UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. ET AL, Plaintiffs, v. CELLTRION HEALTHCARE CO. INC., ET AL., Defendants.	)	C.A. No. 15-10698-MLW 16-11117-MLW

MEMORANDUM AND ORDER

WOLF, D.J. August 19, 2016

For the reasons described in detail in court on August 17 and August 18, 2016, and summarized below, it is hereby ORDERED that:

1. Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,284,471 for Obviousness-Type Double Patenting (the "Gilead Motion") (Docket No. 127) is ALLOWED. Plaintiffs hold U.S. Patent No. 6,284,471 (the "'471 Patent"). The '471 Patent was issued on September 4, 2001. Standing alone, it would expire on September 4, 2018. Plaintiffs previously held U.S. Patent No. 6,790,444 (the "'444 Patent"). The '444 Patent was issued on September 14, 2004 and expired on July 11, 2011. The parties agree that the '471 Patent is not patentably distinct from the '444 Patent. The Court of Appeals for the Federal Circuit held in Gilead Sciences., Inc. v. Natco Pharma Ltd., 753 F.3d 1208 (Fed. Cir. 2014), cert. denied, 135 S. Ct. 1530 (2015), that a later-issuing, earlier-expiring patent can act as a double-patenting reference for an earlier-issuing, later-expiring patent.

The court finds 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 Uruguay Round Agreements Act, codified at 35 U.S.C. §154. In essence, the court concludes that the statute was not intended to alter the judicial doctrine of obviousness double-patenting. See Gilead, 753 F.3d at 1216. Therefore, claims 1, 3, 5, 6, and 7 of the '471 Patent are invalid for obviousness-type double-patenting in light of the patentably indistinct, earlier-expiring '444 Patent.

2. Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,284,471 for Obviousness-Type Double Patenting Based On U.S Patent No. 5,698,195 and U.S. Patent No. 5,656,272 (the "Reexam Motion") (Docket No. 176) is ALLOWED.

(a) The following facts are undisputed. Claims 1, 3, 5, 6, and 7 of the '471 Patent (the "Asserted Claims") claim a genus of antibodies that encompasses the infliximab, or cA2, antibody. Claim 6 of U.S Patent No. 5,698,195 (the "'195 Patent") recites "[a] method of treating rheumatoid arthritis in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF anti[b]ody cA2." Claim 7 of U.S. Patent No. 5,656,272 (the "'272 Patent") recites "[a] method of treating TNFα-mediated Crohn's disease in a human comprising administering to the human an effective TNF-inhibiting amount of chimeric anti-TNF antibody cA2." The application for the '471

Patent, U.S. Pat. App. No. 08/192,093 (the "'093 Application"), was filed on February 4, 1994, and, as indicated earlier, standing alone would expire on September 4, 2018. The application for '272 Patent was also filed on February 4, 1994. The '272 Patent was issued on August 12, 1997 and expired on August 12, 2014. The application for the '195 Patent was filed on October 18, 1994. The '195 Patent was issued on December 16, 1997 and expired on December 16, 2014.

(b) The '471 Patent is not entitled to the protection of the 35 U.S.C. §121 statutory safe harbor (the "Section 121 safe harbor"). The Section 121 safe harbor applies only to applications filed as "divisional." See Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1362 (Fed. Cir. 2008). The '093 Application was filed as a continuation-in-part of U.S. Pat. App. No. 08/013,413 (the "'413 Application"). It was not filed as divisional of the '413 Application. The court does not have discretion to deem the '093 Application divisional. See id.; Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1354 (Fed. Cir. 2009)

(c) The one-way test for obviousness applies to this motion. Under that test, the Asserted Claims are obvious in light of the '195 and '272 Patents. "The two-way test . . . is 'a narrow exception to the general rule of the one-way test . . .' In re Hubbell, 709 F.3d 1140, 1149 (Fed. Cir. 2013) (quoting In re Berg, 140 F.3d 1428, 1432 (Fed. Cir. 1998)). It "is appropriate only in

the 'unusual circumstance' where 'the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first.'" Id. (quoting Berg, 140 F.3d at 1437). However, the application for the '471 Patent was filed on the same day as the application for the '272 Patent. The PTO did not decide the applications in the reverse order of filing. Therefore, the two-way test is not applicable. See United States Patent and Trademark Office, Manual of Patent Examining Procedure (9th ed. Nov. 2015) §804.II(B)(2)(b). Plaintiffs acknowledge that under the one-way test, the Asserted Claims are invalid for obviousness-type double-patenting in light of the '195 Patent and the '272 Patent.

