UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1120

JANSSEN BIOTECH, INC.,

Appellants,

v.

CELLTRION HEALTHCARE CO., LTD.,

Defendants-Appellees.

Appeal from the U.S. District Court for the District of Massachusetts in Case Nos. 15-cv-10698 and 16-11117, Senior Judge Mark L. Wolf

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REPLY IN SUPPORT OF APPELLANTS' MOTION TO EXTEND THE TIME FOR FILING THEIR APPEAL BRIEF BY 30 DAYS

Appellants Janssen Biotech, Inc. and New York University (collectively, "Janssen") submit this reply in further support of their motion to extend the time for filing their initial appeal brief by 30 days, from December 27, 2016 to January 26, 2017.

1. In this motion, Janssen seeks a modest extension of time to file its appeal brief in this important case. The current due date for Janssen's brief falls on December 27, 2016—in between Christmas and New Year's. An extension would allow time for adequate briefing, while permitting counsel time with their families over the holiday period.

2. In opposing this routine extension, Celltrion incorrectly asserts that there is a need for exigency in briefing this appeal.[1] There is no exigency. Celltrion's biosimilar product Inflectra was approved by the Food and Drug Administration on April 5, 2016. Under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Celltrion was permitted to begin commercial sale on October 3, 2016.

3. Prior to making a decision to launch its product, Celltrion sought to have its two separate challenges to the validity of the '471 patent decided in the district court before the launch date. Dkt. No. 164 in C.A. No. 15-cv-01698-MLW at 23-24. Celltrion argued that "very senior levels of management at the company are waiting to hear how this hearing comes out" in order "to make a decision to launch" its product, *id*. at 53, because "this cloud hanging over the '471 patent is a real issue for us," *id.* at 22-23.

4. The district court granted Celltrion's request for a prompt resolution of the pending motions. It held hearings on Celltrion's two summary judgment motions and decided them from the bench on August 16-18, 2016, well in advance of October 3, 2016. The district court granted both of Celltrion's motions that the '471 patent is invalid for obviousness-type double patenting. On Celltrion's first motion, the district court held that the asserted claims of the '471

[1] The Appellees are Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively, "Celltrion").

patent are invalid in view of the '444 patent. Separately, on Celltrion's second motion, the district court held that the '471 claims are invalid for different reasons in view of the '195 and '272 patents. Those separate summary judgment rulings are the subject of this appeal.

5. With this uncertainty removed by the district court's rulings, Celltrion announced on October 17, 2016, that it would begin shipping Inflectra to wholesalers in November 2016.

6. Thereafter, Celltrion received another favorable result with respect to the validity of the '471 patent. On November 14, 2016, the PTO's Patent Trial and Appeals Board ("PTAB") affirmed a final rejection of the '471 patent, in a reexamination Celltrion had initiated, for obviousness-type double patenting in view of the '195 and '272 patents. (The PTAB's decision is the subject of a separate appeal that is co-pending in this Court, captioned *In re Janssen Biotech, Inc.*, No. 17-1257.).

7. Relying on three separate rulings that the '471 patent is invalid, Celltrion began U.S. sales on November 28, 2016. Janssen has a legal right to challenge those rulings, and it is doing so in this appeal and its co-pending appeal, No. 17-1257. But based on these rulings, Celltrion has moved ahead to sell its product in the marketplace – causing irreparable harm to Janssen.

8. Celltrion agrees that Janssen's appeal is important, but it is incorrect when it asserts that the issues raised by this appeal are not complex. Dkt. 29 at 13. The district court's decision on Celltrion's first summary judgment motion, that the asserted claims of the '471 patent are invalid for obviousness-type double patenting in view of the later-issued and earlier-expiring '444 patent, raises an issue of first impression in this Court: Whether a patent issuing from an application filed before the effective date of the Uruguay Round Agreements Act ("URAA") (i.e., a pre-URAA patent) whose statutory term is 17 years from issuance can be invalid for obviousness-type double patenting in view of a post-URAA patent that had a term of 20 years from filing of its earliest priority application, where both patents share the same earliest priority application and the only reason the pre-URAA patent has a longer term is that Congress decided, in 35 U.S.C § 154(c)(1), that pre-URAA patents should have a term of 17 years from issuance or 20 years from filing of the earliest priority application, whichever is longer. This issue has divided the district courts,[2] and it has never been considered by this Court.

