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Remicade® Update: Double Patenting Redoubles in Post-*Gilead* Biosimilar Case

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On August 17, 2016, in *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, District of Massachusetts Judge Mark Wolf faced a double patenting fact pattern that had not been adjudicated in a district court case since the Federal Circuit decided *Gilead Sciences Inc. v. Natco Pharma Ltd*.[i] Judge Wolf held U.S. Patent No. 6,284,471 (the "'471 patent") invalid for obviousness-type double patenting over U.S. Patent No. 6,790,444 (the "'444 patent") because the '471 patent expired later due to the changes to patent terms under the Uruguay Round Agreements Act ("URAA"), even though both patents claim priority to the same application and the '471 patent issued years *before* the '444 patent.[ii]

Background and *Gilead*

Obviousness-type double patenting, as an invalidity defense in patent litigation, is less common than novelty and nonobviousness defenses under sections 102 and 103 of the Patent Act.[iii] *Janssen Biotech*, however, is the second case in two years in which a court invalidated a patent on an FDA-licensed biological product ("branded biologic") for obviousness-type double patenting. The first case involved a patent that covered the biologic drug Humira®, and the Federal Circuit invalidated that patent for obviousness-type double patenting in 2014.[iv] In *Janssen Biotech*, the '471 patent covered the biologic drug Remicade®. In each case, the branded biologic owner sued an applicant seeking approval to market a "biosimilar" drug under the section 351(k) abbreviated approval pathway[v] in the Biologics Price Competition and Innovation Act, and the biosimilar applicant asserted obviousness-type double patenting as a defense.

The doctrine of double patenting prevents the unjustified extension of patent protection beyond a single patent term. Under the doctrine, two patents cannot have different terms if they claim the same subject matter (statutory double patenting) or "patentably indistinct" obvious variations of the same subject matter (obviousness-type double patenting). Double patenting can apply whenever patents share a common owner or inventor, and recent statutory changes restricting certain commonly owned patents from being available as prior art may make double patenting defenses more prevalent.[vi]

Obviousness-type double patenting is a judicially-created doctrine, but it is grounded in section 101 of the Patent Act. Courts have historically applied it to invalidate a *later*-issued patent claim that is patentably indistinct from an *earlier*-issued patent claim. More recently, however, in *Gilead*, the Federal Circuit applied the doctrine to invalidate an earlier-issued patent claim over a later-issued patent claim because the later-issued patent was the first to *expire*.[vii] The Federal Circuit held that "looking to the expiration date instead of issuance date" is an appropriate application of the obviousness-type double patenting doctrine.[viii] In *Gilead*, the patents expired at different times because they each claimed priority to a different application.[ix]

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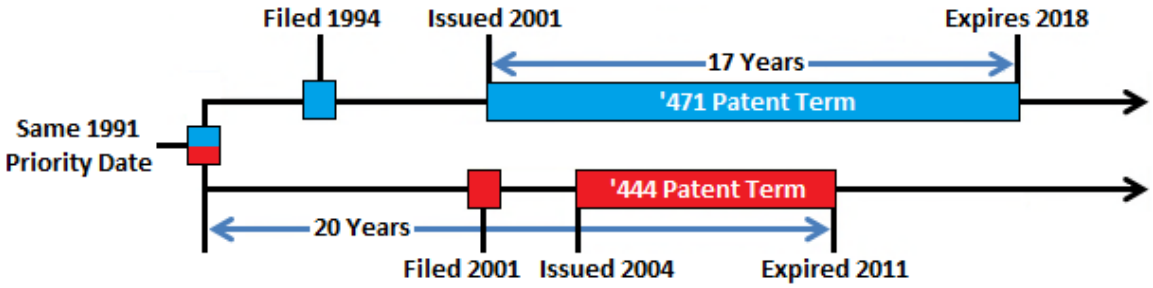
The *Janssen Biotech* Patents

The patents in *Janssen Biotech*, like the patents in *Gilead*, expired in the reverse order of their issuance, i.e., the earlier-issued '471 patent had a *later* expiration date than the later-issued '444 patent. But unlike in *Gilead*, the patents in *Janssen Biotech* expired in reverse order solely due to a change in the law—not because they had different priority dates. The '471 patent and the '444 patent had the same priority date—they both claimed priority to the same parent application filed in 1991. The '471 patent issued from a continuing application filed in 1994, while the '444 patent issued from a continuing application filed in 2001. Under the URAA, codified at 35 U.S.C. § 154, patents filed before June 8, 1995 (pre-URAA patents), like the '471 patent, have terms that run seventeen years from the patent *issue date*, while patents filed on or after June 8, 1995 (post-URAA patents), like the '444 patent, have terms that run twenty years from the earliest effective *filing date*. The result in *Janssen Biotech* was that the '444 patent had a term that ran twenty years from its 1991 priority date—expiring in 2011, while the '471 patent term runs seventeen years from its 2001 issue date—expiring in 2018. Those dates are shown here[x]:



At one time, it appeared as though the URAA changes, measuring patent terms from their filing dates, would limit the prevalence of double patenting,[xi] but here, the URAA caused the patents to expire at different times.