(d) Viewing the evidence in the light most favorable to plaintiffs, there may be a genuine dispute of fact concerning whether the PTO is solely responsible for the '471 Patent issuing after the '195 and '272 Patents. However, any such dispute would not be material because assuming, without finding, that the two-way test applied, the Asserted Claims would also be obvious in light of the '195 Patent and the '272 Patent under that test. Under the two-way test, the court performs the one-way analysis and also analyses "whether the [reference] patent claims are obvious over the [challenged patent] claims." Hubbell, 709 F.3d at 1149 (quotations omitted). Under Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 1387 (Fed. Cir. 2010), it is proper

for the court to consider any utility disclosed in the '471 Patent specification when analyzing whether the '195 and '272 Patent claims are obvious in light of the '471 Patent. The '471 Patent specification describes the infliximab antibody and discloses the same uses for infliximab that are claimed in the '195 and '272 patents: treatment of Crohn's disease and rheumatoid arthritis. "[A] claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1385-86 (Fed. Cir. 2003). The '195 and '272 Patent claims would, therefore, be obvious in light of the '471 Patent. Both prongs of the two-way obviousness test are met. Accordingly, the Asserted Claims are invalid for obviousness-type double-patenting in light of the '195 and '272 Patents under that test as well.

3. The Motion to Supplement Claim Construction Record (Docket No. 217) is ALLOWED.

4. The court construes the disputed term "cell culture media" in claim 1 of U.S. Patent No. 7,598,083 (the "'083 Patent") to mean "nutritive media for culturing cells." This construction is consistent with the plain and ordinary meaning of the term as understood by those skilled in the art. The patentees did alter the meaning of the term by acting as their own lexicographer or disavowing the otherwise broad scope of the term. See Phillips v.

AVH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005); Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012).

5. Plaintiffs' Motion Expedited [sic] Trial On 083 Patent And To Set A Discovery Schedule, If Necessary, For Remaining 471 Patent Issues (Docket No. 166-1) is, as requested by plaintiffs at the August 18, 2016 hearing, WITHDRAWN.

6. Defendants' Cross Motion To Limit Plaintiffs' Remedy As To The '471 Patent (Docket No. 190) is MOOT.

7. Pursuant to the Stipulation of the parties, plaintiffs' Motion For Consolidation And For Bifurcation Of Damages Issues Pursuant To Fed. R. Civ. P. 42 And Local Rule 40.1 (Docket No. 186) is ALLOWED.

(a) Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd., Civil Action No. 1:15-cv-10698-MLW and Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd., Civil Action No. 1:16-cv-11117-MLW are consolidated for pre-trial and trial proceedings.

(b) All discovery deadlines concerning U.S. Pat. No. 7,598,083 set by the Court in Civil Action No. 1:15-cv-10698 apply equally to both actions.

(c) All issues of damages shall be bifurcated and addressed, if necessary, after liability is decided.

8. Defendants shall, by August 22, 2016, file their motion for judgment pursuant to Fed. R. Civ. P. 54(b).

9. Plaintiffs shall, by August 29, 2016, respond to defendants' motion for entry of judgment.

10. The parties shall, by September 21, 2016, confer and report concerning whether these cases have been settled.

11. If necessary, a pretrial conference shall be held on October 6, 2016, at 2:30 p.m. The parties shall, by September 27, 2016, confer and file, jointly if possible, separately if necessary, a proposed agenda for the conference and also file pretrial memoranda addressing, to the extent possible, items (1) through (10) of the attached Procedural Order.