[2] *Compare Brigham and Women's Hospital, Inc. v. Teva Pharms. USA, Inc.*, 761 F. Supp. 2d 210 (D. Del. 2011) (holding that double patenting does not apply in these circumstances), and *Abbott Labs. v. Lupin Ltd.*, 2011 U.S. Dist. LEXIS 53846 (D. Del. May 19, 2011) (same), with *MLC Intellectual Prop., LLC v. Micron Tech., Inc.*, 2016 U.S. Dist. LEXIS 105114, at *10 n.4 (N.D. Cal. Aug. 9, 2016).

9. The district court's decision on Celltrion's second summary judgment motion, that the asserted claims of the '471 patent are invalid for obviousness-type double patenting in view of the '195 and '272 patents, raises separate and distinct issues concerning: (a) whether the statutory safe harbor provided in 35 U.S.C. § 121 is applicable here, notwithstanding the fact that the application that resulted in the '471 patent was labelled a "continuation-in-part," when the application for the '471 patent was filed in response to a restriction requirement, the applicant and examiner both relied on the applicability of the safe harbor during the prosecution of that application, the application was in substance a divisional, and the issued claims are both fully supported by the disclosure of the parent application and fully consonant with the restriction; (b) whether the "two-way test" governs the double patenting analysis when (as required) the application for the '471 patent was filed before the application for the reference patent, but on the same day, presenting a novel question of law; and (c) whether the district court erred in its application of the two-way test by considering the specification of the '471 patent and not limiting its analysis, as required, to the claims .

10. Especially in view of the magnitude of what is at stake on this appeal, a brief 30-day extension is reasonable and appropriate to permit adequate briefing on the issues raised by the decisions on Celltrion's two summary judgment motions.

11. Celltrion exaggerates the burdens that the requested extension would impose on its counsel. Celltrion has no shortage of lawyers working on this case. In the district court, Celltrion listed 13 lawyers on the briefs that it submitted in support of the summary judgment motions and Rule 54(b) motion that give rise to this appeal. On appeal, Celltrion has added five more lawyers. As a result, Celltrion's Certificate of Interest lists 18 lawyers, at three law firms. A decision granting the requested extension would not interfere with Celltrion's ability to adequately brief this appeal. Meanwhile, a decision denying the requested extension would simply reverse the burdens and make Janssen's reply brief due during the upcoming trial. If the extension is granted and Celltrion desires more time to complete its brief on appeal, Janssen would not oppose a reasonable extension.

12. Janssen has not requested any previous extensions of time in connection with this appeal.

13. For the reasons set forth above, this Court should grant Janssen's motion for a 30-day extension of time to file its appeal brief.

Dated: December 7, 2016

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CERTIFICATE OF INTEREST

Counsel for Appellants Janssen Biotech, Inc. and New York University certifies the following:

1. The full names of every party or amicus represented by me are: Janssen Biotech, Inc. and New York University.

2. The names of the real parties in interest represented by me are: Janssen Biotech, Inc. and New York University.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are: Johnson & Johnson, a publicly held corporation, is the parent corporation of Janssen Biotech, Inc. and owns 10 percent or more of its stock. New York University has no parent corporations and does not have stock owned by any publicly held corporations.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

AKIN GUMP STRAUSS HAUER & FELD LLP: Dianne B. Elderkin, Barbara L. Mullin, Angela Verrecchio, Jason Weil

PATTERSON BELKNAP WEBB & TYLER LLP: Andrew Cohen, Gregory L. Diskant, Aron Fischer, Eugene M. Gelernter, Irena Royzman

NUTTER MCCLENNAN & FISH LLP: Alison C. Casey, Heather B. Repicky.

/s/ Eugene M. Gelernter
Eugene M. Gelernter
PATTERSON BELKNAP WEBB & TYLER LLP

CERTIFICATE OF SERVICE

On December 7, 2016, I caused the foregoing document to be served by CM/ECF means on all counsel who have appeared in this appeal.

/s/ Eugene M. Gelernter
Eugene M. Gelernter