No. 17-1120

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY
Appellants,
v.
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.,
Appellees.

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

APPELLEES' OPPOSITION TO APPELLANTS' MOTION FOR EXTENSION OF TIME FOR OPENING BRIEF

Charles B. Klein
WINSTON & STRAWN LLP
1700 K Street, NW
Washington, DC 20006
(202) 282-5100

James F. Hurst
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago IL 60654
(312) 862-2200

Samuel S. Park
Dan Hoang
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago IL 60601
(312) 558-9500

John C. O'Quinn
William H. Burgess
C. Alex Shank
KIRKLAND & ELLIS LLP
655 15th St., N.W.
Washington, D.C. 20005
(202) 879-5000

Melinda K. Lackey
WINSTON & STRAWN LLP
1111 Louisiana Street, 25th Floor
Houston, TX 77002
(713) 651-2600

Peter B. Silverman
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, N.Y. 10022
(212) 446-4800

CERTIFICATE OF INTEREST

1. The full name of every party represented by us is:
Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

2. The name of any real party in interest represented by us, and not identified in response to Question 3, is: N/A.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are:

Celltrion Healthcare Co. Ltd. has no parent corporation. The entities that own 10% or more of Celltrion Healthcare Co., Ltd. include Ion Investments B.V., a Netherlands corporation that is 100% owned by Temasek, an investment company based in Singapore, and One Equity Partners IV, L.P., a Cayman Islands company that is 100% owned by JP Morgan.

Celltrion, Inc. has no parent corporation. The entities that own 10% or more of Celltrion, Inc. include Celltrion Holdings Co., Ltd., a Korean corporation, and Ion Investments B.V., a Netherlands corporation that is 100% owned by Temasek, an investment company based in Singapore.

Hospira, Inc. is an indirect, wholly-owned subsidiary of Pfizer Inc. No publicly held entities own 10% or more stock of Hospira, Inc.

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

Kirkland & Ellis LLP: James F. Hurst, Marcus E. Sernel, Dennis Abdelnour, Elizabeth A. Cutri, Jeanna M. Wacker, Stefan M. Miller, John C. O'Quinn, William H. Burgess, Peter B. Silverman, and C. Alex Shank.

Winston & Strawn LLP: Charles B. Klein, Steffen N. Johnson, Peter E. Perkowski, Samuel S. Park, Melinda K. Lackey, and Dan H. Hoang

Burns & Levinson LLP: Dennis J. Kelly and Andrea L. Martin

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INTRODUCTION

This appeal involves a multi-billion-dollar biologic drug, and is part of a limited class of cases for which Congress has enacted legislation (the BPCIA) to minimize delay and promote certainty over patent rights. As this Court previously recognized, through the BPCIA, Congress sought to "ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016). The extension Janssen now seeks, with virtually no justification, is fundamentally inconsistent with that statutory scheme and the specific findings the district court made in granting a Rule 54(b) final judgment in the first place. Indeed, each additional month of delay benefits Janssen and harms Defendants by exposing them to significant potential damages in the order of tens to hundreds of millions of dollars. Delay certainly harms customers, because, as the district court found, doctors may be reluctant to prescribe a cost-saving substitute that could be withdrawn from the market. This is exactly what expeditious resolution under the BPCIA is supposed to prevent.

Tellingly, at every turn, Janssen has tried to stall the case—seeking the benefits of the statutory scheme by filing this case, but then immediately attempting to delay by staying its own action. The district court, however, rejected Janssen's tactics, denied Janssen's motion to stay, and ultimately entered final judgment under Rule 54(b) over Janssen's objection--precisely because there was no just cause for delay.

Here on appeal, Janssen continues to seek delay for its own benefit, while subjecting Defendants (and/or their potential customers) to the very harms the BPCIA was designed to avoid. Janssen's extension motion asks the Court to add an extra month of delay for no good reason, other than to say this is an important case. Defendants agree it is important, and that is precisely why—consistent with Congress's objectives in the BPCIA—it should not be delayed. For much the same reason the district court denied Janssen's stay motion and granted Defendant's request for a Rule 54(b) final judgment, this Court should deny Janssen's motion for an extension.

RELEVANT BACKGROUND

This litigation arises under the Biologics Price Competition and Innovation Act (BPCIA), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119,

804-21 (2010). In 2015, Janssen[1] sued Defendants[2] under the BPCIA, alleging infringement of U.S. Patent No. 6,284,471 and others. *See* Dkt. 1; Dkt. 249 at 1. The '471 patent claims a group of antibodies including infliximab, an ingredient in Janssen's biologic drug Remicade. Dkt. 249 at 3. Remicade sales generate about $4 billion annually in the United States for Janssen and its parent, with some Remicade regimens costing an individual patient as much as $20,000 per year. Dkt. 249[3] at 3. Defendants' allegedly infringing product, Inflectra, is biosimilar to Remicade and the result of more than $100 million in research and development. *Id.* at 4.