In holding the '471 patent invalid over the '441 patent, Judge Wolf noted that the URAA "was not intended to alter the judicial doctrine of obviousness double-patenting."[xii] Accordingly, the court held that "the reasoning in *Gilead* applies where, as here, the later-issued patent expires earlier because of the change to patent terms resulting from the [URAA]."[xiii]

Looking Forward

Janssen intends to appeal the decision, which will give the Federal Circuit an opportunity to decide whether *Gilead* properly applies to invalidate a later-expiring patent whose later expiration is due to the URAA.[xiv] K&L Gates will continue to monitor this case and send updates regarding developments.

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[i] Before *Gilead* held that a later-issued but earlier-expiring patent claim could be used to invalidate an earlier-issued but later-expiring patent claim, two District Court cases had held that a patent would not be invalid for double patenting under those circumstances. *See* Abbott Labs. v. Lupin Ltd., 2011 WL 1897322 (D. Del. May 19, 2011) (holding that "the obviousness-type double patenting doctrine is intended to address *unjustifiable* extensions of patent terms," which was not the case where the URAA, "an act of Congress," causes the difference in patent terms); Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc., 761 F. Supp. 2d 210 (D. Del. 2011); cf. Ex Parte Pfizer, Inc., Patent Owner & Appellant, 2010 WL 532133 (B.P.A.I. Feb. 12, 2010) (The Board of Patent Appeals and Interferences had, however, previously held the opposite: that an earlier-expiring patent could qualify as an obviousness-type double patenting reference regardless of whether it issued before or after the subject patent.).

Janssen Biotech case is the first post-*Gilead* case to address this issue.

[ii] *See* Janssen Biotech Inc. v. Celltrion Healthcare Co., Memorandum and Order, Nos. 15-cv-10698-MLW; 16-cv-1117-MLW, at 1–2 (D. Mass. August 19, 2016) [hereinafter *Janssen Biotech Order*]. *Janssen Biotech* also held that the '471 patent is invalid for obviousness-type double patenting over two additional patents, but those invalidity grounds are not the subject of this alert.

[iii] The "Patent Act" refers to those provisions found in Title 35 of United States Code, as amended by the Leahy-Smith America Invents Act (AIA).

[iv] AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust, 764 F.3d 1366, 1373–74 (Fed. Cir. 2014).

[v] The section 351(k) biosimilar approval pathway is an abbreviated pathway for products shown to be "biosimilar" to an FDA-licensed biological product.

[vi] The Patent Law Amendments Act of 1984 created pre-AIA 35 U.S.C. § 103(c) to exclude commonly owned patents that were prior art only under 35 U.S.C. § 102(e) from being used as prior art for obviousness under pre-AIA 35 U.S.C. § 103(a). The American Inventors Protection Act of 1999 expanded pre-AIA section 103(c) to exclude commonly owned patents that were prior art only under sections 102(e), (f), and/or (g) from being used as prior art for obviousness under pre-AIA section 103(a). The Cooperative Research and Technology Enhancement (CREATE) Act of 2004 further expanded the exclusion of pre-AIA section 103(c) by expanding the scope of what patents are commonly owned. Specifically, subject matter that otherwise would qualify as prior art under pre-AIA sections 102(e), (f), and/or (g) would be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if: (1) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. See 35 U.S.C. § 103(c).

Under the AIA, pre-AIA sections 103(c) and 102(e), (f), and (g) no longer exist. However, AIA sections 102(b)(2)(C) and 102(c) exclude commonly owned patents defined similarly to the CREATE Act amendments to pre-AIA section 103(c) from being considered prior art for any purpose, not just for obviousness.

[vii] *See* Gilead Sciences Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1215 (Fed. Cir. 2014), *cert. denied,* 135 S. Ct. 1530 (2015).

[viii] *Id*. at 1216.

[ix] *Id*. at 1210, 1215.

[x] *See* Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,284,471 for Obviousness-Type Double Patenting at 3, *Janssen Biotech*, ECF No. 128.

[xi] *See, e.g., In re* Fallaux, 564 F.3d 1313, 1318 (Fed. Cir. 2009) ("[T]he unjustified patent term extension justification for obviousness-type double patenting" may have "limited force in . . . many double patenting rejections today, in no small part because of the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing.").

[xii] *Janssen Biotech Order* at 1. Notably, the parties agreed that the '471 patent is "not patentably distinct" from the '444 patent. *Id.*

[xiii] *Id*. at 2.

[xiv] *See* Johnson & Johnson Announces Ruling Related to REMICADE® in the District of Massachusetts Federal Court Hearing.