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# Another layer of complexity

The Federal Circuit has expanded the scope of obviousness-type double patenting in *Gilead v Natco,* as Gaby L. Longsworth, Ph.D., Marsha Rose Gillentine, Ph.D., and Eric K. Steffe report.

A decision handed down by the Federal Circuit in *Gilead Sciences v Natco Pharma* (Fed. Cir., April 22, 2014) adds another layer of complexity to the already-complicated law of obviousness-type double patenting (ODP). In a split panel decision with Judge Rader dissenting, Judge Chen and Judge Prost held that, "under the circumstances of this case", an earlier-filed, earlier-expiring, but later issued patent can properly serve as a reference to reject a later-filed, later-expiring, but earlier-issued patent for obviousness-type double patenting.

The two Gilead patents at issue in this case, US patent nos. 5,763,483 and 5,952,375, are commonly owned, and have common inventors, but issued out of separate families without a common priority claim. The application resulting in the '375 patent was filed before, but issued after the '483 patent. Due to its earlier filing date, the '375 patent also has an earlier expiration date. The claims in the '375 and '483 patents cover obvious variants of certain antiviral compounds and methods for their use. The timeline on the following page illustrates the relevant dates.

## Background

The district court below held that a later-issued but earlier-expiring patent cannot serve as a reference in an ODP rejection against an earlier-issued but later-expiring patent, a holding that was consistent with other district court decisions in *Abbott Labs. v Lupin Ltd.*, 2011 WL 1897322 (D. Del. May 19, 2011) and *Brigham & Women's Hosp. Inc. . Teva Pharm. USA*, Inc., 761 F. Supp. 2d 210 (D. Del. 2011), but contrary to the Board of Patent Appeals and Interferences' decision in *Ex Parte Pfizer, Inc.*, 2010 WL 532133 (Bd. Pat. App. & Interf. February 12, 2010).

> *The ruling in* Gilead *could have major ramifications for the term of a significant number of existing patents. This is particularly true in the biotech and pharma industries where prosecution of multiple applications in the same family and related families is common.*

## Résumés

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Gaby is sought out by both innovator and generic pharmaceutical companies for her insights and knowledge of intellectual property and brand product lifecycle management strategies. She counsels innovator pharmaceutical clients from around the world in all areas of patent procurement, including domestic and foreign patent preparation, and lifecycle management strategies. She also represents generic pharmaceutical companies in patent cases involving Abbreviated New Drug Applications that include a Paragraph IV certification to one or more Orange Book listed patents.

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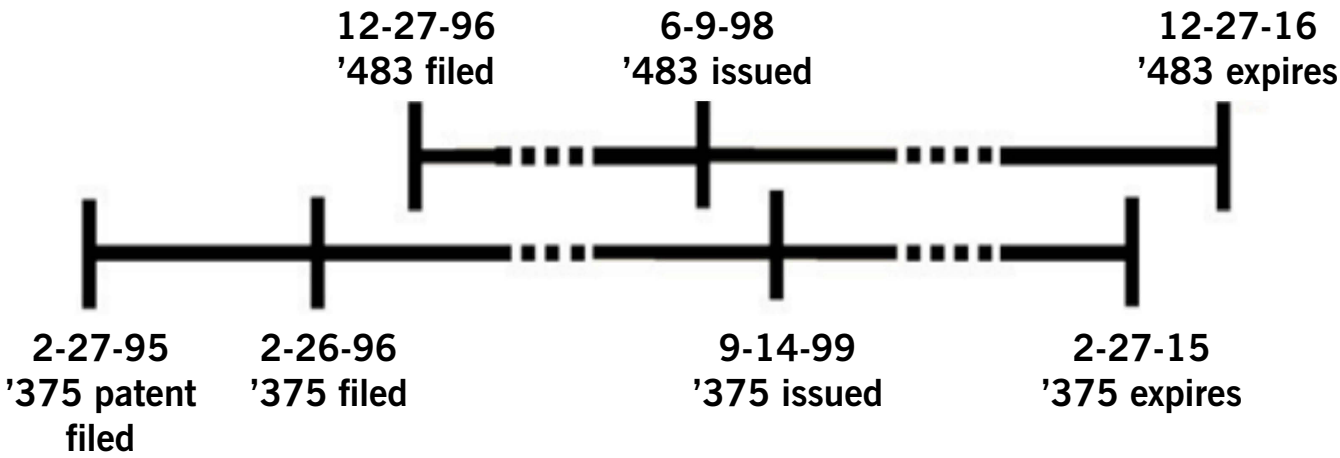
Eric heads the firm's patent prosecution practice and counsels domestic and foreign clients in various matters involving biotechnology patent law. He leads teams who create and manage complicated patent portfolios protecting pipeline and FDA-approved products for companies in the areas of immunology, antisense, protein therapy, personalized medicine and diagnostics, therapeutic antibodies, small molecules and vaccines. He also has significant expertise representing clients involved in contested case proceedings before the USPTO, including *inter partes* review proceedings, *ex parte* and *inter partes* patent reexaminations and interferences.




