from a patent that is granted PTA with the need for filing a terminal disclaimer.

Patent examiners will often reject applications based on ODP along with additional rejections. Although terminal disclaimers can be used to overcome most ODP rejections, practitioners should avoid filing premature terminal disclaimers until all other rejections are resolved, e.g., through amendments to the claims.

In so doing, claim amendments required to resolve other rejections may also resolve the ODP rejection by making the claims patentably distinct subject matter.

Moreover, PTA grants are not uncommon. In fact, PTA was granted in approximately 54 percent of all patents issued by the U.S. Patent and Trademark Office in December 2021 — 27,660 patents — and the average length of PTA granted during that month was about 4.8 months.[18]

The instances in which parties are confronted with ODP issues may also continue to grow.

Sen. Patrick Leahy, D-Vt., and Sen. John Cornyn, R-Texas — members of the Senate Intellectual Property Subcommittee — recently introduced a new bill, the Restoring the America Invents Act, that seeks to expand the available inter partes review grounds to include ODP, where currently an IPR practitioner is limited to patentability grounds raised under Title of the 35 U.S. Code, Sections 102 and 103.[19]

Given the frequency with which PTA is granted and the uncertainty in how it is viewed by the courts in the context of ODP, careful consideration should be given to filing and assertion strategies.

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[1] Novartis Pharms. Corp. v. Breckenridge Pharm. Inc., 909 F.3d 1355 (Fed. Cir. 2018).

[2] In re Hubbell, 709 F.3d 1140, 1145 (Fed. Cir. 2013).

[3] Boehringer Ingelheim Intern. GmbH v. Barr Lab'ys, Inc., 592 F.3d 1340, 1347 (Fed. Cir. 2010) (noting a terminal disclaimer filed to overcome ODP is effective only when the patents are commonly owned and such disclaimer is filed before expiration of the earlier patent).

[4] 35 U.S.C. § 253(b).

[5] 35 U.S.C. § 154(a)(2).

[6] 35 U.S.C. § 154(b)(2).

[7] Gilead Scis., Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014). In Gilead, the reference patent and challenged patent issued from separate "chains," and therefore, did not claim priority to a common application. Id. at 1210.

[8] Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367, 1375 (Fed. Cir. 2018).

[9] Mitsubishi Tanabe Pharma Corp. v. Sandoz Inc., Case No. 21-1876 (Fed. Cir. 2021).

[10] In Kove IO, Inc. v. Amazon Web Servs., Inc., 2021 WL 4515413 (N.D. Ill Mar. 26, 2021), the issue was raised, but not decided.

[11] Amgen, Inc. v. Sandoz Inc., 2021 WL 5366800 (D.N.J. Sept. 20, 2021); see also Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc., 533 F. Supp. 3d 170, 215 (D.N.J. 2021) (finding patent was not invalid under ODP in view of a later-filed, earlier-expiring patent from the same family, where the challenged patent expired later due to PTA), judgment entered, 2021 WL 1601942 (D.N.J. Apr. 5, 2021).

[12] In Amgen, Inc. v. Sandoz Inc., the challenged patent was filed on April 13, 2005; issued on September 23, 2008; and was set to expire on February 16, 2028 based on total PTA and PTE. The reference patent was filed on November 12, 2010; issued on February 11, 2012; and was set to expire on March 19, 2023.

[13] Magna Elecs., Inc. v. TRW Automotive Holdings Corp., 1:12-CV-654, 2015 WL 11430786 (W.D. Mich. Dec. 10, 2015).

[14] In Magna, the challenged patent was filed November 16, 1999; issued March 4, 2008; and was given 418 days of PTA. 2015 WL 11430786, at *3. The reference patent was filed October 6, 2006; issued July 22, 2008; and was given 0 days of PTA. Id.

[15] Ex Parte Cellect LLC, No. 2021-005046, 2021 WL 5755316 (Patent Tr. & App. Bd. Dec. 1, 2021).

[16] Id. at *6.

[17] Novartis, 909 F.3d at 1374.

[18] https://www.uspto.gov/dashboard/patents/patent-term-adjustment.html.

[19] Restoring the America Invents Act; https://www.leahy.senate.gov/imo/media/doc/EHF21A23.pdf.