As the district court recognized, the BPCIA's overriding objective is to provide "certainty to the applicant, the reference product manufacturer, and the public at large.'" Dkt. 249 at 4-5 (quoting *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1363 (Fed. Cir. 2015) (Newman, J., concurring and dissenting) (quoting legislative history)). To achieve that objective, "the BPCIA established an expedited procedure to promote the prompt resolution of claims of patent infringement by biosimilar products." *Id.* at 3.

[1] Appellants Janssen Biotech, Inc. and New York University

[2] Celltrion Healthcare Co., Ltd., Celltrion Inc., and Hospira, Inc.

[3] All citations to "Dkt." refer to docket entries in Case No. 15-cv-10698 in the U.S. District Court for District of Massachusetts.

Among other things, the BPCIA requires biosimilar manufacturers to make prompt disclosures to reference product manufacturers, and it limits the remedies available to reference manufacturers who do not sue promptly for any alleged infringement or who do not prosecute to judgment in good faith. *Id.* at 4 (citing 35 U.S.C. § 271(e)(6) and *Sandoz,* 794 F.3d at 1351-52).

The '471 patent will expire on September 4, 2018. Dkt. 253 at 2. The FDA has approved Inflectra, Dkt. 249 at 4, which Defendants recently launched in the United States. While Defendants have sought the certainty that the BPCIA aims to provide, Janssen has sought delay at every critical juncture in this case.

At the beginning of this case, Janssen filed its complaint promptly to preserve its ability to seek lost profits damages under 35 U.S.C. § 271(e)(6). Rather than prosecuting the case as contemplated by the statute, Janssen moved for a stay ten days later. Dkt. 9 at 1. The district court denied that motion, concluding that the potential prejudice to Defendants and the public outweighed the factors favoring a stay. Dkt. 249 at 6-7; Dkt. 164 at 54-57. The court reasoned that a stay "would undermine a primary purpose of the BPCIA—achieving the expeditious resolu-

tion of the issues of alleged infringement to promote certainty as to whether a biosimilar product could be sold without exposing an innovator to the risk of an award of lost profits, which could be hundreds of millions, if not billions, of dollars in the instant cases." Dkt. 249 at 6.

At other points in the litigation, "despite being offered by the court several opportunities to do so, Janssen did not move for a preliminary injunction to prohibit the sale of Inflectra in the United States pending the outcome of these cases." Dkt. 249 at 5.

Based on two motions Defendants filed early in litigation, the district court granted summary judgment, concluding that the '471 patent is invalid for obviousness-type double patenting. Dkt. 253; Dkt. 255. The district court granted early summary judgment over Janssen's objection that ruling on the issue "would be a waste of th[e] Court's resources." Dkt. 199 at 1. Defendants then moved for entry of final judgment as to the '471 patent under Federal Rule of Civil Procedure 54(b). Dkt. 229; Dkt. 230. Following a familiar pattern, Janssen opposed, again seeking to stop or slow the progress of its own case. Dkt. 237. The district court granted Defendants' motion. Dkt. 249. Much as it had done in denying Janssen's motion for a stay, the district court concluded that there was no just cause for delay,

and emphasized a "primary purpose of the BPCIA—to expedite patent litigation concerning biosimilar products in order to maximize certainty, and diminish the risk that innovators will be unnecessarily deterred from offering those products to the public because of the threat of liability for a patentee's lost profits." Dkt. 249 at 13-14. The court also noted that uncertainty concerning Defendants' infringement of a valid patent could affect the decisions of Defendants' potential investors, and that uncertainty concerning a potential injunction of sales of Inflectra could discourage doctors from even prescribing it. Dkt. 249 at 17.

The district court entered partial final judgment on September 27, 2016. Dkt. 250. Janssen filed its notice of appeal to this Court 27 days later. Dkt. 270. For the issues not immediately appealable under the court's Rule 54(b) order (*e.g.*, those relating to another patent that does not cover Defendants' product), the court scheduled a jury trial for February 2017. Dkt. No. 261; Dkt. 237 at 4, 11.

Janssen now seeks delay yet again. Even though Janssen has known since September 27 that its brief would be due in late December, it requests a 30-day extension, citing nothing more than the upcoming holidays and the "serious and important issues raised by this appeal." Fed. Cir.

Dkt. 24 at 3. For the reasons explained below, that motion should be denied.

ARGUMENT

The Court should deny Janssen's latest attempt to forestall a final decision on the '471 patent's invalidity and, with it, Defendants' potential liability under that patent. Janssen has had ample time to prepare its opening brief on the discrete issues presented in this Rule 54(b) appeal. Additional delay would thwart Congress's statutory objectives under the BPCIA and would substantially prejudice Defendants and the public. Extensions of time require a showing of "good cause," Fed. R. App. P. 26(b), and should not be granted in BPCIA cases such as this without more substantial justification than Janssen offers here.

