

No. 2017-1694

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

MOMENTA PHARMACEUTICALS, INC.,

Appellant,

v.

BRISTOL-MYERS SQUIBB COMPANY,

Appellee.

Appeal from the United States Patent and Trademark Office,
case no. IPR2015-01537

**MOMENTA’S NON-CONFIDENTIAL RESPONSE
TO ORDER TO SHOW CAUSE**

Momenta responds to the Court’s October 23, 2018 order to show cause why this appeal should not be dismissed as moot. This appeal is not moot because Momenta continues to have a concrete interest, just as it did when it filed the appeal. Not even Bristol-Myers Squibb Co. (“BMS”), which would bear the burden of proving mootness, has argued otherwise. BMS October 3, 2018 Letter (Dkt. 99), at 1-2 (arguing only that “Momenta *may soon* voluntarily moot the

appeal” or that future “voluntary discontinuance . . . would” moot appeal) (emphasis added).

A case becomes moot “only when it is impossible for a court to grant ‘any effectual relief whatever to the prevailing party.’” *Knox v. Serv. Emps. Int’l Union, Local 1000*, 132 S. Ct. 2277, 2287 (2012). So “‘long as the parties have a concrete interest, however small, in the outcome of the litigation, the case is not moot.’” *Id.* Although the party invoking a court’s jurisdiction bears the burden of showing initial jurisdiction, the party asserting that later events have mooted the controversy “bears the burden of coming forward” with evidence showing such jurisdiction no longer exists. *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 98-100 (1993).

Momenta continues to have a significant concrete interest in this case. Just as when it filed this appeal more than twenty months ago, Momenta is a party to an agreement with Mylan N.V. (Mylan) to develop jointly a competing biosimilar to BMS’s ORENCIA (abatacept) product. Young Dec. ¶¶ 2, 4-7. As of today, the companies continue to be jointly responsible under that agreement for product development and for sharing the costs of that development, which are substantial. *Id.* And because of BMS’s patent and the Board’s decision upholding it, Momenta and its partner Mylan still face the same fork in the road about the commercial formulation for their biosimilar product—they must decide whether to proceed

with the current formulation or switch to a more expensive and potentially less commercially viable option. *Id.* ¶ 7. That decision and the costs associated with it still turn on the outcome of this appeal.

On October 1, 2018, Momenta announced that it “has initiated discussions with its collaboration partner, Mylan, to exit its participation in the development” of a competing biosimilar to ORENCIA. Momenta October 1, 2018 Letter (Dkt. 98), at 1. The mere start of discussions has not changed the existing and continuing development agreement between Momenta and Mylan. *Young Dec.* ¶¶ 3, 5-7. At the very least, that agreement requires advance written notice of termination. *Id.* ¶ 5. Upon any such notice of termination, the contemplated termination would not even take effect until after the period prescribed by the terms of the agreement. *Id.* ¶ 6. This appeal is thus not moot.

Nor is the appeal likely to become moot in the future. As Momenta’s letter stated, its discussion with Mylan is about Momenta exiting participation in the further development of an ORENCIA biosimilar. The letter does not state that Momenta will no longer have an ongoing financial interest in the ORENCIA biosimilar program. In fact, the terms of the Mylan-Momenta agreement expressly guarantee Momenta such an interest in the circumstances relevant here—a royalty payment based on future sales of the ORENCIA biosimilar. *Young Dec.* ¶ 7. Momenta thus will continue to have a concrete stake in the outcome of this case.

The concreteness of that stake is bolstered by the estoppel provision, which the Board's adverse decision already triggered. 35 U.S.C. § 315(e). Given Momenta's ongoing financial interest in the development of an ORENCIA biosimilar, it has an ongoing interest in having neither Momenta nor Mylan estopped from challenging the patent claims at issue. That is true even were this Court to conclude that the estoppel provision's effect does not confer standing in the first place. *But see* Momenta Op. Br. 59-60 (contending the harm from the estoppel provision confers standing). The interests necessary to preserve ongoing jurisdiction need not be the same, nor rise to the same level, as those necessary to establish standing. *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000).¹

Accordingly, this appeal is not moot, and the Court has jurisdiction to decide it.

¹ BMS has suggested that if Momenta were to "voluntarily discontinu[e]" its participation in developing an ORENCIA biosimilar that would "preclude vacatur" of the judgment under review. BMS October 3, 2018 Letter, at 2. But for the reasons discussed, it would be premature to reach any conclusion that Momenta no longer has an interest in the biosimilar program. In addition, Mylan could have interests and reasons for vacatur separate from those of Momenta.

Dated: November 2, 2018

Respectfully submitted,

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CERTIFICATE OF INTEREST

Counsel for appellant Momenta Pharmaceuticals, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Momenta Pharmaceuticals, Inc.

