UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. ET AL, Plaintiffs, v. CELLTRION HEALTHCARE CO. LTD., ET AL., Defendants.	)	C.A. No. 15-10698-MLW

MEMORANDUM AND ORDER

WOLF, D.J. September 28, 2016

This Memorandum is based on the transcript of the decision rendered orally on August 17, 2016, allowing defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.'s (collectively "Celltrion") Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,284,471 for Obviousness-Type Double Patenting (the "Gilead Motion"). This Memorandum adds citations, and clarifies and amplifies some language.

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I. SUMMARY

Plaintiffs Janssen Biotech, Inc. and New York University, (collectively "Janssen"), are the holders of patents related to a biologic medication called Remicade, which is based on an antibody called infliximab. Plaintiffs allege that Celltrion has infringed these patents by filing an abbreviated Biologic License Application for a product that is "biosimilar" to Remicade.

Two patents are at issue in this motion for summary judgment based on obviousness-type double patenting. They are U.S. Patent Number 6,284,471 (the "'471 patent" or "'471"), and U.S. Patent Number 6,790,444 (the "'444 patent" or "'444"). The '471 patent covers a genus, or group, of compounds that includes infliximab. The '444 patent is for the infliximab antibody specifically.

Plaintiffs concede that the '444 claims are not patentably distinct from the '471 claims. Both patents are based on an application filed in 1991, which is sometimes called the "priority application." The priority date for each patent is 1991.

The '471 patent was filed in 1994, and issued on September 4, 2001. If it stood alone, it would expire on September 4, 2018 because it was filed before the 1995 effective date of the law altering patent terms, the Uruguay Round Agreements Act (the "URAA"). The URAA is codified at 35 U.S.C. §154, most pertinently at §154(c)(1). The URAA provides protection for 20 years from the date of the original, priority application or 17 years after issuance, whichever is longer, for applications filed before 1995. Therefore, if the '471 patent stood alone, it would expire in 2018. However, for applications filed after 1995, patent protection extends for 20 years after the date the original, priority application was filed. The application for the '444 patent was filed in 2001, after the 1995 effective date of the URAA, and was issued

in 2004. As it was based on a 1991 priority application, it expired 20 years later, in 2011.

In Celltrion's Gilead motion, the defendants seek summary judgment of invalidity on Claims 1, 3, 5, 6 and 7 of the '471 patent for obviousness-type double patenting based on the '444 patent. The only question presented by the motion is whether, in view of the Federal Circuit's decision in Gilead Sciences, Inc. v. Natco Pharma Limited, 753 F.3d 1208 (Fed. Cir. 2014), the earlier-expiring '444 patent should be held to be a double patenting reference that invalidates the '471 Patent. I find that it is such a reference and, therefore, the '471 patent is invalid.

Gilead involved two patents based on applications filed after 1995. Therefore, it did not implicate the provision of the URAA that provides patent protection for at least 17 years after issuance if the application for a patent in dispute was filed before 1995. As this case is factually different than Gilead, Gilead is not binding precedent. I find, however, that in enacting the URAA, Congress and the President did not intend to alter the judicially-created doctrine of obviousness-type double patenting or restrict the power of the courts to apply it to patents resulting from applications filed before 1995.

I also find that the Federal Circuit would apply the Gilead ruling to the circumstances of this case and again find that a later-issued but earlier-expiring patent can serve as a reference

that renders an earlier-issued but later-expiring patent invalid for obviousness-type double patenting.

II. PROCEDURAL HISTORY

On August 16, 2016, the court heard oral argument on the Gilead Motion. On August 17, 2016, the court issued an oral decision, allowing the Gilead Motion. On August 19, 2016, the court issued an order summarizing the reasons for its oral decision. This Memorandum, like the August 17, 2016 transcript, more fully explains those reasons.

III. DISCUSSION

In Gilead, 753 F.3d at 1214, the Federal Circuit wrote that "[i]t 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." The court explained that "[t]he public should . . . be able to act on the assumption that upon the expiration of [a] patent it will be free to use not only the invention claimed in the patent but also [any] modifications or variants [of it] which would have been obvious to those of ordinary skill in the art at the time the invention was made." Id. (citing In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985)). "The double patenting doctrine has always been implemented to effectively uphold that principle." Id.

Plaintiffs acknowledge that the invention claimed in the '471 patent is an obvious or patentably indistinct modification of the invention claimed in the '444 patent.

In Gilead, the Federal Circuit stated that "the obviousness-type double patenting doctrine prohibits an inventor from extending his right to exclude through claims in a later-expiring patent that are not patentably distinct from the claims of the inventor's earlier-expiring patent." Id. at 1210. The court noted that federal courts had applied this principle for over a century. See id. at 1212. The Federal Circuit essentially rejected plaintiffs' argument here that the URAA manifests a statutory intent to provide patents emerging from applications filed before 1995 with at least 17 years' protection despite the otherwise applicable judicial doctrine of obviousness-type double patenting. See id. at 1216.

