

**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

**APPELLANTS' MOTION TO EXTEND THE TIME
FOR FILING THEIR APPEAL BRIEF BY 30 DAYS**

Appellants Janssen Biotech, Inc. and New York University

(collectively, "Janssen") respectfully move to extend the time for filing their initial appeal brief by 30 days, from December 27, 2016 to January 26, 2017.

1. This is an appeal by Janssen from a partial final judgment under Rule 54(b) of the Federal Rules of Civil Procedure that the asserted claims of U.S. Patent No. 6,284,471 (the '471 patent) are invalid for obviousness-type double patenting.

2. Janssen's initial brief on appeal currently is due on December 27, 2016. Janssen seeks a 30-day extension of the time for serving and filing that brief, until January 26, 2017.

3. This appeal is of great importance to Janssen. The patent that is the subject of this appeal, the '471 patent, covers a genus on chimeric antibodies that are capable of binding with an epitope specific for human tumor necrosis factor TNF α . Janssen's commercial embodiment of the '471 patent is a biologic drug known as Remicade, which is approved by the FDA for treating Crohn's disease, rheumatoid arthritis, ulcerative colitis and other serious diseases. Since 2011, U.S. sales of Remicade have averaged nearly \$4 billion annually. Appellees Celltrion Healthcare, Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively, "Celltrion") have filed an application to sell a drug that is biosimilar to Remicade.

4. In this appeal, Janssen challenges district court decisions granting two motions for summary judgment that the asserted claims of the '471 are invalid for obviousness-type double patenting. In deciding the first motion, the district court held that the asserted claims of the '471 are invalid for obviousness-type double patenting in view of U.S. Patent No. 6,790,444 (the '444 patent); in deciding the second motion, the district court held that the asserted claims of the '471 are invalid for obviousness-type double patenting in view of U.S. patent Nos. 5,656,272 (the '272 patent) and 5,698,195 (the '195 patent). The decisions on

those motions raise separate and distinct issues. The appeal concerning the first of these motions raises an issue of first impression in this Court, on 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. The appeal on the second motion involves issues concerning:

- (a) the applicability of the statutory safe harbor provided in 35 U.S.C. § 121,
- (b) the applicability of the two-way test for obviousness-type double patenting, and
- (c) the application of the two-way test on the facts of this case.

5. The requested extension is needed in view of the upcoming holidays and to permit Janssen to adequately address the serious and important issues raised by this appeal.

6. Janssen has not requested any previous extensions of time for filing its initial brief in this appeal.

7. Counsel for Appellees have advised us that they do intend to oppose this motion.

Dated: December 2, 2016

/s/ Eugene M. Gelernter

Eugene M. Gelernter

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Attorneys for Appellants

Janssen Biotech, Inc. and

New York University

STATEMENT REGARDING CONSENT

Before filing this motion, counsel for Appellants Janssen Biotech, Inc. and New York University consulted with counsel for Appellees Celltrion Healthcare, Co., Ltd., Celltrion, Inc. and Hospira, Inc., and were advised that Appellees intend to oppose this motion.

Dated: December 2, 2016

/s/ Eugene M. Gelernter
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New York University*

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PROPOSED ORDER

IT IS HEREBY ORDERED that the date for filing of Appellants' initial brief is extended by 30 days, from December 27, 2016 to January 26, 2017.

Dated: December __, 2016

SO ORDERED:

Clerk of Court

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DECLARATION OF EUGENE M. GELERNTER

Eugene M. Gelernter declares as follows:

1. I am an attorney admitted to practice in this Court and a member of the firm of Patterson Belknap Webb & Tyler LLP, counsel for appellants Janssen Biotech, Inc. and New York University (collectively, “Janssen”) in this appeal.
2. I submit this declaration in support of Janssen’s motion to extend the time for filing its responsive brief by 30 days, from December 27, 2016 to January 26, 2017.
3. This is an appeal by Janssen from a partial final judgment under Rule 54(b) of the Federal Rules of Civil Procedure that the asserted claims of U.S.

Patent No. 6,284,471 (the ‘471 patent) are invalid for obviousness-type double patenting.

4. Janssen’s initial brief on appeal currently is due on December 27, 2016. Janssen seeks a 30-day extension of the time for serving and filing that brief, until January 26, 2017.

5. This appeal is of great importance to Janssen. The patent that is the subject of this appeal, the ‘471 patent, covers a genus on chimeric antibodies that are capable of binding with an epitope specific for human tumor necrosis factor TNF α . Janssen’s commercial embodiment of the ‘471 patent is a biologic drug known as Remicade, which is approved by the FDA for treating Crohn’s disease, rheumatoid arthritis, ulcerative colitis and other serious diseases. Since 2011, U.S. sales of Remicade have averaged nearly \$4 billion annually. Appellees Celltrion Healthcare, Co., Ltd., Celltrion, Inc. and Hospira, Inc. (collectively, “Celltrion”) have filed an application to sell a biologic drug that is biosimilar to Remicade.

6. In this appeal, Janssen challenges district court decisions granting two motions for summary judgment that the asserted claims of the ‘471 are invalid for obviousness-type double patenting. In deciding the first motion, the district court held that the asserted claims of the ‘471 are invalid for obviousness-type double patenting in view of U.S. Patent No. 6,790,444 (the ‘444 patent). In

deciding the first motion, the district court held that the asserted claims of the ‘471 are invalid for obviousness-type double patenting in view of U.S. patent Nos. 5,656,272 (the ‘272 patent) and 5,698,195 (the ‘195 patent). The decisions on those motions raise separate and distinct issues. The appeal concerning the first of these motions raises an issue of first impression in this Court, on 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. The appeal on the second motion involves issues concerning:

- (a) the applicability of the statutory safe harbor provided in 35 U.S.C. § 121,
- (b) the applicability of the two-way test for obviousness-type double patenting, and
- (c) the application of the two-way test on the facts of this case.

7. The requested extension is needed in view of the upcoming holidays and to permit Janssen to adequately address the serious and important issues raised by this appeal.

8. Janssen has not requested any previous extensions of time for filing its initial brief in this appeal.

9. Counsel for Appellees have advised us that they intend to oppose this motion.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 2, 2016

/s/ Eugene M. Gelernter
Eugene M. Gelernter

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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

I hereby certify that on December 2, 2016, I caused copies of the foregoing Motion for Extension of Time and the accompanying papers by CM/ECF means on all counsel who have appeared in this appeal.

/s/ Eugene M. Gelernter
Eugene M. Gelernter