On appeal, the Federal Circuit focused on the question: "Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?" The Federal Circuit held that it can, vacated the judgment of the district court and remanded the case for further proceedings.

Specifically, the Federal Circuit stated that "it is a bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." And according to the court, that principle is violated if, when the patent expires, the public is unable to practice obvious modifications of the invention claimed due to a second, later-expiring patent with claims to obvious modifications of that earlier invention. In *Gilead*, even though the '375 patent expires on February 27, 2015, the '483 patent effectively extends the inventors' term of exclusivity another twenty-two months because the '483 patent does not expire until December 27, 2016.

## The ramifications

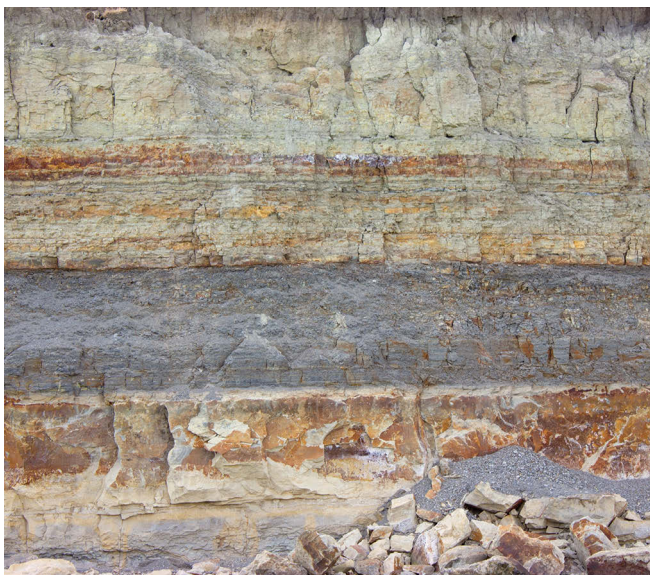
The ruling in *Gilead* could have major ramifications for the term of a significant number of existing patents. This is particularly true in the biotech and pharma industries where prosecution of multiple applications in the same family and related families is common. In addition, as discussed in more detail below, absent careful prosecution valuable patent term may be lost due to the doctrine of ODP.

The doctrine of ODP was judicially created to prevent the issuance of claims in a second patent that are not "patentably distinct" from the claims of a first patent. According to the doctrine, a patent owner should not be able to obtain a second patent with a longer patent term claiming the same or similar invention as an earlier patent. In addition, ODP arose to prevent multiple lawsuits by different patent owners based on essentially the same invention.

To obviate an ODP rejection, an applicant may file a Terminal Disclaimer (TD) to disclaim the term of a second patent extending beyond the term of the reference patent, if the reference patent and the second patent or pending application are commonly owned or subject to a joint research agreement (JRA) as set forth in 35 U.S.C. § 103(c)(2) (3). Thus, if there is a common inventor but different ownership and no JRA, a TD cannot be filed to obviate the rejection as was the case in *In re Hubbell*, 709 F.3d 1140 (Fed Cir. 2013) where the Federal Circuit affirmed the US Patent and Trademark Office's (USPTO) decision to reject CalTech's patent application for ODP.