A. Additional Delay Would Thwart the Objectives of the BPCIA; Harm Defendants, Investors, Doctors, and Patients; and Reward Janssen's Gamesmanship.

The '471 patent has 21 months remaining on its term, and it relates to a drug that generates $4 billion per year in the United States for Janssen and its parent. The district court, however, found Janssen's '471 patent invalid, and Defendants' biosimilar product has been FDA-approved and is now being sold.

Defendants thus face uncertainty that the BPCIA was intended to eliminate. Because Defendants have obtained FDA approval and begun selling their biosimilar Inflectra, they face the potential risk of as much as hundreds of millions of dollars in damages. Even more fundamentally, doctors likewise face uncertainty over whether to prescribe a product that awaits final decision from this Court and theoretically could be pulled from the market on short notice—a point the district court recognized in issuing a 54(b) final judgment.[4] Until this Court resolves this appeal, delay thus benefits Janssen and harms Defendants and the public.

It is precisely that type of high-stakes uncertainty in biologics litigation that Congress aimed to prevent with the BPCIA; indeed, the district court recognized as much each time it confronted one of Janssen's efforts at delay. The BPCIA provides an accelerated avenue for an applicant to receive an FDA license to market a biologic product, if that applicant can show that its product is "biosimilar" to a reference product. The statute

[4] The alternative would have been for Defendants to wait out much of the remaining 21 months of the term of an adjudicated-invalid patent. Defendants would forgo substantial revenue, and would deny the public the benefit of an alternative, lower-cost biologic product in which Defendants have invested more than $100 million. Again, delay would only benefit Janssen and harm Defendants and the public.

details ways in which potential patent disputes may arise between the reference-product sponsor and the biosimilar-product applicant and a path for expeditious resolution of those disputes. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1055-58 (Fed. Cir. 2016). Indeed, as this Court has recognized, Congress aimed through the BPCIA to "ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." *Apotex*, 827 F.3d at 1063 (quoting *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcommittee On Courts and Competition Policy of the House Committee On the Judiciary*, 111th Cong. 9 (July 14, 2009) (statement of Rep. Eshoo)). Those concerns are amplified in this case.

In denying Janssen's motion for a stay at the outset of the case, the district court recognized the undue prejudice to Defendants and the public that the stay would have caused, in addition to its inconsistency with the BPCIA's goal of expeditiously achieving certainty in patent-related biosimilar proceedings. Dkt. 164 at 55-57; Dkt. 249 at 6-7. Likewise, in entering final judgment under Rule 54(b) over Janssen's objection, the district court recognized that there was not only no just cause for delay, but that delay-

ing an appeal would be inconsistent with the BPCIA's goal of expedited litigation as well as prejudicial to Defendants and the public. Dkt. 249 at 11-18; Dkt. 250.

Janssen, for its part, waited nearly the full 30 days allowed by Federal Rule of Civil Procedure 4(a)(1)(A) before filing its notice of appeal from that judgment. Dkt. 250; Dkt. 270. Its unsubstantiated motion for an additional 30 days of delay here is simply its latest effort to benefit itself and harm Defendants and the public by running out the clock with the specter of potential lost-profits damages with each passing month. The extension request should be denied for reasons similar to those the district court previously gave.

Here, as before, the costs of unwarranted delay would fall on Defendants and the public in the ways that the BPCIA was intended to prevent. Although the '471 patent stands invalidated, Defendants are marketing their biosimilar product at-risk, depending on the outcome of this appeal. *See* Dkt. 249 at 5-6, 13-14. Doctors have been put to the choice of prescribing a product that could potentially be pulled from the market, or denying it to patients because of that risk—a predicament which should not be unnecessarily drawn out. *See* Dkt. 249 at 17. Most importantly, the public is

entitled to certainty as well. To the extent people suffering from chronic pain face the possible risk of losing access to a more affordable treatment (Inflectra) in the future, the sooner that risk can be eliminated, the better for all concerned. *See* Dkt. 249 at 5, 7, 17.

Congress recognized that this sort of uncertainty can impose tremendous costs on litigants and the public and adopted the BPCIA to eliminate it. Janssen's conclusory references to the "importan[ce] to Janssen" of this appeal and to "the upcoming holidays" fail to provide good cause to deviate from the statutory scheme or impose for an additional month the very harms on Defendants and the public BPCIA was adopted to prevent.

B. Additional Delay Would Prejudice Defendants by Forcing them to Prepare their Response Brief During Trial.

Granting Janssen's extension would also severely prejudice Defendants by putting them to an unfair choice: either brief the appeal without the benefit of those attorneys who worked on the issues below, or seek further delay in the form of a one-month extension on their own brief, with the risk and costs associated with that.