12. Trial shall commence on February 13, 2017, at 9:30 a.m.

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Janssen Biotech, Inc. et al.
Plaintiff

V.

Celltrion Healthcare Co. Inc., et al.
Defendant

CIVIL ACTION

NOs. 15-10698; 16-11117

PROCEDURAL ORDER
RE: FINAL PRETRIAL CONFERENCE/TRIAL

Wolf, D. J.

The above-entitled action is scheduled for a final pre-trial conference on _____ at _____ in Courtroom #10 on the 5th Floor. Counsel shall be prepared to commence trial of this action on or after _____. Each party shall be represented at the pretrial conference by trial counsel.

In order to secure the just, speedy and inexpensive determination of this action in accordance with the Civil Justice Reform Act of 1990 and Local Rule 16.5, the parties shall meet prior to this conference to accomplish the following:

(1) to discuss and negotiate settlement of the action;
(2) to draft and sign a stipulation as to all uncontested facts;
(3) to narrow the issues to be tried;
(4) to exhibit to all parties any and all photographs, documents, instruments and other objects any party intends to offer as exhibits at trial;
(5) to give notice to all parties of the names and addresses of witnesses a party intends to call at trial, including the names and qualifications of any expert witnesses.

Counsel shall prepare and file, either jointly or separately, pretrial memoranda and/or trial documents which set forth the following:

(1) a concise summary of the evidence that will be offered by the plaintiff, defendant and other parties with respect to both liability and damages (including special damages, if any);
(2) a statement of facts established by the pleadings, by admissions or by stipulations. Counsel shall stipulate all facts not in genuine dispute;
(3) contested issues of fact;
(4) any jurisdictional questions;
(5) any question raised by pending motions;
(6) issues of law, including evidentiary questions, together with supporting authority;
(7) any requested amendments to the pleadings;
(8) any additional matters to aid in the disposition of the action;
(9) the probable length of trial and whether jury or nonjury;
(10) a list of the names and addresses of witnesses who will testify at trial and the purpose of the testimony, i.e., whether factual, medical, expert, etc.;
(11) a list of the proposed exhibits (photographs, documents, instruments, and all other objects) in order of their introduction to the Court. Those exhibits to be introduced without objection shall be identified by a single sequence of numbers and those items to which a party reserves the right to object shall be identified by a single sequence of capital letters, regardless of which party is offering the exhibit.

This material shall be filed, in duplicate, no later than five (5) business days prior to the scheduled date for the initial pretrial conference. A party who intends to object to any proposed exhibit or witness shall give written notice to all parties setting forth the basis for the objection and file said

notice, in duplicate, with the clerk on or before_____ A party who intends to file any motion in limine shall do so no later than _____. Any responses to a motion in limine shall be filed no later than_____.

Five (5) business days prior to the date assigned for trial each party shall file in duplicate:

(A) In cases to be tried to a jury, a trial brief including:

(1) any proposed questions for the voir dire examination of the jury;
(2) requests for instructions to the jury with citation to supporting authority;
(3) any proposed interrogatories or special verdict form.

(B) In nonjury cases, a trial brief including:

(1) any proposed findings of fact and requested rulings of law.

If the trial materials required by this Order have been previously filed with the Court, please advise the Court in writing of the filing date and supplement trial documents, as necessary. Immediately upon receipt of this Order, any counsel who realizes that one or more attorneys have not been notified shall forthwith notify the additional attorney(s) in writing as to the entry of this Order and file a copy of the writing with the clerk.

Compliance with this Order is not excused, absent the actual filing of closing papers or the entry of a Settlement Order of Dismissal in a form prescribed by the Court.

PLEASE NOTE: The Court requires twenty-four hour notice of settlement. Any settlement on the eve of trial may result in the imposition of costs, including the costs associated with bringing in jurors unnecessarily.

By the Court,

_____ _____

Date Deputy Clerk

Copies To:

(Pretrial.ord - 09/92) [proco.]