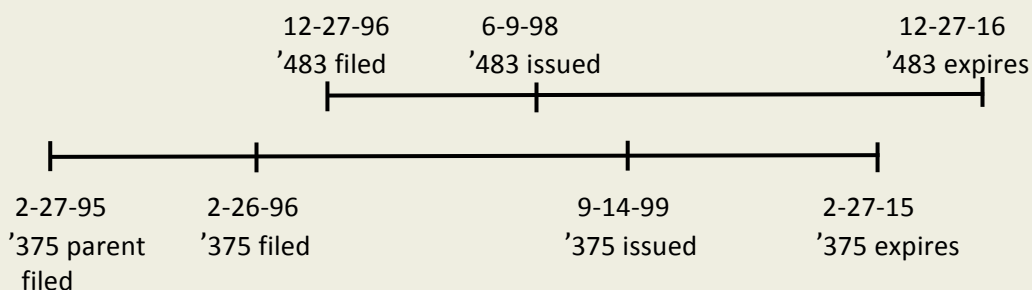


## Novel application of obviousness-type double patenting: *Gilead Sciences*

In *Gilead Sciences, Inc. v. Natco Pharma Ltd.*,<sup>1</sup> the Federal Circuit applied the doctrine of obviousness-type double patenting in a novel way. The court held that a patent that issued after but expired before another patent could serve as an obviousness-type double patenting reference against the other, earlier-issued patent.<sup>2</sup> The court thus vacated the district court decision and remanded the case to the district court.<sup>3</sup> Chief Judge Rader dissented.

Gilead owns U.S. Patent Nos. 5,763,483 and 5,952,375. The two patents have similar disclosures and claim antiviral compounds and methods of using them.<sup>4</sup>

The earliest effective non-provisional U.S. application underlying the '375 patent was filed twenty-two months before that underlying the '483 patent. Both patents expire twenty years after the respective earliest effective non-provisional U.S. filing date, so the earlier-issued '483 patent has a later expiration date than the '375 patent. This is illustrated below.



Gilead sued Natco under the Hatch-Waxman Act for infringing the '483 patent. Natco asserted that the '483 patent was invalid for obviousness-type double patenting ("OTDP") over the '375 patent. Gilead asserted that the '375 patent did not qualify as an OTDP reference because it issued after the '483 patent.<sup>5</sup> The district court agreed with Gilead,

<sup>1</sup> *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, No. 13-1418 (Fed. Cir. April 22, 2014).

<sup>2</sup> *Id.*, slip op. at 6, 16.

<sup>3</sup> *Id.* at 16-17.

<sup>4</sup> *Id.* at 2, 3.

<sup>5</sup> Typically, an obviousness-type double patenting analysis entails comparing "claims in an earlier patent to claims in a later patent or application." See *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n. 1 (Fed. Cir. 2003). The comparison consists of two steps. *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008). First, the court "construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences." *Id.* Second, the court "determines whether those differences render the claims patentably distinct." *Id.* "A later claim that is not patentably distinct from," that is, "is obvious over, or anticipated by," "an earlier claim in a commonly owned patent is invalid for obvious-type double patenting." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). While a "one-way" comparison of the relevant

relying on two cases from the District of Delaware.<sup>6</sup> Because the district court held that the '375 patent did not qualify as a reference, it did not decide whether OTDP was present.

The Federal Circuit therefore decided only the issue of whether the '375 patent qualified as a reference. As noted above, the majority held that the '375 patent qualified as a reference and therefore vacated the district court's decision.<sup>7</sup> The court reasoned that a patent represents a bargained-for exchange. OTDP preserves the integrity of the exchange by preventing the extension of the patentee's right to exclude beyond the term of the first patent to expire that covers the claimed subject matter and obvious variants thereof.<sup>8</sup> "[W]hen 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."<sup>9</sup> In view of this principle, the court concluded that the '483 patent effectively extended the '375 patent's term of exclusivity (assuming that OTDP is present, which the court did not decide).<sup>10</sup> The court noted that its decision served to prevent gaming the system to obtain an overlong period of exclusivity.<sup>11</sup>

Chief Judge Rader dissented on various grounds, including a preference for judicial restraint and reasoning that "Gilead's conduct" did not "warrant[] the creation of a new rule proscribing its patent rights."<sup>12</sup>

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claims typically is applied in the OTDP analysis, in certain circumstances a "two-way" comparison is applied. See, e.g., *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). The court in *Gilead* did not address this aspect of the analysis.

<sup>6</sup> *Abbott Labs. v. Lupin Ltd.*, 2011 WL 1897322 (D. Del. May 19, 2011), *Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc.*, 761 F. Supp. 2d 210 (D. Del. 2011).

<sup>7</sup> See *id.* at 6.

<sup>8</sup> *Id.* at 6-8.

<sup>9</sup> *Id.* at 11.

<sup>10</sup> *Id.* at 11-12.

<sup>11</sup> *Id.* at 13-14.

<sup>12</sup> See *id.* at 3 and 6-7; *id.* at 4.

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