The URAA is silent on this issue. It does not state that pre-URAA patents will always have 17 years' protection. Nor does it reference the doctrine of obviousness-type double patenting.

Generally, the Supreme Court "presumes that legislatures act with case law in mind." Abuelhawa v. United States, 129 S.Ct. 2102, 2106 (2009); see also Miles v. Apex, 111 S.Ct. 317, 325 (1990). Consistent with this well-established canon, the Federal Circuit wrote in Gilead that "Congress could not have intended to inject the potential to disturb the consistent application of the doctrine of double patenting by passing the URAA." Gilead, 253

F.3d at 1216. "[T]he primary ill avoided by enforcement of the double patenting doctrine is a restriction on the public's freedom to use the invention claimed in a patent and all obvious modifications after that patent expired." Id. at 1215. Therefore, the Federal Circuit held that "an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent under the circumstances here." Id. at 1217.

In Gilead, the Federal Circuit found that the district court had erroneously relied on the reasoning of two pre-Gilead decisions involving, as this case does, pre- and post-URAA patents. See id. at 1211. Plaintiffs rely on the same two cases here--Abbott Labs v. Lupin Limited, 2011 WL 1897322 (D. Del. May 19, 2011), and Brigham and Women's Hospital v. Teva Pharm. USA, Inc., 761 F. Supp. 2d 210 (D. Del. 2011). See Opp. at 17-18.

In Gilead, the Federal Circuit noted that in Ex Parte Pfizer, Inc., Patent Owner & Appellant, 2010 WL 532133 (Bd. Pat. App. & Interf. Feb. 12, 2010), the Board of Patent Appeals, on facts analogous to the facts of the instant case, found that the later-issued but earlier-expiring patent invalidated an earlier-issued later-expiring patent under the doctrine of obviousness-type double patenting because the later-expiring patent, in the Board's opinion, would impermissibly block the public from practicing the invention and obvious derivations of it disclosed in the patent that expired first. See Gilead, 253 F.3d at 1211 n.2. This

reference to Pfizer, as well as the other reasoning in Gilead, indicates that the Federal Circuit would in this case find the '471 patent obvious and invalid in view of the expired '444 patent.

If plaintiffs' position were correct, the public would be prevented from practicing the expired '444 patent and an obvious, patentably indistinct variation of it. This would violate "the "bedrock principle . . . 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," id. at 1214, which is at the heart of the obviousness-type double patenting doctrine and which the Federal Circuit has found to be unaltered by the URAA.

The obviousness-type double patenting doctrine was well established when plaintiff applied for and when it accepted the '444 patent, which it knew would expire in 2011. Plaintiffs decided to take at least the risk that the '471 would be deemed invalid when the '444 expired. Infliximab was covered by the '471 genus patent, which plaintiff obtained, and by the '444 species patent that specifically claimed that antibody. As plaintiffs' counsel acknowledged at the August 16, 2016 hearing, such narrower patents are generally acquired to protect against claims of invalidity or infringement.[1] That risk was real here as the PTO has, in the

[1] Although not material to the analysis, I note that plaintiffs had a significant incentive to try to avoid the risk of invalidity of

pending reexamination, found that the '471 is obvious and invalid in view of two other patents plaintiffs held, U.S. Patent Nos. 5,656,272 and 5,698,195. See Final Rejection U.S. Pat. Reexam. No. 90/012,851, (Feb. 12, 2015); Advisory Action, U.S. Pat. Reexam. No. 90/012,851 (Apr. 29, 2015) (attached as Exs. 25, 26 to Defs' Stmnt.).

In Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust, 764 F.3d 1366, 1374 (Fed. Cir. 2014), the Federal Circuit confirmed that the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates. It reiterated the ruling of Gilead that if the later-expiring patent is merely an obvious variation of the invention disclosed and claimed in the reference patent, the later-expiring patent is invalid for obviousness-type double patenting. See id. at 1379. The reasoning of Abbvie is equally applicable to the facts of this case.

More specifically, the court finds that the expired '444 patent is a reference for the '471 Patent. The '471 patent is not patentably distinct from the '444 patent. Therefore, claims 1, 3, 5, 6, and 7 of the '471 patent are invalid. This conclusion is consistent with what is evidently the only other decision on

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the '471 patent by obtaining the '444 patent. As the parties agreed and informed the court, Remicade has generated sales in the United States of more than $4 billion a year.

comparable facts, MLC Intellectual Property v. Micron Tech., Inc., 2016 WL 4192009, at *3 n.4 (N.D. Cal. August 9, 2006).

IV. ORDER

In view of the foregoing, as ordered previously on August 19, 2016, Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,284,471 for Obviousness-Type Double Patenting (Docket No. 127) is ALLOWED.

UNITED STATES DISTRICT JUDGE