In addition, if only one claim in an issued patent is anticipated or held obvious over a claim in an earlier issued reference patent, the patent owner must file a TD over the reference patent. Thus, filing a TD truncates the term of the entire patent based on an ODP rejection of a single claim. Moreover, while a TD can be filed during litigation after a finding that the challenged patent is invalid for ODP, a TD cannot be filed if the earlier-issued reference patent has already expired as in *Boehringer Ingelheim Int'l GmbH v Barr Labs., Inc.*, 592 F.3d 1340, 1347 (Fed. Cir. 2010).

Because filing a TD requires disclaiming any patent term extending beyond the expiration date of the reference patent, any patent term adjustment (PTA) that had accrued in the earlier-filed application could be lost. According to 35 U.S.C. § 154(b)(2), filing a TD truncates PTA.[1]



## Patent family

In *Gilead*, the '375 and '483 patents issued out of separate families. However, if future holdings extend this case to applications issuing out of the same patent family, it will add new complexity to prosecuting patent applications and invalidating patents.

As one example, if a parent patent receives significant PTA, one should reconsider whether to permit continuation applications to issue (that may receive less or no PTA) as under the logic of this case, the later-issued but earlier-expiring continuation application (CON) could serve as the basis of an ODP rejection. The rationale behind ODP is to prevent an "unjustified" extension of time by the patentee to exclude others from making or using the invention claimed in the earlier-issued reference patent. One could argue that PTA is not an "unjustified" extension by the patentee – rather it is a result of delay by the Patent Office. However, the Federal Circuit did not address whether the extension in *Gilead* was "unjustified" and therefore it is unclear whether such an argument would be successful in an ODP challenge.

Clearly, filing CONs to seek further embodiments of an invention has been pretty standard practice in the biotech and pharma industry for many years. While still viable, one should no longer permit CONs to issue "blindly."

One way to try to get around ODP would be to elicit a restriction requirement (RRQ) in applications, so that all divisional applications are shielded from an ODP rejection in accordance with 35 U.S.C. § 121. One drawback is that § 121 protection is available only to divisional applications filed pursuant to a RRQ, but not continuation or continuation-in-part applications. Thus, it is critical to specify, when possible, that a child application is a divisional and not a continuation application. *See Pfizer Inc. v Teva Pharmaceuticals Inc.*, 518 F.3d 1353 (Fed. Cir. 2008) and *Amgen Inc. v F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009). Also, for § 121 to apply, consonance with the claim groupings in the original RRQ must be maintained in all future continuation and divisional applications. In other words, the later application or applications must strictly follow the claim groupings set forth in the USPTO's restriction requirement. *See Symbol Techs., Inc. v Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991) and *Gerber Garment Tech., Inc. v Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).

Although not at issue in *Gilead*, careful consideration should be given before including a "laundry list" of uses when drafting patent applications. While it is well-settled that ODP rejections must be based on the claims of a reference patent (rather than the disclosure), an exception to this rule is where a later-filed application attempts to claim a "method of use" described in the reference patent. In such a scenario, the Federal Circuit has upheld ODP rejections even where the described "method or use" was not claimed in the reference patent. *See Geneva Pharmaceuticals, Inc. v GlaxoSmithKline PLC*,

349 F.3d 1373 (Fed. Cir. 2003); *Pfizer, Inc. v Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008); and *Sun Pharmaceutical Industries, Ltd. v Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010).

Perhaps the reach of the court's holding in *Gilead* will be clarified in further Federal Circuit decisions, but in the meantime, one should take care when prosecuting applications in the same or related families.

[1] Incidentally, while outside the scope of this paper, filing a TD does not truncate Patent Term Extension under 35 U.S.C. § 156. *See Merck & Co. v Hi-Tech Pharmacal. Co., Inc.*, 482 F. 3d 1317 (Fed. Cir. 2007).