2. The name of the Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:

In addition to Momenta Pharmaceuticals, Inc., Mylan Ireland Limited, Mylan N.V., Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH, and Mylan Institutional LLC were identified as additional real parties in interest under 37 C.F.R. § 42.8(b)(1), but they are not represented by me. These additional real parties in interest are separately represented by: Deanne M. Mazzochi at Rakoczy Molino Mazzochi Siwik LLP.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Momenta Pharmaceuticals, Inc. has no parent corporation, but publicly held BlackRock Inc. and FMR LLC each own more than 10% of Momenta Pharmaceuticals, Inc.'s stock, based on currently available ownership reports filed with the SEC.

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 (and who have not or will not enter an appearance in this case) are:

FISH & RICHARDSON P.C.: Dorothy P. Whelan, Anita L. Meiklejohn, Michael J. Kane

Although not appearing for the party represented by me, I note that the following appeared in the agency:

RAKOCZY MOLINO MAZZOCHI SIWIK LLP: Deanne M. Mazzochi (representing additional real parties in interest Mylan Ireland Limited,

CERTIFICATE OF COMPLIANCE

This response complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) and Fed. R. App. P. 32(g) because the response contains 779 words, excluding the parts of the motion exempted by Fed. R. App. P. 27(d) and Federal Circuit Rule 27(d).

This response complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this response has been prepared in a proportionally spaced typeface using Microsoft Word 2014 using 14-point Times New Roman.

Dated: November 2, 2018

/s/ Deanne E. Maynard
Deanne E. Maynard

**NON-CONFIDENTIAL DECLARATION OF
YOUNG KWON IN SUPPORT OF MOMENTA'S
RESPONSE TO ORDER TO SHOW CAUSE**

CONFIDENTIAL MATERIAL

The non-confidential version of this declaration redacts material that discloses Momenta Pharmaceuticals, Inc.'s highly confidential business information.

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**DECLARATION OF YOUNG KWON IN SUPPORT OF
MOMENTA'S RESPONSE TO ORDER TO SHOW CAUSE**

I, Young Kwon, declare under penalty of perjury as follows:

1. I make this declaration in support of Momenta Pharmaceuticals, Inc.'s Response to this Court's October 23, 2018 Order to show cause why this appeal should not be dismissed as moot. The following declaration is based on my personal knowledge. If called to testify, I could testify competently as to the matters set forth herein.

2. I am Chief Business Officer at Momenta. I oversee development of the company's business opportunities, including its work on biosimilar candidates such as a biosimilar to the ORENCIA® (abatacept) product from Bristol-Myers

Squibb Co. I am also a primary contact, historically and presently, for Momenta's partner, Mylan N.V., relating to discussions about Momenta's and Mylan's Collaboration Agreement, which governs the development and commercialization of an ORENCIA biosimilar and other biosimilar candidates.

3. Under the terms of the Collaboration Agreement, Momenta and Mylan are jointly responsible for developing an ORENCIA biosimilar candidate. To date, Momenta has invested substantial sums into researching and developing an ORENCIA biosimilar, as detailed in the earlier declaration of Momenta's President and Chief Executive Officer Craig A. Wheeler. *See* Wheeler Declaration, at ¶¶ 20-21 (Dkt. 26 April 27, 2017).

4. The Collaboration Agreement has specific provisions governing how a party can terminate all or part of the agreement. It requires written notice to the other party. Given the advanced stage of development for the parties' ORENCIA biosimilar candidate, under the circumstances here the Collaboration Agreement would require written notice at least [REDACTED] before any termination would become effective.

5. On October 1, 2018, Momenta announced that it has initiated discussions with Mylan for Momenta to exit participation in the development of an ORENCIA biosimilar candidate. Those discussions are only just beginning. The parties have not yet reached an understanding about whether or when any termination notice will be delivered, nor have they settled on any details about the form or contents of any such termination. To date, [REDACTED]

6. The Collaboration Agreement specifies the parties' rights upon provision of written notice and completion of the contractually prescribed termination-notice period. Specifically, [REDACTED] the terms

of the Collaboration Agreement entitle Momenta to royalty payments from Mylan based on future net sales of the ORENICIA biosimilar candidate.

7. Momenta and Mylan still face the same patent and legal challenges to bringing their ORENICIA biosimilar candidate to market that they faced when Momenta petitioned for inter partes review and filed this appeal, as outlined in the Wheeler Declaration at ¶¶ 23-34 (Dkt. 26). A decision on unpatentability from this Court would still provide needed certainty and increase the likelihood of bringing an ORENICIA biosimilar to market quickly.

Executed on this 2nd day of November, 2018, at Cambridge, Massachusetts.

By: 

Young Kwon

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system on November 2, 2018.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: November 2, 2018

/s/ Deanne E. Maynard

Deanne E. Maynard