That is because, if Janssen's extension request is granted, Defendants' response time would overlap almost entirely with the trial scheduled

on the matters that remain pending in the district court. Specifically, if Janssen files its brief at or before its current deadline, Defendants' response brief will be due no later than February 6, 2017. Fed. Cir. R. 31(a). If Janssen's motion is granted, however, Defendants' will not receive Janssen's brief until January 27, 2017 and their response would be due March 7. However, the trial on the remaining issues in the district court is scheduled for February 13-24, 2017, with the inevitable post-trial briefing that would follow. *See* Dkt. 260 (district court scheduling order). Moreover, the pretrial conference is scheduled for January 24 and 25, just days before Janssen's brief would be due, and the ramp-up to trial would, of course, continue throughout early February as well.

Janssen's extension would thus mean, as a practical matter, that Defendants either would be unable to have their attorneys most knowledgeable about this case actively involved in drafting Defendants' response or would themselves be forced to seek an extension and further exacerbate the delay they are trying to avoid. That is fundamentally inequitable. Janssen offers no good cause for imposing that burden on Defendants, and there is no basis for doing so.

C. Janssen Does Not Show Good Cause for an Extension.

Finally, Janssen's motion should be denied because if fails to meet the threshold requirement of demonstrating good cause. *See* Fed. R. App. P. 26(b). This Court's rules provide Janssen ample time to file its opening brief. The district court entered judgment on September 27, 2016. Dkt. 250. Janssen's brief is due December 27, 2016—91 days later. There is no surprise to Janssen, and no reason it cannot have its brief ready by the due date. Janssen already took nearly the maximum time permitted simply to file its notice of appeal.

Janssen's motion states that "[t]his appeal is of great importance to Janssen." No doubt; the appeal is of great importance to Defendants too, which is why Defendants oppose further delay. Indeed, importance counsels *against* an extension: As discussed above, that is exactly why Congress created an *expedited* regime for resolving disputes such as these in the BPCIA. Surely, given its importance, Janssen and its attorneys can prioritize this discrete appeal over the other, unspecified matters before it, and explain whatever disagreement Janssen has with the district court's decisions during the time this Court's rules allow. Moreover, although the appeal certainly is important, it is not unusually complex. It involves a

single patent and two theories of a single basis for invalidity (obviousness-type double patenting).

Janssen also refers vaguely to "the upcoming holidays," but the next federal holiday is December 26, the day before Janssen's brief is due.[5] "The upcoming holidays" may affect the last few days before Janssen's deadline, but they surely do not justify a month-long extension under these circumstances.

But beyond these vague references to "importance" and "the upcoming holidays," Janssen offers no "good cause" for an extension. There are no exigent circumstances nor anything else competing for its time that Janssen deems important enough to mention. Its motion should thus be seen for what it is: delay for the sake of delay, with costs and risks to Defendants and the public. That cannot be enough.

Finally, it bears noting that Janssen can, and does, move swiftly when it wants to. When Janssen wanted to stay the entire district court litigation, Janssen needed only ten days after filing its complaint to file its stay motion (which the district court denied). Dkt. 9 at 1; Dkt. 164 at 55-

[5] OPM, 2016 Holiday Schedule, *at* https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/federal-holidays/#url=2016

57; Dkt. 249 at 6-7. And just last month, Janssen filed a notice of appeal from an adverse decision in an *ex parte* reexamination involving the '471 patent just four days after the Patent Trial and Appeal Board issued its decision, *see Ex parte Janssen Biotech*, Appeal No. 2016-006590, 2016 WL 6921121 at *2 (PTAB Nov. 14, 2016), even though 35 U.S.C. § 142 allowed Janssen 60 days to do so. Janssen should have no legitimate difficulty filing its brief within the time this Court's rules allow.

CONCLUSION

Janssen's motion should be denied.

December 6, 2016

Respectfully submitted,

/s/ John C. O'Quinn

Charles B. Klein
WINSTON & STRAWN LLP
1700 K Street, NW
Washington, DC 20006
(202) 282-5100

James F. Hurst
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago IL 60654
(312) 862-2200

Samuel S. Park
Dan Hoang
WINSTON & STRAWN LLP
35 West Wacker Drive
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KIRKLAND & ELLIS LLP
655 15th St., N.W.
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Melinda K. Lackey
WINSTON & STRAWN LLP
1111 Louisiana Street, 25th Floor
Houston, TX 77002
(713) 651-2600

Peter B. Silverman
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, N.Y. 10022
(212) 446-4800

Counsel for Appellees

CERTIFICATE OF SERVICE

On December 6, 2016, the foregoing document was submitted to the Court, and thereby served on all parties, by the CM/ECF system.

/s/ *William H. Burgess*